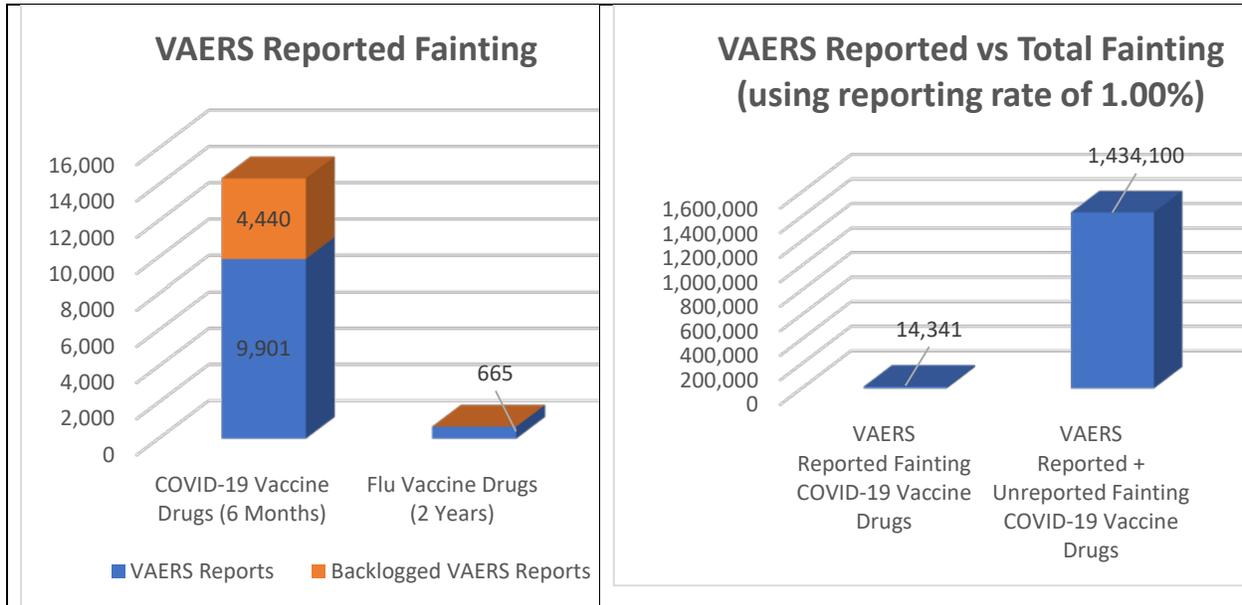


COVID-19 Vaccine Drug Reactions: Fainting

Preliminary Notes – Reactions Listings Start on Page 2 Below



1. Fainting cases Reported through June 4, 2021 in the United States to the Vaccine Adverse Event Reporting System (VAERS).
2. In order to understand the two charts above:
 - a. The VAERS COVID-19 vaccine drug reported cases + backlogged cases **versus** the flu vaccine reported cases
 - b. The VAERS reported cases versus the total cases in the United States

It is **crucial** to at least one time, carefully read through the two answers in the FAQs related to backlogged cases and then the VAERS reporting rate:

https://www.covid19vaccinefacts.net/VAERS_FAQ.shtml#Backlog

https://www.covid19vaccinefacts.net/VAERS_FAQ.shtml#ReportingRate

3. The cases listed below were pulled from the VAERS raw data files with a query that looked for fainting reactions. Please keep in mind that while some of the cases may seem mild, other cases involve a litany of very serious symptoms after the vaccination often including losing consciousness. As you read through the cases below, it is possible that there will be an occasional erroneous case not related to fainting because of the query criteria. The exact query is as follows:
(symptom_text like "*passed out*" or symptom_text like "*fainted*" or symptom_text like "*fainting*")

Fainting: COVID-19 Vaccine Drugs

| <i>VAERS_ID</i> | <i>RECVDATE</i> | <i>STATE</i> | <i>AGE_YRS</i> | <i>SEX</i> | <i>VAX_DATE</i> | <i>ONSET_DATE</i> | <i>SYMPTOM_TEXT</i> |
|-----------------|-----------------|--------------|----------------|------------|-----------------|-------------------|--|
| 1374304 | 6/4/2021 | VA | 19 | M | 5/14/2021 | 5/25/2021 | My son developed severe fatigue, muscle aches, fainting, headache, tachycardia for 1 week (up to 164 in the ED), fever, feelings of chest heaviness. |

| <u>VAERS_ID</u> | <u>RECVDATE</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1373307 | 6/4/2021 | WI | 68 | F | 3/9/2021 | 3/9/2021 | <p>broke her ankle; blacked out and passed out; trouble breathing; didn't feel good; nauseated; felt light headed; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (blacked out and passed out) in a 68-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No medical history was provided. Concomitant products included PREDNISOLONE, TIMOLOL, LABETALOL and LOSARTAN for an unknown indication. On 09-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 09-Mar-2021, the patient experienced DIZZINESS (felt light headed), MALAISE (didn't feel good) and NAUSEA (nauseated). On 09-Apr-2021, the patient experienced DYSPNOEA (trouble breathing). On 11-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (blacked out and passed out) (seriousness criterion medically significant) and JOINT INJURY (broke her ankle). At the time of the report, LOSS OF CONSCIOUSNESS (blacked out and passed out), DIZZINESS (felt light headed), JOINT INJURY (broke her ankle), DYSPNOEA (trouble breathing), MALAISE (didn't feel good) and NAUSEA (nauseated) outcome was unknown. Treatment medications were not provided. Based on current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded.; Sender's Comments: Based on current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded.</p> |

| <i>VAERS_ID</i> | <i>RECVDATE</i> | <i>STATE</i> | <i>AGE_YRS</i> | <i>SEX</i> | <i>VAX_DATE</i> | <i>ONSET_DATE</i> | <i>SYMPTOM_TEXT</i> |
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| 1373366 | 6/4/2021 | | 23 | M | | | lightheadedness; This is a spontaneous report from a non-contactable health care professional (other HCP). A 23-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection; Batch/Lot Number: EN6205; Expiration date was not reported), via an unspecified route of administration on an unspecified date (at the age of 23-years-old) as first dose, single dose for COVID-19 immunisation. Medical history included lightheaded from an unknown date and unknown if ongoing; it was reported that the patient stated the he always gets lightheaded when he gets a shot. The patient's concomitant medications were not reported. On an unspecified date, during the patient's 15-minute waiting period after the injection, the patient experienced lightheadedness. The patient denied difficulty breathing, difficulty swallowing, throat tightness, nausea and any episodes of syncope in the past. The outcome of the event was recovered on an unspecified date; lightheadedness resolved prior to discharge. No follow-up attempts are possible. No further information is expected. |

| <u>VAERS_ID</u> | <u>RECVDATE</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1373702 | 6/4/2021 | OH | 34 | F | 4/13/2021 | 4/13/2021 | Throat swelling; Trouble swallowing; Coughing; Facial tingling; Facial numbness; Face got hot; Face was swelling; Rash on legs and back and arms; really her heart was racing after she got the vaccine; This is a spontaneous report from a Pfizer sponsored program via a contactable consumer (patient). A 34-year-old female patient received second dose of BNT162B2 (Lot Number: EN6203), via an unspecified route of administration, administered in right arm on 13Apr2021 at 14:30 at age of 34-year-old as single dose for covid-19 immunisation. Medical history included ongoing Hashimoto's thyroiditis (autoimmune conditions, had the Hashimoto's since she was around 16, that is when she started getting symptoms), ongoing neurocardiogenic syncope (kind of an autoimmune, started when she was 16). The patient previously received first dose of BNT162B2 (Lot Number: EN6203), via an unspecified route of administration, administered in right arm on 23Mar2021 at 14:30 at age of 34-year-old as single dose for covid-19 immunisation, and face got hot and face was swelling on 23Mar2021. None other vaccines administered on same date with the Pfizer vaccine considered as suspect. None other Prior Vaccinations within 4 weeks. None family medical history relevant to AEs. Concomitant medications were not reported. On 13Apr2021 at 17: 00 or 17: 30, the patient experienced throat swelling, facial numbness, trouble swallowing, coughing, face got hot, face was swelling, facial tingling, rash on legs and back and arms and really her heart was racing after she got the vaccine. Caller came on the line. She had throat and facial swelling, facial numbness, and a rash on her legs and back and arms. Then, she didn't know if she has nerve damage or what, she still had tingling in her face where it was originally numb. Caller was just wondering if there was a program in place. She was told to go to the ER because she was having a reaction. The hospital had no way of billing it as a Covid-19 vaccine reaction. After the second dose her face got hot and she took a lot of medication and the facial swelling and hotness went away. Her cheeks were red and hot, she was not sure if it was swelling. Her face was hot and bright red, she doesn't know why. It kind of seemed puffy, but she was not sure if that was what it was. She had swelling about a week after the second dose her face was swollen and puffy, but she thought it's gone like the hotness was gone. She |

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thought the tingling in her face was related to that. Her face was tingling and hot and swollen, she thought the tingling was a lasting effect. She didn't still have swelling in her face and it wasn't hot. It was in the same area as the tingling. With the second dose she had the hotness and swelling 30 minutes after the vaccine, and it was a kind of a puffy tingling numbness. The hotness and swelling went away a little bit later, about 45 minutes after she had the vaccine. She had trouble swallowing after the second dose. She didn't know if it was because her throat was swelling. She had autoimmune issues and thyroid problems. She didn't know if her thyroid was swelling. She didn't realize she had the rash until a few hours after the second dose of the vaccine. Her throat was swelling after the second dose. She took diphenhydramine hydrochloride (BENADRYL) immediately and that helped. She took it right when she started noticing her throat was swelling and it went down some at that point so she didn't feel like panicking. She went to the ER and they gave her steroids and antihistamines, and it was completely gone after that. She did not have an NDC, lot, or expiration date available for the Benadryl she took. She recovered completely. It went away that same day. She thought the facial numbness after the second dose was a little better. It still felt tingly, but it had gotten a little better. She was not really sure, the numbness and tingling were kind of together and she didn't know how to describe it. She didn't want to be dramatic, she thought that people should get the vaccine. Reactions were normal for her. She had trouble swallowing about 30 to 40 minutes after she had the second dose of the vaccine. She was driving and realized she was having trouble swallowing or tightness in her throat area. When she went to the hospital she was still having trouble swallowing and was coughing. She thought the coughing was just from the throat swelling. It got better. She only still had the tingling. They did monitor her heart rate, really her heart was racing after she got the vaccine and did slow down after she got medication. They monitored her heart rate and blood pressure on 13Apr2021, results not provided. She hasn't had any other bloodwork or anything. The patient went to the hospital close to home and went to the ER but was not admitted. They gave her medications and everything returned to normal. She guesses they

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| 1373725 | 6/4/2021 MD | 50 F | 5/15/2021 | 5/16/2021 | <p>wanted her to stay, but she was ready to go home. Once everything resolved she left. She was there for a couple hours in the ER. No arrived physician office. The outcome of events throat swelling, trouble swallowing, coughing, face got hot, face was swelling was recovered on 13Apr2021, of event, rash on legs and back and arms and really her heart was racing after she got the vaccine was recovered on unknown date, of event facial tingling and facial numbness was recovering. Information on Lot/Batch number was available. Additional information has been requested.</p> <p>Fainted; Feeling very light-headed; Slightly nauseous; This is a spontaneous report from a non-contactable consumer (patient). A 50-year-old female patient received 2nd dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, LOT number: EW0179, expiration date unknown) via unspecified route of administration on left arm on 15May2021 at 12:00 PM at age of 50-year-old at single dose for COVID-19 immunization. Patient was not pregnant at time of vaccination and events onset. Medical history included back pain. Patient had no known allergies. Patient previously received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, LOT number: EW0171, expiration date unknown) on 24Apr2021 at 12:00 PM at age of 50-year-old via unspecified route of administration on left arm for COVID-19 immunisation. Concomitant medications included cyclobenzaprine, gabapentin, both administered within 2 weeks of vaccination. Patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient wasn't diagnosed with COVID-19. Since the vaccination, patient hasn't been tested for COVID-19. In the morning after the injection on 16May2021 at 09:30 AM, patient was in the kitchen and started feeling very light-headed and slightly nauseous. Patient sat in a chair but still felt the same. She got up to go lie down and fainted. After crawling to the couch and lying down for a few minutes, she felt better. The events didn't result in emergency room visit or physician office visit. Outcome of the events was recovered. No treatment received for the events. No follow-up attempts are possible. No further information is expected.</p> |
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| 1373769 | 6/4/2021 | VT | 78 | F | 2/21/2021 | 2/22/2021 | syncope; Acute subarachnoid hemorrhage involving both hemispheres; acute on chronic right subdural hematoma up to 7 mm thick; hemorrhagic contusion with edema; hemorrhagic contusion with edema; fatigue; malaise; HA; This is a spontaneous report from a contactable physician. A 78-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular, administered in arm left on 21Feb2021 (Lot Number: EN6200) (at the age of 78-year-old) as single dose for COVID-19 immunisation. Medical history included hypertension (HTN), hyperlipidemia (HDL) and hypothyroidism, all from an unknown date and unknown if ongoing. The patient's concomitant medications were not reported. Prior to vaccination the patient was not diagnosed with COVID-19 and since the vaccination the patient has not been tested for COVID-19. The patient previously took SSRI, PNC (unknown), sulfa and oxycodone; the patient previously received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular, administered in arm left on 31Jan2021 (Batch/Lot Number: EL9265) as single dose for COVID-19 immunisation. Within 12 hours of vaccine (on 22Feb2021) the patient developed symptoms of fatigue, malaise, headache (HA) and severe and near syncope. She visited the emergency department (ED) the following day. Work up at that time including blood work and no imaging. She was treated with IVFs and discharged. Symptoms of malaise, fatigue and HA persisted for > 1 week. A computerized tomogram (CT) of the head was performed on 05Mar2021, this CT showed the following: acute subarachnoid hemorrhage involving both hemispheres; acute on chronic right subdural hematoma up to 7 mm thick; 2X3 left front hemorrhagic contusion with edema. The events required emergency room visit and physician office visit. Therapeutic measures were taken as a result of the events and includes conservative measures (as reported). The patient outcome of the event was recovered with sequel.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of reported events cannot be excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the |

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| | | | | | | | Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate. |
| 1374011 | 6/4/2021 | WV | 15 | M | 6/3/2021 | 6/3/2021 | Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Additional Details: Patient fainted once, then almost again. Called 911 to have evaluated before leaving. Was feeling ok upon departure |
| 1374012 | 6/4/2021 | CA | 25 | M | 6/3/2021 | 6/3/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Severe, Systemic: Nausea-Medium, Additional Details: Extreme sweating, nausea & short fainting spell. Gave patient water and sugary snack. Mentioned he may not have eaten enough that morning |
| 1374081 | 6/4/2021 | TX | 26 | M | 6/3/2021 | 6/3/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Mild |
| 1374088 | 6/4/2021 | CA | 17 | F | 6/3/2021 | 6/3/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Shakiness-Mild, Additional Details: Patient received 1st dose of pfizer vaccine. Less than 1 minute later patients mother alerted us that the patient had lost consciousness. She was immediately laid down and gained consciousness within 10 seconds. She stated feeling lightheaded, sweaty, looked pale and felt like she was in a trance. 1st BP reading (111/67), 2nd BP reading done 15 min later (106/59 & HR 65). After 30 min of monitoring patient was able to leave. |

| <i>VAERS_ID</i> | <i>RECVDATE</i> | <i>STATE</i> | <i>AGE_YRS</i> | <i>SEX</i> | <i>VAX_DATE</i> | <i>ONSET_DATE</i> | <i>SYMPTOM_TEXT</i> |
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| 1374113 | 6/4/2021 | CA | 46 | F | 6/3/2021 | 6/3/2021 | Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Severe, Systemic: Seizure-Severe, Systemic: Shakiness-Severe, Systemic: Tingling (specify: facial area, extremities)-Medium, Systemic: Weakness-Medium, Additional Details: <5 min post dose patient noted feeling short of breath, numbness, dizzy, sweaty, shaky and then lost consciousness. I was able to catch her head so she didnt hit a hard surface. Patient was unresponsive for 10 seconds. She started to seize and her eyes rolled to the back of her head. After she regained consciousness she was moved into the pharmacy and laid down. Pt was given a cool towel and water.1st BP (112/70 & HR74), 2nd BP 15min later (110/70 & HR 84). After 45 min pt left with family member |

| <u>VAERS_ID</u> | <u>RECVDATE</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1373298 | 6/4/2021 | | | U | 2/1/2021 | 2/1/2021 | Passed out in the shower; Could not taste; Could not smell; Fever; Chills; Very ill for 28 hours; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out in the shower) in a patient of an unknown age and gender who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. In February 2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. In February 2021, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced MALAISE (Very ill for 28 hours). On an unknown date, the patient experienced LOSS OF CONSCIOUSNESS (Passed out in the shower) (seriousness criterion medically significant), AGEUSIA (Could not taste), ANOSMIA (Could not smell), PYREXIA (Fever) and CHILLS (Chills). At the time of the report, LOSS OF CONSCIOUSNESS (Passed out in the shower), AGEUSIA (Could not taste), ANOSMIA (Could not smell), PYREXIA (Fever) and CHILLS (Chills) outcome was unknown and MALAISE (Very ill for 28 hours) had resolved. No relevant concomitant medications were reported. No treatment information was provided. Based on current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded.; Sender's Comments: Based on current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded. |
| 1374224 | 6/4/2021 | MD | 34 | M | 5/25/2021 | 5/25/2021 | PATIENT EXPERIENCED SYNCOPE/DIZZINESS SHORTLY AFTER GETTING A SHOT |

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1373710 | 6/4/2021 | CT | 53 | F | 5/14/2021 | 5/15/2021 | <p>completely passed out; she was going to pass out; chills; headache; nausea; feeling very sick; She states it felt like she had the COVID virus again; This is a spontaneous report from a contactable consumer (patient). A 53-years-old female patient received bnt162b2 (BNT162B2), dose 1 via an unspecified route of administration, administered in Arm Left on 14May2021 16:30 (Batch/Lot Number: EW0176) as SINGLE DOSE for covid-19 immunisation. Medical history included asthma, she was diagnosed as a child, she was in treatment because her pulmonologist said the airflow in her lungs were very low; this was before she got COVID in February and before she got the vaccine. She was in treatment for her asthma since Dec2020; Vasovagal syncope, she explained she has always had this problem, but she didn't know what it was, she was diagnosed around 10 years ago because it kept getting worse and worse; Covid-19 from 12Feb2021 to an unknown date, she passed out at home and she went to the hospital; acid reflux; she had regular allergies from trees and stuff; she was suffering from allergies 2 weeks before the shot, She went to take the COVID shot and she was sneezing, and had a sore throat. She asked everybody if it was okay to take it and everybody said it was fine so she took it. She was not sure if it has anything to do with it, but she was already suffering from her allergies with the sneezing and sore throat when she took the COVID shot. Concomitant medications included fluticasone furoate, umeclidinium bromide, vilanterol trifenate (TRELEGY) taken for asthma from Dec2020 to an unspecified stop date; Montelukast, taken for asthma from Dec2020 to an unspecified stop date; salbutamol (ALBUTEROL HFA) taken for asthma from Dec2020 to an unspecified stop date; famotidine taken for acid reflux from Dec2020 to an unspecified stop date; colecalciferol (VITAMIN D3 1000) taken for an unspecified indication from Dec2020 to an unspecified stop date; prednisone taken for asthma from Dec2020 to an unspecified stop date, and antibiotics taken for asthma from Dec2020 to an unspecified stop date, she confirmed these medications were before the vaccine, she wasn't taking the antibiotic or Prednisone at the time of the vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. She had the vaccine last Friday, 14May2021. The patient woke up feeling very sick the next day, 15 May 2021. She spent all day in bed</p> |

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with chills, headache, nausea. Around 11:00, her husband had to call 911 because she completely passed out. She went to the hospital. She explained now, she was feeling much better, but she was still feeling like her body wanted to still go to bed. On 15 May 2021, she woke up thinking she was going to pass out. Her husband tried to help her; she didn't want to go to the hospital. The whole day she was going downhill. She spent all day in bed with chills, headache, and nausea. She stated it felt like she had the COVID virus again. She felt like she has improved. She still had a little bit of a headache, and she still felt like her body wanted to stay in bed, but she doesn't feel as bad as she did on Saturday. She was taken to the Emergency Room (ER) around 12:30AM Sunday morning, 16 May 2021. She confirmed she was never admitted into the hospital, she was only seen in the ER. She left the ER at 5:00 AM. Her second dose is supposed to be on 04Jun2021. Right now, she was afraid to get her second shot. Patient wanted to know was there any other risk with getting the second shot. The outcome of the events was recovering.

| <u>VAERS_ID</u> | <u>RECVDATE</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1374311 | 6/4/2021 | | | U | | | Fainting; Based on the current case data, this case has been classified as invalid. This spontaneous case was reported by a consumer and describes the occurrence of SYNCOPE (Fainting) in a patient of an unknown age and gender who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient experienced SYNCOPE (Fainting) (seriousness criterion medically significant). At the time of the report, SYNCOPE (Fainting) outcome was unknown. Concomitant product use was not provided by the reporter. Treatment information was not provided. The patient received both scheduled doses of mRNA-1273 prior to the events therefore, action taken with the drug in response to the event is not applicable. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. |
| 1374341 | 6/4/2021 | MI | 23 | F | 6/3/2021 | 6/4/2021 | ?Pfizer-BioNTech Covid 19 Vaccine EUA? The night of getting the first shot I barely slept because I had chills all night long & my entire body was so sore it hurt to lay in any position. In the morning, I still had extreme muscle pain all over. I was extremely light headed & dizzy, I had a throbbing headache so I took 2 aleve pills. I was getting super nauseous and almost passed out while trying to get to my bathroom just in time to throw up only water. Just before throwing up my vision went fuzzy, my ears were ringing, I was dripping sweat, it was getting hard to breathe, & my hands were shaking. After taking a cold shower, laying down, & drinking some water I feel a bit better but not 100% normal. |

| <u>VAERS_ID</u> | <u>RECVDATE</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1374354 | 6/4/2021 | CA | 17 | M | 6/2/2021 | 6/2/2021 | Patient passed out at the discharge table 15 minutes after Pfizer COVID-19 vaccine. Medical assistant at discharge table able to catch patient and patient was assisted to ground by clinic staff. Patient skin warm to touch and pale. BP @ 1700 147/77, HR 68, RR 16, O2 saturation 94 % on roomair. Patient complains of dizziness and numbness tingling sensation to vaccinated left arm. Patient verbalized eating a small meal this am, exercising , and not drinking fluids. Ice pack applied to patients neck. Patient drinks water and sports drink. Doctor present to assess patient. Patient observed in discharge area an additional 30 minutes. Patient ambulated for 5 minutes in the discharge area per physician instructions. Patient stable, denies any dizziness, or numbness to left arm. BP @1727 was 149/85, HR 76, RR 18, O2 saturation 96% roomair. Patient ambulated independently to exit with family. |
| 1374361 | 6/4/2021 | NE | 12 | F | 6/3/2021 | 6/4/2021 | Patient awoke the morning after her 1st COVID vaccination. Reported she slept well. Her arm was sore from COVID shot. She was up for approximately 20 min and had brushed her teeth and did her hair. She was going to get dressed for the day and states she got a sudden pounding headache and felt nauseous. She was on her way out to the kitchen to tell us she didn't feel good when she blacked out. She face planted, hitting her forehead on the hardwood floor witnessed by both parents. She was out for approximately 30 seconds. Her blood pressure was 90/60, HR 120, O2 on rm air was 98%. She has no previous history of syncope. After spell heart rate ran in the 100-110s for about 30 min and then normalized around 88-95. Was tired and sleepy for 2 hours after. (No post ictal sx to suggest seizure) Patient also received Tdap and meningococcal vaccine in other arm at the time of 1st Covid vaccination. The night of her COVID shot patient had normal appetite and activity level. |
| 1374419 | 6/4/2021 | FL | 21 | M | 6/4/2021 | 6/4/2021 | patient sat for 10 minutes was good , stood up too fast then walked a few aisles and then fainted |
| 1374469 | 6/4/2021 | | 44 | F | 6/2/2021 | 6/2/2021 | Pt w/ dizziness, pre-syncope, shakes, muscle weakness, pallor. BP 121/72, HR 83, RR 16. Pt stable and released from the vaccination site. |

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| 1374494 | 6/4/2021 | IL | 14 | F | 6/4/2021 | 6/4/2021 | Patient fainted after receiving vaccination. After a period of 15 minutes, patient was able to leave under her own power. |
| 1374498 | 6/4/2021 | CA | 12 | F | 6/3/2021 | 6/4/2021 | Upon getting up, patient experienced brief spike in fever (felt very hot to touch), unsteadiness and fainted. Temperature after fainting was 100 and patient was sweaty, fatigued and had 'wobbly' legs. About 5 minutes later, fever subsided and patient has generally recovered. |
| 1374522 | 6/4/2021 | MO | 35 | M | 6/4/2021 | 6/4/2021 | Following injection patient passed out, was diaphoretic and had low BP of 56/35. Became responsive then speech became garbled and went into seizure (posturing and clonic movement) for approximately 3 seconds. Called 911. Became responsive before EMS arrived and refused ambulance to the hospital. |
| 1374545 | 6/4/2021 | MO | 35 | M | 6/4/2021 | 6/4/2021 | Immediately following injection patient passed out and was diaphoretic with a low BP of 56/35. Became responsive but speech garbled and then experienced seizure (posturing and clonic movement) that lasted 3 seconds. Called 911, became responsive before EMS arrived on scene and refused ambulance. |
| 1374198 | 6/4/2021 | WA | 15 | M | 5/25/2021 | 6/2/2021 | Syncope event caused ER trip where abnormal ECG resulted with possible pericarditis |

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| 1373746 | 6/4/2021 | IL | | F | | | blood sugar was 500/high blood sugar; fainted because of hypoglycemia; fainted because of hypoglycemia; This is a spontaneous report from a contactable physician. A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration on an unspecified date (batch/Lot number was not reported) as single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. Caller mentioned her oncologist who stated that his wife didn't have diabetes. Ten days after his wife (patient) got the second dose of the Covid Vaccine her blood sugar was 500. Caller stated that her oncologist wife was placed on medication for the high blood sugar and then fainted because of hypoglycemia. She says the wife was taken back off of the medication and was fine. Outcome of events was unknown. No follow-up attempts are needed; information about lot/batch number cannot be obtained.; Sender's Comments: Based on available information, a possible contributory role of BNT162B2 vaccine can not be excluded for the reported events of blood sugar increased due to temporal relationship. The events 'fainted because of hypoglycemia' were associated with blood sugar medication and unrelated to BNT162B2 vaccine. Case will be re-assessed upon the additional information provided. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate. |
| 1371480 | 6/3/2021 | OH | 18 | M | 5/25/2021 | 5/25/2021 | Reported that pt "passed out" in parking lot |
| 1371108 | 6/3/2021 | NY | 19 | F | 5/4/2021 | 5/5/2021 | Passed out twice, woke up in a pool of blood. Resulted in a concussion and possible broken nose. |

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| 1371140 | 6/3/2021 | IA | 14 | F | 6/2/2021 | 6/2/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient fainted while walking down aisle with dad. She immediately regained consciousness. Although she was conscious, EMTs were called to assess vitals. She was cleared by the EMTs to go home. No injuries were sustained. |
| 1371171 | 6/3/2021 | | 12 | F | 6/3/2021 | 6/3/2021 | Patient with history of vasovagal syncope. Patient took the vaccine at 0817 and felt light headed. Patient did not lose consciousness, however felt light headed and leaned toward her mom. Patient was laid down, given ice, juice/water and snacks. Patient was observed for a little while until she felt better, then went home. |
| 1371193 | 6/3/2021 | IN | 67 | F | 6/1/2021 | 6/3/2021 | I got up in the middle of the night to go to the bathroom as usual, and after washing my hands, apparently passed out. My husband heard and attended to me (I have a large bump on the back of my head, and a cut on my forehead). This morning, I'm okay except for a slight blurriness when reading. My physician recommended going to urgent care, which I am doing. I cannot remember ever having fainted in my entire life. |
| 1371206 | 6/3/2021 | PA | 16 | F | 6/3/2021 | 6/3/2021 | Patient experienced mild nausea and lightheadedness about 10 minutes after her shot. Some alternating warmth and cold feelings. No chills. No symptoms to suggest allergic reaction. No near syncope or syncope. Symptoms were self limiting and resolved on their own. VSS throughout her stay. no orthostasis. |
| 1371215 | 6/3/2021 | KY | 18 | F | 6/3/2021 | 6/3/2021 | Patient passed out immediately after receiving vaccination |
| 1371085 | 6/3/2021 | AZ | 27 | M | 6/2/2021 | 6/2/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Hypotension-Medium, Additional Details: Patient fainted after dose and was slow to respond to questions. BP: 70/40, 65/40. Patient states he did not eat very much during day prior to vaccine. Patient was kept for observation for 45 minutes until recovered, still shaky/dizzy afterward. |

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| 1371696 | 6/3/2021 | TX | 61 | F | 6/3/2021 | 6/3/2021 | Pt reported severe anxiety and syncope when receiving injectable medication and blood draws. Pt was agreeable to receive vaccine and a plan was made ahead of time to administer to her in her vehicle with the seat laid flat. Upon receiving the vaccine, the pt immediately stated, " I don't feel good" and began to hyperventilate and complaint of tingling in all extremities. Pt then vomited and an EMS crew on standby was notified to evaluate the patient. The patient was eventually transported to the ER due to near syncope and hypotension. |
| 1371070 | 6/3/2021 | NJ | 19 | M | 5/25/2021 | 5/25/2021 | At approximately 7pm, patient felt light headed and fainted and hit his head. He ended up in the hospital where they took blood and did a CAT scan. He had very low blood sugar and low blood pressure. Everything else was normal. |
| 1371258 | 6/3/2021 | NC | 39 | M | 6/2/2021 | 6/2/2021 | Pt with vasovagal response after vaccination. Started feeling ?hot? and like was going to pass out. Pt was seated and became extremely diaphoretic and had brief (<3 seconds) episode of syncope. Applied ice pack to neck and coached Pt on slow breathing. Vital signs remained stable throughout. Extended observation time from 15 to 30 mins and Pt was responding appropriately and ambulated to vehicle unassisted but accompanied by two colleagues. |

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| 1371279 | 6/3/2021 | IL | 34 | F | 5/28/2021 | 5/31/2021 | At 1:30pm on Monday 5/31 I started to feel cramps in my pelvic area. I had gotten my period 2 days early, and was bleeding heavier than normal and had surprising diarrhea. I took 600mg of Advil and texted a friend at 2:10 that: "the womanly cramps are ripping up my insides and making me so sick." Still I though this was an incredibly painful but normal mensural cycle. By 2:45 when the Advil normally would have kicked in and made the cramping almost disappear, I had gotten much worse. I was spending the day with a friend who is an internal medicine doctor and so she monitored me closely. I had extreme chills and was very cold to the touch but was profosely sweating. I was unable to drink or eat anything due to the nausea. Sharp and constant pain radiated from my mid-pelvic area down to my knees and up to my chest. On a fairly consistent bases my legs contorted in involuntary cramping. I felt like I was bleeding heavily (turns out I was not) and we attempted to go to the bathroom. I just the act of gently standing up I fainted and my friend caught me, gently returning me to the ground. When I became conscious she had my legs up and we went to the ER. |
| 1371286 | 6/3/2021 | NC | 48 | M | 1/27/2021 | 1/28/2021 | I had the vaccine and I had fever, chills, achy and weak, I almost felt like I had Covid. Then about 3 or 4 days after I continued to remain sick and I passed out on the kitchen floor, my wife called the ambulance and they took me to the ER. They gave me some fluids and ran an EKG on my heart. I was observed for a few hours and released to go home later. They did not give me any medications. |
| 1371293 | 6/3/2021 | MO | 18 | F | 6/3/2021 | 6/3/2021 | Patient received J&J vaccine and walked to sit down for her post injection wait time. Patient had previously fainted after a vaccine so she was suppose to sit for 30 minutes anyway. Patient immediately after sitting down got extremely light headed, pale, and dizzy. We immediately moved her to the floor and put her feet up. After approximately 3 minutes, patient regained color and was feeling a lot better. EMS was called but father who was with her called to cancel and refuse after patient felt better so quickly. Patient had history of anxiety with shots and it seemed to be truly an anxiety issue. |

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| 1371298 | 6/3/2021 | OH | 16 | F | 6/2/2021 | 6/2/2021 | This young lady was at the school to receive her second dose of the Pfizer vaccine, she answered all the questions with a No answer, she stated she was feeling well and had minimal reaction to first vaccine. She appeared to be nervous as reported by the nurse. after receiving her second shot, as the nurse was finishing up paperwork and filling out card, the student felt like passing out, one of the other nurses that were at her side, caught her as she fainted out of chair, she was placed on the ground and EMS was called at 10:10 and Nursing Supervisor was notified at 10:15. EMS determined she had a Vasovagal Syncope. EMS attended to patient and it was unknown if she was released after observation or taken to ED for further evaluation. a field emergency record was recorded and return to the nursing supervisor at the health department. |
| 1371302 | 6/3/2021 | NJ | 25 | M | 6/2/2021 | 6/2/2021 | Patient fainted about 5 minutes after vaccination. Did not hit head. Regained consciousness in about 30 seconds. He reported fainting with prior injections. Patient refused emergency care when they arrived due to cost. |
| 1371424 | 6/3/2021 | VA | 57 | M | 5/30/2021 | 5/30/2021 | He got his vaccine, towards later evening he started to get chills and shakes. Then somewhere between 11-12:00 PM he started having breathing problems, but it was so bad that he was considering having somebody take him to the hospital, but he did not. This went on for hours until he finally passed out and went to sleep and woke up the next morning and was fine. He was fatigued the entire next day and had a really bad headache, which he took some Naproxen sodium and took an Excedrin, and the headache did go away, and he seems to be back to normal. |
| 1371443 | 6/3/2021 | IN | 27 | F | 6/1/2021 | 6/2/2021 | Currently 31 weeks pregnant, estimated delivery Aug 5 Chills, fever, vomiting, joint pain, nausea, headache, dizziness, syncope Resolved at 12:30 on 6/3 |
| 1371230 | 6/3/2021 | VA | 20 | F | 6/1/2021 | 6/1/2021 | PATIENT HAD SYNCOPE REACTION TO RECEIVING SHOT AND APPEARED TO HAVE A SEIZURE THAT LASTED A FEW SECONDS. PATIENT CAME TO AND WAS CONSCIOUS AND COHERENT. |

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| 1370544 | 6/3/2021 | NV | 52 | M | 5/15/2021 | 5/15/2021 | dizziness; nausea; He did not feel well at all and was not able to feel well enough to stand up.; definite lack of coordination; he vomited on himself; his cholesterol was high at 208.; had very little strength; started feeling like something was wrong; just had sort of a feeling like being really drunk; passed out (fainted) in his car 3 times; He was told he had a vasovagal reaction; This is a spontaneous report from a contactable consumer (patient). A 52-years-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in Arm Left on 15May2021 10:50 (Lot Number: EW0173; Expiration Date: 31Aug2021) as 1ST DOSE, SINGLE DOSE for covid-19 immunisation. Medical history included vasovagal reactions in high school. No other vaccinations within four weeks prior to the first administration date of the suspect vaccine. The patient's concomitant medications were not reported. Within 2 minutes of receiving the Covid 19 vaccine he started feeling like something was wrong. He pulled to the side in the parking garage and as soon as he stopped the car he passed out. He woke back up and was able to put the car in park and he passed out a second time. He woke up again and his foot was on the gas pedal and he tried to roll down the window. He was able to roll down the window but he wasn't able to get anyone's attention. He passed out a third time. When he woke up again he wasn't able to get the door open and he was nauseated. He basically had nausea, dizziness, and a definite lack of coordination. He just had sort of a feeling like being really drunk. He doesn't drink. He had very little strength but he was able to push his car horn. He was out of it. He could see someone in his car mirror a little ways behind his car and the horn didn't get the person's attention so he honked a second time and someone came to help him, maybe from the fire department and maybe some emergency medical technicians. He was placed on a golf cart or ATV to be transported downstairs to a waiting ambulance and while on the ride he vomited himself. He mentioned that the EMTs called it a vasovagal reaction. He was brought to the hospital in which he had a lot of tests done. He did not feel well at all and was not able to feel well enough to stand up. He had tests done at the hospital, a chest x-ray and his blood was drawn. He had a cardiac ultrasound later in the afternoon the next day |

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on 16May2021. The doctor's didn't find anything wrong other than his cholesterol was high at 208. He was admitted to the hospital on 15May2021. He continued to have his blood drawn through the night and the next morning, on 16May2021, he had a CAT scan. For his cholesterol he was told to eat better and maybe follow up with a doctor in a couple months to check his cholesterol again. No one had any answers to the effect of what happened to him. Everything was fine, his tests were normal. He was told he had a vasovagal reaction. He's had vasovagal reactions before and he can tell this was much different than the vasovagal reactions he's had before. In the past when he's had vasovagal reactions the world went black like looking through a small circle, his vision got blacker and blacker and then he'd pass out. He did not have this feeling with the Covid 19 vaccine. He can only describe this feeling that he had like an occasion in his past when he's drank to much and he's stumbling around. He may have passed out briefly to someone helping him move to a bed and his arms are weighted and he can't lift them and he's disoriented but still has a sense of what's going on but he feels like he could vomit at any second. He's comparing his experience to the Covid 19 vaccine to drinking to much alcohol and then falling asleep or passing out. He was pretty much out of it for 5 hours. Between the fourth and fifth hours after receiving the Covid 19 vaccine he was comfortable enough to stand on his own for brief moments. He was feeling better and was able to use the restroom. By the next day, around the 24 hour period after the vaccine he was feeling almost normal. He was released from the hospital the next day, 16May2021 at around 4:00PM. He was maybe in the hospital for about 27 to 28 hours. At the hospital he had all these tests and he was found to be healthy with no problems. He also had a Covid 19 virus test, he never asked what the results were but he's going under the assumption that if he was Covid 19 virus positive the hospital staff would have told him. Passing out, nausea, dizziness required a visit to Emergency Room. The outcome was unknown.

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| 1371102 | 6/3/2021 | IL | 23 | M | 6/2/2021 | 6/2/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Headache-Mild, Additional Details: Pt fainted about 5 minutes after injection for less than 1 min. Did not require EMS call. Pt sat for 20 minutes before leaving and drank water. Slight headache also reported. Pt states this has happened about 10 years post vaccination - most likely panic attack, not a fan of needles. |
| 1369962 | 6/3/2021 | NV | 16 | F | 6/2/2021 | 6/2/2021 | Immediately following administration, patient walked out of room and sat down in waiting area. Patient felt very dizzy and almost fainted. Complained of hearing loss then tinnitus. Initial BP was 82/31 then gradually increased back towards normal over 20-30 minute period. Hearing loss recovered after 1-2 minutes then complaint of tinnitus which then stopped after 5-6 minutes. Approx 30 min after admin, pt felt much closer to normal and parent felt comfortable bringing her home. |

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| 1370327 | 6/3/2021 | OR | | F | | 3/20/2021 | <p>Passed out; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 0470 2orZ 1A) for COVID-19 vaccination. No medical history was provided by the reporter. On 20-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced LOSS OF CONSCIOUSNESS (Passed out) (seriousness criterion medically significant). At the time of the report, LOSS OF CONSCIOUSNESS (Passed out) outcome was unknown. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown Route) and mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Concomitant product use was not reported. Treatment information was not provided. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Further information has been requested.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Further information has been requested.</p> |

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| 1370336 | 6/3/2021 | | | U | | | Fainted; Anxiety; Based on the current case data, this case has been classified as invalid. This spontaneous case was reported by a consumer and describes the occurrence of SYNCOPPE (Fainted) in a patient of an unknown age and gender who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient experienced SYNCOPPE (Fainted) (seriousness criterion medically significant) and ANXIETY (Anxiety). At the time of the report, SYNCOPPE (Fainted) and ANXIETY (Anxiety) outcome was unknown. No relevant concomitant medications were provided the reporter. Patient had anxiety and fainted. Patient had received the second dose and was fine. No treatment information was provided. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. This case was linked to Patient Link.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |

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| 1370339 | 6/3/2021 | NY | 74 | F | 4/26/2021 | 4/26/2021 | Faint; Weak; Chills; Feverish; This spontaneous case was reported by a consumer and describes the occurrence of SYNCOPE (Faint) in a 74-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 0402B1A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included COVID-19 in November 2020. On 26-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 26-Apr-2021, the patient experienced CHILLS (Chills) and PYREXIA (Feverish). On 27-Apr-2021, the patient experienced SYNCOPE (Faint) (seriousness criterion medically significant) and ASTHENIA (Weak). At the time of the report, SYNCOPE (Faint), ASTHENIA (Weak), CHILLS (Chills) and PYREXIA (Feverish) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In December 2020, SARS-CoV-2 antibody test: positive (Positive) Positive. In March 2021, SARS-CoV-2 antibody test: negative (Negative) Negative. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Concomitant medications taken by the patient included thyroid medications and cholesterol medications. No treatment information was provided. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |

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| 1370366 | 6/3/2021 | MO | | F | | | fainted; swelling in the area /skin around pacemaker; real bad lymph node swelling; had an itch on the skin; vomiting; This is a spontaneous report from a contactable consumer (patient). A female patient of age 32 (units: unknown) received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Solution for injection, Lot number: unknown), dose 2 via an unspecified route of administration on unspecified date as 2nd dose, single dose for COVID-19 immunization. Patient medical history and concomitant medications were not reported. Patient previously received bnt162b2, dose 1 on an unspecified date for COVID-19 immunization. The patient had Pfizer vaccine and had a question about the side effects because she couldnt find any information on it and her doctor hadnt heard of it. On an unspecified date, the patient experienced swelling in the area/skin around pacemaker, real bad lymph node swelling and had an itch on the skin. She went to emergency room with vomiting and fainted about 20 minutes after receiving the vaccine. Patient underwent lab test and procedures include work up: there was all negative. The patient questioned about the side effects because she couldn't find any information on it and her doctor hadn't heard of it. The outcome of all the events was unknown. Information about lot/ batch number has been requested. |

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| 1370510 | 6/3/2021 | NC | | M | 3/15/2021 | 3/15/2021 | leg cramps; headache; muscle and joint pain; muscle and joint pain; electricity feeling in his legs felt like electricity going through his veins down to his toes and comes back up; This is a spontaneous report from a contactable consumer or other non hcp (patient). A 75-year-old male patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, solution for injection, Batch/Lot Number: EN9581, expiration date not reported), via an unspecified route of administration on 15Mar2021 as 2nd dose, single and first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, solution for injection, Batch/Lot Number: EN6202, expiration date not reported) intramuscular, administered in Arm Left on 23Feb2021 as 1st dose, single both for covid-19 immunization. Reportedly, adverse events following prior vaccinations arm hurt, headache, leg cramps like electricity going through veins and toes, joint pain comes and goes in his back, knees ankle and toes, leg muscle pain part of thigh and knees comes and goes, most of time it is in his calf. The patient medical history included high blood pressure and arthritis. The patient concomitant medications were not reported. There were no other prior vaccinations (within 4 weeks) prior to the first administration date of the suspect vaccine. On 15Mar2021, the patient experienced electricity feeling in his legs felt like electricity going through his veins down to his toes and comes back up. On 16Mar2021 leg cramps, headache and muscle and joint pain. Patient stated that after he got his second dose on 15Mar 2021 the electricity feeling in his legs began that night. Patient stated it felt like electricity going through his veins down to his toes and comes back up. Patient stated it does not happen 24/7, it comes and goes. Patient reported the leg cramps, headache and muscle and joint pain, started the next day. Patient stated the muscle and joint pain are not 24/7 either, it comes and goes. Patient stated he was able to move around but felt it when he walks around. Reportedly, patient received his second dose of Pfizer COVID vaccine and had the same symptoms as the first dose, however, from his first dose, his symptoms went away 7 to 8 days after. Patient confirmed that they did go away and he was fine. On his second dose, which he received on 15Mar2021, he was still experiencing symptoms today on 09Apr2021. Patient was asking if his |

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| 1371090 | 6/3/2021 MA | 20 M | 5/9/2021 | 5/13/2021 | <p>symptoms will go away. Patient stated next Thursday will be a month since he took the second dose and the feeling comes and goes. Patient stated he has a headache and muscle pain that was still going on and cramps in his legs. Patient reported that it was (second dose) originally scheduled sooner than that but due to snow and bad weather it was rescheduled for the 15Mar2021. Patient wanted to know if this was something that he was going to have to deal with for the rest of his life or would it go away. Patient also stated, saw on the news people taking the Johnson and Johnson vaccine and fainting. Patient also added that he also saw on the news that a lot of doctors and nurses are refusing to take the COVID-19 shot. Therapeutic measures were taken as a result of adverse events. Patient stated he has been taking extra strength Tylenol three times when it first started, and now he was taking it 2 times a day. No relevant tests were done. The outcome for all the events was not recovered as reported. No follow-up attempts are needed. No further information is expected.</p> <p>Site: Pain at Injection Site-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Additional Details: patient nodded off into a faint when I went to get him a snack, he remained in his chair but dropped his water. Patient said he was feeling sweaty and seeing black. He rested with head down & on the floor. Had some water and a snack. Side effects lasted 5-6 min, patient remained in pharmacy for an additional 15 min without any further events.</p> |
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| 1370538 | 6/3/2021 | VA | 59 | F | 4/13/2021 | 4/14/2021 | I passed out; This is a spontaneous report from a contactable consumer (patient). A 59-year-old female patient received BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: ER 8737), administered in right arm, on 13Apr2021 at 14:30 (at the age of 59-years-old) at unknown, single for COVID-19 immunisation. The patient was not pregnant at time of vaccination. Medical history included known allergies to sulfa. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient had not been tested for COVID-19. Concomitant medications included paroxetine, ciclosporin (RESTASIS), fluticasone propionate (FLONASE), vitamins nos (MULTIVITAMIN); all reported as other medications the patient received within 2 weeks of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient previously took codeine and experienced allergies. The patient passed out on 14Apr2021 at 03:00. The event was reported as non-serious, required emergency room/department or urgent care. Therapeutic measures were taken as a result of the adverse event and included treatment with intravenous fluids. The patient was recovering from the event. |
| 1371238 | 6/3/2021 | NJ | 27 | M | 6/3/2021 | 6/3/2021 | Approximately 1 minute after administering vaccine, patient asked for water with complaints of lightheadedness. As he walked up to pharmacy door for water, he collapsed to the ground. He went in and out of consciousness while laying on the ground for about ten minutes. He had no other complaints other than lightheadedness. He did not eat any food today. He said in the past he had fainted after getting a numbing injection for a dental procedure and believes it may be a similar reaction. The paramedics were called and evaluated him. His blood pressure and HR were within normal limits. He refused to be taken to the hospital for further evaluation. |

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| 1370555 | 6/3/2021 | IL | 30 | M | 5/16/2021 | 5/18/2021 | My fiance has now fainted 3x times 32 hours after having his second dose.; This is a spontaneous report received from a non-contactable consumer reported for 30-year-old male consumer (reporter's fiance). A 30-years-old male patient received second dose bnt162b2 (PFIZER-BIONTECH COVID 19 VACCINE), via an unspecified route of administration, administered in Arm Left on 16May2021 15:00 (at 30 years old age) (Lot Number: EW0173) at single dose for covid-19 immunisation . The patient medical history and concomitant medications were not reported. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient previously received first dose bnt162b2 (PFIZER-BIONTECH COVID 19 VACCINE), via an unspecified route of administration, administered in Arm Left on 25Apr2021 15:00 (at 30 years old age) (Lot Number: EW0172) at single dose for covid-19 immunisation. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Reporter's fiance had now fainted 3x times 32 hours after having his second dose. The last time was just after a couple minutes of standing and he started to sieze before coming to. They wouldn't be able to work today because we need to monitor it. Reporter would bring him to the ER if it continued. Adverse event start date was 18May2021. Adverse event start time was 03:00 AM. No treatment was received for the adverse event. The event did not result in death and caused/prolonge hospitalization, was not Life threatening, disabling/incapacitating, congenital anomaly/birth defect. Facility where the most recent COVID-19 vaccine was administered was Public Health Clinic/Veterans. Since the vaccination, the patient has not been tested for COVID-19. The outcome of the event was not recovered. |

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| 1370594 | 6/3/2021 | OH | 14 | U | 5/18/2021 | 5/19/2021 | fainted morning after shot.; Sore arm; Headache all day; tired; This is a spontaneous report from a contactable consumer reported for self. This 14-year-old patient of unspecified gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot#: Ew0177) at single dose in left arm on 18May2021 16:00 for COVID-19 immunisation. There was no medical history, no allergies. Concomitant medication within 2 weeks of vaccination included cetirizine hydrochloride (ZYRTEC). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. On 19May2021 07:30, patient fainted morning after shot, experienced sore arm, headache all day, tired. There was no treatment received for the events. The reporter considered report as non-serious, not resulted in death, not life threatening, not caused/prolonged hospitalization, not disabling/incapacitating, not congenital anomaly/birth defect. The outcome of events was resolving. No follow-up attempts are possible. No further information is expected. |

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| 1370640 | 6/3/2021 | TX | 27 | F | 5/18/2021 | 5/19/2021 | fainted; At 3am I woke up feeling very sore; came to drenched in sweat; felt very heavy; having trouble moving my limbs and holding my head up; experienced palpitations band an elevated heart rate; experienced palpitations band an elevated heart rate; threw up; diarrhea; This is a spontaneous report from a contactable nurse (patient). A 27-year-old non-pregnant female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EW0176, expiration date not provided), 2nd dose via an unspecified route of administration, administered in Arm Left on 18May2021 14:15 at age of 27 years old as a single dose for COVID-19 immunisation. Medical history included irritable bowel syndrome (IBS). The patient's concomitant medications were not reported. The patient previously took BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EW0176, expiration date not provided), 1st dose via an unspecified route of administration, administered in Arm Left on 27Apr2021 14:15 as a single dose for COVID-19 immunisation. The patient experienced 'fainted, at 3am I woke up feeling very sore, came to drenched in sweat, felt very heavy, having trouble moving her limbs and holding her head up, experienced palpitations band an elevated heart rate, threw up, diarrhea', all on 19May2021 03:00. At 3am she woke up feeling very sore so she got up and walked to the bathroom to take some Tylenol. Before she could take any she fainted. After it passed she tried to sit up with her back against the wall and fainted again. She came to drenched in sweat and felt very heavy. She was having trouble moving her limbs and holding her head up because they felt too heavy. She also experienced palpitations band an elevated heart rate during this. Then she threw up and had diarrhea. No treatment received. The outcome of the events was recovering. The report was reported as non-serious. The patient was not pregnancy at time of vaccination. The patient had no known allergies. The patient had not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient received within 2 weeks of vaccination included oral birth control. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. Information on the lot/batch number has been requested.; Sender's Comments: Based on the current available information |

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and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of event faint cannot be excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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| 1370652 | 6/3/2021 | | | M | | | fainted immediately following vaccination; Mom described movements as tonic clonic with stiffening of muscles and jerking movements during fainting episode; This is a spontaneous report from a contactable pharmacist (parent). A 12-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as UNKNOWN, SINGLE DOSE for covid-19 immunisation. Medical history included fainting where the mother reports withheld has fainted in the past following administration of a vaccine. Unsure of the vaccine and exact date not known. The patient's concomitant medications were not reported. On an unspecified date, the patient fainted immediately following vaccination. The mother described movements as tonic clonic with stiffening of muscles and jerking movements during fainting episode. The outcome of the events was unknown. Information about the lot/batch number has been requested.; Sender's Comments: Based on the close temporal relationship, the association between the events "fainted immediately" and "tonic clonic with stiffening muscles and jerking movements" with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate. |
| 1371018 | 6/3/2021 | NH | 14 | M | 6/2/2021 | 6/2/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium |
| 1371029 | 6/3/2021 | IN | 30 | M | 6/1/2021 | 6/2/2021 | Had bloody stool followed by dizziness, ringing in ears, loss of strength, heavy sweats-- nearly passed out. Most symptoms passed after event but was weak for the rest of the day. |

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| 1371042 | 6/3/2021 | IA | 26 | M | 5/28/2021 | 5/28/2021 | Approximately 10 minutes after receiving the injection, patient states that he felt hot, lightheaded, and had stomach pain. As he was moving to a recliner, patient passed out. The pharmacist called 911, and raised patient legs onto a chair. Patient woke back up, and the pharmacist said that his eyes were "not normal". Paramedics arrived, and transported patient to the emergency room. Patient states that he was at the ER for approximately 2 hours, and then discharged. While at the ER, he received IV fluids and blood work was performed. He has not had any other complications besides a sore arm at the site of injection. |
| 1371050 | 6/3/2021 | NY | 29 | F | 6/2/2021 | 6/2/2021 | Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Mild, Systemic: Nausea-Severe, Systemic: Vomiting-Severe, Systemic: Weakness-Medium, Additional Details: patient was initially feeling nauseous and vomited. She did not lose consciousness or forget memory. She was unresponsive to questions, but were able to move her body and hands to touch. Her breathing did not stop -- but seemed like it was slowing down. She received one dose of epipen. After few minutes, she was responsive and was able to reply in short words and was aware of the situation and where she was. |

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| 1370520 | 6/3/2021 | FL | | F | | 3/11/2021 | <p>just went out cold; fell flat on tile in bedroom; still have pain being treated by plastic surgeon that operated in hospital; The initial case was missing the following minimum criteria: reporter with firsthand knowledge. Upon receipt of follow-up information on 18May2021, this case now contains all required information to be considered valid. This is a spontaneous report from a contactable consumer (patient). An 80-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), via an unspecified route of administration, administered in the right arm on 18Feb2021 (Batch/Lot Number: EL9267) as 1st dose, single and via an unspecified route of administration, administered in the right arm on 11Mar2021 14:00 (Batch/Lot Number: EN6205) as 2nd dose, single for COVID-19 immunization. The patient had no prior vaccinations within 4 weeks. The patient's medical history included heart attack from 25Aug2017 to an unknown date (stent right coronary artery (RCA)). Concomitant medications included escitalopram; vitamin D NOS; cyanocobalamin (B-12); ubidecarenone (COQ 10); calcium; omeprazole; fluticasone furoate, vilanterol trifenate (BREO ELLIPTA); ketotifen fumarate (ZADITOR); ticagrelor (BRILINTA); alprazolam; telmisartan; atorvastatin; montelukast; fluticasone; salbutamol sulfate (VENTOLIN HFA); and unspecified probiotic; all taken for an unspecified indication from an unspecified start date and ongoing. The patient reported that she has never passed out or fainted. On an unspecified date at 07:30 pm, she had no warning and just went out cold. Emergency room visit was required. The patient further reported that she fell flat on tile in the bedroom. There was no warning. The patient reported the events as serious with seriousness criteria hospitalization (in the hospital for 5 days) and important medical event. The patient stated "Both knees, left eye, left arm (shoulder, left) 3 layers of stitches in the upper lip. Still have pain, being treated by plastic surgeon that operated in hospital". The patient was hospitalized for 5 days and she was treated by plastic surgeon - underwent plastic surgery and reconstruction of lips. The outcome of the events was unknown.</p> |

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| 1371825 | 6/3/2021 | NJ | 21 | M | 6/3/2021 | 6/3/2021 | The patient recieved the janssen covid vaccine at about 2:35pm. Patient passed out by his chair. It was about a few minutes after getting the janssen covid vaccine. We called 911. I went to assist him and was alert. He sat on the floor and I checked his pulse. He was pale. I offered him water which he drank after about 5 minutes. The EMT's arrived after a few minutes and checked him out. Took his vitals and looked him over. The patient left after 20 minutes. |
| 1372133 | 6/3/2021 | NY | 36 | M | 6/3/2021 | 6/3/2021 | patient passed out for a few minutes but regain conscious quickly, patient complained of being light headed and appeared pale. Paramedics arrived to check patient's condition. Patient blood pressure, heart rate and respiration was evaluated. Patient refused to go to the hospital and remained at our sigh for observation for 30 minutes |
| 1372089 | 6/3/2021 | CA | 32 | M | 6/3/2021 | 6/3/2021 | Patient was vaccinated and within few seconds he was feeling disoriented, light headed and dizzy for over 10 minutes. Pt did not loose his consciousness. He was sweating profusely and appeared pale. Could have been possible syncope. Called 911, paramedics arrived at the scene and checked his vitals. Blood pressure was 117/ 70. Pt was was feeling normal when paramedics arrived. Paramedic checked his blood sugar using finger prick.(His blood sugar was around 150) Pt immediately fell little disoriented and dizzy and recovered in 2 minutes. Pt was not admitted to hospital. He was doing well when he left the pharmacy after 30 minutes or so. Pt said that he had similar episode when blood was drawn for some lab tests in the past. |
| 1372057 | 6/3/2021 | CT | 70 | F | 2/10/2021 | 2/11/2021 | After receiving the first vaccine my right arm was extremely sore and painful. Then after taking my second shot on March 10 my arm was still sore and painful. On March 11 I passed out after taking my allergy medicine, mometasone. I am still suffering from these side effects. The first shot was not given properly in my arm. Not in the muscle. The orthopedic refered me to see a physical therapist. I have been seeing the pt from March to the present. I am restricted from doing many things that I did before the shot. |

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| 1372008 | 6/3/2021 | WA | 23 | M | 6/3/2021 | 6/3/2021 | Patient became syncopal within seconds of receiving the shot. Passed out for about 10 seconds. Felt dizzy and nauseous after. Lay pt down on cot, elevated feet. BP supine 110/68 P 66 R 16. Postural drop when seated, lay back down. After about 20 minutes pt maintained pressure when seated and standing, dizziness subsided. Pt declined further treatment or transport and friend drove him home. Advised to call 911 if began to feel worse. |
| 1371977 | 6/3/2021 | MA | 54 | M | 6/1/2021 | 6/3/2021 | On the 2nd day after 2nd Pfizer vaccination I experienced dizziness then fainted, with fatigue and nausea |
| 1371961 | 6/3/2021 | CA | 30 | M | 6/3/2021 | 6/3/2021 | Patient Fainted 2 minutes after vaccine. He was sitting in chair and fell (caught by family) and woke up instantly. As I arrived, 10 seconds after fall, his eyes were open but he could not see anything. He was able to state his name, date of birth, and where he was, just couldnt see. "Everything is all black." After closing eyes for 30 seconds, opened and he could see, but everything was green. Vision color was back to 100% after 20 minutes but still blurry. Patient BP was normal. Sweating. |
| 1371948 | 6/3/2021 | IL | 18 | F | 4/26/2021 | 4/26/2021 | Fever and syncope followed by chronic headaches since |
| 1372138 | 6/3/2021 | TX | 55 | F | 1/22/2021 | 1/23/2021 | The next day, I felt so nauseous; I had gotten up to go to the bathroom to vomit and I passed out and hit my head on the bathtub. I got some medication to help with the nausea. I slept all day. I felt a little better the next day after. I had a headache, feeling weak and not back to par. On February 2, my blood pressure was so high that I just wanted to lay down; I came home early from work. My chest started feeling tight. I went to Urgent Care. My blood pressure had been 185 over something. and it came down to 130s. The doctor there started me on Propanol. Later, I saw my PCP on March 3, 2021 - She started to change my meds on that date and I saw her a couple of times - April 16, I think was the next time. I saw her again on May 14th. My PCP took me off of that and increased my Locinaprol and she added HCTZ , a diuretic and Carvedilol- and doubled dose on that. With those meds my high blood pressure is back under control. Probably Mid-April by the time all of that started to feel better. The blood pressure is back to being controlled. |

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| 1371506 | 6/3/2021 | CA | 32 | M | 3/18/2021 | 3/18/2021 | Patient with history of fainting after receiving shots, seen slipping off chair, assisted to ground by staff, patient altered level of consciousness and weak. Patient assisted to gurney chair, placed in trendelenburg position, vitals taken, HR in the high 40s, patient slowly began to regain consciousness, able to speak, take in fluids and crackers, assisted to sitting position, tolerated well. Patient then allowed to stand, denied dizziness. Patient declined ED transfer or medical follow up, red flag symptoms discussed, Alert and Oriented x 4, transferred via wheelchair to car, fiance drove car. |
| 1371878 | 6/3/2021 | MI | 16 | F | 6/3/2021 | 6/3/2021 | Vasovagal event. Pt fainted and immediately came to. Pt felt better after about 15 minutes and was able to walk. |
| 1371225 | 6/3/2021 | PA | 17 | F | 6/3/2021 | 6/3/2021 | Patient developed warmth, clamminess, nausea and lightheadedness shortly after her shot. She admitted to near syncope, but there was no LOC. No tunnel vision. Symptoms resolved on their own. VVS throughout. No orthostasis. |
| 1371788 | 6/3/2021 | TX | 12 | M | 6/3/2021 | 6/3/2021 | Pt stated feeling nausea, mother stated pt passed out for 15 seconds then gained consciousness. Pt left at 2:25 feeling better P:80 BP: 126/79 O2: 99% T: 77.5 F RR: 14 |
| 1371780 | 6/3/2021 | | 18 | M | 6/3/2021 | 6/3/2021 | While in observation after vaccine was given, 18 y/o male had a tension of body and fainted out of chair from sitting position. Head did hit the concrete floor. Male immediately jumped up once he hit the floor. Syncopal event occurred. HE was brought back into treatment area and placed on EKG along with vitals. Normal sinus rhythm, BP and HR stable. Small laceration to right side of temporal lobe about 1cm long, minimal depth, no stitches required, bleeding stopped immediately and ice pack placed. Neurological intact, pupils equal and reacted to light. AAOX4, No nausea, vomiting or dizziness. Male is stable condition with brother. Advised to seek further eval with x-ray of skull for precaution. He was in agreement and understood. |

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| 1371775 | 6/3/2021 | CA | 22 | M | 6/2/2021 | 6/2/2021 | Pt received 2nd dose Pfizer @1330 & noted to have fainting episode @1335 in observation area. Woke up with TRN support & was transferred from chair to w/c. Brought to triage area, noted w/dizziness, cool sweat & pale complexion. Pt state he has history of fainting in past. Denied CP, SOB & other abnormal sx. BP 105/57; HR 84; O2 Sat 97%) Monitored patient for 15 min & increased hydration/fluids. Pt was stable & released from vaccination site |
| 1371766 | 6/3/2021 | TX | 12 | M | 6/3/2021 | 6/3/2021 | Pt stated feeling nausea, mother stated pt passed out for 15 seconds then gained consciousness. P:80 BP: 126/79 O2: 99% T: 77.5 F RR:14 |
| 1371746 | 6/3/2021 | GA | 34 | M | 6/3/2021 | 6/3/2021 | Patient was fine at time of injection. Patient stated he started feeling the vaccine throughout his body and that he was going to pass out. Patient passed out and came back to quickly; patient drank a bottle of water once he came to. I had the patient wait for 30 minutes in the pharmacy; he was fine at the time he left. Called back at 3:11pm; he states he is doing fine. He passed out with the first vaccination as well. |
| 1371733 | 6/3/2021 | IN | 57 | F | 6/3/2021 | 6/3/2021 | Patient fainted during observation period after pfizer covid vaccine. The patient was laid flat on her back with feet elevated and the pharmacy called EMS. The pt left with EMS |
| 1371718 | 6/3/2021 | AR | 38 | M | 6/3/2021 | 6/3/2021 | Patient received a dose of the Jassen covid vaccine and was sitting in the waiting room for his 15 minutes of observation. After about 10 minutes he passed out and fell out of his chair bumping his head on the way down. |

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| 1371888 | 6/3/2021 | PA | 24 | F | 1/31/2021 | 1/31/2021 | So at around 9pm the evening of my shot, I started feeling feverish so I went to the other room to get my temperature and while I was waiting for my temperature to be recorded, I started to feel lightheaded and I called out for help. I woke up on the floor, I woke up to my roommate and boyfriend standing over me. They were on the phone with 9-1-1. I was out for about a minute and unresponsive. According to them, my arm was flailing and seizure-ish. I went to the ER, I was taken by EMS services. They gave me fluids and ran bloodwork and monitored me. They sent me home, I did have another episode of what I think was an episode of memory loss/passed out. I just remembered waking up in a room alone. I was at the ER for about 4-5 hours. They gave me IV fluids and I don't remember what else, some sort of supplement. It was magnesium oxide they gave me. When I left the ER I was really exhausted, and feverish and gross and I was pretty sick for the remaining two days. I didn't sleep well that night, I had a fever the following day and into the second day upon returning home as well. |
| 1371607 | 6/3/2021 | MD | 66 | M | 3/31/2021 | 4/8/2021 | he felt achey and weak for a day or two then had syncope then he had syncope again this morning. found to have NSTEMI. received PCI with a DES x1. recovered and discharged home |
| 1371822 | 6/3/2021 | AL | 18 | M | 6/3/2021 | 6/3/2021 | Approximately 5 minutes after receiving the vaccine, the patient passed out and his eyes rolled back (possible seizure activity). This activity lasted for approximately 1 minute. Patient also felt dizzy, sweaty, nauseous, and became pale. Patient was given a cold ice pack to lower his body temperature. Patient was also given crackers for nausea, and a bag just incase he had to vomit. Patient's mother was also here to tend to the patient. The mother also gave him clear fluids (sprite) to help with the nausea. After approximately 10 minutes, the patient was able to stand without feeling dizzy. He left the store with his mother to be watched closely (His mother is a nurse.) They also refused emergency medical services. |
| 1372299 | 6/3/2021 | WI | 21 | M | 6/3/2021 | 6/3/2021 | before the shot, the patient reported that he has a history of fainting. Patient fainted shortly. was given ice pack, and recovered over about 20 minutes. |

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| 1371550 | 6/3/2021 | MA | 30 | F | 6/3/2021 | 6/3/2021 | fainted and looked pale |
| 1371573 | 6/3/2021 | PA | 25 | M | 6/3/2021 | 6/3/2021 | Patient fainted after receiving shot. He came too after 1 to 2 minutes. He was pale in the face but was back to normal after waiting for 30 minutes after the episode. |
| 1371651 | 6/3/2021 | NC | 21 | M | 6/3/2021 | 6/3/2021 | Patient had two syncope events after vaccine administration lasting approximately 5-10 seconds. He was monitored continuously. EMS were called and checked blood pressure, blood glucose, and did an EKG - all values were normal. Additionally, patient remained being monitored for 30 minutes until picked up by family member. Patient recovered from adverse events. |
| 1372929 | 6/3/2021 | CA | 25 | F | 6/3/2021 | 6/3/2021 | 25 year old female with prior history of syncope was at public vaccine clinic when she syncopated 9 minutes s/p receiving her 1-time IM dose of J&J COVID-19 vaccine in her L deltoid. When she syncopated, she fell forward while sitting in a chair and hit her head on concrete. She suffered a 1cm superficial laceration on her L frontal scalp. There was a brief moment of generalized seizure-like activity that lasted for about 10 seconds. After this, she woke up and was able to sit up. Patient appeared anxious. She was alert and oriented x 3 once she was up with a GCS of 15. |
| 1372919 | 6/3/2021 | CO | 57 | F | 6/3/2021 | 6/3/2021 | 09:07 10 minute after receiving the 2nd Pfizer vaccine, pt.c/o being hot and clammy. Pt. states she had the same reaction after the 1st Pfizer vaccine. There was no syncope event, hr 71, O2 98%, and AAO. Cold pack applied to her head and water given. Pt. monitored for 30 min, feelings resolved. Pt. discharged from clinic and accompanied by her husband. |
| 1372906 | 6/3/2021 | IL | 14 | M | 6/3/2021 | 6/3/2021 | Patient fainted approximately 5 minutes after receiving the vaccine. He fell to the ground hitting his head on some shelving while falling. He was quickly revived by his father, but still felt dizzy and complained of blurred vision. Patient was given a bottle of water and comforted by his father and brother. When I checked on him about 20-30 minutes later, he said he felt fine. He looked a lot better too. |

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| 1372542 | 6/3/2021 | CA | 16 | F | 6/3/2021 | 6/3/2021 | patient fainted a few minutes after getting pfizer covid vaccine. She felt better 5 minutes later, Her blood pressure was 113/69 pulse 73. Her blood pressure was 98/64, pulse 80 30 minutes after. But she felt perfectly fine then. |
| 1372786 | 6/3/2021 | TX | 28 | M | 6/3/2021 | 6/3/2021 | Syncope and Sweating. Laying down and water. Fully recovered after 30 or so minutes. |
| 1372767 | 6/3/2021 | MO | 54 | M | 6/3/2021 | 6/3/2021 | Patient reported feeling funny and then fainted for a couple of minutes. When he regained consciousness he was sweating profusely. |
| 1372761 | 6/3/2021 | OR | 73 | M | 5/19/2021 | 5/19/2021 | SYNCOPE within an hour |
| 1372603 | 6/3/2021 | | 34 | M | 6/3/2021 | 6/3/2021 | Pt in for 2nd dose of COVID vaccine, negative reaction to first vaccine. Pt states he felt very dizzy after the injection. Staff (not including myself) witnessed pt have vasovagal fainting response (for about 3 seconds) and he fell straight down to ground from standing position. Paramedic(s) state they heard the pt hit the ground, and responded to the nurse stn quickly. This writer was passing out water to another pt when noticed the activity happening and was beckoned to come to the nurse's stn. Pt alert at this time, has c/o HA, no N&V, states does feel some dizziness, v/s 144/92, O2= 98%, R=16, responds to commands but keeps asking ?What happened? ? hand strength is stable, pupils are equal and reactive to light, no bleeding of head,ears, nose,etc, noted. Ice pack applied to pt?s forehead, does have profuse sweating. No significant medical hx, no allergies. 1205pm: 133/84, p=87, O2= 98% R 16, aware of name/ place/location, but continues to ask ?what happened?, no LOC noted. Advised team to call 911, pt needs to go for further exam of head injury, though he remains stable and alert. GF of pt unable to drive pt because she doesn't know how to drive stick shift. 1210pm: 135/86, p 94, R 16, O2 sat 98%, pt remains alert, sweating has stopped,denies dizziness at this time, does continue to say that ?back of head hurts? 1220pm paramedics have arrived. BP 128/68, p 85, R 16, O2 sat 98%. Assessment done by paramedics. Pt to go to hospital via ambulance, 1225pm pt left via gurney to ER. GF waiting for a ride for someone to come drive the car for her to meet pt at ER. Pt left alert, slowly starting to remember that he fell after injection he states. |

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| 1372592 | 6/3/2021 | WA | 38 | M | 4/10/2021 | 4/11/2021 | Immediately after the shot, I began to feel light headed. The first time I felt like I was going to faint was 04/11/2021 within 24 hours of getting the shot. I began to feel lightheaded over the next few weeks. On May 2, 2021, I collapsed and fainted |
| 1372902 | 6/3/2021 | TN | 12 | F | 6/3/2021 | 6/3/2021 | Patient fainted after immunization. She waited 15 minutes after and was walking to car and fainted. EMS was called and came to evaluate her. No treatment was needed. |
| 1371569 | 6/3/2021 | MO | 13 | M | 5/20/2021 | 5/23/2021 | Sharp chest pains, difficulty breathing and passed out for about 30 seconds. |
| 1372326 | 6/3/2021 | GA | 23 | M | 6/3/2021 | 6/3/2021 | Patient fainted several minutes after receiving Moderna COVID vaccination and became conscious several seconds later. Sweating, loss of consciousness were the symptoms. Laid patient on the ground with feet elevated and ice pack on forehead. He received some water, juice and food and felt better within 30 minutes and was taken home by family members. |
| 1368845 | 6/2/2021 | CA | 37 | M | 6/2/2021 | 6/2/2021 | Client received 1st COVID vaccine of Pfizer (Lot #EW0187, expiration 06/28/21). Client reported pressure on left side of head near left ear at 1333. RN and EMT responded to this event. At 1334, vital signs are blood pressure 144/78, heart rate 87, oxygen saturation 95%. Client reported he was clenching his jaw during vaccine administration. At 1339, vital signs are blood pressure 136/79, heart rate 79, oxygen saturation 97%. RN and PHN responded to this event. Client reports a history of anxiety and fainting after needles. Client reports no medication usage. Client reports no chest pain, no dizziness, no shortness of breath, no blurred vision, no nausea. At 1349, vital signs are blood pressure 131/76, heart rate 88, oxygen saturation 91%. Client reports that the pressure on the left ear started at the time of administration. At 1351, Client reports that the pressure as subsided and no new symptoms. At 1354, vital signs are blood pressure 138/76, heart rate 88, oxygen saturation 90%. Client reports a history of fainting after vaccinations. Client was educated about ED precautions and common adverse effects of COVID vaccine. At 1358, Client stood up with no complaints and a steady gait. Client walked out of facility at 1358. |

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| 1368832 | 6/2/2021 | NY | 3 | F | 6/2/2021 | 6/2/2021 | Pt became lightheaded at recovery table near syncope . brought to cot to lie down, elevated feet. ice pack to back of neck. no LOC, No SOB, no N/V. Pt stated she is menstruating. Rt arm vac site benign. VS 108/58, HR 80 Reg, strong, resps 12 reg, non labored, SPO2 98%. Gave water for hydration, provided reassurance. After lying down flat for 15 min, pt stated "I feel better, I OK". Ok'd to exit with family. |
| 1368825 | 6/2/2021 | NC | 43 | M | 6/2/2021 | 6/2/2021 | PATIENT DID WELL UPON IMMEDIATE RECEIPT OF VACCINE. MOVED PATIENT TO OBSERVATION AREA. WITHIN 10 MINUTES PATIENT FAINTED ONTO FLOOR,HIT HEAD AND BECAME NONRESPONSIVE. WE CALLED 911. WITHIN SECONDS HE BECAME RESPONSIVE AND DID NOT WANT EMS TO COME. WE GOT ICE PACKS FOR THE BACK OF HIS NECK AND FOREHEAD AND MADE HIM COMFORTABLE ON THE FLOOR. HE CONTINUED TO SAY HE WAS FEELING BETTER AND THAT IT JUST CAME ON VERY QUICKLY. AFTER 20MINUTES HE WANTED TO SIT UP IN THE CHAIR. AFTER A FEW MINUTES WE MOVED HIM TO A MORE COMFORTABLE CHAIR. PATIENT CONTINUED TO TALK AND RESPOND. AFTER 15 MORE MINUTES HE DECIDED HE WAS GOOD ENOUGH TO LEAVE. |
| 1368763 | 6/2/2021 | | 35 | F | 5/28/2021 | 5/28/2021 | Patient fainted/ passed out after receiving vaccine. Patient was flush, tensed up and non responsive for short period of time. Came back confused and dizzy. After an extended period color came back and patient was responsive. |
| 1368732 | 6/2/2021 | WA | 40 | F | 5/29/2021 | 5/31/2021 | On 5/31/21, patient's husband described that the patient fainted and experienced seizure-like activity. She reported nausea and dizziness before and after the episode. It took approximately 2 minutes for her to regain consciousness and she didn't have any recollection of what had happened. On 6/1/21, patient's daughter contacted nurse triage after she experienced forgetfulness and word-finding trouble, performed a FAST exam, and patient was admitted. Work-up pending. |
| 1368683 | 6/2/2021 | MS | 62 | M | 6/2/2021 | 6/2/2021 | AFTER ABOUT 1 MINUTE, PATIENT FAINTED, SWEATED PROFUSELY, LIPS TURNED WHITE |

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| 1368669 | 6/2/2021 | CA | 23 | F | 6/2/2021 | 6/2/2021 | Patient fainted for 3-4 seconds after receiving the Janssen vaccine. Patient fainted in chair, woke up after a few seconds. Per patient, has history of fainting (but not due to vaccines). Patient stated that she worked an overnight shift and had nothing to eat or drink all day. |
| 1368645 | 6/2/2021 | NJ | 16 | F | 6/2/2021 | 6/2/2021 | syncope |
| 1368893 | 6/2/2021 | CA | 48 | F | 5/29/2021 | 5/29/2021 | I got a little dizzy within 15 minutes, but it let up so they let me go. About 7 hours later, I started getting chills and nausea. I dozed off, and when I woke up, I was extremely nauseous and dizzy. So much so that i almost passed out. I tried to walk to the bathroom and fell down. It felt like my legs weren't working. When I tried to get back in bed, I collapsed on the floor and was sweating and freezing at the same time. My heart was racing as well. I fell back to sleep and a few hours later, I was able to walk a bit better. Sunday, my temp hovered around 99.8 for a few hours and then started dropping, and I was feeling better. |
| 1369584 | 6/2/2021 | OR | 14 | M | 6/2/2021 | 6/2/2021 | pt mom yelled for help. other employee dialed 911. mom reporting that patient keeps fainting/feeling nausea. used smelling salt x 2. then had patient have small sips of orange juice. patient began feeling nausea again and threw up. pt started breathing heavy/flushed/wheezing administered epi-pen (1st dose incomplete- bent needle) 2nd dose successful in muscle of right thigh. patient reported feeling better. took bp 94/54 pulse 88. ems arrived and took over. patient left with ems |
| 1368679 | 6/2/2021 | WA | 74 | F | 3/10/2021 | 3/11/2021 | Patient received 2nd dose of Moderna vaccination in her right deltoid on 3/10/2021 at 1242. On 3/11/2021, patient passed out and landed on face. Patient was taken to hospital in ambulance and received stitches from fall and claimed to have nausea and vomiting. Patient still feels numbness on face. |
| 1368903 | 6/2/2021 | FL | 44 | M | 6/2/2021 | 6/2/2021 | Patient was sitting for 15 minute observation and suddenly passed out for about 10 seconds. He was sweaty and pale and mentioned being light headed. |

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| 1369036 | 6/2/2021 | WA | 34 | F | 6/2/2021 | 6/2/2021 | Patient fainted a couple minutes after receiving COVID vaccination. Patient has a history of fainting after prior vaccinations. Patient was observed for a few minutes, an ice pack was applied to the back of the head, and patient was provided orange juice. Patient was observed until she stated she was feeling back to normal. |
| 1369046 | 6/2/2021 | WI | 25 | F | 6/2/2021 | 6/2/2021 | Patient did not indicate any precautions or contraindications on the Vaccine Administration Sheet. Following the immunization she left the Personal Services Room to wait the required 15 minutes post vaccination observation period in the waiting area where there are chairs for the patient. As the Pharmacist came back into the Pharmacy the patient, while standing in the waiting area by the chairs, complained of dizziness. She then fainted and fell to the floor, hitting her head on a wall on the way down. The Pharmacist had a technician call 911 and tended to her. She was instructed to lay still on the floor in the position she was in on her back. A nurse was in the area and also rendered assistance. Patients blood pressure was checked and she was offered water. The paramedics came and evaluated her. She was later released to a family member who came and picked her up. |
| 1369072 | 6/2/2021 | NY | 18 | M | 6/2/2021 | 6/2/2021 | syncope, fatigue, eyes heavy |
| 1369080 | 6/2/2021 | SC | 28 | M | 6/2/2021 | 6/2/2021 | ABOUT 10 SECONDS AFTER TIME OF INJECTION, PATIENT LOST CONSCIOUSNESS AND PASSED OUT AND SLUMPED OVER. AFTER ABOUT 20 SECONDS, HE CAME REGAINED CONSCIOUSNESS AND WAS SHAKING FOR ABOUT 3 SECONDS OR SO. PATIENT WAS VISIBLY NERVOUS AND CLAMY TO THE TOUCH. PATIENT WAS ABLE TO COMMUNICATE WITH US WHILE EMS WAS CHECKING VITAL SIGNS. |

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| 1369314 | 6/2/2021 | TX | 40 | M | 6/2/2021 | 6/2/2021 | Shortly after receiving the Janssen vaccine, he saw his wife also receive the vaccine after which he felt extremely nauseous and looked very pale. His blood pressure was checked and measured 120/66, he said he was starting to feel warm but did not have any chest tightness, difficulty breathing, or swelling. After about 2 more minutes he said he was starting to feel better and then after 5 more minutes his blood pressure was 120/81, and he was starting to show more color to his face. He said he felt fine to leave. In hind-sight he stated that he has fainted in the past after seeing his wife receive a previous immunization as well. |
| 1369328 | 6/2/2021 | CA | 14 | F | 6/2/2021 | 6/2/2021 | On 6/2 patient received her first dose of covid19 (Pfizer vaccine). After a couple minutes, it was reported to us by her brother that the patient passed out. However, she was alert within seconds. Paramedics were called upon brother's request. Patient was transported out of store. |
| 1369348 | 6/2/2021 | CO | 38 | M | 6/2/2021 | 6/2/2021 | patient fainted within 5 minutes after receiving vaccine; fainting lasted less than 1 minute . patient reports excessive sweating/feeling hot. patient reported on form no reaction to vaccine on patient questionnaire. patient states that fainting happens at the dentist and in the past when getting a vaccine after the episode. patient also reports that he had not eaten all day, had 3 hours of sleep as well. patient remained in vaccine area for 30 minutes after recovery, drank 2 small bottles of water. patient declined additional emergency services . patient stated he was feeling well and left the pharmacy. advised pt to sign up |

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| 1369954 | 6/2/2021 | TX | 41 | M | 6/1/2021 | 6/1/2021 | I felt completely fine for the first 5 minutes. I left the store. After 5 more minutes I started feeling bad (I was seated). My whole body was sweating and my vision was affected (everything was bright). I was able to return to the store but was close to passing out. I sat down for about 10-15 minutes while the symptoms persisted and I was not able to see well. After that time the sweating stopped and my sight was no longer affected. This was not anxiety and I have no history of fainting with shots. This was a reaction to the shot. After about an hour I felt fine except for muscle soreness at the injection sight. If the reaction was any worse I would have passed out or asked for help. I am hesitant to get a second dose out of concern that the reaction could be worse. |
| 1368644 | 6/2/2021 | WA | 29 | M | 5/31/2021 | 5/31/2021 | This description was reported to this writer. The patient had just arrived and sat down in the post vaccination area. He was sweating profusely on his head. The patient was assisted to the floor by the nurse. The patient did say to the nurse that he was "feeling lightheaded". He stated that he had a needle phobia. Patient denied a history of fainting and of diabetes. Vital signs were taken. EMTs were notified to attend to patient. Patient was assisted to a chair. Encouraged to drink fluids. Patient was released by EMTs after 30 minutes. |
| 1369335 | 6/2/2021 | AZ | 15 | M | 6/2/2021 | 6/2/2021 | AFTER PT RECEIVED THE PFIZER COVID VACCINE THE PT SAT DOWN AND SHORTLY AFTER FAINTED. THE PT WOKE UP AND WE GAVE HIM COLD WATER AND AN ICE PACK. PER PARENTS, PT HAS NO PREVIOUS HISTORY OF FAINTING OR ANY OTHER HEALTH CONDITIONS. PT LOOKED DEHYDRATED. SPOKE WITH PTS PARENTS AND TOLD THEM THEY NEED TO GO TO THE EMERGENCY ROOM AND THAT WE CAN CALL AN AMBULANCE. PARENTS REFUSED AMBULANCE AND INSTEAD TOOK THE CHILD TO THE EMERGENCY ROOM ACROSS THE STREET. SPOKE TO THE MOTHER AFTERWARDS. SHE STATES THAT HER SON WAS SENT HOME. THE DRS BELIEVE HE FAINTED DUE TO A LACK OF FOOD AND WATER (DEHYDRATION). THEY SENT HIM HOME AND TOLD THE PARENTS IT WAS OK FOR HIM TO RECEIVE A 2ND COVID VACCINE 21 DAYS LATER. |

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| 1367146 | 6/2/2021 | MA | | F | 5/16/2021 | 5/1/2021 | She fainted when she had it and she has a headache; She fainted when she had it and she has a headache; This is a spontaneous report from a contactable consumer reported for daughter. A female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 16May2021 (Batch/Lot number was not reported) as 1st dose, single for covid-19 immunisation. She fainted when she had it on 17May2021 and she had a headache in May2021. Outcome of the events was unknown. Information about Lot/ batch number has been requested |
| 1367873 | 6/2/2021 | NJ | 52 | F | 5/27/2021 | 5/28/2021 | Fainted. in addition to vomiting, severe sweating, headache, achy, fever, chills, etc. |
| 1367865 | 6/2/2021 | NY | 29 | F | 6/1/2021 | 6/1/2021 | Systemic: Fainting/Unresponsive-Mild. |
| 1367860 | 6/2/2021 | TX | 15 | F | 6/1/2021 | 6/1/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Hypotension- Medium |
| 1367857 | 6/2/2021 | GA | 17 | M | 6/1/2021 | 6/1/2021 | Systemic: Fainting / Unresponsive-Severe, Systemic: patient had a seizure about 5 mins following administration-Severe, Systemic: Seizure-Severe, Additional Details: ems was called and patient was evaluated and pt was cleared with normal vitals and alert from ems parent refused to go to er i tried calling to follow up with patient and now answer on best contact number |
| 1367856 | 6/2/2021 | NC | 13 | M | 6/1/2021 | 6/1/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Additional Details: Mom reports that patient has a history of fainting after vaccine administration. Patient complained of feeling dizzy and lightheaded after receiving Covid vaccine. Patient fell from standing position and hit his forehead against store aisle. NP was called by Pharmacist, to assist/evaluate. Patient alert and oriented upon NP arrival. BP 116/60, pulse 76, O2 sat 99% on room air. Patient with normal neuro exam. Patient returned to baseline. |
| 1367853 | 6/2/2021 | PA | 25 | F | 6/1/2021 | 6/1/2021 | Systemic: Fainting / Unresponsive-Medium |
| 1367851 | 6/2/2021 | FL | 16 | M | 6/1/2021 | 6/1/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild |

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| 1367848 | 6/2/2021 | IN | 24 | M | 6/1/2021 | 6/1/2021 | Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Severe, Systemic: Exhaustion / Lethargy-Mild, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Shakiness-Medium, Additional Details: Pt fainted after 3 mins of getting vaccine. He asked for water and passed out. His head jerked every 3 seconds slightly for 25 seconds. Alcohol was provided under nose but provided no relief. After 25 seconds of LOC, he woke up. He drank water and caprisun, and felt better. |
| 1367809 | 6/2/2021 | WA | 12 | M | 5/25/2021 | 5/26/2021 | Syncope. No treatment needed. |
| 1367803 | 6/2/2021 | OH | 54 | M | 3/10/2021 | 4/2/2021 | 2 weeks after the first dose Awful pain and stiffness in both hands. went to DR on 4/12 did blood work diagnosed with RA. Did not think about the vaccine until two weeks after the second dose I struggle to walk with severe pain in my legs, arms, and hands. Life since has been pretty rough passed out from the pain on May 16th had to have 9 staples in my head. Now my life is trying to balance medication so I can sleep at night. And get through the days at work. I have had to miss days. |
| 1367785 | 6/2/2021 | TX | 13 | F | 6/1/2021 | 6/1/2021 | Passed out. Seizure without shaking muscles contracted and fists clenched. Dizziness. Tingle in arms. |
| 1367740 | 6/2/2021 | CO | 63 | M | 5/14/2021 | 5/15/2021 | Started with not being able to wake up but being aware of surroundings. He then got very dizzy and passed out. 911 was called and EMS was dispatched to his home. He experienced cardiac arrest and need to be resuscitated 7 times. He was flighted to hospital where he had surgery to place a pacemaker. |
| 1367880 | 6/2/2021 | IN | 24 | F | 6/1/2021 | 6/1/2021 | Immediately after vaccine patient stood up and became dizzy and passed out. B/P 95/61 at 6:02 had patient lay down and gave crackers and juice. B/P 101/65 at 6:39. Patient was feeling better and left with significant other |
| 1367463 | 6/2/2021 | VA | 30 | F | 6/1/2021 | 6/2/2021 | body aches, nausea,, subjective fever/chills, near syncope. |

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| 1367530 | 6/2/2021 | | | U | | | SEIZURE LIKE ACTIVITY; SYNCOPE; CHEST PAIN; HYPOTENSION; DIZZINESS/LIGHTHEADEDNESS; VOMITING; PALLOR; DIAPHORESIS; TACHYCARDIA; ANXIETY-RELATED EVENTS; NAUSEA; This spontaneous report was received from multiple patients. No past medical history or concurrent conditions were reported. The patients received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin, and batch number were not reported) dose, start therapy date were not reported, 1 total administered for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patients experienced seizure like activity, syncope, chest pain, hypotension, dizziness/lightheadedness, vomiting, pallor, diaphoresis, tachycardia, anxiety-related events, and nausea. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the anxiety-related events, syncope, chest pain, hypotension, dizziness/lightheadedness, nausea, vomiting, pallor, diaphoresis and tachycardia was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210553168-covid-19 vaccine ad26.cov2.s-syncope and seizure like activity. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s). |

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| 1366969 | 6/2/2021 | FL | 44 | F | 2/2/2021 | 2/2/2021 | left arm was stiff this morning; injection site pain; she just realized the Arnicare Gel was expired, saying she was surprised the Arnicare Gel still worked; has a charley horse pain in her left arm; This is a spontaneous report from a contactable consumer or other non hcp. A 44-years-old female patient received bnt162b2 (BNT162B2, Solution for injection, Batch/Lot Number: EN5318), via an unspecified route of administration, administered in Arm Left on 02Feb2021 as 1st dose single for COVID-19 immunization. Medical history included microcytic anemia and thalassemia from an unknown date and unknown if ongoing. Restless legs syndrome from 2015 to an unknown date Verbatim. Concomitant medications included cyanocobalamin, biotin and folic acid taken for microcytic anemia from an unspecified start date and ongoing. Ethinylestradiol, norgestimate taken for hormone therapy from Oct2020 and ongoing. She said she started taking Estarylla 0.25mg/0.035mg oral birth control pill for hormone regulation in Oct2020, saying she has been taking the Estarylla for 4 months steady now. The patient previously took ropinirole for Parkinson's disease and experienced syncope from an unspecified date. Reported she tried the Parkinson medicine, Ropinirole, and that the Ropinirole knocked her out, and she didn't like that, so she stopped taking the Ropinirole 2 years ago. On 02Feb2021 patient experienced has a charley horse pain in her left arm, injection site pain and she just realized the Arnicare gel was expired, saying she was surprised the arnicare gel still worked. Left arm was stiff this morning on 03Feb2021. Stated she has a bad left shoulder, saying she thinks she has a pinched nerve, so she asked to get the vaccine in her left arm. She said her left arm pain has improved on 03Feb2021. Therapeutic measures were taken as a result of he has a charley horse pain in her left arm and left arm was stiff this morning. Treatment received with Arnica gel to help with the left arm muscle soreness. She said the Arnica gel helped. The outcome of the events was recovered, whereas injection site pain was recovering. Follow-up attempts are completed. No further information is expected. |

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| 1366915 | 6/2/2021 | VA | 26 | F | 4/2/2021 | 4/2/2021 | No blood clot but testing shows signs of blood clot; Unable to eat; Chest pains; Red spots; Muscles feel like needles; She has not taken second dose; Fainted; hand turned red; Palpitations; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (No blood clot but testing shows signs of blood clot) and SYNCOPE (Fainted) in a 26-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 02-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 02-Apr-2021, the patient experienced SYNCOPE (Fainted) (seriousness criterion medically significant), ERYTHEMA (hand turned red) and PALPITATIONS (Palpitations). On an unknown date, the patient experienced THROMBOSIS (No blood clot but testing shows signs of blood clot) (seriousness criterion medically significant), FEEDING DISORDER (Unable to eat), CHEST PAIN (Chest pains), RASH MACULAR (Red spots), MYALGIA (Muscles feel like needles) and INCOMPLETE COURSE OF VACCINATION (She has not taken second dose). At the time of the report, THROMBOSIS (No blood clot but testing shows signs of blood clot), SYNCOPE (Fainted), ERYTHEMA (hand turned red), PALPITATIONS (Palpitations), FEEDING DISORDER (Unable to eat), CHEST PAIN (Chest pains), RASH MACULAR (Red spots), MYALGIA (Muscles feel like needles) and INCOMPLETE COURSE OF VACCINATION (She has not taken second dose) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Coagulation test: signs of blood clot (abnormal) signs of blood clot. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. It was reported that within 3 minutes of receiving dose, patient's hand turned red and she fainted. Patient was brought to the hospital and was released a couple hours later when palpitations stopped. No medication given to treat symptoms. The patient was receiving unspecified acid reflux medication. Company comment Very limited information regarding these events has been provided at this time. Further information has been requested. Company causality for events |

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| 1366910 | 6/2/2021 | WA | | F | 5/1/2021 | 5/22/2021 | <p>Thrombosis, Syncope, Erythema, Palpitations, Feeding disorder, Chest pain, Rash macular and Myalgia cannot be excluded, while company causality for Incomplete course of vaccination is assessed as not applicable.; Sender's Comments: Very limited information regarding these events has been provided at this time. Further information has been requested. Company causality for events Thrombosis, Syncope, Erythema, Palpitations, Feeding disorder, Chest pain, Rash macular and Myalgia cannot be excluded, while company causality for Incomplete course of vaccination is assessed as not applicable.</p> <p>Passed out; Seizure; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out) and SEIZURE (Seizure) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 004C21A) for COVID-19 vaccination. Concomitant products included COLECALCIFEROL (VITAMIN D [COLECALCIFEROL]) for an unknown indication. On 01-May-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 22-May-2021, the patient experienced LOSS OF CONSCIOUSNESS (Passed out) (seriousness criterion medically significant) and SEIZURE (Seizure) (seriousness criterion medically significant). On 22-May-2021, LOSS OF CONSCIOUSNESS (Passed out) and SEIZURE (Seizure) had resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No treatment information was provided. Company comment: Very limited information regarding this event/s has been provided at this time. Further information has been requested.; Sender's Comments: Very limited information regarding this event/s has been provided at this time. Further information has been requested.</p> |

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| 1366891 | 6/2/2021 | CA | 67 | F | 3/4/2021 | 4/5/2021 | Unconscious; Fainted; head was rapidly spinning then developed severe vertigo; broke her 3 ribs on her left side; hurt her left leg; She thought "i was dying"; This spontaneous case was reported by a physician and describes the occurrence of LOSS OF CONSCIOUSNESS (Unconscious) and SYNCOPE (Fainted) in a 67-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 029A21A) for COVID-19 immunisation. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Allergy to antibiotic and Environmental allergy. Concomitant products included LIRAGLUTIDE (VICTOZA) for an unknown indication. On 04-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 01-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 05-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (Unconscious) (seriousness criterion medically significant), SYNCOPE (Fainted) (seriousness criterion medically significant), VERTIGO (head was rapidly spinning then developed severe vertigo), RIB FRACTURE (broke her 3 ribs on her left side), PAIN IN EXTREMITY (hurt her left leg) and FEELING ABNORMAL (She thought "i was dying"). The patient was treated with IBUPROFEN at a dose of for the first couple of weeks; ASPIRIN [ACETYLSALICYLIC ACID] at a dose of for the first couple of weeks and PARACETAMOL (TYLENOL) at a dose of for the first couple of weeks. At the time of the report, LOSS OF CONSCIOUSNESS (Unconscious), SYNCOPE (Fainted), VERTIGO (head was rapidly spinning then developed severe vertigo), RIB FRACTURE (broke her 3 ribs on her left side), PAIN IN EXTREMITY (hurt her left leg) and FEELING ABNORMAL (She thought "i was dying") outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. The patient was unconscious on the bathroom floor but unaware of how many minutes she was unconscious. It was reported that overall her pain scale was 8. The patient did not go to the hospital, just stayed at home and laid in bed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the |

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reporter did not provide any causality assessments. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

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| 1366868 | 6/2/2021 | MD | 19 | M | 5/7/2021 | 5/7/2021 | Dizziness/ dizzy; Weakness/ very weak; Seizures; Fainted; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of SEIZURE (Seizures), SYNCOPE (Fainted), DIZZINESS (Dizziness/ dizzy) and ASTHENIA (Weakness/ very weak) in a 19-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 07-May-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 07-May-2021, the patient experienced SEIZURE (Seizures) (seriousness criteria hospitalization and medically significant) and SYNCOPE (Fainted) (seriousness criteria hospitalization and medically significant). On 16-May-2021, the patient experienced DIZZINESS (Dizziness/ dizzy) (seriousness criterion hospitalization) and ASTHENIA (Weakness/ very weak) (seriousness criterion hospitalization). The patient was hospitalized on 07-May-2021 due to SEIZURE and SYNCOPE, then on 16-May-2021 due to ASTHENIA and DIZZINESS. The patient was treated with PARACETAMOL (TYLENOL) at an unspecified dose and frequency. At the time of the report, SEIZURE (Seizures) and SYNCOPE (Fainted) outcome was unknown and DIZZINESS (Dizziness/ dizzy) and ASTHENIA (Weakness/ very weak) had not resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No concomitant medications were reported. Description: During the day of the injection, at 5 to 10 minutes, the patient fainted and had seizures that required hospitalization. Also, on 16 May 2021 the patient required hospitalization again because of the dizziness and weakness. The patient was still dizzy and was very weak. The patient had a consult with a neurologist and who told that the symptoms were probably because of the vaccine. Other treatment information included unspecified pill for dizziness at the hospital. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship |

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| 1366861 | 6/2/2021 | FL | 64 | F | 4/19/2021 | 4/17/2021 | Face is red as a tomato; Face is swollen; Throat is closed and cannot breathe; Chest pain; Body aches; Her throat keeps closing up on her/ throat began to close up and off; Almost passing out; Almost passing out; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of THROAT TIGHTNESS (Her throat keeps closing up on her/ throat began to close up and off), NEAR DEATH EXPERIENCE (Almost passing out), ERYTHEMA (Face is red as a tomato), SWELLING FACE (Face is swollen), DYSPNOEA (Throat is closed and cannot breathe), CHEST PAIN (Chest pain), PRESYNCOPE (Almost passing out) and MYALGIA (Body aches) in a 64-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 031B21A and 031B21A) for COVID-19 vaccination. No Medical History information was reported. On 19-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 17-May-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 17-Apr-2021, the patient experienced PRESYNCOPE (Almost passing out) (seriousness criterion hospitalization). On 17-May-2021, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced THROAT TIGHTNESS (Her throat keeps closing up on her/ throat began to close up and off) (seriousness criteria hospitalization and life threatening) and NEAR DEATH EXPERIENCE (Almost passing out) (seriousness criteria hospitalization and medically significant). On 18-May-2021, the patient experienced ERYTHEMA (Face is red as a tomato) (seriousness criterion hospitalization), SWELLING FACE (Face is swollen) (seriousness criterion hospitalization), DYSPNOEA (Throat is closed and cannot breathe) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization) and MYALGIA (Body aches) (seriousness criterion hospitalization). The patient was hospitalized until 18-May-2021 due to CHEST PAIN, DYSPNOEA, ERYTHEMA, MYALGIA, NEAR DEATH EXPERIENCE, PRESYNCOPE, SWELLING FACE and THROAT TIGHTNESS. At the time of the report, THROAT TIGHTNESS (Her throat keeps closing up on her/ throat |

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| | | | | | <p>began to close up and off) had not resolved and NEAR DEATH EXPERIENCE (Almost passing out), ERYTHEMA (Face is red as a tomato), SWELLING FACE (Face is swollen), DYSPNOEA (Throat is closed and cannot breathe), CHEST PAIN (Chest pain), PRESYNCOPE (Almost passing out) and MYALGIA (Body aches) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 18-May-2021, Chest X-ray: (Inconclusive) Lungs look good. No concomitant medications were reported. Treatment included epinephrine (EpiPen), morphine, 2 breathing treatments (unknown) and diphenhydramine (Benadryl). Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 18-May-2021: Additional information received on 18 May 2021. The product details updated. Event details updated.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p> | | |
| 1366854 | 6/2/2021 | CA | 17 | M | 6/1/2021 | 6/1/2021 | <p>Patient felt lightheaded, dizzy, popping and ringing in ears, blurred vision, and fainted for a few seconds. This occurred about 5-10 min following vaccination. Most likely a vasovagal syncope reaction. No history of allergic reactions nor syncope. After laying patient down and elevating his legs, he felt much better. Patient remained in this position for about 15 minutes. He then sat up, ate a snack, and drank water and was observed for an additional 15 minutes. Vitals were within normal range. Patient stated feeling "normal" and "fine" after this and he was able to go home without additional issues.</p> |

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| 1366841 | 6/2/2021 | CA | 74 | M | 1/29/2021 | 2/26/2021 | <p>Loss of balance; Disorientation; Difficult breathing; Was extremely cold; Was trembling; no strength; passed out; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (passed out) in a 74-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 011A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Penicillin allergy, Fruit allergy (The patient have allergy towards bananas.) and Pollen allergy. Concomitant products included FENOFIBRATE, SERTRALINE, ASCORBIC ACID, BETACAROTENE, COPPER, NICOTINAMIDE, SELENIUM, TOCOPHEROL, XANTOFYL, ZINC (LUTEIN +) and VITAMIN D3 for an unknown indication. On 29-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 26-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 26-Feb-2021, the patient experienced LOSS OF CONSCIOUSNESS (passed out) (seriousness criterion medically significant), FEELING COLD (Was extremely cold), TREMOR (Was trembling) and ASTHENIA (no strength). On 27-Feb-2021, the patient experienced BALANCE DISORDER (Loss of balance), DISORIENTATION (Disorientation) and DYSPNOEA (Difficult breathing). On 26-Feb-2021, LOSS OF CONSCIOUSNESS (passed out) had resolved. On 27-Feb-2021, FEELING COLD (Was extremely cold), TREMOR (Was trembling) and ASTHENIA (no strength) had resolved. At the time of the report, BALANCE DISORDER (Loss of balance), DISORIENTATION (Disorientation) and DYSPNOEA (Difficult breathing) outcome was unknown. Patient wok up 10 to 12 hours after receiving second shot and was extremely cold, trembling or shaking uncontrollably. All limbs and jaw could not stop trembling. Got out of bed to find another blanket and raise thermostat. Could not find thermostat (disoriented) struggled to find blanket. By the time patient found blanket he began to have great difficulty breathing. By the time patient stumbled into bed, he was gasping as if there was no air in the room. Stayed in bed gasping, trembling and freezing till he fell asleep or passed out.</p> |

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Patient had no strength to call for help, thought he was dying. Patient woke up about 8:00 AM with no illness, aches, pains or any physical issues. Patient had no further issues till date of report. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 29-Apr-2021: No specific follow-up information recorded. On 24-May-2021: Follow up received on 25 May 2021 and it contain significant information. Additional new event added and one event upgrade the case to serious. Patient demographics updated. History, concomitant and narrative information also get updated.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

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| 1366839 | 6/2/2021 | CA | | F | 1/27/2021 | 1/27/2021 | heart racing; hyperventilation; shaking of arms and legs; panic attack; Faint after covid vaccine on awakeing,Vasovagal, Passed out; This spontaneous case was reported by a health care professional (subsequently medically confirmed) and describes the occurrence of SYNCOPE (Faint after covid vaccine on awakeing,Vasovagal, Passed out) in a 27-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 042L20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Allergy to nuts (Allergy to peanuts and tree nuts). On 27-Jan-2021 at 10:29 AM, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 27-Jan-2021, the patient experienced SYNCOPE (Faint after covid vaccine on awakeing,Vasovagal, Passed out) (seriousness criterion medically significant) and PANIC ATTACK (panic attack). On 27-Jan-2021 at 10:29 AM, the patient experienced HYPERVENTILATION (hyperventilation) and TREMOR (shaking of arms and legs). On 27-Jan-2021 at 10:40 AM, the patient experienced PALPITATIONS (heart racing). On 27-Jan-2021, SYNCOPE (Faint after covid vaccine on awakeing,Vasovagal, Passed out) and PANIC ATTACK (panic attack) had resolved. At the time of the report, PALPITATIONS (heart racing), HYPERVENTILATION (hyperventilation) and TREMOR (shaking of arms and legs) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 27-Jan-2021, Blood pressure measurement: 148/88 mmHg (High) 148/88. On 27-Jan-2021, Heart rate: 100 (normal) 100. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitantly the patient was taking medications for birth control (unspecified). The patient received treatment with oxygen via NRB @15L. It was reported that patient approximately had 3 episodes. She reported no loss of consciousness and no loss of bladder or bowel control. Patient used pulse oximeter Based on the current available information and temporal association |

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between the use of the product and the start date of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 25-May-2021: Significant follow up serious event updated; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

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| 1366794 | 6/2/2021 | CA | 56 | F | 4/1/2021 | | <p>ARTRIAL FLUTTER (HEART RATE HIGH, HEART PALPITATIONS, FELT FAINTING, DIZZINESS); SHOULDER PAIN; SORE ARM; NAUSEA; INJECTION SITE PAIN; CALF SWELLING; This spontaneous report received from a patient concerned a 56 year old female. The patient's height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient was previously treated with influenza vaccine inact sag 3v for prophylactic vaccination. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 041A21A, and expiry: UNKNOWN) dose was not reported, 1 total, administered to left arm, on 05-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On 05-APR-2021, at 18:00, vaccination provider gave shot on side way as she could find the muscle, immediately felt at 3 sites severe pain, at injection site, front and back of the shoulder, top of the shoulder. On the same day, after taking shot, around 14:30 minutes, patient had nausea, dizziness, and felt fainting. The vaccination provider gave her some orange juice and after 2-3 minutes later after drinking orange juice, patient felt better. Patient reported that arm remained sore for two weeks and had no other symptoms. Patient usually wore sock during night on a daily basis. On an unknown date in APR-2021, in the morning, patient noticed swelling (calf swelling) up to the sock at the line where elastic, around mid-calf area. On 28-APR-2021, at evening, patient felt heart beating out of rhythm, heart palpitation, and unusual feeling in the chest. On 29-APR-2021, she went to urgent care at 8:00. Patient was checked with electrocardiogram (EKG) machine, took blood test. Physician Assistance advised patient to go to emergency room (ER). On the report, it said vital signs noted as afebrile and cardio no rubs, no peripheral edema, heart rate was showing a normal rhythm with a rate in the 150s. They gave IV (intravenous) and bunch of fluids. On the same day, patient went to emergency room around 10:00. Patient was connected with EKG machine, had blood test and covid test, and monitored heart around 11:00, arterial fluttered atrium beating 2 times faster than ventricles high based on chest and no other issue. Patient was mildly sedated and was performed cardio version. Patient woke up around 13:30 and did not feel heart beating unusual</p> |

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| | | | | | <p>way. Patient was discharged on same day from emergency room referred to cardio electro physiologist. Patient was given prescription medication metoprolol tartrate 25 mg take 1 tablet 2 times a day dispensing quantity 30, blood thinner xeralto 20 mg take 1 tablet by mouth once daily 30 tablets but patient did not buy medication. Physician said patient had risk of clotting. Laboratory data included: Blood test (NR: not provided) Unknown, COVID-19 virus test (NR: not provided) Unknown, Cardiac monitoring (NR: not provided) Arterial fluttered Atrium beating 2 times faster than ventricles high, EKG (NR: not provided) 150, and Vital signs measurement (NR: not provided) afebrile. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from sore arm on APR-2021, and injection site pain, and the outcome of nausea, calf swelling, artrial flutter (heart rate high, heart palpitations, felt fainting, dizziness), shoulder pain was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210557841-covid-19 vaccine ad26.cov2.s-artrial flutter (heart rate high, heart palpitations, felt fainting, dizziness). This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p> |
| 1366577 | 6/2/2021 IL | 14 F | 6/1/2021 | 6/1/2021 | <p>Patient felt dizzy immediately after the shot was given. She said she was going to pass out, and did for about 10 seconds. She was sitting up in a chair during this time, with her mom holding her up. She came to, the about 20 seconds later, she passed out again for another 10 seconds. She came to, and was given some water to drink, but 20 seconds after that she threw up the water. I took her blood pressure, and it was 60/40, with a pulse of 60. She was very pale. After resting in the chair and taking deep breaths, her color returned and she felt much better. she also said her vision wasn't blurry anymore. Ten minutes later, she left with her mom, feeling ok. She was very anxious about getting the shot, and told me she had passed out in the pass after giving blood.</p> |

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| 1366576 | 6/2/2021 | CA | 15 | F | 6/1/2021 | 6/1/2021 | After patient got her 1st dose of Pfizer Covid 19 vaccine, she was instructed to wait 15 minutes at the resting area in front of pharmacy. On her way from immunization room to the resting area, she fainted. Since her mom was holding her, she didn't fall. She was put down on the floor and regain consciousness within a minute. 911 was called. While waiting for paramedics, Rph took her blood pressure with result of 110/71 HR 89. Patient then walked back to immunization room with mom and Rph's help. When paramedics arrived, they took her blood and it was low. They provided IV fluid and she was taken to hospital by ambulance. |
| 1368650 | 6/2/2021 | FL | 20 | M | 6/2/2021 | 6/2/2021 | Fainting |

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| 1367559 | 6/2/2021 | IL | 59 | F | 9/1/2020 | 4/1/2021 | Procedure for slight heart blockage; Passed out, Recurred passed out; RECURRENT OSTEOARTHRITIS ON RIGHT KNEE; IRREGULAR HEARTBEAT; LOWER BELLY CRAMPS; Chest pain; Sweaty; WHOLE BODY WAS KILLING; Head was hurting; COLITIS; CLOSTRIDIUM DIFFICILE; VEIN BLOCKAGE; DEHYDRATION; WORSENERD JOINT PAINS; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of ATRIOVENTRICULAR BLOCK (Procedure for slight heart blockage), LOSS OF CONSCIOUSNESS (Passed out, Recurred passed out), CLOSTRIDIUM DIFFICILE COLITIS (CLOSTRIDIUM DIFFICILE), VENOUS OCCLUSION (VEIN BLOCKAGE), DEHYDRATION (DEHYDRATION), COLITIS (COLITIS), OSTEOARTHRITIS (RECURRENT OSTEOARTHRITIS ON RIGHT KNEE), HEART RATE IRREGULAR (IRREGULAR HEARTBEAT), ABDOMINAL PAIN LOWER (LOWER BELLY CRAMPS), CHEST PAIN (Chest pain), HYPERHIDROSIS (Sweaty), FEELING ABNORMAL (WHOLE BODY WAS KILLING), ARTHRALGIA (WORSENERD JOINT PAINS) and HEADACHE (Head was hurting) in a 59-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 016B21A) for COVID-19 vaccination. Co-suspect product included non-company product ADALIMUMAB (HUMIRA) injection for Rheumatoid arthritis. The patient's past medical history included Cigarette smoker, Alcoholic and Gallbladder removal in September 2020. Concurrent medical conditions included Osteoarthritis since 2019, Rheumatoid arthritis since 2010, Depression, High cholesterol, Blood pressure high, Diabetes and Sulfonamide allergy. Concomitant products included LISINOPRIL for Blood pressure high, BUPROPION HYDROCHLORIDE (BUPROPION [BUPROPION HYDROCHLORIDE]), DULOXETINE and QUETIAPINE for Depression, SIMVASTATIN for High cholesterol, TIZANIDINE for Muscle spasm, ALUMINIUM HYDROXIDE, DICYCLOVERINE HYDROCHLORIDE, MAGNESIUM OXIDUM LEVE (DICYCLOMINE CO) for Stomach cramps, MULTIVITAMINS & MINERALS PLUS LUTEIN for Supplementation therapy, PROBIOTIC 10, CALCIUM and CALCIUM CARBONATE, COLECALCIFEROL (VITAMIN D 2000) for an unknown |

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indication. On 01-Sep-2020, the patient started ADALIMUMAB (HUMIRA) (Subcutaneous) 40 mg. On 27-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 24-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. In April 2021, the patient experienced ARTHRALGIA (WORSENEED JOINT PAINS) (seriousness criterion hospitalization prolonged). On 13-May-2021, the patient experienced CLOSTRIDIUM DIFFICILE COLITIS (CLOSTRIDIUM DIFFICILE) (seriousness criteria hospitalization prolonged and medically significant) and COLITIS (COLITIS) (seriousness criterion hospitalization prolonged). In May 2021, the patient experienced VENOUS OCCLUSION (VEIN BLOCKAGE) (seriousness criterion hospitalization prolonged) and DEHYDRATION (DEHYDRATION) (seriousness criterion hospitalization prolonged). On an unknown date, the patient experienced ATRIOVENTRICULAR BLOCK (Procedure for slight heart blockage) (seriousness criterion hospitalization prolonged), LOSS OF CONSCIOUSNESS (Passed out, Recurred passed out) (seriousness criteria hospitalization prolonged and medically significant), OSTEOARTHRITIS (RECURRENT OSTEOARTHRITIS ON RIGHT KNEE) (seriousness criterion hospitalization prolonged), HEART RATE IRREGULAR (IRREGULAR HEARTBEAT) (seriousness criterion hospitalization prolonged), ABDOMINAL PAIN LOWER (LOWER BELLY CRAMPS) (seriousness criterion hospitalization prolonged), CHEST PAIN (Chest pain) (seriousness criterion hospitalization prolonged), HYPERHIDROSIS (Sweaty) (seriousness criterion hospitalization prolonged), FEELING ABNORMAL (WHOLE BODY WAS KILLING) (seriousness criterion hospitalization prolonged) and HEADACHE (Head was hurting) (seriousness criterion hospitalization prolonged). The patient was treated with POTASSIUM at an unspecified dose and frequency; VANCOMYCIN for Clostridium difficile colitis, at an unspecified dose and frequency; COLESTYRAMINE (QUESTRAN) for Diarrhea, at an unspecified dose and frequency; NITROGLYCERIN at an unspecified dose and frequency; LOPERAMIDE at an unspecified dose and frequency; GLUCOSE, POTASSIUM CITRATE, SODIUM CHLORIDE

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(PEDIALYTE 30) at an unspecified dose and frequency and ACETYLSALICYLIC ACID (ASPIRIN (E.C.)) at an unspecified dose and frequency. At the time of the report, ATRIOVENTRICULAR BLOCK (Procedure for slight heart blockage), VENOUS OCCLUSION (VEIN BLOCKAGE), COLITIS (COLITIS) and OSTEOARTHRITIS (RECURRENT OSTEOARTHRITIS ON RIGHT KNEE) had not resolved, LOSS OF CONSCIOUSNESS (Passed out, Recurred passed out) and CLOSTRIDIUM DIFFICILE COLITIS (CLOSTRIDIUM DIFFICILE) had resolved and DEHYDRATION (DEHYDRATION), HEART RATE IRREGULAR (IRREGULAR HEARTBEAT), ABDOMINAL PAIN LOWER (LOWER BELLY CRAMPS), CHEST PAIN (Chest pain), HYPERHIDROSIS (Sweaty), FEELING ABNORMAL (WHOLE BODY WAS KILLING), ARTHRALGIA (WORSENERD JOINT PAINS) and HEADACHE (Head was hurting) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In October 2020, Computerised tomogram: inconclusive (Inconclusive) UNKNOWN. In October 2020, Ultrasound abdomen: inconclusive (Inconclusive) unknown. In October 2020, X-ray: inconclusive (Inconclusive) unknown. In March 2021, Stool analysis: negative (Negative) negative. In April 2021, Cardiac stress test: inconclusive (Inconclusive) unknown. In April 2021, Electrocardiogram: unknown (Inconclusive) UNKNOWN. On 04-May-2021, Colonoscopy: inconclusive (Inconclusive) UNKNOWN. In May 2021, Catheterisation cardiac: inconclusive (Inconclusive) UNKNOWN. On an unknown date, Clostridium test: inconclusive (Inconclusive) UNKNOWN. On an unknown date, Computerised tomogram abdomen: inconclusive (Inconclusive) unknown. Company comment: Very limited information regarding this event/s has been provided at this time. Further information has been requested. This case was linked to MOD-2021-102034, MOD-2021-102034 (Patient Link).; Sender's Comments: Very limited information regarding this event/s has been provided at this time. Further information has been requested.

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| 1368542 | 6/2/2021 | NM | 35 | M | 6/2/2021 | 6/2/2021 | Patient passed out, after vaccine. Patient complained about sever back pain before vaccine, but insisted on recieving the vaccine on 6/2/21. Patient was transferred to clinic, and placed under care and then transported by ambulance from pharmacy. |
| 1368395 | 6/2/2021 | TN | 18 | F | 6/2/2021 | 6/2/2021 | Patient received the first dose Moderna she was a little scared but she was ok. She got her shot and was told to stay around for 15 minutes, she starting walking with her mom, when she told her mom she felt dizzy, then she passed out unto her mom's arms, her mom put her on the floor, did not heart her head. Mom helped her to get up and came back to the pharmacy, sat her down again. We called 911 for help, patient asked for water, while her mom went to get her some water, pharmacist was watching her when she had a short convulsion for about 2 to 3 seconds, she stretched her body to the back. When 911 came, she had already recovered her color, her vitals where ok, she was breathing normal. Patient refused to get on the ambulance, signed her release and left. Emergency personel advised her to follow up with her doctor. |
| 1368407 | 6/2/2021 | | 23 | F | 5/26/2021 | 5/27/2021 | Syncope, several events with associated severe headaches and fatigue. |
| 1368409 | 6/2/2021 | NC | 26 | M | 6/2/2021 | 6/2/2021 | Approximately 60 to 90 seconds after administering vaccine to patient, the patient experienced a vasovagal syncope episode. The patient briefly lost consciousness. The pharmacist was able to catch the patient as he lost consciousness and prevent him from falling and further injuring himself. The patient was then moved to a mat on the floor to rest and recover. The patient regained consciousness as he was being moved to a mat on the floor. The patient then maintained consciousness and recovered fully from the event after approximately 20 minutes. The patient was monitored for 30 minutes prior to leaving the pharmacy. He also had a family member (his father) who accompanied him to the appointment and was the patient's driver to and from the pharmacy for his vaccination. |

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| 1368412 | 6/2/2021 | PA | 14 | F | 6/2/2021 | 6/2/2021 | Vasovagal syncope immediately after IM injection. Lowered pt to floor and elevated LE on chair. Pt responsive and AOx4. Taken to Med Obs 1 for VS, assessment and further observation. VS WNL and no reported or objective s/s distress noted during assessment. Pt reported symptoms resolved and escorted to doors from Med Obs 1 at approx 0848 VS Sitting 0832 BP 108/67 HR 83 RR 16 SpO2 98% RA Sitting 0845 BP 113/58 HR 76 RR 16 SpO2 98% RA Standing 0846 BP 1108/62 HR 74 RR 16 SpO2 100% RA |
| 1368631 | 6/2/2021 | NV | 16 | F | 6/2/2021 | 6/2/2021 | Within minutes of receiving the 2nd dose of Pfizer vaccine the patient start to feel light headed, she saw stars, she vomited, she started to look pale and felt tightness in her chest. We called the EMTs and we advised the patient that syncope is something we have seen in children receiving the vaccine and the EMTs advised of the same thing. They took her vitals all normal and the patient began to see the symptoms disappear. The patient once better and cleared by EMTs went home per their advise. |
| 1368364 | 6/2/2021 | | 60 | M | 3/31/2021 | 4/20/2021 | Patient presented to the ED and was subsequently hospitalized within 6 weeks of receiving COVID vaccination. This occurred on 4/20/21 for small bowel obstruction and on 5/2/21 with near syncope. |
| 1368524 | 6/2/2021 | IL | 21 | F | 6/2/2021 | 6/2/2021 | Patient started feeling dizzy and fainted. Paramedics came and took her. |
| 1368425 | 6/2/2021 | OR | 48 | M | 5/28/2021 | 5/29/2021 | Started feeling light headed at 4am and had syncope x 2, his wife stated he was talking nonsense during this time, at 8am he had a fib, HR went from 40-155s, B/P 116/60, went to ER with chest pain and SOB, temp. 100.2, spent 3-4 hours in ED. He was sedated and converted. |
| 1368566 | 6/2/2021 | NY | 18 | F | 6/1/2021 | 6/2/2021 | minutes after receiving the 2nd dose, patient felt dizzy and passed out on the floor. she regained consciousness within a few seconds, and was responsive, she waited about 20 minutes before leaving the store, EMS was not called, she reported no other adverse effects |

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| 1368574 | 6/2/2021 | FL | 39 | F | 3/8/2021 | 3/8/2021 | Immediately I started to feel a warm sensation like a wave come over my body. My heart started racing and I told the woman who administered the vaccine. I started to feel like I was going to faint so I sat in a chair with my legs up on another chair. The hot wave feeling kept getting more intense and so did the feeling like I was going to faint. I never fainted but the feeling kept coming on strong then going away. The woman kept telling me I was ok because I didn't have hives or trouble breathing. At one point she walked away from me and I had a started to shake uncontrollably. I called paramedics because my heart was racing and the shaking got even worse. At this point I laid on the ground because I couldn't sit in the chair from the shaking. The paramedics were very dismissive and asked if I had a history of panic attacks. I repeatedly told them and the woman who administered the vaccine that I was not having a panic attack and that I felt fine before the vaccine and that I do not have a fear of needles. They took my blood pressure and pulse and said I was fine. I didn't feel fine and kept shaking throughout the examination (on the floor). I was unable to stand up for 2 hours. It was awful laying on the floor of a grocery store for that long and feeling so terrible. The shaking lasted 2 hours but the rapid heartbeat and feeling of waves of heat lasted days. |
| 1368591 | 6/2/2021 | MO | 16 | F | 6/1/2021 | 6/1/2021 | Pt had loss of consciousness x 2 immediately after injection. , shaking of extremities described. Lasting approx 1 min each. return to baseline after . Differential was seizure vs. more likely vagal syncope |
| 1367888 | 6/2/2021 | CA | 22 | F | 6/1/2021 | 6/1/2021 | Systemic: Fainting / Unresponsive-Medium, Additional Details: Patient received first dose of vaccine with her mother. Prior to administration, patient mentioned she was anxious receiving shots having a history of fainting. Immediately after administration, patient stated that she was relieved. About 2 minutes later, patient's mother called for the pharmacist for help claiming patient was having convulsions and was unconscious. Paramedics were called. Patient regained consciousness after 20 secs with nausea & no recollection of loss of consciousness. |

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| 1367223 | 6/2/2021 | NY | 52 | M | 5/8/2021 | 5/8/2021 | feels like there are little tiny baby hands pinching his internal organs throughout his abdomen; Eyes swollen and his vision was diminished; Eyes swollen and his vision was diminished; On his injection arm- 2 inches away from the injection site appeared a size of a gigantic golf ball/A huge lump appeared a few inches from injection site; Numbness from his ankle to his feet and from his knees to his feet/numbness in legs and feet; feels like it's cold and tingly; feels like it's cold and tingly; ringing ears; pressure in his neck to his injection site; back pain/pain in back; vision is blurry; throat was swollen.; Toes locking up; Really dizzy and really lightheaded; Mind has been foggy; Glands were swollen; Arm soreness; Nose is bone dry; tiredness/tired; injection site pain/injection site soreness; This is a spontaneous report from a contactable consumer (patient, self-reported). A 52-years-old male patient received first dose of BNT162B2 (PFIZER-BIONTEC COVID-19 mRNA VACCINE, Solution for injection, lot number: EW0173 and expiry date was not reported), via an unspecified route of administration, in Arm Left, on 08May2021 at 02:38 PM, as a single dose for COVID-19 immunization. The patient did not receive any other vaccine in four weeks. The patient's medical history included Bug bite (happened 5 days prior to 30Apr2021 and regimen of an antibiotic). He was completely done with the rotation for at least 8 days before he got the vaccine. It might have something to do with this. concomitant medication included dicloxacillin (started it on 30Apr2021 and it was for 5 days. He did not know what it did was). The patient reported that on 08May2021, day one, he experienced, tiredness and injection site pain. On day 2, until now side effects which had not gone away. It hadn't gotten worse, but it was not any better. The patient felt like congestion, but his nose was bone dry, like crusty dry. It hurts a little bit because it was so dry and he had arm soreness, nothing out of the ordinary. The arm soreness was just normal injection stuff. At first it was a little tender on the injection spot. It went away after about a day. On 10May2021, the patient felt like there were little, tiny baby hands pinching his internal organs randomly throughout his abdomen. It was not a sharp pain, more like a little squeeze all through his abdomen. It felt like his whole throat was swollen. It was not visually swollen, it more felt like a football in his neck. Stretching it was helping. His |

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toes have been locking up like a pre-clamping. He had numbness from his ankles to his feet for 8 days, and now he has numbness from his knees to his feet. It was not completely numb, but it was not normal. The feeling of baby hands pinching his internal organs started the second day after the vaccine and has stayed consistent. The patient's eyes swollen, and his vision was diminished. Day 2 through today, it felt like his eyes were swollen, his vision was seriously diminished, he had a golf ball sized welt on his arm not at the injection site but 2 inches from it, and he was really dizzy and really lightheaded and almost fainted at the corner store. The feeling like his eyes were swollen started on day 3 after the vaccine. The crease of his eye below the eyebrow and on top of the socket got red and puffy and looked like sunburnt skin does. It was at the point that now it feels swollen all the time almost like he had pink eye and his vision has been diminished about 30%. He had a test done yesterday and his vision was 20/25. Some-times he could not even read a text and had to stare at his phone for 10 minutes to make out words. He did not have these issues before. The feeling of his eyes being swollen was a little better in the mornings and about 1300 it gets worse when he gets lightheaded to where was when it started. His vision became diminished about day 3 after the vaccine. It was a little better in the morning, but in the afternoon, it goes to exactly the same as when it started. He noticed the golf ball sized welt on his arm about 3 days ago. The doctor seemed to think a drop of the injection might had travelled from the injection site and his body was creating a defense to it. It was scary to take a shower and then see that. It didn't hurt. It was not painful, but it was a weird foreign entity. The cramping in his toes started probably day 3 and was consistent. The numbness started on day 2 after the vaccine, and up until 3 days ago it was just his ankles and feet. 3 days ago, it got to the point where it was from his knees to his feet. It has gotten worse since it was now travelling up his legs. On his injection arm- 2 inches away from the injection site appeared a size of a gigantic golf ball - when asked with his doctor he said that he thinks that a drop of the vaccine travelled and his body building a reaction to it and it was very abnormal. The patient also had numbness from his ankle to his feet worsened and from his knees to his feet- almost feels like it was cold and

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tingly. The patient also had dizziness and lightheaded about day 2 after the vaccine and it was the same. It came in waves but was consistent throughout the day. He would be fine then had a wave of dizziness. He has been laying down so much because he was so tired, ringing ears, felt like his glands were swollen, pressure in his neck to his injection site, and back pains. The patient stated that his doctor was only form urgent care. The patient Felt like whole throat was swollen, toes locking up, really lightheaded, mind has been foggy, and arm soreness. The patient had bizarre side effects from the Covid Vaccine for 11 days now. He thought it was the smart thing to report them to Pfizer. He didn't like to give personal information. He declined to give his mailing address or his email address. He hated when asked for race, but he guessed it might be important. He did not have a mailing address, phone number, or email address handy for his physician. He went to Urgent Care yesterday to have it checked and they did an EKG and said he had to be sent by ambulance to the ER. The doctor did bloodwork, and she said everything looked alright and to rest a few more days and keep hydrated. The patient underwent the lab work and procedures which included chest X-ray with unspecified result. He thinks it was on 18May2021. His mind has been foggy with all of that. It was yesterday or the day before. He could not be sure. He has been sleeping so much and was in a complete daze. The fogginess he had the whole time as his other symptoms, and it was the same. He has been eating well and hydrating and taking a multivitamin and Gatorade, all the things' people say to do. He asked if Pfizer has heard of this before. He was panicked it might be chronic, and he worries about the safety of the second shot for him. He was sure many people haven't reacted, but these are freaky side effects. He asked for advice and if Pfizer had heard of this before or if he was some weird anomaly. On his way to get the vaccine he asked 2 people at the city health line if they had taken it and they both said no. He asked 3 other patients and they said they took the Pfizer. One woman said she will take it when they make her. The guy who gave him the shot lied and said he wasn't eligible. It might have been his way of not having to discuss it. The events resulted in doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care. The patient

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| | | | | | | | was not diagnosed with Covid prior vaccination. The patient was tested for Covid post vaccination with Nasal Swab on 18May2021. The outcome of the events was not recovered. Device Date: 23May2021,Additional information has been requested. |
| 1368639 | 6/2/2021 | PA | 67 | F | 2/20/2021 | 4/12/2021 | Ventricular tachycardia with syncope |
| 1368452 | 6/2/2021 | CA | 80 | F | 4/15/2021 | 4/16/2021 | The day after the shot, patient developed low-grade fever which lasted 3 days. For 3 days, the patient was lethargic and had no energy to perform normal household duties. On the 3rd day after the shot, patient developed tachycardia for several minutes, became feverish with a clammy sweat and had vertigo saying the room was spinning and said she felt like fainting. She could not recognize her son, asking him, "Who are you?" Patient lost site in her eyes which was recovered several minutes later. Patient felt better starting the 4th day. |
| 1368002 | 6/2/2021 | CO | 19 | M | 6/1/2021 | 6/1/2021 | Systemic: Chills-Mild, Systemic: Confusion-Severe, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Mild, Systemic: Hypotension-Medium |
| 1367917 | 6/2/2021 | AK | 66 | M | 5/21/2021 | 5/22/2021 | Site: Itching at Injection Site-Medium, Site: Pain at Injection Site-Medium, Systemic: Allergic: Itch (specify: facial area, extremities)-Medium, Systemic: Chills-Medium, Systemic: Exhaustion / Lethargy-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Fever-Medium, Systemic: Pain and Neuropathy-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Neurological Disorder (diagnosed by MD)-Medium, Systemic: Numbness (specify: facial area, extremities)-Medium, Systemic: Tingling (specify: facial area, extremities)-Medium, Systemic: Weakness-Medium, Additional Details: Pt states they are experiencing tingling sensations and pain in joints |
| 1368510 | 6/2/2021 | MN | 20 | M | 6/2/2021 | 6/2/2021 | Patient was sitting in the observation area after his vaccine and his companion alerted us that he had fainted. He slumped to the side for a few seconds, we held him up and he came to rather quickly. He said he had felt dizzy. He had some water and sat for about 20 more minutes until he felt back to normal. |

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| 1367995 | 6/2/2021 | CA | 20 | F | 6/1/2021 | 6/1/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Shakiness-Mild, Additional Details: Patient appeared to have short (<1min) seizure approximately 5 minutes after having COVID vaccine administered. She woke up, eventually alert and oriented. EMS was called and responded to call. She refused ER visit stating she was feeling fine, just a little shook up. |
| 1368005 | 6/2/2021 | MD | 42 | F | 6/2/2021 | 6/2/2021 | Patient was given 0.5mL of Janssen vaccine IM into her right deltoid muscle. Post vaccine patient, fainted during the 15 minute wait period. She was promptly attended to, and did not exhibit signs of anaphylaxis. EMS came to assess patient even though she felt "completely normal" after she fainted. |
| 1368015 | 6/2/2021 | NC | 28 | F | 6/2/2021 | 6/2/2021 | Patient reports sharp pain in left upper chest area and into the under arm area and reports she may pass out. Patient had a vasovagal syncope episode followed by vomiting. After 30 mins of resting, she reports she was no longer lightheaded or nauseous. Chest pain resolved. Patient does report headache at departure. 12:53 - BP 152/82, P-73, R-20, Pulse Ox-97%. 13:00 - BP 140/80, P-87, R-20, Pulse Ox-100%. 13:10 - 122/78. |
| 1368033 | 6/2/2021 | MI | 22 | F | 6/2/2021 | 6/2/2021 | Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Medium, Systemic: Hypotension-Mild |
| 1368039 | 6/2/2021 | FL | 14 | M | 6/2/2021 | 6/2/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Nausea-Mild, Systemic: Tinnitus-Mild, Systemic: Visual Changes/Disturbances-Mild, Additional Details: Patient recovered and mom says she was taking him to the doctors office for follow-up |
| 1368050 | 6/2/2021 | NY | 23 | F | 6/2/2021 | 6/2/2021 | Systemic: Chills-Mild, Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Shakiness-Mild, Systemic: Weakness-Medium, Additional Details: EMT and paramedics came |

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| 1368062 | 6/2/2021 | OH | 16 | M | 5/28/2021 | 5/30/2021 | Patient received second dose of Pfizer COVID-19 vaccine on 5/28/21. Within 12 hours patient experienced chills and subjective fever. The follow day patient reported developing fever. The day prior to admission (admitted 5/31/21) patient developed chest pain but worsened to 8-9 out of 10. Pain described at pressure in the center/sternal area of chest or like bricks on his chest. No pleurisy or radiation of pain, pain worsened when supine. Negative for shortness of breath, syncope, palpations. Did no improve with acetaminophen or ibuprofen at home. Patient presented to outside hospital where troponin was 0.37 and EKG showed ST abnormalities. Patient received 30 mg of ketorolac and 4 mg of ondansetron and was transferred to this facility. In our ED, pain improved to 4-5 out of 10. Diffuse ST elevations on EKG, troponin elevated to 7.38. Chest X-ray and rapid covid test were negative. Patient was started on naproxen sodium 500 mg enteral BID 5/31/21 through discharge on 6/2/21. |
| 1368078 | 6/2/2021 | MO | 31 | F | 3/16/2021 | 5/9/2021 | Suffered a stroke on May 9, 2021. Rushed to the ER and administered TPA, then surgery was performed to get out the rest of the clot. Symptoms: Fainting, Right side paralysis, slurred speech |
| 1368080 | 6/2/2021 | WA | 16 | M | 5/22/2021 | 5/24/2021 | Two days later my grandson fainted, had a seizure and was taken to the ER. At the ER a CT scan of the head was performed. Also while getting an IV, my grandson also had a seizure. I do not have his CT scan results at this time. My grandson is also prepping for a surgery coming in June. |
| 1368088 | 6/2/2021 | FL | 28 | M | 6/2/2021 | 6/2/2021 | Patient was sitting for 15 minute observation period when he started convulsing and fainted. He again started convulsing and then he came to, was nauseas and dizzy and pale. |

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| 1368103 | 6/2/2021 | MN | 27 | M | 6/1/2021 | 6/1/2021 | Patient received a vaccine and was told that he needed to stay in the store for 15 minutes. He went to purchase a water about 5 minutes after vaccine in a different register and was feeling lightheaded. After the transaction he fainted with the back of his head fell on the hard floor. He was being assisted by the store staff as well as a pedestrian who claimed to be a health care professional. He was given an orange juice, one water and a battery powered fan to provide cool air. He also requested to lay down on the floor, and he ended up laying on the floor for about 30 minutes. After that he stood up and regained color on his face. He then walked out of the store. Staff asked him if he wanted the ambulance to be called and he declined. Pharmacist called patient the next day to check on patient, and was unable to reach the patient. |
| 1368126 | 6/2/2021 | NC | 24 | F | 6/2/2021 | 6/2/2021 | Pt had received her first vaccine and was in the observation area. She was seen to have slumped in her chair, preceding a syncopal episode. The patient remained in her chair during the episode. Pt informed us after the syncopal episode that she had felt as if she fell asleep. She has no medical history of seizures or syncope in the past. She did have limb movement during the period of syncope. The episode seemed to last no more than 15 seconds. The patient quickly woke and began speaking to us. She was clammy and sweaty, vitals were completely normal as taken by the RNs. She was observed in the private area for > 15 minutes, given drink and crackers, tolerated well. She ambulated well and had her fiancé pick her up. She will follow up with her PCP this week. vitals: BP: 120/80, P 72, O2 98% |
| 1365086 | 6/1/2021 | | 22 | F | 3/19/2021 | 3/19/2021 | Tingling; Fainted. EMS at side. |
| 1364800 | 6/1/2021 | TN | 20 | M | 5/28/2021 | 5/28/2021 | vasovagal syncope 10 minutes after injection |
| 1364825 | 6/1/2021 | MD | 13 | F | 5/15/2021 | 5/15/2021 | fainted right away, pale, sweaty, eyes closed and then rolling back in the head. This never happened before. |
| 1364844 | 6/1/2021 | VA | 37 | M | 6/1/2021 | 6/1/2021 | Fainted, excessive sweating |
| 1364847 | 6/1/2021 | NE | 20 | F | 6/1/2021 | 6/1/2021 | fainted. light headedness. vomiting. dizziness |

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| 1364873 | 6/1/2021 | PA | 20 | F | 6/1/2021 | 6/1/2021 | approximately two minutes after administration of vaccination patient had sat down in waiting area and became lethargic/dizzy/blurred vision. She had passed out with face pale and lips turning blue, minimally responsive. Called 911 and while awaiting for ambulance patient had recovered from all symptoms with the exception of "spotted visions." Observed patient for over an hour while a family member came and upon the time of departure there was resolution of all adverse events. |
| 1364900 | 6/1/2021 | NY | 23 | F | 6/1/2021 | 6/1/2021 | Patient seemed fine after dose then complained of feeling dizzy. She passed out after sitting down. |
| 1364901 | 6/1/2021 | ID | 24 | M | 6/1/2021 | 6/1/2021 | Diaphoresis with light-headness and fainting |
| 1364916 | 6/1/2021 | TX | 13 | F | 6/1/2021 | 6/1/2021 | Patient had likely syncope. Fainted/felt dizzy after immunization. Patient waited at the pharmacy for 30min until she felt better, then went home. |
| 1365122 | 6/1/2021 | MI | 19 | M | 4/7/2021 | 5/31/2021 | HPI This is a 19-year-old male that presents for complaint of witnessed seizure-like activity. He arrives by EMS. Patient is currently awake alert and oriented x3. Today, he was out on the golf course with friends. It was a normal day and he returned home. When he got home, he was complaining of a headache to his mother. She gave him Motrin. Mother then heard a noise from the other room and found the patient on the floor unresponsive, displaying tonic-clonic activity, and eye rolling into the back of the head. This lasted for 4-5 minutes per mother. EMS arrived on scene he was postictal. Patient is never had this happen before. He denies any illicit substance, alcohol or medication use. Review of Systems Constitutional: Negative for chills, fatigue and fever. HENT: Negative for facial swelling and trouble swallowing. Respiratory: Negative for cough, shortness of breath and wheezing. Cardiovascular: Negative for chest pain and palpitations. Gastrointestinal: Negative for abdominal pain, diarrhea, nausea and vomiting. Genitourinary: Negative for dysuria and frequency. Musculoskeletal: Negative for back pain and neck pain. Skin: Negative for rash and wound. Neurological: Positive for seizures and syncope. Negative for weakness, light-headedness and headaches. Psychiatric/Behavioral: Negative for confusion. The patient is not nervous/anxious. |

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| 1365041 | 6/1/2021 | MA | 42 | F | 6/1/2021 | 6/1/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Mild |
| 1364751 | 6/1/2021 | CA | 23 | M | 5/29/2021 | 5/29/2021 | At 7:57am, Patient came in to clinic to received Covid 19 vaccination given by Medical Assistant. Patient was in sitting position and fainted after receiving vaccination. Fell and hit left side of face on stand. I Medical Assistant ran out to get provider on site. Blood pressure, pulse ox and assessment was done by medical doctor. Ice pack and orange juice were ordered by Dr. and given to patient. Patient remained sitting for 15 minutes and left clinic. This patient had same reaction during the first dose. |
| 1365135 | 6/1/2021 | MI | 13 | F | 5/28/2021 | 5/28/2021 | Very pale, pupils dilated, non responsive, passed out immediately after vaccination |
| 1365185 | 6/1/2021 | TX | 15 | F | 5/23/2021 | 5/23/2021 | Syncope approximately 2 minutes after receiving COVID shot. Diaphoresis and pale in color. |
| 1364963 | 6/1/2021 | FL | 18 | M | 6/1/2021 | 6/1/2021 | Patient experienced syncope upon getting up from the chair after getting the shot |
| 1364476 | 6/1/2021 | CT | 44 | F | 5/28/2021 | 5/28/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient was seated waiting after her vaccination. She collapses to the floor. I went out after being alerted what happened and flipped her from her face, she was awake and confused as to what had happened. I sat with her while our front store manager grabbed her water. I asked if she felt she needed an ambulance and seeing as she was breathing fine and starting to come to she said she did not want an ambulance. She later informed our front store manager that she had fainted 3 times that morning. |

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| 1366353 | 6/1/2021 | | 38 | F | 6/1/2021 | 6/1/2021 | At 09:40 attendee reported dizziness and shortness of breath and then fainted in the chair and slumped over. When she aroused about 10-15 seconds later, she had slurred speech, was cold and clammy, shortness of breath, and her respirations were tachypneic and labored. 09:45 - Lifted onto a cot that they brought to the area by her chair. Almost seemed like she was drunk or having a stroke. HR: 184 BP: 112/99 O2Sat%: 100. 10:05 – Fainted 7+ times over 15 minutes, they were so busy caring for the attendee that EMS was not called, until now. 10:15 –EMS arrived and took over care of the attendee. 10:23 EMS departed with attendee to the Emergency Room. |
| 1365193 | 6/1/2021 | TX | 18 | F | 6/1/2021 | 6/1/2021 | SYNCOPE IS WHAT PATIENT EXPERIENCED. PATIENT LOST CONSCIOUS COUPLE MINUTES AFTER RECEIVING THE VACCINE. SHE FALL OFF THE CHAIRE SHE WAS SITTING AT , BUT WOKE UP DIRECTLY AFTER. PATIENT DID NOT HIT HER HEAD AGAINST THE FLOOR, NOR DID SHE HAVE ANY INJURY OTHER THAN A SCRATCH ON HER ARM. SHE WAS ALLERT, ORIENTED AND HAVE PROVIDED ME WITH EVERY SINGLE INFORMATION I NEEDED TO COMPLETE THIS REPORT. SHE LEFT THE PHARMACY WITH HER FATHER. |

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| 1363718 | 6/1/2021 | ID | 43 | M | 3/17/2021 | 3/17/2021 | <p>Syncope; Fall; Head injury; Hyperhidrosis; This regulatory authority case was reported by an other health care professional and describes the occurrence of SYNCOPE (Syncope) in a 43-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 031A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 17-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 17-Mar-2021, the patient experienced SYNCOPE (Syncope) (seriousness criterion medically significant), FALL (Fall), HEAD INJURY (Head injury) and HYPERHIDROSIS (Hyperhidrosis). At the time of the report, SYNCOPE (Syncope), FALL (Fall), HEAD INJURY (Head injury) and HYPERHIDROSIS (Hyperhidrosis) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 17-Mar-2021, Vital signs measurement: consistent with fainting episode (abnormal) Vital signs consistent with fainting episode and stabilized within fifteen minutes.. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication use was reported. Treatment information was not reported. On 17Mar02021, it was noted by the reporter that the patient was observed kneeling by a chair as diaphoretic immediately post vaccine. The reporter asked the patient if he would lie down to be assessed. The patient then fainted and fell to the floor, hitting the back of his head on the floor. The code team was called for immediate assistance. The patient's head and neck were supported. The patient's vital signs were consistent with fainting episode and stabilized within fifteen minutes. The patient was transferred by EMS to the hospital for evaluation of head injury. It was noted by the reporter that the initial assessment showed no immediate neurological deficits and no superficial bleeding at head impact location on the patient. Further clinical course is unknown/not reported at this time.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be</p> |

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excluded.

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| 1363972 | 6/1/2021 | AZ | 66 | F | 1/19/2021 | 2/17/2021 | Fainting spell; She couldn't remember her job or her boss's name, with whom she worked since 2009/she can't remember as good; Her right arm got kind of sore; Chills; Vomiting; Nausea; Fever; Diarrhea; Dizziness; Weak; She lost 6 pounds in 3 days; Confusion; Off work X 6 days; This spontaneous case was reported by a patient and describes the occurrence of SYNCOPE (Fainting spell) in a 66-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 012L20A and 029K20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Penicillin allergy, Diabetes, Heart disease, unspecified and Asthma. Concomitant products included ACETYLSALICYLIC ACID (ASPIRIN (E.C.)) for an unknown indication. On 19-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 16-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 17-Feb-2021, the patient experienced DIARRHOEA (Diarrhea), DIZZINESS (Dizziness), ASTHENIA (Weak), WEIGHT DECREASED (She lost 6 pounds in 3 days), CONFUSIONAL STATE (Confusion), IMPAIRED WORK ABILITY (Off work X 6 days), PYREXIA (Fever), VOMITING (Vomiting) and NAUSEA (Nausea). On an unknown date, the patient experienced SYNCOPE (Fainting spell) (seriousness criterion medically significant), AMNESIA (She couldn't remember her job or her boss's name, with whom she worked since 2009/she can't remember as good), PAIN IN EXTREMITY (Her right arm got kind of sore) and CHILLS (Chills). The patient was treated with ONDANSETRON (ZOFTRAN [ONDANSETRON]) ongoing since an unknown date at an unspecified dose and frequency. At the time of the report, SYNCOPE (Fainting spell), AMNESIA (She couldn't remember her job or her boss's name, with whom she worked since 2009/she can't remember as good), DIARRHOEA (Diarrhea), DIZZINESS (Dizziness), ASTHENIA (Weak), WEIGHT DECREASED (She lost 6 pounds in 3 days), CONFUSIONAL STATE (Confusion), IMPAIRED WORK ABILITY (Off work X 6 days), PAIN IN EXTREMITY (Her right arm got kind of sore), PYREXIA (Fever), CHILLS (Chills), VOMITING (Vomiting) and NAUSEA (Nausea) |

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outcome was unknown. Concomitant medication use included medications for diabetes, heart disease and high blood pressure. Specific medications were not provided by the reporter. Treatment of the events included Zofran. On 11Feb2021, after receiving the first dose of vaccine but before the second, the patient "had a nuclear injection" before she went on a treadmill. The patient also stated that "she had radiation that may have affected her reaction to the vaccine." No further information was provided. Further clinical course is unknown at this time. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. This case was linked to MOD-2021-155323 (Patient Link). Most recent FOLLOW-UP information incorporated above includes: On 20-May-2021: Follow-up received on 20-May-2021included additional events were added.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

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| 1363973 | 6/1/2021 | DE | 56 | M | 4/5/2021 | 4/12/2021 | <p>Passing out, dry cough so bad that he would faint; Stood up to cough, passed out, and fell and his head hit the concrete; Head hit the concrete floor, hitting head on floor; Bad, dry cough; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (Passing out, dry cough so bad that he would faint) in a 56-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. G17-C21A and G26-B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Smoker (30+ years of smoking.) and Vapor cigarette smoker (vaping the past two years.). Concomitant products included BENZTROPINE [BENZATROPINE], FLUOXETINE, TAMSULOSIN, CLONAZEPAM, AMLODIPINE and LURASIDONE HYDROCHLORIDE (LATUDA) for an unknown indication. On 05-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 03-May-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 12-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (Passing out, dry cough so bad that he would faint) (seriousness criterion medically significant), FALL (Stood up to cough, passed out, and fell and his head hit the concrete), HEAD INJURY (Head hit the concrete floor, hitting head on floor) and COUGH (Bad, dry cough). On 12-May-2021, LOSS OF CONSCIOUSNESS (Passing out, dry cough so bad that he would faint) and COUGH (Bad, dry cough) had resolved. At the time of the report, FALL (Stood up to cough, passed out, and fell and his head hit the concrete) and HEAD INJURY (Head hit the concrete floor, hitting head on floor) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In April 2021, SARS-CoV-2 test: negative (Negative) Went to get tested for COVID-19 due to dry, bad cough and came back negative. The patient stated that approximately one week after the first dose, he was having a bad dry cough. The dry cough was so bad that when he was sitting on recliner he would cough so bad, he would faint and pass out. One time the patient stood up to cough, passed out, and fell and his head hit the concrete floor. He went to emergency department</p> |

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three times because of this cough. On 12 MAY 2021, the patient stopped experiencing coughing and passing out. The patient also stated that he has no other side effects and that his healthcare provider thinks this experience was attributed to the first vaccine. Patient was prescribed an "inhaler" from his healthcare provider to help with "lungs and stuff." The patient also has an appointment with a pulmonologist in June. Action taken with mRNA-1273 in response to the events was not applicable. Head injury was due to fall and thus cannot be directly associated with mRNA-1273 use. The other events are temporarily associated with the product use and a causal relationship cannot be excluded. This case was linked to MOD-2021-138832 (Patient Link).; Sender's Comments: Head injury was due to fall and thus cannot be directly associated with mRNA-1273 use. The other events are temporarily associated with the product use and a causal relationship cannot be excluded

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| 1363981 | 6/1/2021 | NC | 74 | M | 2/22/2021 | 2/22/2021 | <p>Did not go for 2nd shot; Passed out; Extreme arm pain; Could not lift up arms; Trouble with bowels; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out) in a 74-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 22-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 22-Feb-2021, the patient experienced LOSS OF CONSCIOUSNESS (Passed out) (seriousness criterion medically significant), PAIN IN EXTREMITY (Extreme arm pain), HYPOKINESIA (Could not lift up arms) and ABDOMINAL DISCOMFORT (Trouble with bowels). On an unknown date, the patient experienced INTENTIONAL DOSE OMISSION (Did not go for 2nd shot). At the time of the report, LOSS OF CONSCIOUSNESS (Passed out), PAIN IN EXTREMITY (Extreme arm pain), HYPOKINESIA (Could not lift up arms) and ABDOMINAL DISCOMFORT (Trouble with bowels) outcome was unknown and INTENTIONAL DOSE OMISSION (Did not go for 2nd shot) had resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Concomitant product use was not provided by the reporter. Treatment information was not provided. Company Comment : Very limited information regarding the events has been provided at this time. Further information has been requested.; Sender's Comments: Very limited information regarding the events has been provided at this time. Further information has been requested.</p> |

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| 1363779 | 6/1/2021 | MA | 60 | M | 4/1/2021 | | <p>FAINTING SPELL; PASSED OUT; This spontaneous report received from a consumer (wife) concerned a 60 year old male of unspecified race and ethnicity. The patient's height, and weight were not reported. The patient's concurrent conditions included Crohn's disease (diagnosed years ago), bee stings allergy, non smoker, non alcohol user, and marijuana abuse. The patient did not have primary care provider (PCP) and had not been to the doctor for 35 years. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 042A21A, and expiry: unknown) dose was not reported, 1 total administered on 01-APR-2021 to right arm for prophylactic vaccination. No concomitant medications were reported. Five or ten minute after vaccination patient's eyes rolled back and he passed out at the vaccine centre. Reporter was not sure if he fainted or had a seizure. He came back for a bit but then started having the fainting spell again. The patient taken by the ambulance to the hospital. In hospital, did a few tests which included blood pressure, blood sugar, electrocardiogram (EKG) but everything came back fine. He had not eaten before getting the vaccine. Healthcare professional (HCP) could not find any reason for his symptom. He had not eaten before getting the vaccine but it was nothing unusual. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from fainting spell, and passed out on 01-APR-2021. This report was serious (Other Medically Important Condition).; Sender's Comments: V0:20210546973-covid-19 vaccine ad26.cov2.s-Fainting spell, passed out. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p> |

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| 1364315 | 6/1/2021 | | | F | 4/1/2021 | 4/1/2021 | Syncopal Episode; hit her head; Malaise; Felt weird; Feeling a little flat; She "passed out"; Syncope; This is a spontaneous report from a contactable consumer (patient). An unspecified year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: not reported, Expiration date: Unknown), via an unspecified route of administration in the left arm on 01Apr2021, as a 1ST DOSE, SINGLE for COVID-19 immunization. The patients medical history and concomitant medications were not reported. The patent stated that on an unspecified date (9 days later) in Apr2021, she had a syncopal episode while she got up to go to the bathroom and passed out in the morning after waking. She hit her head and ended up in the hospital. She had undergone blood work and said because this event was 9 days after the vaccine, it was probably not related to the vaccine. The patient has been feeling a little flat since the first shot. She experienced syncope, malaise, felt weird, Syncopal Episode, Feeling a little flat. Patient was just feeling the general malaise since the first shot. Patient had a syncope, day nine after the first shot. The outcome of all the events were Unknown. No follow up attempts are needed. Information about lot/batch number cannot be obtained. |
| 1364713 | 6/1/2021 | CA | 19 | F | 5/30/2021 | 5/30/2021 | PATIENT PASSED OUT. SHE LOST CONSCIOUSNESS. THOUGH HAD NORMAL PULSE AND BREATHING. BUT WE GAVE SOME COLD WATER AND JUICE FROM THE MOM, USED COLD ICE PACK ON THE FACE AND NECK AND WE LAY THE PATIENT DOWN IN A SUPINE POSITION, MAINTAINED AIRWAYS AND RAISED HER LEGS. WE CONTINUED TO CHECK PULSE AND BREATHING WHICH WAS NORMAL AND WE FANNED THE PATIENT SO SHE CAN GET SOME VENTILATION. SHE GOT REVIVED IN ABOUT 20-25MINUTES |

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| 1364477 | 6/1/2021 | CT | 44 | F | 5/28/2021 | 5/28/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient was seated after vaccination then collapsed. I went over after was alerted and flipped patient from her face. She was awake but confused at what happened. I sat with her while she came to and our front store manager got her water. She was breathing well and was starting to become aware, and she refused an offer to call an ambulance. We sat until she felt comfortable to get up and the store manager walked with her. She reported to him that was not the first time she had passed out that day |
| 1364494 | 6/1/2021 | NC | 54 | F | 4/13/2021 | 4/14/2021 | I had, chills, fainting, left eye dropping, headache and body ached. |
| 1364595 | 6/1/2021 | WI | 17 | F | 5/27/2021 | 5/27/2021 | received the Covid 19 Pfizer vaccine and passed out approximately 2 minutes after the vaccine. Was seated at the time. Physical support until patient regained consciousness approximately 30 seconds after. Assisted via wheelchair to cot to lay down and water provided. Mother with. Instructed to lay down for second dose of vaccine when receiving it. Left with mother ambulatory in stable condition approximately 30 minutes after dose administered. |
| 1364654 | 6/1/2021 | CT | 61 | F | 6/1/2021 | 6/1/2021 | Syncope. Her face was pale. Within 10 mins she was normal after we apply cold compress. |
| 1364694 | 6/1/2021 | PA | 81 | F | 2/1/2021 | 3/1/2021 | A whole-body rash was evident 2-3 weeks after the first vaccine dose. Subject was unsure at the time if it was vaccine related. Severe swelling of hands and legs began the same day after the second vaccine dose with general malaise and concerns about fainting. Oral steroids were prescribed for 2 weeks, and progression of the symptoms seem to stabilize during steroid treatment. After steroid treatment, the symptoms resumed at full strength with swelling in the hands and legs causing the superficial skin to peel off and split down into the dermis with bleeding and pain. Joints in the hands and legs were painful. Severe swelling and pain in the hands and legs persisted for at least 6 weeks after the second vaccine dose. A diuretic was prescribed at about 4-5 weeks after the second vaccine dose. The subject is currently reporting improved symptoms. |

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| 1364700 | 6/1/2021 | FL | 12 | M | 5/29/2021 | 5/29/2021 | After taking the vaccine patient stated that he felt like he was going to pass out. Mother stated that this happens every time he gets a shot. Patient was walked to chair where he was given water. Patient passed out briefly and was taken to medic station. |

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| 1364022 | 6/1/2021 | CA | 53 | F | 4/21/2021 | 4/21/2021 | third degree or full thickness burn on her right upper thigh; second degree burns on her left breast and underneath her right breast; Subsequent cellulitis in right thigh and left breast; Passed out; nauseous; had a hard time sleeping at night because her entire body ached; entire body ached; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of BURNS THIRD DEGREE (third degree or full thickness burn on her right upper thigh), BURNS SECOND DEGREE (second degree burns on her left breast and underneath her right breast), CELLULITIS (Subsequent cellulitis in right thigh and left breast) and LOSS OF CONSCIOUSNESS (Passed out) in a 53-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 006C21A and 016B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 21-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 21-Apr-2021, the patient experienced INSOMNIA (had a hard time sleeping at night because her entire body ached) and MYALGIA (entire body ached). On 22-Apr-2021, the patient experienced BURNS THIRD DEGREE (third degree or full thickness burn on her right upper thigh) (seriousness criteria hospitalization and medically significant), BURNS SECOND DEGREE (second degree burns on her left breast and underneath her right breast) (seriousness criterion hospitalization), CELLULITIS (Subsequent cellulitis in right thigh and left breast) (seriousness criteria hospitalization and medically significant), LOSS OF CONSCIOUSNESS (Passed out) (seriousness criterion medically significant) and NAUSEA (nauseous). The patient was hospitalized from 22-Apr-2021 to 25-Apr-2021 due to BURNS SECOND DEGREE, BURNS THIRD DEGREE and CELLULITIS. At the time of the report, BURNS THIRD DEGREE (third degree or full thickness burn on her right upper thigh), BURNS SECOND DEGREE (second degree burns on her left breast and underneath her right breast) and CELLULITIS (Subsequent cellulitis in right thigh and left breast) had not resolved and LOSS OF CONSCIOUSNESS (Passed |

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out), INSOMNIA (had a hard time sleeping at night because her entire body ached), MYALGIA (entire body ached) and NAUSEA (nauseous) outcome was unknown. No concomitant medications were reported. The patient had a hard time sleeping during the night she received her second vaccine because her entire body ached. On the next morning, she was nauseous so she got out to make herself some tea. While standing at the stove waiting for the water to boil, her nausea got worse. As she was pouring hot water from the kettle into her cup, she passed out, spilling the boiling hot water on herself and woke up as her father was picking her up from the floor. She sustained third degree or full thickness burn on her right upper thigh and second degree burns on her left breast and underneath her right breast. Subsequently, she had cellulitis in her right thigh and left breast. As a result, she was admitted to hospital with unspecified intravenous antibiotics and was hospitalized for three and half days. At the time of this report, she was at home and had a follow up appointment with plastic surgeon for debridement of her wounds. She did not have daily medications, but had continued pain in her right thigh and under right breast that is tolerable. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

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| 1365891 | 6/1/2021 CA | 14 M | 6/1/2021 | 6/1/2021 | PT STARTED TO FEEL NERVOUS. PT SAID HE FELT HE NEEDED SOME AIR SO HE WALKED OUTSIDE. MOTHER WITNESSED HIS FALL. PT FELL ON HIS ELBOWS, HANDS SHOOK FOR 2 TO 3 SECONDS. PT DID NOT RECALL FAINTING. REPORTED HAVING A HEADACHE IMMEDIATELY AFTER. |
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| 1366332 | 6/1/2021 | NJ | 44 | M | 4/13/2021 | 4/20/2021 | 1st shot 4/13, no issue with injection site. About a week later had trouble breathing, chest pain, felt like lungs were hurting in my back, weak, tired, couldn't catch my breath when i went upstairs and almost passed out. 2nd shot 5/04, felt pain at injection site (that was expected), that night started to get a bad headache and got worse and worse. Next morning, whole body aching, upper body, lower back, bad headache, Left underarm (lymph) swollen. 2nd day slight headache, neck ache, left underarm swollen. That night had rash on arms, chest, and stomach. 3rd day, nighttime rash arms, chest, stomach. Still red where band aid was over injection site. Over a week later still have redness shape of band aid, Seems I have sensitive skin since the 2nd covid shot. 10 days after 2nd shot I still have redness the shape of the Band Aid on my left arm. Got a red spot on my nose (looks like Rosacea). 4 weeks later, still have a red spot on my nose. I have itchiness between fingers left hand, on my face left side, neck, arms (left wrist, right arm in places) redness on chest, and rashes on back, left buttocks, and itchiness on legs. i noticed that it gets worse at night. As far as i know i did not get the Covid Virus, i did the rapid test and regular test and both were negative. But i was very sick with my stomach and had issues breathing in late 2019 and again early 2020, took medication (antibiotics) both times. I had to write on this form over and over again kept getting frozen with error from the PDF. Even if I hit OK, it keeps popping up and does not let me finish, so I can imagine that lots of people gave up, like I may. Pfizer 4/13/2021 EW0162. After 5pm Pfizer 5/04/2021 EW0170. After 2pm |
| 1365525 | 6/1/2021 | CA | 17 | M | 6/1/2021 | 6/1/2021 | PT PASSED OUT. HAD HX OF PASSING OUT AT SCHOOL WHILE IN CLASS. PARAMEDIC CAME, HYDRATION OFFERED. SX RESOLVED, NO TRANSPORT. |
| 1365535 | 6/1/2021 | IL | 15 | M | 6/1/2021 | 6/1/2021 | Patient and his Mother were in the vaccination room. appox 30 sec to 1 min following Vaccination patient stated he feels like he is going to pass out and before his mother or administering pharmacist could respond the patient fainted/ lost consciousness for approximately 30seconds |

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| 1365546 | 6/1/2021 | TX | 15 | M | 5/21/2021 | 5/30/2021 | My son was evaluated by ER after experiencing 2 fainting episodes within an hour. ER report stated reason for visit as Loss of Consciousness with diagnoses of Syncope (Vasovagal) and Concussion. |
| 1365574 | 6/1/2021 | NM | 13 | F | 6/1/2021 | 6/1/2021 | pt passed out turned while and grey stopped breathing received on dose of epi pen 0.3 mg came to and a sugar drink, emt called and came, blood pressure was good |
| 1365519 | 6/1/2021 | | 38 | M | 5/1/2021 | 5/26/2021 | 5 minutes after receiving the J&J vaccine, I went lights out. As I was sitting in the monitoring area, I was completely fine and then a wave came crushing down on me and I was out for about 5 minutes. The nurses said it looked like I was having a seizure. The EMTs called it a syncope event. I am a member of the military and have been pumped full of vaccines. I get my annual flu shot every year. I have survived 6 rounds of Anthrax vaccines and every other vaccine the military has pumped into me. This is the First Time I have ever REACTED this way. It was CRAZY! |
| 1365749 | 6/1/2021 | AZ | 16 | F | 5/31/2021 | 5/31/2021 | Pt passed out. Experienced extremely low blood pressure. Pulse couldn't be detected for a couple of seconds. Pt woke and was clear and coherence. Paramedics saw pt and provided IV fluids. Pt left under own power. |
| 1365509 | 6/1/2021 | CA | 63 | F | 5/26/2021 | 5/27/2021 | I wasn't feeling too ill the day of the vaccination and only had a sore arm when going to bed that first night. However, when I woke up the next day, I was quite ill. I never ran a temperature but I had diarrhea and vomiting and could not keep any liquid down. As I was kneeling beside the toilet to vomit, I completely lost consciousness, fainted, and bruised a rib on the fall. I finally was able to get Gatorade to stay down. The arm of the vaccination site doubled in size due to edema and my arm was red from the top of my shoulder to the bottom half of my arm. It was also very itchy. Completely out that first day, just sleeping and laying on the couch downstairs. Four days out, the arm was still ballooned up and red. Five days out, the redness started to disappear. Still some edema and redness on the sixth day out, still fatigued, but gaining a little more normalcy. Huge bruise from faint on my left rib cage. Appetite now back to normal. |

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| 1365908 | 6/1/2021 | CA | 18 | F | 6/1/2021 | 6/1/2021 | While we were observing patient for 15 minutes after the vaccination, patient fainted and hit her head on the floor on 6/1/21. |
| 1365910 | 6/1/2021 | | 16 | M | 5/31/2021 | 5/31/2021 | Patient fainted and had convulsions for 5-10 seconds. He came to and was just fine. |
| 1366129 | 6/1/2021 | AL | 69 | F | 2/1/2021 | 5/14/2021 | Abrupt syncope with cessation of pulse and respirations at 11:15AM at main office. CPR was started by the workers present. 911 activated and code was activated by EMS and continued during transport and arrival at ER. All resuscitation efforts failed to restore breathing and cardiac activity. A large amount of blood was encountered upon intubation, so Dr. informed next of kin that cause of death was likely a large pulmonary embolus. |
| 1366158 | 6/1/2021 | FL | 30 | F | 6/1/2021 | 6/1/2021 | Patient received the covid19 vaccine at about 940am on 06/01/21 - dose 1 by Pfizer. Less than 5 minutes later, patient came to me saying she wasn't feeling good. I was still sitting at the immunization table. She sat down and said she was feeling very tired. I asked if she wanted me to call 911 and she said no. She just wanted to rest. She then slumped over and fainted. I was able to hold her in the seat while carefully supporting her head. I loosened her mask and she was breathing normally, but just fainted. About 2 minutes she woke up and then proceeded to vomit. I sat with the patient about 15 minutes or so. The color returned back to her lips and we called her roommate. When he arrived, the patient got up and started walking and began to feel better. Patient went home. |
| 1366338 | 6/1/2021 | CA | 26 | M | 6/1/2021 | 6/1/2021 | Patient just got the shot and immediately feel a weird sensation. He sat on the chair to be observed and passed out almost immediately. We rushed to him and called out for him. He opened his eyes and slowly told us that he thinks he fainted. I helped him elevated both legs on the chair and talked to him if he's hurt or any other weird feeling. He told me he's feeling fine again. I have him lay down with his legs elevated for another 5 minutes and helped him sit up. He was able to get up by himself and sat back on the chair. A couple minutes later, I took his blood pressure and it was 129/85 and pulse was 61. |

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| 1365701 | 6/1/2021 | NY | 29 | M | 6/1/2021 | 6/1/2021 | 5 minutes after receiving vaccine patient "zoned out" and felt like he could not move. Looked like he was on the verge of fainting or blacking out but never lost consciousness. Patient was sweating after as if he fainted or had a panic attack. This event only lasted 1 minute and patient denied an ambulance. |
| 1365707 | 6/1/2021 | CO | 17 | F | 6/1/2021 | 6/1/2021 | Patient was very anxious and breathing heavy. About 5 minutes after the vaccination they started to hyperventilate and ended up throwing up. After letting them sit and relax for 5 minutes, the patient then had to throw up again and told their mother they felt like they were going to faint. Mother and myself stood by, while patient did end up fainting. We slowly lowered them to the ground, and on the way down their body got stiff and patient had uncontrollable movements and was hardly responsive. Mother and myself finally got her safely to the floor as they came to and was responding to verbal ques and stimulation from mother. Mother went to get water and i stayed with the patient to ensure no other things happen. Patient ended up doing alright after relaxing for a few and then i walked them and mother to their car and ensured they were feeling good enough to go home. I then advised the mother to seek medical attention. |
| 1365431 | 6/1/2021 | CA | 16 | F | 5/13/2021 | 5/14/2021 | Syncope x 3 in the early morning hours (around 3am) about 14-15 hours after vaccine. She had had headaches that is intermittent, throbbing, phonophobia but no photophobia, from back of head to top of head and behind eyes, taking Advil or Excedrin intermittently with relief for a week prior to covid19 vaccine. Syncope, longest lapse was two minutes, her sister found her. She went to Medical Center ER at 0400, was assessed and scanned, neg CT scan of head, and was discharged home. Has felt some fatigue today due to not sleeping early the night before, has returned to school since concussion, with normal learning, and denies any exertional physical activity due to pre-existing torn ACL, torn medial meniscus L knee. After evaluation by ER, was given IV fluids, determined cause to be dehydration. |

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| 1365236 | 6/1/2021 | KS | 31 | F | 6/1/2021 | 6/1/2021 | She bleed at the injection site . Held cotton ball to injection site for about 1&1/2 minutes until the bleeding stopped. There was swelling at injection site. About 2 minutes later after Band-Aid had been applied she passed out and fell to the left. Immunizer caught her just as her head hit the counter top. Held her until she came to for about one minute. Room was closed and could not call for help. Patient then put her head between her legs and started to feel better and decided to walk out of immunization room after about 5 minutes to sit in waiting room. Got her a bottle of water and patient said she wanted to lie down. Went to immunization room and patient laid down for about 15 minutes. Immunizer kept her talking and watched for any reactions. Patient then said she was okay and sat in waiting room for another 10 minutes before leaving. |

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| 1365276 | 6/1/2021 | MI | 41 | F | 5/27/2021 | 5/28/2021 | <p>Symptoms started 5/28. Symptoms include: Constant Severe pt received the Moderna Covid-19 vaccine on 5/27 at 1930. Pt stating that pt's symptoms started this am. Pt developed fever (current temperature at 104.7 via forehead thermometer), severe head and neck pain, lightheadedness. pt feeling like pt's hands are "on fire". pt stating that pt's hands "feel weird". Pt passed out in pt's computer chair x 2 this am. Pt has not reacted to vaccines in the past. Pt A & O x 4. Pt c/o tachypnea. Patient Has tried prescribed "headache" medication with none improvement. Pertinent negatives include: No chest pain. No diarrhea. No vomiting. No injury. No rash. Pertinent Medical History: none Patient went to ED 5/28- This is a 41-year-old female with history of migraines 12 hours post 2nd mid during the COVID immunization who presents emergency department for evaluation of myalgias, fever at home, fatigue, headache. Headache is similar to previous migraines. Patient has a benign exam with a normal neurologic exam. Initially noted to be tachycardic at triage on recheck this is normal she is not tachycardic on my evaluation. Participant should decision making the patient. Symptoms thought to be likely related to immune response to immunization. She did note feeling dizzy earlier notes she has been eating and drinking normally. Offered her screening labs, EKG, migraine cocktail and she declined each. She notes she would prefer to go home and rest as this will often alleviate her headache symptoms. Given dose of Tylenol here. Provided with work note. Normal sequela of COVID immunization discussed return precautions discussed. Patient notes she had COVID the end of March and testing today could be a remnant positive from this would not recommend repeat She and husband are comfortable plan. Patient is reassured, agreeable with plan, educated regarding return precautions, discharged in stable condition, all questions answered.</p> |

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| 1365334 | 6/1/2021 | CA | 44 | M | 4/27/2021 | 5/19/2021 | Would occasionally have difficulty catching my breath while not doing anything. I occasionally felt my heart flutter or it would possibly skip a beat. Mild chest pain below above the sternum but I get that feeling from my Eosinophilic Esophagitis. I've become more concerned recently as I almost fainted once on 5/19 while working at my computer. I've had two other instances of feeling faint, most recently occurring on 5/27. I historically have had no heart issues and can ski and hike all day and feel great so this recent change has been concerning. After reading articles on the covid vaccines I realized that my symptoms are similar to the heart related issues and took ibuprofen when I felt additional chest pressure. That has helped to alleviate the pressure at least. |
| 1365336 | 6/1/2021 | | 28 | F | 5/4/2021 | 5/4/2021 | Pain in the arm where I got the shot about 2 hours after receiving the vaccine, Chills after 10 hours, Fever and Headache after 12 hours, Tiredness and Fainted on the 2nd day |
| 1365380 | 6/1/2021 | NY | 38 | M | 5/25/2021 | 5/26/2021 | The morning after receiving the shot, I woke up at roughly 9am with a High fever (100+), headache, and general felt very sick. Upon getting up and going to the bathroom, I fainted while peeing (standing up). Upon waking up on the floor of the bathroom, I got up, was light headed, took 4 steps to the bathroom door, and fainted a second time. Upon waking up the second time, I made it to bed and fell back asleep until 11:30. I took my temperature at 11:30 and found it was 99.9 degrees. I was feeling cooler (less fevered) than I had been at the time of the fainting incident. I called a nurse through my insurance company, who instructed me to go to the ER. I waited 3 hours in the ER waiting room, and then received Fluids, A CT head scan, an ECG 12 lead, and blood work. All normal. I felt better, if banged up, by the time I left the ER. I hit my head and Left shoulder in the fall. |

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| 1365524 | 6/1/2021 | MN | 13 | F | 6/1/2021 | 6/1/2021 | Prior to the vaccine patient and parent were given teaching about concerns for fainting. She was questioned if she had something to eat and drink prior to coming to the clinic and both indicated that she had. It was volunteered that patient has never had a fainting spell from receiving injections/vaccines. She was administered 0.3 ml of the Pfizer vaccine at 4:47 p.m. while seated securely in a chair. At about 4:50 p.m. she lost consciousness and assumed a prone position. She was held by both the R.N. and her mother and never fell or injured herself. She was unconscious for approximately 8-10 seconds and regained consciousness. She was alert and oriented. She was reassured and given some apple juice and a graham cracker which she consumed. Charge nurse and nurse manager appeared on the scene. EMT was summoned who brought a wheel chair and patient was transported to the observation area in the wheel chair. She was conversing and appeared oriented prior to going to the observation area. |
| 1365409 | 6/1/2021 | MA | 64 | M | 3/6/2021 | 3/7/2021 | I started feeling bad the first night. I woke up with energy @ 1am and then later that day I started feeling extremely drain and exhausted and very tired and weak. I woke up @ 11:30pm and I passed out and hit hit the floor, face first and my wife don't know how long I was passed out up to 30- to 60 mins. I had to put frozen meat on my face. I felt like I was about to pass out again. Felt like my legs was giving out. I do have a spinal disease and it felt worse then that. Then it took my headache away. I felt like a different person. |
| 1365215 | 6/1/2021 | VA | 18 | M | 6/1/2021 | 6/1/2021 | about 5 minutes after patient received shot , he came to pharmacy counter to say he felt light headed, as I (the pharmacist) headed out to have him sit down, dropped to a sitting position on the floor, I was able to get him up to a chair and was fanning him and we got him some water. he the passed out and his head lobbed backwards, I got behind him so he did not hit his head and he went into a mini seizure which only lasted about 5 seconds and then he came out of, he was in sweats and we called 911. He declined to go to hospital and his mom came and picked him up |

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| 1365442 | 6/1/2021 | FL | 47 | F | 5/3/2021 | 5/6/2021 | Feeling lack of oxygen and felt faint and high, passed out later. Still feel issues including various levels of inebriation. Prescribed potassium pills. Much better but still dealing with event. Also, had chills, heart racing, and short of breath. |
| 1365444 | 6/1/2021 | MA | 20 | F | 5/12/2021 | 6/1/2021 | I went to the bathroom and realized I had gotten my period and was feeling lightheaded, I went to go get water and passed out while walking, my moms found me and called an ambulance, I had an MRI. EKG, and chest X-rays done at the hospital, they said I was fine but I have never passed out before, especially from my period. |
| 1365446 | 6/1/2021 | WV | 26 | F | 6/1/2021 | 6/1/2021 | 10 minutes after vaccine patient stated she felt warm and clammy, gave her sip of water and cold rag, after 25 minutes she stated she felt a little better and wanted to go to bathroom, had syncope event on way to bathroom and passed out. 10 minutes vomitted. did not want to go to er and mom did not want her to. mom took her home. |
| 1365469 | 6/1/2021 | GA | 32 | M | 6/1/2021 | 6/1/2021 | The patient fainted and urinated. He said he was feeling pain briefly in his neck. He also said he had pain in his right chest. He laid down for 40 minutes. He did not want us to call an ambulance. He had someone pick him up and he said he was going to the emergency room. |
| 1365470 | 6/1/2021 | CA | 31 | F | 5/8/2021 | 5/8/2021 | Dizziness and passed out for unknown period of time Fall down form chair and blood came from Nose Difficulty breathing Low blood pressure Ambulance was called at vaccination center and taken to emergency rooms |

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| 1365477 | 6/1/2021 | TX | 29 | F | 6/1/2021 | 6/1/2021 | Patient was getting their 2nd covid immunization. They marked that they once had fainted from a previous immunization and had needle anxiety. I asked her if she had fainted anytime recently or during the first covid vaccine and she said no. Gave her the vaccine and let her remain in the chair. She then had gotten a little dizzie for a moment, and then told us she had just fainted. We called store management code white. We got her history, some soda, and ice pack. She didn't fall out of the chair but thought it would help her feel better. She stated she hadn't eaten much today and just got done working out at the gym and had low blood sugar. We checked her pulse O ₂ and heart rate and everything was within normal limits. We had her remain to she felt comfortable to leave. She didn't have any HX of seizures and no signs of allergic reaction. Staff Said when she was here first time she had immunization anxiety and hung out for 40ish minutes but didn't faint first time. |
| 1365398 | 6/1/2021 | KY | 18 | M | 6/1/2021 | 6/1/2021 | Pt received 1st Moderna covid vaccine at approx 10:25am with no apparent issue. He was sitting outside pharmacy in observation area playing on cell phone and approximately 10 minutes after receiving vaccine fell in the floor, hitting his head. EMTs were called immediately as a precaution. He was conscious when pharmacist reached his side. He reported remembering a buzzing in his ears and then woke up in floor. Pt reported no hx of seizures or fainting. He remained in floor for several minutes, reporting his head hurt, but was able to tell his name, location, and date with no issue. |
| 1365565 | 6/1/2021 | MN | 16 | F | 6/1/2021 | 6/1/2021 | After receiving the injection the patient fainted. Patient was offered juice and after taking a sip she had a small amount of emesis. A cold towel was placed on patient's forehead and then observed by EMS. |
| 1362131 | 5/31/2021 | NY | 29 | M | 5/25/2021 | 5/25/2021 | Systemic: Fainting / Unresponsive-Severe, Systemic: Hypotension-Medium, Additional Details: the next day patient said he was okay. |
| 1362196 | 5/31/2021 | PA | 51 | M | 1/12/2021 | 2/20/2021 | Pre-syncope after exercise. found to have orthostatic hypotension and dysautonomia, diagnosed in the weeks following the second vaccination. Persistent light headedness, urinary symptoms, weight loss. Possible pure autonomic failure. Evaluation ongoing. |

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| 1362166 | 5/31/2021 | MS | 18 | F | 5/30/2021 | 5/30/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Shakiness-Mild, Additional Details: patient said she felt dizzy, and the passed out. Her boyfriend was with her, and helped me lay her on the floor. She Shook or seized for a few seconds and then came to. She was confusion at first, but then recognized her boyfriend. She asked him to call her Mom. I talked to her Mom on the phone while she was starting to feel better. We got her some water and a fan. I had her wait an extra 30 minutes after she come to. |
| 1362161 | 5/31/2021 | TN | 35 | M | 5/28/2021 | 5/28/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Was informed to sit after the vaccine. Waited a few minutes, then sat over by the clinic. Technician informed pharmacy staff that he fainted. Staff offered him water after he regained composure. Patient stated he had a previous history of adverse events from vaccines. Will eat and drink more fluids before coming back for second vaccine. |
| 1362150 | 5/31/2021 | CA | 18 | F | 5/29/2021 | 5/29/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient got the pfizer vaccin 11:00am and after 2-3 min after din't answer back my question like you have to stay 15 min then i'll give your immunization card which will be 11:15am but was mummering and showed syncope symptomes sol make th patient kind of lie down and check patient in 2 min. but she was still said feld so dizzy so I had to call 911 and 911 came check bp & Temp. BP was low so 911 team took her ER. About 4:33 pm patient came home checked 5-30-21 she was fine |
| 1362145 | 5/31/2021 | FL | 15 | F | 5/30/2021 | 5/30/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: PATIENT FAINTED WITHIN 15 MINUTES OF VACCINE, ABOUT NOON. SHE RECOVERED WITHIN 5-10 MINUTES. THE PARAMEDICS CAME AND CHECKED HER VITALS AND WERE NORMAL. PATIENT WENT THEN HOME WITH MOM. I SPOKE WITH MOM AT 6PM when store closed AND MOM SAID Patient WAS DOING OK. |

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| 1362141 | 5/31/2021 | AZ | 33 | U | 5/29/2021 | 5/29/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Nausea-Mild, Systemic: Seizure-Mild, Systemic: Shakiness-Mild, Additional Details: Patient felt normal after the injection and for the remainder of the day. She woke up in the middle of the night to use the restroom and fainted in the bathroom. She then returned to bed where she felt like she "blacked out for a short period". Her husband reported that she was shaking uncontrollably and her eyes were darting back and forth (this lasted about 10 sec). She was encouraged to be examined by a physician for any further issues. She stated that she is currently feeling ok. |
| 1362139 | 5/31/2021 | CA | 14 | M | 5/29/2021 | 5/29/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Medium |
| 1362265 | 5/31/2021 | VA | 39 | M | 5/31/2021 | 5/31/2021 | injection given into left deltoid, within 5 minutes, patient complained of syncope, then became flaccid. He never lost consciousness and kept talking to immunizer. we applied a cold compress to neck and gave water and accompanied patient until he departed the store |
| 1362133 | 5/31/2021 | NH | 30 | M | 5/30/2020 | 5/30/2020 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Medium |
| 1362096 | 5/31/2021 | TX | 34 | F | 5/28/2021 | 5/28/2021 | Systemic: Confusion-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Seizure-Mild, Additional Details: Pt was unresponsive approximately 5 mins after receiving COVID vax. Pt was sitting next to husband and husband called for help. Upon viewing the pt, pt appeared unconscious and possibly seizing. EMS (911) was called and in the mean time Rph attended to pt. By the time EMS arrived pt was starting to respond and gradually aware of environment and self. Pt was recommended to visit hospital for further check up, but pt and husband declined. said shes doing fine and much better and husband agreed. |
| 1362129 | 5/31/2021 | IL | 33 | M | 5/29/2021 | 5/29/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium |

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| 1362114 | 5/31/2021 | CA | 21 | M | 5/30/2021 | 5/30/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Hypotension-Mild, Additional Details: called 911 and paramedics took him to hospital to further assess his low blood pressure paramedics said most likely not reaction to vaccine |
| 1362104 | 5/31/2021 | CT | 29 | M | 5/30/2021 | 5/30/2021 | Systemic: Chills-Medium, Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Exhaustion / Lethargy-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Seizure-Medium, Additional Details: Patient stated that he smoked marijuana earlier in the day. Patient fell over onto the floor after administration. Woke up less than 30 seconds after falling over |
| 1362100 | 5/31/2021 | CA | 43 | M | 5/28/2021 | 5/28/2021 | Systemic: Fainting / Unresponsive-Medium, Additional Details: Patient passed out a few minutes after receiving the shot, and hit his head when falling over. He quickly came about. First aid was provided. No sign of confusion. |
| 1362078 | 5/31/2021 | WA | 23 | F | 5/24/2021 | 5/24/2021 | Tired shortly after my shot. Had chills and sweats overnight. Woke up to shower and passed out in the shower, had blurry vision, passed out again after getting out of the shower. Rapid heart rate and chills with migraine. No appetite, did not leave my bed for 24 hours, very lightheaded and nauseous. I have been having serious headaches for a week now after the shot |
| 1362651 | 5/31/2021 | | 33 | M | 5/12/2021 | 5/12/2021 | Patient fainted within 5-10 minutes after receiving shot but it only lasted about 10 seconds |
| 1362134 | 5/31/2021 | FL | 14 | F | 5/29/2021 | 5/29/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Hyperventilation-Severe, Systemic: Shakiness-Medium |
| 1362606 | 5/31/2021 | CO | 22 | F | 5/31/2021 | 5/31/2021 | Patient fainted approximately 5-10 minutes after receiving her second Covid-19 vaccination |
| 1362300 | 5/31/2021 | FL | 54 | M | 5/31/2021 | 5/31/2021 | Pt experienced syncope in his chair in the post-vaccine waiting area, fell out of his chair, and hit his head on the ground. Upon assessing the patient, he did not know where he was, but he did know his own name, pt appeared pale and was trembling. Paramedics were called for further assistance and took pt to hospital. |

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| 1362554 | 5/31/2021 | FL | 26 | F | 5/31/2021 | 5/31/2021 | After receiving the second dose of Moderna vaccine, patient felt nauseous, lightheaded and very weak then passed out. Patient was back in few seconds and declined 911 call. Patient was provided with Gatorade and Pedialyte to get some electrolytes. Patient was under pharmacist observation for 45 minutes. Her BP was checked 20 minutes after the shot was administered, which was 105/61. Patient confirmed history of dizziness but no history of low BP. Patient felt nauseous again and almost passed out and again declined 911. Her BP was checked again, it was 103/59. At this point pharmacist recommended her to take some more electrolytes to ensure she is hydrated and to see if her BP is due to dehydration. Final BP was checked 45 minutes after getting the shot. Patient was hydrated and alert and her BP when measured was 124/85. Patient was stable when left for home with her husband. |
| 1362499 | 5/31/2021 | IA | 15 | M | 5/31/2021 | 5/31/2021 | Nausea, and the fainted |
| 1362495 | 5/31/2021 | NY | 28 | M | 5/31/2021 | 5/31/2021 | patient fainted |
| 1362489 | 5/31/2021 | TX | 40 | F | 5/31/2021 | 5/31/2021 | Patient was super anxious before getting shot. Patient felt dizziness and fainting after getting vaccine. Cold compress pouch was given patient was still sweating. Patient was also asked to lie down on floor and blood pressure was taken. Her BP was 150/105 mm Hg. Upon asking her for 911, she declined it. Patient was given water and food to eat as well after which she felt better and left store after 15 min. |

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| 1362488 | 5/31/2021 | NV | 36 | F | 5/28/2021 | 5/28/2021 | patient felt light headed and a person standing by notified pharmacy. I, staff RPh, assessed patient quickly and helped her to a supine position on the floor with legs elevated. Patient fainted as she was being helped to the floor. Patient's eyes was dilated, we called 911 and I grabbed the BP unit and checked pulse. Pt regained consciousness after about 7 to 8 seconds. Pt was able to identify herself and answer all questions. We grabbed an orange juice for the patient as she had not had anything to eat and had just worked out. Pt's BP was 108/90 and remained around that range for about 5 or so readings. PT drank and was encouraged to lie in supine position with legs elevated for 15 more minutes even though she stated she thought she was fine. Pt waited until 12:55pm and also stated she had fainted with a past blood draw. Pt appeared fine by 12:55pm, bp still around 100/80, pupils is back to normal. 911 was cancelled per patients request shortly after regaining consciousness. |
| 1362471 | 5/31/2021 | CA | 32 | F | 5/19/2021 | 5/23/2021 | Moderna COVID-19 Vaccine EUA. About 3-4 days after the second dose, I experienced off and on moderate chest pain for about 1.5 weeks, so far. Symptoms seem to be declining now. It was a moderate aching in the center of my chest up to my left pec and shoulder. I also experienced off and on heart pounding (not necessarily elevated heart rate, and not necessarily concurrent with the chest pain). No fainting, mild headaches. *I also experienced off and on heart pounding 12-72 hours after the first dose, but no chest pain. |
| 1362408 | 5/31/2021 | NY | 24 | F | 5/31/2021 | 5/31/2021 | patient fainted within minutes of vaccine; recovered after being laid on floor and legs elevated |

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| 1362310 | 5/31/2021 | NJ | 45 | F | 4/9/2021 | 4/10/2021 | I had a completely normal evening after receiving the vaccine. I woke up the next morning and didn't feel quite well. I started washing my hands and I woke to my husband calling an ambulance. I had passed out. I refused to go to the hospital per their request because of worries about COVID. I called my PCP and I discussed the situation with him and he told me to get rest and stay hydrated. I met him a couple days later for a virtual appointment. At this point the vaccine had been paused and I was very concerned about the potential of blood clots. I was still feeling fatigue after my episode, but I was feeling better. He told me to take a baby aspirin, once daily for a month, to help prevent any blood clots. After 5-6 weeks of receiving the vaccine, I started coughing, gagging and choking and had to get my daughter to get my husband. My husband gave me an alavert and I was able to breathe better around 10 minutes later. We think it was a severe reaction to possible pollen, or something in the air, but that has never happened before. |
| 1362392 | 5/31/2021 | WA | 45 | F | 4/10/2021 | 4/17/2021 | I suddenly felt very lightheaded and weak. I thru up and passed out. Then I went to sleep. It happened again a couple of weeks later, and I went to the ER room. The doctors have not found out any correlating event that would make sense yet. I was told to follow up with a cardiologist, I haven't done this yet. I am not sure if this is from the shot or not. |
| 1362386 | 5/31/2021 | NY | 14 | F | 5/30/2021 | 5/30/2021 | Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Nausea-Mild |
| 1362374 | 5/31/2021 | RI | 34 | F | 5/31/2021 | 5/31/2021 | Administered vaccine to patient . A few moments after patient reached the observation area they signaled they wanted some help. Once I arrived the patient stated they felt like fainting. Patient fainted for 3-5 seconds before regaining consciousness. Patient refused going with first responders. |
| 1362371 | 5/31/2021 | NJ | 28 | M | 5/31/2021 | 5/31/2021 | Systemic: Chills-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild |

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| 1362355 | 5/31/2021 | NJ | 17 | F | 5/31/2021 | 5/31/2021 | The patient felt dizzy and weak then fainted while her mom was holding her . Her mom gradually led her to the floor from a sitting position. She felt nauseous and dizzy. I laid her on floor with her feet elevated on a chair with her head to the side so she would not aspirate if she vomitted.. She felt better after a while and wanted to sit. When she was sitting in the armchair she vomitted and said she felt worse, so I then called 911. They evaluated her and her blood pressure was very low and they gave her iv fluids and took her to the emergency room |
| 1362347 | 5/31/2021 | RI | 47 | M | 5/31/2021 | 5/31/2021 | fainted for a short period of time |
| 1362301 | 5/31/2021 | ME | 29 | F | 5/31/2021 | 5/31/2021 | minutes after vaccine patient fainted. when i went over to check on her she had a very mild seizure like rxn. then cam to and said "where am I". we administered cold pack to fore head, checked pulse. she came around a bit more and we gave her cold water. then a glucose tablet. color started to come back into her face. gave her peanut butter crackers and a banana. she stayed for about 1 hr. called her sister to come get her. |
| 1362585 | 5/31/2021 | WA | 19 | F | 5/31/2021 | 5/31/2021 | Patient start having nausea and vomiting symptoms about 10 min after administration. She also mentioned blurry vision and loss of vision in one side. She was fainting too. Patient was positioned on her side in the waiting room Her blood pressure was 111/71 and pulse 60 when checked by the pharmacist. EMT was notified. They arrived and check her vitals, she was doing better. they didn't consider that any future evaluation is needed. |
| 1362393 | 5/31/2021 | PA | 91 | F | 5/26/2021 | 5/26/2021 | Systemic: Fainting / Unresponsive-Severe, Additional Details: Pt fell out of chair, bleeding from bridge of nose according to paramedics. Took her to the Hospital, left message for pt at only working number provided (family member), no response. |

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| 1361498 | 5/30/2021 | TX | 34 | F | 5/28/2021 | 5/28/2021 | Systemic: Confusion-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Seizure-Mild, Systemic: Shakiness-Mild, Additional Details: Pt was unresponsive appr 5 mins after receiving COVID Vax. Pt was sitting next to husband and husband called for help. Upon galncing at the pt, pt appeared unconscious and shaking, possibly seizing. EMS (911) was called and in the mean time RPH attended to pt. By the time EMS arrived pt was starting to respond and gradually aware of environment and self. Pt was recommended visit ER for further check up, but pt and husband declined, she stated she is doing fine and much better and husband agreed |
| 1361501 | 5/30/2021 | VA | 44 | F | 5/29/2021 | 5/29/2021 | Site: Pain at Injection Site-Medium, Systemic: Allergic: Difficulty Breathing-Severe, Systemic: Fainting/Unresponsive-Severe, Systemic: Flushed/Sweating-Medium, Systemic: Hypotension-Severe, Systemic: Weakness-Severe, Additional Details: Patient fainted 5 minutes after vaccine. called 911. Nurse practitioner came to assist. Customer regained consciousness. Paramedics arrived and took customer. |
| 1361542 | 5/30/2021 | ID | 16 | F | 5/30/2021 | 5/30/2021 | After leaving the immunization room the patient fainted and fell on the floor. Patient lost consciousness for a moment but then was breathing and talking without difficulty. 911 was contacted. At some point before the patient left the store she vomited. Patient parent was contacted the next day; patient did go to hospital and was checked out and given the all clear and was then at home resting. |
| 1361546 | 5/30/2021 | WI | 17 | F | 5/29/2021 | 5/29/2021 | PATIENT FAINTED IMMEDIATELY AFTER VACCINE ADMINISTRATION. PATIENT DID NOT INJURE HERSELF, WAS CAUGHT IN MOM'S ARMS. PATIENT WAS EXTREMELY WARM AND CLAMMY AND SHAKY. SHE KEPT SEATED, FAN BLOWING, PROVIDED WITH GATORADE AND FELT NORMAL AFTER 10 MINUTES. PATIENT ADMITTED TO NOT EATING PRIOR TO VACCINE. |

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| 1361653 | 5/30/2021 | CA | 57 | M | 5/29/2021 | 5/29/2021 | After Vaccination client was waiting in observation area when he complained of ?feeling dizzy? approximately 15 mins into his observation. Client was placed in anti-gravity chair by EMT. Vital Signs were taken at 1115am BP 132/86 HR 61 RR 14 O2 96%. Client stated he has a history of syncope and anxiety prior to shots. Client has a history of high blood pressure. Client reported not having breakfast in the morning and was given a snack at 1115am. He was recommended to stay an additional 30mins for observation, client complied. Vital Signs 1120: BP 186 HR 66 RR14 O2 96% at same time client stated he ?felt better.? Client continued to be in anti-gravity chair in no apparent distress. He was able to answer all questions with no issues. Vitals 1125: BP 132/J80 HR 62 RR 14 O2 95% 1130: BP 129/ HR 62 RR14 O2 95%. Client was alert and oriented throughout the entire observation. No further interventions were necessary, and client was ready to head home. Emergency Precautions were given by EMT, if his symptoms worsened to seek emergency care. He was also recommended to follow with his Primary Care Provider. |
| 1361462 | 5/30/2021 | VA | 13 | F | 5/29/2021 | 5/29/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient felt light-headed about 5 minutes after vaccine and then fainted. She was responsive again almost immediately, but we called 911 to have her checked out before she left. She did not require further care. EMS advised parent to get her to urgent care if that happens again. She does have history of fainting after dental procedure, also. |
| 1361578 | 5/30/2021 | MD | 38 | M | 5/30/2021 | 5/30/2021 | Syncope |
| 1361494 | 5/30/2021 | MD | 49 | F | 5/25/2021 | 5/26/2021 | I started to black out minutes after waking up the morning after administration. In doing so I hit my head on the table resulting in a laceration and 8 staples in my head. I was diagnosed vasovagal syncope while my blood pressure remained low throughout testing at the clinic. That day (5/26) I had chills and a headache. I have had dizziness the past 2 days (5/28 and 5/29). |

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| 1361484 | 5/30/2021 | NC | 24 | M | 5/29/2021 | 5/29/2021 | Site: Pain at Injection Site-Medium, Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Hyperventilation-Severe, Systemic: Hypotension-Severe, Systemic: Numbness (specify: facial area, extremities)-Medium, Systemic: Shakiness-Medium, Systemic: Tachycardia-Medium, Systemic: Visual Changes/Disturbances-Medium, Additional Details: Pt has history of vaso vagal syncope. Patient entered an episode of syncope and quickly recovered. Paramedics arrived to futher consult patient to recovery. |
| 1361476 | 5/30/2021 | GA | 65 | F | 5/29/2021 | 5/29/2021 | Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Severe, Systemic: Exhaustion / Lethargy-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Shakiness-Mild, Additional Details: LOSS OF URINARY CONTROL |
| 1361471 | 5/30/2021 | FL | 15 | M | 5/27/2021 | 5/27/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Vomiting-Mild |
| 1361461 | 5/30/2021 | CA | 12 | F | 5/29/2021 | 5/29/2021 | Systemic: Fainting / Unresponsive-Severe, Additional Details: PATIENT WAS GIVEN A PFIZER COVID 19 VACCINE INSTRAMUSCULARLY. IMMEDIATELY AFTER BAND AID WAS PLACED, PATIENT APPEARED TO BE FROZEN FOR SEVERAL SECONDS AND WOULD NOT RESPOND TO MY QUESTION. MOM ASKED QUESTION AND HELD PATIENT, AT WHICH TIME THE PATIENT COLLAPSED AND HER EYES ROLLED BACK. SO SHE PUT IN A SUPINE POSTION AS I RAN AND CALLED 911. PARAMEDICS ARRIVED TO THE SCENE AND MONITORED HER VITALS FOR NEARLY 30 MINUTES. THEY OFFERED TO TAKE HER TO THE HOSPITAL BUT PATIENT'S MOM DECLINED. |
| 1361685 | 5/30/2021 | CO | 14 | F | 5/30/2021 | 5/30/2021 | 5/30/2021 11:04 AM After 4 minutes of receiving vaccine, pt became weak, diaphoretic and fainted. 911 was called. Pt's v/s HR 46,BP80/64. Pt woke up 2 minutes later, able to pronounce name and date of birth and able to drink 3 oz of apple juice. Pt's HR 65 BP 88/58. Transfer of care to ambulance personnel at 11:12. Ambulance record. |

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| 1361866 | 5/30/2021 | TX | 57 | F | 4/27/2021 | 4/27/2021 | Patient Fainted and hit her head |
| 1361475 | 5/30/2021 | AZ | 24 | F | 5/29/2021 | 5/29/2021 | Systemic: Fainting / Unresponsive-Severe, Systemic: Seizure-Severe |
| 1361895 | 5/30/2021 | OR | 58 | M | 5/30/2021 | 5/30/2021 | PATIENT RECEIVED VACCINE. WAS WAITING IN THE LOBBY FOR THE REQUIRED 15 MINUTES WHEN HE STARTED TO LOOK REALLY PALE. PATIENT LOST CONSCIOUSNESS AND TWO EMPLOYEES AND HIS WIFE LOWERED HIM TO THE GROUND SAFELY. ANOTHER EMPLOYEE CALLED 911. PATIENT HAD A PULSE AND WAS BREATHING, ALTHOUGH BREATHS SEEMED IRREGULAR. EMTS ARRIVED AND TOOK HIS VITALS. AT THIS POINT PATIENT HAD REGAINED CONSCIOUSNESS AND WAS RESPONSIVE. THEY SAT PATIENT UP AND HE FAINTED AGAIN. THEY TOOK PATIENT TO THE HOSPITAL FOR EVALUATION. I ASKED WIFE TO CALL ME WITH AN UPDATE AFTER THEY KNOW MORE. |
| 1361988 | 5/30/2021 | TX | 24 | M | 5/30/2021 | 5/30/2021 | After administration, pt went shopping with his wife and kid. While shopping within the store, pt reports he fainted, fell down to the ground on his forehead and sustained a deep cut injury right above his left eye. He was bleeding profusely, first aid was rendered and his wife drove him to the ER |
| 1361981 | 5/30/2021 | CA | 14 | M | 5/30/2021 | 5/30/2021 | patient fainted after 10 minutes of receiving the Pfizer vaccine. He revived really quickly. Did not require paramedic help. Patient was confused for a very short period. Bumped his right knee but no head injury. |
| 1361949 | 5/30/2021 | TX | 21 | M | 5/30/2021 | 5/30/2021 | Patient fainted after he got his shot. It took about 10 seconds for the patient to be oriented. Patient was with older brother who said he was not surprised(he expected it) since it happens when he get shots or anything with needles. But he is also fine after a short period. No epipen given and no EMS called |
| 1361850 | 5/30/2021 | KS | 24 | F | 5/28/2021 | 5/28/2021 | THE PT WAS ADMINISTERED THE VACCINE. SHE THEN GOT UP FROM THE CHAIR TO MOVE TO OUR WAITING AREA AND FAINTED (VASOVAGAL SYNCOPE). SHE ALMOST IMMEDIATELY GOT BACK UP. NO INJURIES REPORTED |

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| 1361900 | 5/30/2021 | AZ | 36 | M | 5/28/2021 | 5/28/2021 | Patient passed out for multiple seconds. The person accompanying the patient alerted the pharmacist that the patient was doing well. the pharmacist found the patient incoherent/ pale/ warm/ sweaty. The pharmacist offer the patient cold water and a cold cloth. the patient came to and stated he has passed out there after her left the vaccination room to wait in the waiting room. the patient completely recovered from this episode and left the pharmacy area after 15 minutes of observation. |
| 1361695 | 5/30/2021 | RI | 14 | M | 5/29/2021 | 5/29/2021 | Systemic: Fainting / Unresponsive-Severe, Additional Details: Patient has long history of fainting whenever getting vaccines. No history of seizures, per mom. |
| 1361880 | 5/30/2021 | KY | 14 | F | 5/30/2021 | 5/30/2021 | Patient fainted after vaccine given and fell from the exam table onto the floor landing on her left side bumping the left side of her head and left shoulder. An ambulance was called. She quickly regained consciousness after approximately 10 seconds. She was alert and oriented to place, date and her birthday. She was able to move all extremities with 5/5 strength; no misalignment, asymmetry, or defects noted in head, neck, spine and major joints. She had full range of motion in all extremities and neck . Pupils equal and react to light. Left side of head above ear was slightly tender without any defects. Left shoulder was slightly tender to palpation anteriorly without difficulty with full range of motion. There were no bruises noted. She denied any difficulty breathing. BP was 88/60 and HR 125. After evaluation and assessment, patient was stable and the ambulance was cancelled per father's request. Patient remained in clinic and drank approximately 8 oz of water without difficulty. Patient's blood pressure was checked standing after 45 minutes and patient became slightly light headed again. Patient was instructed to remain in the clinic for 15 more minutes. Patient's blood pressure was re-evaluated and was 84/60 after standing for 2 minutes; she was asymptomatic and denies feeling like she would faint. HR 100. Discussed signs and symptoms of a concussion, warning signs to monitor (sleepiness, difficulty moving, headache, or vomiting), and when to go to ER. Father verbalizes understanding. Patient was able to walk out of the clinic with father and brother in a stable condition. Patient instructed to f/u with doctor in two days or ER sooner if worsening |

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| 1361855 | 5/30/2021 | CA | 26 | M | 5/17/2021 | 5/17/2021 | Patient reported dizziness, nauseous and had syncope. EMS was called, vitals were checked, patient refused hospital services and was stable after 10 minutes. Patient received hydration and left at 1pm. |
| 1362004 | 5/30/2021 | | 20 | M | 5/27/2021 | 5/28/2021 | patient reports that he passed out before coming to ED, states felt nauseas. states received J&J vaccine yesterday, started having chills, nausea last night. denies V/D/fever. |
| 1361835 | 5/30/2021 | OR | 23 | F | 5/29/2021 | 5/29/2021 | Patient fainted |
| 1361756 | 5/30/2021 | IN | 48 | M | 5/29/2021 | 5/29/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Patient began to fall back in chair, with help of son, got -Mild |
| 1361732 | 5/30/2021 | NJ | 26 | M | 5/28/2021 | 5/28/2021 | FAINTING EMS WAS CALLED. PARAMEDICS INTERVIEWED THE PATIENT. PATIENT WAS RELEASED WITH NO ADVERSE REACTION. |
| 1361720 | 5/30/2021 | CT | 31 | F | 5/21/2021 | 5/22/2021 | Felt neck ache and back ache the morning after as well as headache and fatigue. That Monday had a pounding headache, nausea, vomiting, light headed, weak. Was prescribed Zofran. Nausea subsided but dizziness, pulsing headache, fatigue and light headed continued all week. That Friday I almost fainted and my head felt like there was liquid wooshing around and kept pulsating. Went to walk in and was sent to ER. Was prescribed Promethazine at ER. Here I am a week and two days after the second dose feeling constant dizziness and light headed. |

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| 1361707 | 5/30/2021 | NY | 12 | F | 5/30/2021 | 5/30/2021 | After receiving vaccination, syncopal episode while sitting in the chair. Mom held child from falling to the ground and slowly placed her on the floor. LOC for less than 2 minutes. Alert and talking, ice pack to forehead and fluids offered. Placed in wheelchair and sent to med evaluation for further evaluation. Mom present at all times. VS taken 104/80 HR 72 Resp 16, diaphoretic with c/o's of lightheaded and foggy feeling. Lying on cot with Gatorade/water offered. Pt has never passed out with a vaccination in the past, had carrots for breakfast and little fluid intake. Very anxious with getting the shot. Discussion with mom & pt. importance of hydration eating when the next dose given, it will be in the med evaluation area lying down. Pt alert an ambulatory with 1/2 Gatorade and 1/2 eater prior to discharge with mom. Discussed s/s of reaction and call pediatrician with any further concerns. Verbalized understanding, discharged ambulatory with mom. |
| 1361919 | 5/30/2021 | TX | 18 | M | 5/30/2021 | 5/30/2021 | The patient passed out a couple of minutes after receiving the vaccine. I asked if he had had any reaction or problems to vaccines or shots before and him and his parents and him both said no. After he passed out they told me he was mildly autistic and had passed out at the doctors office when getting a shot and in biology class dealing with dissection. They repeatedly said it was just anxiety. After laying him down and elevating his feet he started feeling better. At no time did he display any breathing problems or any anaphylactic symptoms. And he did not hit anything when being laid down. I monitored him for 30 minutes and let them go after they said he was 100 percent feeling fine and he seemed like he was ok. |
| 1361354 | 5/29/2021 | IN | 14 | F | 5/28/2021 | 5/29/2021 | Daughter was tired and went to sleep not long after shot. Woke up with sore arm around 12:30 am. And went back to sleep after taking Advil. She woke up and took a shower at around 9 am and fainted while showering. She?s never had a history of fainting ever. |
| 1361331 | 5/29/2021 | AZ | 30 | M | 5/28/2021 | 5/28/2021 | as soon as got the shot he passed out , not responding , gave him epinephrine 0.3 mg auto injector, with in 5 minutes paramedics came and took care of him , he is fine, talking good, , feeling , after few minutes he walked away with family member |

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| 1361320 | 5/29/2021 | MN | 17 | F | 5/27/2021 | 5/28/2021 | She fainted and collapsed about 18 hours after receiving the second dose (6:30 am). She was confused for about an hour after she fainted. She was on ibuprofen (400 mg taken at 5:30 am). Other than weakness, headache, and fever, she has had no other adverse reactions so far besides the single fainting episode. |
| 1361260 | 5/29/2021 | CA | 14 | F | 5/28/2021 | 5/28/2021 | Patient received the first dose of Pfizer on 5/28/21 and during the 15 minute waiting time after the immunization, patient fainted. Patient did not fall or hit head, due to father being in the proximity and able to protect her from hitting the floor. Patient regained consciousness quickly within seconds and was moved to the floor while her feet were elevated. Patient stated that she saw a bit blurry and feeling shaky right before fainting. Patient was seen to be a bit pale in the lips but color came back after a few minutes. When patient's mother came, it was learned that the patient had a similar experience with an allergy shot in the past. Patient blood pressure was 110/71. Patient laid on the floor for a while before sitting back up. |
| 1360696 | 5/29/2021 | NY | 17 | F | 5/28/2021 | 5/28/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Headache-Mild, Systemic: Shakiness-Medium, Systemic: Weakness-Severe, Additional Details: Patient was given Pfizer vaccine, told to remain in waiting area for 15 minutes. Immediately after shot she seemed and and was conversing with me normally. 2-3 minutes later her dad noticed that she was tipping over and called for help. When I rushed over, pt was moved to the floor, close to passing out, very weak and shaky. We called 911 - she was responsive. she laid on the floor until ems arrived at which point they took over and took patient to get further checked out. |

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| 1360527 | 5/29/2021 | MI | 29 | F | 5/14/2021 | 5/14/2021 | Fainting spell; Loss of feeling in hands and feet; Dangerously low blood pressure; Sweating profusely; Chills; Overall weakness; This is a spontaneous report from a contactable consumer. A 29-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in the left arm on 14May2021 08:00 (at the age of 29 years) (Batch/Lot number was not reported) as 2ND DOSE, SINGLE for covid-19 immunisation. Medical history included penicillin allergy. The patient previously received the 1ST DOSE of BNT162B2 administered on the left arm on 16Apr2021 at 08:00 (at the age of 29 years) for COVID-19 immunization. On 14May2021 08:00, the patient experienced fainting spell, loss of feeling in hands and feet, dangerously low blood pressure, sweating profusely, chills, overall weakness and "nautilus". The event fainting was assessed as serious (medically significant). Therapeutic measures were taken as a result of all the events. The outcome of the events was recovering. No follow-up attempts are possible, information about the batch number cannot be obtained. |
| 1360531 | 5/29/2021 | NY | 52 | F | 4/6/2021 | | she has syncope and migraine; she has syncope and migraine; she did not feel good after the first shot.; This is a spontaneous report from a contactable consumer for herself. A 52-years-old female patient received bnt162b2 (BNT162B2), dose 1 via an unspecified route of administration on 06Apr2021 (Batch/Lot number was not reported) as single dose for covid-19 immunisation. Medical history included cataract . The patient's concomitant medications were not reported. The patient experienced syncope on an unspecified date with outcome of unknown , migraine on an unspecified date with outcome of unknown , she did not feel good after the first shot on an unspecified date with outcome of unknown. No follow-up attempts are needed. No further information is expected. |

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| 1360592 | 5/29/2021 | CA | | F | 5/4/2021 | 5/5/2021 | cold and clammy; is not energetic like normal; she is feeling a little bit anxious and she feels like her strength is not yet fully recovered.; she is feeling a little bit anxious and she feels like her strength is not yet fully recovered.; passed out; Vomiting; tired; This is a spontaneous report from a contactable consumer (Patient). A 63-years-old female patient received second dose of bnt162b2 (BNT162B2, Solution for injection, Batch/Lot Number: ER8733), via an unspecified route of administration, administered in Arm Left on 04May2021 as 2nd dose, single for COVID-19 immunization. Historical vaccine of BNT162B2 was administered as first dose on 12Apr2021. Patient was not ill at the time of vaccination. The patient medical history and concomitant medications were not reported. She says well the first one is just the start, where it has the first dose. She clarifies she received the product so that her husband would be safe since he had his vaccine she figured she would get it too. He has a lot of health issues so she figured she should get it, now she wishes she had not but it is okay. She confirms for COVID 19 prevention. She says she takes no medications other than just Tylenol if she has a headache. On 05May2021 patient experienced passed out at 08:30AM, vomiting at 01:00 and tired. She would say the vomiting stopped at 5 am on 05May2021. This started 05May2021 for sure. The tiredness is ongoing, because last night she went to bed at 7, she is not doing half of what she used to do. It is awkward she does not know what else to blame but the vaccine. She is not energetic like normal, she is a healthy person. The tiredness has improved but she still has it. Also experienced cold and clammy, is not energetic like normal, she is feeling a little bit anxious and she feels like her strength is not yet fully recovered (anxiety and asthenia) on an unspecified date. Time the Vaccination Was Given as her appointment was at 10 so it was within 20 minutes. She would say it was 10:20 AM or so and then she had to wait 15 minutes. Her husband, when she came to, he wanted to call the paramedics she said no, she was fine. He called the Paramedics and they took vitals, they checked blood sugar, checked oxygen, EKG, blood pressure, O2 and everything was okay, all her vital signs were okay. They wanted to take her to the ER but since her vitals were okay she did not want to go into the ER with all the sick people so she had to sign a waver |

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| | | | | | | and they told her to follow up with her doctor. She is feeling better than how was but she doesn't feel that she is at 100 percent and she is a healthy person she didn't even want to get the vaccine. The outcome of the event fatigue was recovering and all the other events was unknown. Follow-up (19May2021): This is a spontaneous report from a Pfizer-sponsored program. A 63-year-old female consumer (patient) reported that, added with event onset date and time. |
| 1360594 | 5/29/2021 | OH | 34 | F | 3/23/2021 | 3/1/2021 First dose: Face got hot; First dose: Face was swelling; tingling on her face; This is a spontaneous report received from a contactable consumer (patient). A 34-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Lot Number: EN6203), via an unspecified route of administration, administered in right arm on 23Mar2021 14:30 as single dose for COVID-19 immunisation. Medical history included ongoing hashimotos thyroiditis which is kind of autoimmune conditions (since she was around 16 and that was when she started getting symptoms), ongoing neurocardiogenic syncope which is kind of an autoimmune (started when she was 16). Concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 23Mar2021, the patient's face got hot and face was swelling with the first dose right after she had the vaccine, she no longer has hotness but does have tingling on her face in Mar2021. The event hot face was recovered on 23Mar2021, swollen face was recovered with sequel on 23Mar2021 and tingling on her face was recovered in Mar2021. No follow-up attempts are needed. No further information is expected. |
| 1360664 | 5/29/2021 | IN | 33 | M | 5/27/2021 | 5/27/2021 Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Shakiness-Mild, Systemic: Weakness-Mild, Additional Details: Urinated on himself |
| 1360667 | 5/29/2021 | MA | 19 | M | 5/28/2021 | 5/28/2021 Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Medium |

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| 1360751 | 5/29/2021 | CA | 25 | M | 5/28/2021 | 5/28/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Additional Details: Pt fainted a couple minutes after vaccine administration, pt woke up seconds later, said had no injury. |
| 1360685 | 5/29/2021 | PA | 40 | M | 5/28/2021 | 5/28/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Weakness-Medium, Additional Details: pt's forehead felt cold and sweaty and he tried to lift his legs up and kept his hands high - he described that he faints after a blood taken for a test or after a vaccing, and this might be a mental predisposition to this reaction. we called an ambulance, but patient felt better in 5-7 min and requested to cancel ambulance. He spent 10-20 min on the chair and felt ok to get up and walk around. He left stating he fill better. |

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| 1360496 | 5/29/2021 | OH | 16 | F | 5/5/2021 | 5/6/2021 | <p>passed out; BP was 70/44; could not sit or stand; EKG-Potential abnormal Twave; Calcium was low; This is a spontaneous report received from two contactable consumers reporting for her daughter. A 16-years-old female patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), vaccinated at the age of 16 years old, via an unspecified route of administration, administered in Deltoid Left on 05May2021 15:00 (Batch/Lot Number: ER8735; Expiration Date: 31Jul2021) as single dose for covid-19 immunisation. Patient received the first dose on unknown date. Her daughter had no reaction from the first one that was three weeks prior. The patient medical history included Attention deficit hyperactivity disorder. Concomitant medications included lisdexamfetamine mesilate (VYVANSE) taken for attention deficit hyperactivity disorder, start and stop date were not reported. Last Wednesday, at 3 pm, caller's daughter received the second vaccine. Her daughter had no ill effects. Her daughter got up the next morning, 18 hours after administration, and passed out. Caller states that they called the squad and her daughter's BP was 70/44. They pushed an IV, transported her daughter, and they were in the ER for 10 hours. The local hospital gave her daughter 2 1/2 bags of fluid and transported her daughter to Hospital. Caller adds that there were 4 liters of fluid given, and her daughter could not sit or stand without her blood pressure dropping for about 8 hours after the incident. There were 2 transports and 2 ER's. Caller asks why were they not told that this is a symptom. She was grateful that she could catch her daughter before she hit her head, but what about parents who leave their kids alone. Last Wednesday, caller's daughter received the vaccine 05May2021 at 3 pm and passed out 06May2021 in the morning. It was the only time she passed out and caller states she saw her daughter's head drop and then was trying and caught her. She was trying to talk to her and her eyes were in the back of her head, and was trying to arouse her. She was out for over a minute. She went to Emergency Room in. They were there for 6 hours. Then, when she could not sit up and her blood pressure was dropping, they recommended Hospital. She was there, this all took place, on Thursday from 9 am or around 8:50 am when she passed out and then they were discharged after 9 pm. It was a 12 hour</p> |

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situation where they were transported and she spent 12 hours in 2 emergency rooms. The only one she had at time was vyvance but she did not take this before passing out. The last time that she took this would have been nine hours before administration of the vaccine on 05May2021. She did not take it on 06May2021 when the incident happened. She was just getting up. She had only been on this for about a week. It is a stimulant drug but it is out of the system in the evening so people can sleep. She asked each doctors if this had any role in it and they said no. They told her to take it again which they have not started back yet. She has no other medical conditions. Investigations: caller does not provide dates or specific test results. The first ER did bloodwork, urine, chest x-ray. They wanted a CAT scan of her head but caller declined because she thought it was unnecessary. They did an EKG at first in the ER. Nothing was abnormal. She did have some things out of range in bloodwork which is not surprising because she was taking in fluids. Her calcium was low. Nothing was way out of range, nothing was abnormal. The second ER did a follow up EKG but no other tests or bloodwork. According to three physicians, the EKG was fine. A cardiologist reviewed the 2nd EKG and she got a phone call that they wanted her to follow up because of potential abnormal T waves which could have been a result of that much fluid intake and electrolytes being out of sync after that much fluid. They are following up on this. Her father has as vasovagal response hat he has experienced 4-5 times in his lifetime. He has never passed out following a vaccine. Caller had no idea that was even a response to vaccine. He has passed out after giving blood, with severe pain, coming out of anesthetic, and with severe stress. He has never had an extended period of time where his blood pressure was low. She, they could not get, her blood pressure up with fluid after fluid which is why she was transported to the second ER because they thought they did not know what was going on there. Caller states does she think that there may be some relationship and her daughter has this tendency to vasovagal - yes. Was it brought on by the vaccine? Yes. She has never fainted in her life. Caller adds she can see how some many say this may not be related to the vaccine but 18 hours after administration, they can not get her blood pressure up and were in the ER for 12

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| 1360709 | 5/29/2021 | CA | 28 | M | 4/23/2021 | 4/23/2021 | hours. Treatment included all the fluid, and 2 capsules of acetaminophen. No other treatment. Outcome of events was unknown. Information on Lot/Batch number was available. Additional information has been requested |
| 1360715 | 5/29/2021 | MI | 15 | F | 5/28/2021 | 5/28/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: patient did not report to the the rph on duty. but told me when getthing his secound shot. made sure it wasnt a allergic reactions. |
| 1360719 | 5/29/2021 | MA | 31 | M | 5/27/2021 | 5/27/2021 | Patient fainted about 2 minutes after vaccination after standing up for about 30 seconds. Patient recovered quickly, brought patient Apple juice and grand parent brought up some food. Patient states she hadn't eaten since lunch time. |
| 1360722 | 5/29/2021 | MO | 22 | M | 5/28/2021 | 5/28/2021 | Systemic: Fainting / Unresponsive-Severe, Additional Details: Patient received the Moderna shot and fainted and loss of consciousness while sitting down waiting for the 15 minutes being observed. He was unresponsive and slipped from the chair to the floor. Wife alerted the Rph on duty and Rph went over and administer the epipen to him and called 911 for ambulance. Patient became responsive before the ambulance arrived but was taken to the hospital to have everything checked out. He then got discharged a few hours after on the same night. |
| | | | | | | | Site: Pain at Injection Site-Mild, Site: Redness at Injection Site-Mild, Systemic: Confusion-Mild, Systemic: Fainting / Unresponsive-Severe, Additional Details: On 5-28-21 the patient was given the COVID vaccine, following the vaccine he passed out. When the patient came to he said he must have gone to sleep. The patient stated he passed out the week before and thought it was due to not eating. EMS checked vitals, and all vitals were good. Pt refused to go to the hospital, he left with his wife and she drove. I told the patient I would follow up with him via a phone call to see how he was feeling. I called pt at 5 pm on 5-28, he stated he was fine |

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| 1360728 | 5/29/2021 | AL | 17 | F | 5/27/2021 | 5/27/2021 | Systemic: Chest Tightness / Heaviness / Pain-Medium, Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Weakness-Medium |
| 1360742 | 5/29/2021 | NY | 31 | F | 5/28/2021 | 5/28/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Additional Details: Looked over at chair patient was passed out, thought she was having a seizure. Had technician call 911. It took a minute for patient to come to. She felt hot, and kept feeling like she was going to pass out. Ambulance/Fire came and she signed off, they stated that she just passed out, that it is common. Patient left feeling ok and on her own. |
| 1361281 | 5/29/2021 | CA | 45 | F | 5/29/2021 | 5/29/2021 | NEAR SYNCOPE, C/O DIZZINESS, LIGHTHEADED, COLD, CLAMMY, DIAPHORECTIC. CODE GREEN CALLED, BP 99/66, HR 74, BLOOD SUGAR 94, HAD COFFEE FOR BREAKFAST. HYDRATION OFFERED, SX RESOLVED, NO TRANSPORT |
| 1360677 | 5/29/2021 | PA | 27 | F | 5/28/2021 | 5/28/2021 | Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Nausea-Severe, Systemic: Vomiting-Severe, Additional Details: pt recieved the vaccine and after 6-7 mins passed out on the floor... she was woken up after 10-15 seconds and was moved to an upright position,. she then started to vomit 2-3 times 911 was called and emt took to hospital |
| 1360119 | 5/29/2021 | NY | 24 | F | 5/29/2021 | 5/29/2021 | A 24 y.o female fainted and appeared to have a seizure. She loss consciousness and had muscle contractions. The seizure was approximately 2 minutes. Patient did not hit her head or injury any part of her body. She was gradually dismounted from the chair and placed on the floor. 1st B/P reading was 70/40, then 108/63. Patient after waking up was alert and oriented X3. Once EMS arrived she was assessed and encouraged to go to the hospital for follow up. Patient and father refused to go to the hospital. They verbalized "She has an important exam for school". Patient stated she will follow up after her exam. |

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| 1359871 | 5/29/2021 | MN | 15 | M | 5/21/2021 | 5/23/2021 | On 5/23 two days after vaccine he was irritable, tired, fatigued, not sleeping well. He could not complete his track meet . He had abdominal pain, felt bloated, and he felt this nausea & discomfort. He thought he might be constipated, so he took MiraLAX and then he had diarrhea all day yesterday. on 5/26 he had a temperature of 99.2, he had acute chest pain retrosternal and feeling of compression on the chest, head fullness as if he is going to explode. He had nausea, insomnia. Ibuprofen was given to him by his mother and this helped a lot But he woke up on morning of 5/27 , but the chest pain returned with increased pressure, very nauseous, agitated, unable to be comfortable. No fever., the pain was a sharp pressure. He had no syncope or chest shortness of breath He was seen at Hospital ER where a chest x-ray was normal. Echocardiogram was done, ,noted to have EKG changes. Troponin was elevated. He had a cardiac catheterization done emergently at hospital through the right radial artery and was noted to have normal coronaries. He also had a chest x-ray done which was negative for pulmonary lesions, and his abdominal pain he says was relieved after the MiraLAX and the diarrhea. His twin sister who received the vaccine 15 minutes after him is completely asymptomatic. |
| 1359891 | 5/29/2021 | CA | 40 | F | 4/17/2021 | 4/17/2021 | Within 10 minutes of injection vasovagal syncope occurred in vehicle while parked in observation area. Due to being in seat was not able to prevent syncope and nurses had to treat for 15 minutes until symptoms subsided. Blood pressure was monitored and dropped to 50/20. Finger pulse oximeter would not register. Nurses provided ice packs, alcohol wipes for smelling, and water. Unable to lay flat and extend legs so episode lasted longer than expected. |
| 1359896 | 5/29/2021 | CA | 50 | F | 5/24/2021 | 5/25/2021 | First I felt weak, difficult to breath, fast but weak heart beats, then I had sudden extensive sweating from all over my body, then I fainted for maybe half a minutes. I started to regain consciousness after that. My son helped me to lie down in the sofa, and I was able to recover slowly after that without treatment. My heart beat also gradually slowed down after that event, but it was still about 108/minute when I was in bed at around 5pm that day (about 5 hours after I fainted). |

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| 1359909 | 5/29/2021 | OR | 49 | F | 1/29/2021 | 1/30/2021 | Loss of consciousness; Dizziness; Ear discomfort; Pain; Headache; Nausea; This case was received via VAERS on 18-May-2021 and was forwarded to Moderna on 18-May-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of LOSS OF CONSCIOUSNESS (Loss of consciousness) in a 49-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Traumatic brain injury and Dizziness. Concurrent medical conditions included Allergy to grains, Fistula (TBI w bilateral perilymph fistula causing gluten issue was reported.) and Gluten intolerance (TBI w bilateral perilymph fistula causing gluten issue was reported.). Concomitant products included VIT D [VITAMIN D NOS]. On 29-Jan-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 30-Jan-2021, the patient experienced LOSS OF CONSCIOUSNESS (Loss of consciousness) (seriousness criterion medically significant), DIZZINESS (Dizziness), EAR DISCOMFORT (Ear discomfort), PAIN (Pain), HEADACHE (Headache) and NAUSEA (Nausea). At the time of the report, LOSS OF CONSCIOUSNESS (Loss of consciousness), DIZZINESS (Dizziness), EAR DISCOMFORT (Ear discomfort), PAIN (Pain), HEADACHE (Headache) and NAUSEA (Nausea) had not resolved. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Treatment information was not provided by the reported. The patient received both scheduled doses of mRNA-1273 prior to the event; therefore, action taken with the drug in response to the event is not applicable. Patient passed out 8n bathroom from lain and nausea. She could left bed till 4pm that day due to body pain, chills and headache. 72 hours later still she had left ear full, very dizzy and slight nausea.; Sender's Comments: Very limited information regarding these events has been provided at this time. The events are probably related to the patient's comorbidities, further information required. |

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| 1359911 | 5/29/2021 | CA | 21 | F | 2/3/2021 | 2/3/2021 | <p>Syncope; Excessive eye blinking; Fall; This case was received via on 18-May-2021 and was forwarded to Moderna on 18-May-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of SYNCOPES (Syncope) in a 21-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 004M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 03-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 03-Feb-2021, the patient experienced SYNCOPES (Syncope) (seriousness criterion medically significant), EXCESSIVE EYE BLINKING (Excessive eye blinking) and FALL (Fall). At the time of the report, SYNCOPES (Syncope), EXCESSIVE EYE BLINKING (Excessive eye blinking) and FALL (Fall) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 03-Feb-2021, Respiratory rate: increased (High) increased. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant and treatment medications were reported. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p> |

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| 1359913 | 5/29/2021 | MO | 49 | M | 3/2/2021 | 3/2/2021 | Seizure like phenomena; Breath sounds abnormal; Dizziness; Dyskinesia; Eyelid function disorder; Fall; Hyperhidrosis; Hypopnoea; Hypotonia; Muscle twitching; Pallor; Presyncope; Restless legs syndrome; Tremor; This case was received via FDA VAERS on 18-May-2021 and was forwarded to Moderna on 18-May-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of SEIZURE LIKE PHENOMENA (Seizure like phenomena) in a 49-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 011A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Vagal reaction (patient stated he has experienced vagal responses to injections in the past). On 02-Mar-2021 at 5:46 PM, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 02-Mar-2021, the patient experienced SEIZURE LIKE PHENOMENA (Seizure like phenomena) (seriousness criterion medically significant). 02-Mar-2021, the patient experienced BREATH SOUNDS ABNORMAL (Breath sounds abnormal), DIZZINESS (Dizziness), DYSKINESIA (Dyskinesia), EYELID FUNCTION DISORDER (Eyelid function disorder), FALL (Fall), HYPERHIDROSIS (Hyperhidrosis), HYPOPNOEA (Hypopnoea), HYPOTONIA (Hypotonia), MUSCLE TWITCHING (Muscle twitching), PALLOR (Pallor), PRESYNCOPE (Presyncope), RESTLESS LEGS SYNDROME (Restless legs syndrome) and TREMOR (Tremor). At the time of the report, SEIZURE LIKE PHENOMENA (Seizure like phenomena), BREATH SOUNDS ABNORMAL (Breath sounds abnormal), DIZZINESS (Dizziness), DYSKINESIA (Dyskinesia), EYELID FUNCTION DISORDER (Eyelid function disorder), FALL (Fall), HYPERHIDROSIS (Hyperhidrosis), HYPOPNOEA (Hypopnoea), HYPOTONIA (Hypotonia), MUSCLE TWITCHING (Muscle twitching), PALLOR (Pallor), PRESYNCOPE (Presyncope), RESTLESS LEGS SYNDROME (Restless legs syndrome) and TREMOR (Tremor) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 02-Mar-2021, Blood pressure measurement: 120/72 (normal) 120/72 mmHg. On 02-Mar-2021, Heart rate: 64 (normal) |

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64 beats per minute. On 02-Mar-2021, Oxygen saturation: 99 (normal) 99%. On 02-Mar-2021, Respiratory rate: 20 (normal) 20 breaths per minute. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were provided. The patient remained in the vaccination chair for 5 minutes after injection and he reported feeling well and moved to the observation chair without any problems [~10ft]. After being in the observation chair the patient stood up and took 4-5 steps toward the wall and sat down on the floor. The patient stated he felt dizzy and then became limp and slumped to the right side, his eyes remained open with dilation of pupil fixed at 2mm with no blinking noted. The patient's breathing pattern became shallow and snoring sounds were noted. The patient did not respond when spoken to nor did he respond to soft shaking of the shoulders. The patient began to demonstrate large jerky body movements similar to seizure activity. The seizure like activity continued for 3-4 minutes before the patient was able to become aware of surroundings and answer orientation questions. The patient was diaphoretic, pale, shaking of hands and arms, restlessness of lower limbs with frequent repositioning/twitching of legs. EMS (emergency medical services) arrived to find the patient regaining stability. The patient reported to EMS that he is familiar with this type of response and declined to be taken anywhere. Treatment medications were not reported. Based on current available information and the temporal association between product use and the start date of the event a causal relationship cannot be excluded. The Company believes the event of Restless leg syndrome is not supported in the source documents and should be delete.; Sender's Comments: Based on current available information and the temporal association between product use and the start date of the event a causal relationship cannot be excluded. The Company believes the event of Restless leg syndrome is not supported in the source documents and should be delete.

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| 1359980 | 5/29/2021 | DE | 56 | M | 4/5/2021 | 4/12/2021 | <p>passed out, faint; Bad dry cough; fell and his head hit the concrete; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of LOSS OF CONSCIOUSNESS (passed out, faint) in a 56-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. G26-B21A and G17-C21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Past medical history included, smoking for 30+ years and vaping for past two years. The patient's past medical history included Ex-smoker. Concurrent medical conditions included Vapor cigarette smoker. Concomitant products included BENZTROPINE [BENZATROPINE], FLUOXETINE, TAMSULOSIN, CLONAZEPAM, AMLODIPINE and LURASIDONE HYDROCHLORIDE (LATUDA) for an unknown indication. On 05-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 03-May-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 12-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (passed out, faint) (seriousness criterion medically significant), COUGH (Bad dry cough) and FALL (fell and his head hit the concrete). On 12-May-2021, LOSS OF CONSCIOUSNESS (passed out, faint), COUGH (Bad dry cough) and FALL (fell and his head hit the concrete) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In April 2021, SARS-CoV-2 test: negative (Negative) Negative. Treatment information included, an inhaler to help with the "lungs and stuff", cough syrup for a night was provided. Very limited information regarding these events has been provided at this time. No follow up is possible. This case was linked to MOD-2021-139015 (Patient Link).; Sender's Comments: Very limited information regarding these events has been provided at this time. No follow up is possible.</p> |

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| 1360518 | 5/29/2021 | NY | 24 | F | 5/29/2021 | 5/29/2021 | A 24 y.o female fainted and appeared to have a seizure. She loss consciousness and had muscle contractions. The seizure was approximately 2 minutes. Patient did not hit her head or injury any part of her body. She was gradually dismantled from the chair and placed on the floor. 1st B/P reading was 70/40, then 108/63. Patient after waking up was alert and oriented X3. Once EMS arrived she was assessed and encouraged to go to the hospital for follow up. Patient and father refused to go to the hospital. They verbalized "She has an important exam for school". Patient stated she will follow up after her exam. |

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| 1359987 | 5/29/2021 | TX | 81 | M | 4/1/2021 | 4/2/2021 | <p>passed out 4 times; Withering away and is dying/wont live long enough; lost 20 pounds; He is still experiencing dizziness and too weak to get out of bed; Weak; Nausea; dry heaving 3-4 times/day; Swollen arm; Stopped eating; This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 19-May-2021 and was forwarded to Moderna on 19-May-2021. This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of LOSS OF CONSCIOUSNESS (passed out 4 times) in an 81-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 013A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 01-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 02-Apr-2021, the patient experienced PERIPHERAL SWELLING (Swollen arm), FOOD REFUSAL (Stopped eating), RETCHING (dry heaving 3-4 times/day) and NAUSEA (Nausea). On 23-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (passed out 4 times) (seriousness criteria hospitalization and medically significant), DIZZINESS (He is still experiencing dizziness and too weak to get out of bed) and ASTHENIA (Weak). On an unknown date, the patient experienced GENERAL PHYSICAL HEALTH DETERIORATION (Withering away and is dying/wont live long enough) and WEIGHT DECREASED (lost 20 pounds). The patient was hospitalized until 23-Apr-2021 due to LOSS OF CONSCIOUSNESS. At the time of the report, LOSS OF CONSCIOUSNESS (passed out 4 times), GENERAL PHYSICAL HEALTH DETERIORATION (Withering away and is dying/wont live long enough), WEIGHT DECREASED (lost 20 pounds), PERIPHERAL SWELLING (Swollen arm), FOOD REFUSAL (Stopped eating), DIZZINESS (He is still experiencing dizziness and too weak to get out of bed), RETCHING (dry heaving 3-4 times/day), ASTHENIA (Weak) and NAUSEA (Nausea) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No</p> |

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| 1360499 | 5/29/2021 | MA | 17 | F | 5/3/2021 | 5/4/2021 | <p>concomitant medications were provided. Treatment with Reglan and magnesium oxide pertained to the events experienced. Based on current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded.; Sender's Comments: Based on current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded.</p> <p>passed out; vomited; This is a spontaneous report from a contactable consumer (patient). A 17-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in left arm left on 03May2021 15:30 (Batch/Lot Number: EW0153) as 2nd dose, single for COVID-19 immunisation. The patient had no relevant medical history. She had no allergies to medications, food, or other products. Concomitant medication included fluoxetine taken for an unspecified indication within 2 weeks of vaccination. The patient previously received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in right arm on 12Apr2021, 03:30 PM (Batch/Lot Number: EW0153) as 1st dose, single for COVID-19 immunization. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. She was not diagnosed with COVID-19 prior to vaccination. On 04May2021 12:00, the patient passed out and vomited at the same time while in a sitting position. There were no additional side effects once the episode passed. The event resulted in doctor or other healthcare professional office/clinic visit. Events were reported as non-serious. No treatment was received. Outcome of the events was recovered in May2021. The patient had not been tested for COVID-19 since the vaccination. Information on Lot/Batch number was available. Additional information has been requested.</p> |

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| 1360190 | 5/29/2021 | CO | 68 | M | 2/21/2021 | 2/21/2021 | Minor site pain and lump after 4hrs; Minor site pain and lump after 4hrs; This is a spontaneous report from a contactable consumer (patient himself). A 68-year old male patient receive his first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via unspecified route of administration on the right arm on 21Feb2021 at 01:45 PM (at the age of 68-year old) at single dose for COVID-19 immunization at Hospital. relevant medical history included osteoarthritis and syncope (have pacemaker). Concomitant medications included atorvastatin, omeprazole and ergocalciferol (VIT D). On 21Feb2021 at 06:00PM the patient experienced minor site pain and lump. They disappeared after 24 hours (outcome recovered). Information on the lot/batch number has been requested. |
| 1360400 | 5/29/2021 | TN | 65 | F | 3/15/2021 | 3/25/2021 | i had a mild headache; This is a spontaneous report from a contactable consumer (patient). A 65-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, Lot number: EN6204), via intramuscular route of administration on 15Mar2021 at 13:00 (at the age of 65-year-old) as 2nd dose, single in upper left arm for COVID-19 immunisation at public health department. The patient's medical history and concomitant medications were not reported. The patient did not receive any other medications prior to the vaccination. The patient previously received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, Lot number: EN6201) via intramuscular route of administration on 24Feb2021 at 01:00 PM, as single dose in upper left arm for COVID-19 immunisation. On 25mar2021, at 06:00 AM, the patient experienced mild headache. There was no treatment received for the adverse events. Patient did not experienced nausea and fainting. The clinical outcome of the event was recovered. No follow-up attempts are possible. No further information is expected. |

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| 1360445 | 5/29/2021 | | 18 | F | 4/20/2021 | 4/1/2021 | Problems with her heart; Shortness of breath; Pain the chest; Low blood pressure; Passed out; Started shaking "like a seizure"; Started shaking "like a seizure"; Dizziness; Tiredness; Stomach pain; Chills; Fever; Sweats; Nausea; Vomiting/throwing up; Inflammation in the chest, muscle or maybe heart inflammation; Inflammation in the chest, muscle or maybe heart inflammation; Inflammation in the chest, muscle or maybe heart inflammation; Pain in the heart; Not feeling well; Had a severe allergic reaction; Headache; Weak; This is a spontaneous report from a contactable consumer (patient's mother). An 18-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EW0169; Expiration date was not reported) on the left arm on 20Apr2021 as a 1st dose, single dose, with route of administration unspecified, for COVID-19 immunization. The patient had no relevant medical history and concomitant medications. On 20Apr2021, the patient had passed out; started shaking "like a seizure"; dizziness; tiredness; stomach pain; chills; fever; sweats; vomiting/throwing up; and nausea. The patient was brought to urgent care/emergency room (ER) due to the reported events. On 21Apr2021, the patient had shortness of breath; pain in the chest; and low blood pressure. On 22Apr2021, the patient had problems with her heart. The patient was brought to urgent care/emergency room (ER) due to the reported events, and for cardiac work up. On an unspecified date in 2021, the patient was not feeling well; had a severe allergic reaction; headache; and was weak. In Apr2021, the patient had "inflammation in the chest, muscle or maybe heart inflammation". The patient received treatment for the events, pain in the chest and "inflammation in the chest, muscle or maybe heart inflammation" (double dose of naproxen. The patient's laboratory tests included normal blood pressure on 22Apr2021; chest x-ray on 21Apr2021 (results were not provided); echo sonogram on 22Apr2021 (results were not provided); electrocardiogram (EKG) was normal on 21Apr2021, 22Apr2021 and 23Apr2021. The outcome of the events was not recovered for tiredness; was recovered on an unspecified date in 2021 for chills, sweats, vomiting/throwing up; was recovering for pain in the chest; and was unknown for all the other events. The |

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patient's primary care provider was writing a doctor's note recommending that she not receive the second dose based on her reaction to the first dose, and the PCP recommended that the mother call Pfizer as well.

passed out; not breathing; shaking; not awake; not coherent; not feeling good; arm was aching a little bit/her arm was hurting and her arm was achy; This is a spontaneous report from a contactable consumer (patient) and patient's mother. A female patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on 13May2021 20:30 (Batch/Lot number was not reported) as single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. Patient got to work on 14May2021 at 08:00 and the manager let her go home because her arm was hurting and her arm was achy, and she was not feeling good, but she was feeling fine when she got home. At 11:00 AM, she came home and went into the house and came back outside. The patient's mom said that they were on the front porch and her daughter passed out and looked like she was having a seizure kind of thing (shaking really bad), she was not awake, not coherent and not breathing. They got her into the house once she came to, they cooled her off and let her sleep for about 45 minutes. Patient said that she felt like she went to sleep and what she remembered next she felt like she was waking up. She said that she slept and nowshe feels fine. Outcome of events was recovered. Information about Lot/Batch number has been requested.

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| 1360481 | 5/29/2021 | CA | 21 | F | 5/13/2021 | 5/14/2021 | I started to lose my sight, at first it was my entire peripheral vision and it looked like I was looking through a black holed telescope and then I completely lost sight; Crashed into a stand and passed out; I got really dizzy; I sat in a chair where I became incredibly hot; Sweat through all my clothes; Immediately extremely cold; crashed into a stand; This is a spontaneous report from a contactable consumer (the patient). A 21-year-old non-pregnant female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EW0173) via an unspecified route of administration in left arm on 13May2021 18:00 at age of 21-year-old at single dose for COVID-19 immunisation. Prior to vaccination, the patient diagnosed with COVID-19. No known allergies. No other medical history. Concomitant medication included: the patient received birth control medication within 2 weeks of vaccination. The patient previously took the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EP7533) via an unspecified route of administration on 19Apr2021 01:15 PM at age of 21-year-old for COVID-19 immunization. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient had not been tested for COVID-19 since the vaccination. The patient got really dizzy, then as she tried to walk away she started to lose her sight, at first it was her entire peripheral vision and it looked like she was looking through a black holed telescope and then she completely lost sight. She became very dizzy and crashed into a stand and passed out. While she was passed out on the floor she uncontrollably defected. Once someone helped her up, she sat in a chair where she became incredibly hot, sweat through all her clothes and then immediately extremely cold. The events onset date reported as 14May2021 09:00AM. No treatment received for the events. The outcome of the events was recovering. The report was non-serious. |

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| 1360486 | 5/29/2021 | MD | | M | 5/1/2021 | 5/1/2021 | Fainting episode upon rising from a chair; This is a spontaneous report from a contactable consumer (patient). A 12-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in arm left on May2021 (Batch/Lot Number: EW0183) as 1st dose, single dose for covid-19 immunisation. The patient received the vaccine in a Public Health Clinic. Medical history included juvenile idiopathic arthritis from an unknown date and unknown if ongoing (Previously diagnosed with JIA, but resolved with diet change), mold, gluten and lactose intolerance from an unknown date and unknown if ongoing. The patient's concomitant medications were not reported. The patient previously took gluten for food allergy and experienced food allergy. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced fainting episode upon rising from a chair on May2021. No treatment was received in response to the event. The patient was recovering from the event. Follow-up attempts are needed. Additional information has been requested. |
| 1360762 | 5/29/2021 | MA | 32 | M | 5/28/2021 | 5/28/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Weakness-Medium |

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| 1359982 | 5/29/2021 | | 80 | F | 1/1/2021 | 1/1/2021 | <p>patient received Dose 1 of the Moderna COVID-19 vaccine in 01Jan2021 and not received 2nd dose till now; passed out; chest burning; leg pain; severe pain on one side; This spontaneous case was reported by a pharmacist (subsequently medically confirmed) and describes the occurrence of LOSS OF CONSCIOUSNESS (passed out) in an 80-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 01-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 01-Jan-2021, the patient experienced LOSS OF CONSCIOUSNESS (passed out) (seriousness criterion medically significant), CHEST PAIN (chest burning), PAIN IN EXTREMITY (leg pain) and PAIN (severe pain on one side). On an unknown date, the patient experienced PRODUCT DOSE OMISSION ISSUE (patient received Dose 1 of the Moderna COVID-19 vaccine in 01Jan2021 and not received 2nd dose till now). On 02-Jan-2021, LOSS OF CONSCIOUSNESS (passed out), CHEST PAIN (chest burning), PAIN IN EXTREMITY (leg pain) and PAIN (severe pain on one side) had resolved. At the time of the report, PRODUCT DOSE OMISSION ISSUE (patient received Dose 1 of the Moderna COVID-19 vaccine in 01Jan2021 and not received 2nd dose till now) had resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant medication information was provided. No treatment medication information was provided. Company comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p> |

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| 1361179 | 5/29/2021 | NY | 12 | F | 5/28/2021 | 5/28/2021 | 5 mins after being on the observation area patient experienced a feeling of dizziness while being with her mother, she fainted but didnt fall as she supported her body, mother expresses that something similar happened recently when she went to obtain blood work for her ab test. Also fx hx of vasovagal sx as per discussion. Denies any chest pain, no SOB, no HA, no palpitations. Pt was transferred via wheelchair to the medical stretcher area and was observed and lie down in supine position with elevation of her legs for 30 mins. Patient left home without further episodes and stable, VS at time were 100/64 HR 67 Dr and EMS were at the site. Medical Advised provided |
| 1361072 | 5/29/2021 | IN | 54 | F | 5/21/2021 | 5/22/2021 | The day following vaccination, I was doing light yard work, came in the house, got a drink and it got caught in my throat, I sat down in a chair and woke up on the floor(presuming I had passed out.) I was out for a few minutes. When I awoke I was disorientated and had suddenly a headache, nausea, sweaty and clammy skin. |
| 1361091 | 5/29/2021 | KY | 31 | M | 5/29/2021 | 5/29/2021 | Patient was given the vaccine at 10:40am. He was being monitored and at 10:53am, stood up and immediately passed out falling face first. He came about immediately and refused medical attention but has a large swollen area on his forehead. |
| 1361098 | 5/29/2021 | OR | 22 | F | 5/28/2021 | 5/28/2021 | Fever symptoms, aching, cold sweat, uncontrollable shivering in warm clothes/room. Headache. Morning after vaccine: nausea, dizziness, fainting |
| 1361101 | 5/29/2021 | CA | 18 | F | 5/28/2021 | 5/28/2021 | Patient passed out and fell on a cardboard display box, fortunately her dad who was standing next to her picked her up immediately, and said that she had anxiety and she was ok. I spoke to the patient and when she said she was ok I had her sit down on the chair. After about 15 minutes patient and father left and confirmed that she was doing ok. Next morning patients dad called and said she was doing fine, that we might need to fill out paper work regarding the incident to submit it at patients school so she would not have to take the second dose. |
| 1361120 | 5/29/2021 | NC | 17 | M | 5/29/2021 | 5/29/2021 | Patient passed out after receiving Vaccine. I called the paramedics they observed the patient and released him to his father. |

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| 1361160 | 5/29/2021 | IA | 28 | M | 5/29/2021 | 5/29/2021 | <p>Syncopal event. Patient felt dizzy initially after receiving vaccine, moments later (within 1 to 2 minutes) the patient lost consciousness and started sliding out of chair as patient's wife caught him and sat him down on the floor. Patient regained consciousness just as we were coming out to assist (within 5 to 10 seconds). We had him remain on the floor for a couple minutes before we sat him back in his chair and we watched him for an additional 15 minutes (30 minutes total). Also questioned and monitored patient, evaluating for any signs of anaphylaxis/allergy type symptoms as he recovered.</p> |
| 1360745 | 5/29/2021 | PR | 24 | M | 5/29/2021 | 5/29/2021 | <p>Patient started feeling dizzy, malaise and then patient had a syncopal event where he also started having uncontrollable movements.</p> |
| 1361164 | 5/29/2021 | WA | 17 | F | 5/18/2021 | 5/19/2021 | <p>Dizziness, presyncope with exertion, nausea, occurring daily</p> |
| 1361036 | 5/29/2021 | NC | 19 | F | 5/29/2021 | 5/29/2021 | <p>Patient passed out and hit face on the floor which resulted in a severe nose bleed. She was taken into the ambulance. I do not know if she was taken to the hospital or not. This happened about 15 minutes after her vaccination.</p> |
| 1361192 | 5/29/2021 | | 17 | F | 5/29/2021 | 5/29/2021 | <p>Syncopal event. Patient was found lying on the ground after being vaccinated with Pfizer first dose. Pt had prior history of fainting, and was vaccinated in a supine position. Pt stayed in a supine position for about 7 minutes and walked to the observation area with her mom. Patient was assessed by paramedics and myself. She regained consciousness approximately 10 seconds after even or less. Initial BP 121/83, HR 64, O2 100% room air. Pt vitals retaken at 10:37 BP 110/74, HR 72, O2 100% room air. Pt was advised to stay for an additional 15 minutes and reassessed. Patient left in stable condition with mom.</p> |
| 1361208 | 5/29/2021 | MA | 37 | F | 5/29/2021 | 5/29/2021 | <p>PATIENT FAINTED AFTER ABOUT 8 MINUTES OF WAITING UNDER OBSERVATION. PATIENT UNCONSCIOUS FOR ABOUT 3 MINUTES THEN TOOK SOME TIME TO COME OUT OF IT .</p> |

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| 1361220 | 5/29/2021 | FL | 26 | M | 5/29/2021 | 5/29/2021 | 5 MINUTES AFTER GETTING THE VACCINATION, PATIENT FAINTED WHILE SITTING IN THE CHAIR AND WAS GASPING FOR AIR FOR A FEW SECONDS BUT CAME TO RIGHT AWAYS AND SEEMED ALERT. PATIENT REPORTED EXTREME NAUSEA AND WAS SWEATING PROFUSELY. EMS was contacted and patient was taken to the hospital. A lot of tests were ran and it was concluded that patient vasovagled and was released from the hospital. |
| 1361225 | 5/29/2021 | CA | 32 | M | 5/29/2021 | 5/29/2021 | PATIENT RECEIVED J&J COVID VACCINE AT 11:15AM ON 5/29/21. WHILE WAITING FOR 15 MINUTES PERIOD AFTER VACCINATION, HE WAS FAINTING AND SAT DOWN ON THE FLOOR IN FRONT OF PHARMACY AT 11:20AM. PATIENT WAS SHAKING. HIS BODY TEMPERTURE TURNED COLD. HIS SKIN TURNED PALE. |
| 1361236 | 5/29/2021 | PA | 25 | F | 3/10/2021 | 3/15/2021 | five days after my first COVID vaccination, i fainted and split my chin open. we believe i got a concussion upon impact and was given a tetanus booster at the same time they glued my chin together |
| 1361241 | 5/29/2021 | NC | 25 | M | 5/29/2021 | 5/29/2021 | PT PASSED OUT UNCONSCIOUS FROM A SEATED POSITION 5 MINUTES AFTER RECEIVING HIS SECOND DOSE OF THE COVID SHOT. |
| 1361330 | 5/29/2021 | CA | 24 | M | 5/29/2021 | 5/29/2021 | patient fainted within minutes of getting the vaccine. they reported they were afraid of needles and was advised to take a seat in the waiting ares. patient fainted breifly, were sweating. emergency services was called immediately and they questioned the patient and determined it was just the result of anxiety from the fear of needles. patient was okayd to leave the facility by emt at around 3.50 pm. (within about 20 mins from starting of incident) patient then left the facility without any other issues. follow will be done by rph in a few days. there were no signs of an allergic reaction or history of one |
| 1361162 | 5/29/2021 | OH | 14 | F | 5/29/2021 | 5/29/2021 | Syncope and paleness |
| 1360983 | 5/29/2021 | VA | 47 | F | 5/28/2021 | 5/28/2021 | Systemic: Fainting / Unresponsive- Mild, Additional Details: Pt fainted a few minutes after injection, but quickly came to and was responsive. Spouse stated pt had history of fainting after giving blood. |

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| 1360855 | 5/29/2021 | | 38 | F | 5/26/2021 | 5/27/2021 | Thursday at noon felt nauseas after waking up, went to bathroom, became sweaty, hot. Woke up laying on bathroom floor, unknown how long was out for. Fainted at least twice. First faint resulted in deep laceration on chip and broken tooth due to fall. |
| 1360870 | 5/29/2021 | | 14 | M | 5/29/2021 | 5/29/2021 | AE: patient passed out post vaccine administration, however; the patient did not hit head on the hard surface or become unresponsive. |
| 1360893 | 5/29/2021 | IL | 14 | M | 5/28/2021 | 5/28/2021 | Pt with presyncope event. Pt complained of sudden onset of nausea and feeling ?weird.? Clinician immediately at chair side. Initial vitals 102/58, HR 49, RR 18, O2 sat 98%. Pt assisted with receptacle for emesis-none. EMS medic 153 on scene and present. 4:25p BP 102/64, HR 62. 428p transferred to avail cot to lay supine. Aox3 and verbal entire time. Ice pack to neck. Water to drink without difficulty. Orthostatic vitals assessed ,WNL. Parent present throughout event. Mom refused transport. 446p EMS called verbal report to hospital MD as part of release for transport refusal. Permission granted to refuse transport . Pt up, walking around. States he now feels fine at 452p |
| 1360926 | 5/29/2021 | MA | 70 | M | 3/27/2021 | 4/7/2021 | Symptom onset afternoon of 4/7 while playing golf, with feelings of fatigue and leg weakness, worsening leg weakness in the evening while taking a bath, followed by inability to get out of tub, but eventually able to drag self to bed where he passed out. Woke hours later and called EMS. |
| 1360937 | 5/29/2021 | PA | 16 | F | 5/29/2021 | 5/29/2021 | Patient had an episode of vasovagal syncope right after receiving the vaccine. Her blood pressure dropped to 92/50 at 11:15, but then it resolved to 102/60 within 5 mins. Gave 8 oz. of orange juice and patient reports feeling normal after 15 mins. Monitored for about 20 mins and no other symptoms were observed. |

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| 1360956 | 5/29/2021 | MA | 14 | M | 5/25/2021 | 5/27/2021 | <p>Patient received 1st dose Pfizer COVID vaccine at a store/pharmacy on 5/25/21. Presented to ED with chest pain on 5/28. Diagnosed with myocarditis and admitted to the hospital. ED attending note: Patient presents with acute onset of chest discomfort in the sternal area 2 days after the first dose of Covid vaccine. Patient's not had any fevers. No respiratory symptoms. No difficulty with respirations or any pleuritic chest pain. Denies any cough. No chest wall trauma. No back pain. No palpitations or syncope. No orthostasis. No peripheral edema. On physical exam he was mildly tachycardic in the 80s to low 90s with no murmur and no gallop. No JVD. Clear lungs. No rub. Bedside ultrasound performed by HCP had bilateral lung sliding and normal gross function based on 2 views. No pericardial effusion. EKG had ST changes. Chest x-ray was obtained without any effusions or pulmonary infiltrates. Normal cardiac silhouette. Troponin sent elevated. Cardiology consulted for possible postvaccination myocarditis. Child remained stable. Resting heart rates in the 70s and low 80s. Cardiology came to see the patient. Plan to admit to cardiology service. Presumed diagnosis of myocarditis. Cardiology admitting note: Pt. is an otherwise healthy 14yM who presents with acute onset atraumatic chest pain i/s/o recent covid vaccine, found to have mildly elevated inflammatory markers and troponin with borderline ST changes on EKG most consistent with mild peri/myocarditis at this time given overall well appearance on exam without hemodynamic or respiratory compromise and grossly normal function on POCUS, though plan for formal echo in AM. EKG w/ non-specific ST-T wave changes in precordial leads, no evidence of strain or block. Admitted to the cardiology service for serial troponins, ECHO, and close monitoring. HPI per cardiology consult note: "Patient is a healthy 14 year old with a history of alopecia who presented to the ED with mild chest pain 4 days following his first Covid vaccine (Pfizer). He had no symptoms in the days immediately following vaccine, and played basketball the day following with no symptoms, but after waking up today began having dull mid sternal chest pain. It was a 4/10, worse with lying down, non pleuritic, not sharp, and not radiating pain and not associated with any other symptoms including SOB, numbness, GI pain, cough, or anything else. Has not taken any meds for the</p> |

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| | | | | | | pain. Has not exercised today. Felt "warm" this AM, but didn't check temperature and felt better throughout the day. No palpitations, dizziness. Denies ever having chest pain before and no recent illnesses or sick contacts. No notable hfx of cardiac disease. In the ED, troponin mildly elevated to 0.12 ng/mL and CRP 5 with low ESR and BNP. Bedside point-of-care US reportedly showed no clear effusion with grossly normal function. HR mainly in 70s in ED and normotensive. EKG with borderline nonspecific ST elevation in V3-V6.~~ | |
| 1360962 | 5/29/2021 | CA | 32 | M | 5/28/2021 | 5/28/2021 | Patient was tense and nervous to get his COVID-19 vaccine (Pfizer) after seeing another patient feeling light-headed after his respective vaccine. The patient was pacing back and forth deciding if he should get his vaccine or come back another day. He decided to get vaccinated. Immediately after the vaccine was administered the patient, while still sitting down, passed out and leaned forward falling on the floor. As the intern reached down to help the patient he came to and was able to get back on the chair on his own. At that point the PIC and the intern remained with the patient for observation and provided water. The patient remained under observation for about half an hour and expressed he felt well enough to go home. |
| 1361062 | 5/29/2021 | VA | 30 | M | 4/28/2021 | 4/28/2021 | Patient fainted after about 10 seconds of Covid-19 Moderna (2nd dose) administration. Patient reported to lose consciousness for about 10 seconds. Patient was then helped getting back to his chair staying that he was feeling fine. I sat with patient for about 2 minutes and noticed that he was a little pale and sweating. I asked patient if he wanted to lie down and he refused. I told patient to remain still while I was getting help and called 911. I again fainted and I put patient down on the floor and monitored his breathing, heart rate. I gained consciousness back after 10 to 15 seconds. Store manager arrived. Patient drank some water. Patient seems to be aware of surroundings. EMTs arrived soon after. During the time that EMTs were monitoring patient. Patient fainted again and was taken to hospital. |

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| 1360978 | 5/29/2021 | TX | 18 | M | 5/29/2021 | 5/29/2021 | Patient fainted after 5 minutes of being vaccinated. Patient began to lean to the right and was immediately assisted by 2 pharmacists. Patient was laid down and monitored by pharmacists. Patient lost consciousness for less than a minute. Patient was alert and oriented to person, place, and time. Patient's blood pressure was assessed by paramedics with a reading of low to normal. Patient was observed for an additional 20 minutes. |
| 1361054 | 5/29/2021 | NC | 16 | M | 5/29/2021 | 5/29/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient was very worked up and nervous before receiving vaccine. Seemed to calm down after vaccine administration. Within a few minutes patient fainted. Had patient lie down with feet up. Once patient could sit up, blood pressure reading 75/42. Patient was given water and laid down/sat for about 30 minutes. Feeling better and blood pressure reading of 98/69 before leaving store. |
| 1360989 | 5/29/2021 | MN | 19 | F | 5/29/2021 | 5/29/2021 | Patient's mother came up to pharmacy and said her daughter called her while she was waiting the 15 min and started to feel faint and felt like she was going to pass out. After a few minutes she said she felt better and I had her sit down and gave her some water in which she said she felt much better and felt well enough to go home. She did mention that she had a donut earlier. Her mom also said she has fainted with other vaccines before. |
| 1360996 | 5/29/2021 | TN | 50 | M | 5/29/2021 | 5/29/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild |
| 1361001 | 5/29/2021 | MA | 19 | F | 5/29/2021 | 5/29/2021 | patient passed out in a chair for a few seconds and was pallor. she did not hit her head. she had not eaten breakfast or drank anything all day. we called 911 and the ambulance was dispatched. she drank some water and began feeling better and color returned to her face almost immediately. ambulance emts evaluated patient and determined no need to send her to the hospital. she felt fine and left with emts. |

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| 1361002 | 5/29/2021 | ND | 13 | F | 5/29/2021 | 5/29/2021 | Approximately 3 minutes after receiving the shot, the patient fainted for approximately 15 to 20 seconds while seated in the waiting area. Patient reported feeling nauseous but did not vomit. EMT was called to the scene and checked her pulse/ox was at 100 and pulse was at 60 approximately 13 minutes after shot injection. |
| 1361004 | 5/29/2021 | NC | 31 | M | 5/29/2021 | 5/29/2021 | Fainting, sweating,. After about 15 minutes the customer felt better |
| 1361020 | 5/29/2021 | MA | 14 | F | 5/28/2021 | 5/28/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: Hypotension-Medium, Systemic: Shakiness-Medium, Additional Details: pt passed out immediately after vaccination briefly, when she regained consciousness she convulsed for about 2 seconds, heart rate at 58, with weak pulse, called 911, pt taken to er as a precaution |
| 1361266 | 5/29/2021 | CA | 22 | M | 5/29/2021 | 5/29/2021 | Patient fainted shortly after receiving the vaccine. He was instructed to go have a seat in our observation area and wait for 15 minutes and I believe he fainted before he even sat down. As I approached him he was already conscious again and i had him stay put just to make sure he was ok before getting back into the chair. He was given water and he was closely monitored until his 15 minutes was up. A family member came to take him home just to be safe. While he was waiting he said it wasn't a seizure and he probably fainted because of his fear of needles. He mentioned it has happened multiple times before whenever he gets tattoos. None of this was indicated when he filled out his vaccine consent form. |
| 1360963 | 5/29/2021 | TX | 17 | F | 5/29/2021 | 5/29/2021 | Syncope approximately 3 minutes after shot with resulting head injury. Pt conscious on paramedic evaluation with hematoma on forehead. Unable to walk without assistance. Pt's mother chose to drive her for follow up at ED against recommendations of reporter. Fire Department wheeled pt to personal vehicle. Unknown dispositions/outcome. |

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| 1361284 | 5/29/2021 | CA | 33 | M | 5/28/2021 | 5/28/2021 | Patient said he had a history of fainting/passing out after stressful medical events. He received 1st dose of Pfizer vaccine from my intern without incident. He proceeded to the waiting room to wait the 30 minutes that was recommended. After about 5 min. passed, his girlfriend alerted us that he was feeling faint. I went to check on him and after talking with him for a few minutes, his head rolled back and he lost consciousness for approx 5-10 seconds. I went into the pharmacy to dial 911. When I got back to him, he was already back awake. Fire dept was dispatched and they checked his vitals and he signed a form to go AMA to the hospital. |
| 1358040 | 5/28/2021 | MO | 18 | M | 5/22/2021 | 5/22/2021 | Staff notices patient was breathing deeply and slowly. Asked patient if he is feeling unwell. Patient states he feels lightheaded. Patient then became diaphoretic. Took patient to medical tent via wheelchair. Vital signs stable. Gave patient orange juice and water and applied a cold damp towel. Patient stopped sweating and states he no longer feels dizzy. Too BP sitting and standing. Stable both ways. Symptoms noted: paleness, sweating, fainting, lightheadedness,; Orientation x 3. Vital Signs: 12:47pm - bp 116/62, p 71, r 15, pulse ox 98; Vital signs: 12:53pm - bp 120/76, p 74, r 16, pulse ox 98; patient treated at vaccine location, stabilized and discharged to home, alert and oriented with no further complaints. |
| 1357774 | 5/28/2021 | OH | 58 | F | 1/25/2021 | 1/25/2021 | It started at 10:30 that night with a fever, about 02:30am I woke up in the most horrific pain, I have never experienced anything like it, I was shaking so hard that my teeth were chattering, I fainted toward the end of that week hit my head and wound up with a mild concussion and went to the ER. I had not been feeling well at all. I was almost delirious, when I woke up I was vomiting . I wound up with a huge knot on my head. |

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| 1357792 | 5/28/2021 | CA | 16 | M | 5/9/2021 | 5/10/2021 | Received 2nd Pfizer COVID vaccine 5/9. On the evening of 5/10 he awoke with severe 7/10 CP located centrally and radiating down both arms. Not a distinct pain such as sharp, stabbing, burning, throbbing but located in center of chest and was really uncomfortable. No other associated CV symptoms (palpitations, SOB, syncope). Pain slightly worse supine. Pain self-resolved but recurred on 5/12. he had no symptoms of COVID disease. |

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| 1357812 | 5/28/2021 | | 22 | M | 3/19/2021 | 3/20/2021 | <p>Chest Pain, Myopericarditis; From EPIC: From cardiologist healthy man who comes to the ER with left anterior chest discomfort for the last 36 hours or so. Symptoms are made worse by deep inspiration. Were improved following self administration of 600 mg of ibuprofen earlier today. 2 days ago he received his second COVID-19 vaccine (Pfizer). Following day he experienced arm pain muscular aches and pains severe discomfort of the right arm (injection site) later in the day there was nausea and vomiting on one occasion (nonheme). By last night he was able to eat dinner but subsequently felt short of breath with worsening chest discomfort morning the left arm continued to ache with musculoskeletal pains. Developed more discomfort in the left anterior chest radiating to the throat made worse by deep inspiration. Does not describe typical sharp catching pain of pericarditis. No cough sputum bruising bleeding abdominal pain change in color or character of bowels. Sign in the emergency room he was hemodynamically stable, in sinus rhythm with a normal EKG. Torrey work-up notable for an initial troponin of 1.28 and a follow-up troponin of 2.14. Chest x-ray perfectly normal. Elevated d-dimer. CT angiography negative for pulmonary embolism vascular injury, cardiomegaly, pericardial effusion but the radiologist did note thickening of several right posterior and lateral axillary lymph nodes raising a question of recent right-sided vaccination or injury/infection to the right arm. Presently he is perfectly comfortable able to take a deep inspiration with mild chest discomfort, breathing easily. I met him in July 2018 He came to the emergency room with a 3-day viral syndrome manifested as headache nausea vomiting diarrhea and abdominal discomfort and then developed chest discomfort. He was found with diffuse mild J-point elevation on EKG consistent with a viral type pericarditis with troponins which rose to a maximum of 10.4. Work-up for myocarditis was negative. Echocardiogram perfectly normal. Symptoms responded to a course of nonsteroidal anti-inflammatory agents and colchicine. Seen in follow-up of repeat echocardiogram was perfectly healthy. Our diagnosis was myopericarditis. There is no history of shortness of breath dyspnea on exertion decrement of exercise capacity peripheral edema orthopnea PND palpitations lightheadedness syncope or collapse. No ill contacts. He works in a high security</p> |

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| | | | | | | | position and therefore qualified for early administration of the Pfizer COVID-19 vaccine. Graph past medical history notable only for the episode of myopericarditis and a remote tonsillectomy. There is no significant family history of sudden cardiac death or unusual heart disease. He takes no medications. Patient was recommended to take 4 weeks of ibuprofen and colchicine if needed for worsening chest pain. Patient was recommended to follow-up closely with his primary care doctor and check ESR, C-reactive protein as well as renal function. Needs close follow-up with cardiology as an outpatient. |
| 1357834 | 5/28/2021 | NY | 24 | M | 5/28/2021 | 5/28/2021 | pt rec'd vaccine, waited 15 min in recovery stood up ad became lightheaded, dizzy, pale, diaphoretic no LOC near syncope, + nausea, no vomit. Ice pack to head and back of neck. refused to lie down. Gave water for hydration provided reassurance. Pt stated no nourishment taken in prior to vaccine. VS taken 122/80, HR 88 reg strong, resps 16 reg non labored, 94% O2 sat. L arm vaccine site benign. Monitored 30 min. at 9:50 pt stated, " I feel great can I go" Paleness and diaphoresis subsided. OK'd to exit with friend. |
| 1357870 | 5/28/2021 | FL | 31 | M | 5/28/2021 | 5/28/2021 | Patient fainted almost immediately after needle was withdrawn and bandage was applied. Patient reports always fainting with any shot he gets. Was out for about 3-5 seconds, then came to, and no other issues afterwards. |
| 1357884 | 5/28/2021 | | 16 | F | 4/15/2021 | 4/17/2021 | Myocarditis. Chest pain started 2 days after the 2nd shot. Elevated troponin and went upto 20. Near syncope and tiredness. |
| 1357903 | 5/28/2021 | OH | 17 | F | 5/18/2021 | 5/18/2021 | Passed out/ got chills and sweats after receiving vaccine at the Pharmacy. Proceeding the vaccine she had headaches and still gets them and it?s currently 05/27/2021 which it?s been 9 days since also for 3 days after vaccine was extremely exhausted. |
| 1357941 | 5/28/2021 | OH | 25 | M | 5/28/2021 | 5/28/2021 | patient went to waiting area. patient sat down then he pass out. Fell out of chair onto the floor. patient got up walk over to pharmacy said he passed out |

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| 1358243 | 5/28/2021 | OR | 32 | M | 5/28/2021 | 5/28/2021 | Patient reported tunnel vision and subsequently passed out, seized for 5 seconds, and then regained consciousness. Patient afterwards reported having a history of this type of reaction to vaccines, tattoos, and dental work. Patient became very warm, received water, and an ice pack. Patient was cooled down and left 30 minutes after the event. |

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| 1357979 | 5/28/2021 | CA | 22 | M | 5/27/2021 | 5/27/2021 | Client received his first dose of the Pfizer Covid-19 vaccine (Lot # EW0185 Exp. 08/2021) on 5/27/21 at 1036 AM. At approximately 1045 the client walked up to the EMT asking for water and stating that he felt lightheaded. " Client was a 22-year-old male alert and tracking with his eyes and beginning to stumble. The client had a chief complaint of syncope. EMT managed to assist the client to the observation bed while an additional EMT and RN arrived for further assistance. The client was positioned supine on the cot and proceeded to lose consciousness. The client did not fall or injure himself in any way. He regained consciousness after approximately 15 seconds. He was alert and oriented to person, place, time, and situation immediately upon regaining consciousness. Client stated that he did not have anything to eat or drink before arriving at the vaccination site. The client had no known allergies and denied any medical history. The client was negative for hives, swelling, discoloration, signs or symptoms of shortness of breath, or other signs of anaphylaxis. The client's airway, breathing, and circulation were intact. The first set of vital signs were taken at 1045 and are as follows: blood pressure 110/76, pulse 52, O2 saturation 96%, skin pale, sweaty and hot. The client consented to stay an additional 30 minutes after his initial vitals were taken and his vitals were reassessed every five minutes until his symptoms resolved. After approximately 10 minutes, the client was fully pink in his face and denied any further lightheadedness. At 1051 the second set of vital signs were: bp 122/82, p 56, O2 96%, skins pink, normal, and warm. Client was assisted to an upright seated position and was given Pringles and juice. At 1059 clients vitals were - 124/84 BP, 74HR O2 99%, Resp 16. At 1109 vitals: bp 122/82, p 68, O2 97%, skins pink, normal and warm. At the completion of his additional 30-minute observation, the client stated that he was feeling better. All pertinent information was given to client by EMT and RN and he was encouraged to follow up with his primary before his next dose. The client was also instructed to call 911 if a severe allergic reaction occurred later in the evening and was reminded to eat before his next vaccination. RN educated client about the possible signs and symptoms of an allergic reaction. The client at 1115 in positive disposition with his mother. |

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| 1357676 | 5/28/2021 | PA | 15 | M | 5/27/2021 | 5/27/2021 | Systemic: Chills-Mild, Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Visual Changes/Disturbances-Mild, Additional Details: PATIENT RECIEVED VACCINE AT 2P. Sat in waiting area for about 10 minutes. Our observer noticed that the patient was sliding in his seat and looked dizzy. Patient starting to flutter his eyes and lost consciousness for about 5 secs. He complained about blurry vision, feeling hot, sweating, but with chills. Patient was given water. After he drank the bottle of water patient felt fine. The ambulance was called and arrived, patient reported he felt fine. Patient did not eat/nor drink water today. |
| 1358041 | 5/28/2021 | NY | 20 | M | 5/25/2021 | 5/25/2021 | Syncope reaction - IMMEDIATE REACTION. DROP IN BLOOD PRESSURE, FAINTNESS, PROFUSE SWEATING, BLURRED VISION, COLOR DRAINED FROM FACE, NEVER LOST CONSCIOUSNESS. WAS UNABLE TO GET BP DUE TO SMALL SIZE OF HIS ARMS. I HAD TROUBLE LOCATING THE PEDIATRIC CUFF. WHEN EMS ARRIVED THEY TOOK BP AND IT WAS 58/40. EMTS HUNG FLUIDS AND TOOK PT TO EMERGENCY DEPARTMENT. Pt called pharmacy at 8:30p reporting leaving emergency department feeling fine after fluids administered. |
| 1358089 | 5/28/2021 | VA | 14 | F | 5/28/2021 | 5/28/2021 | Patient became dizzy and very pale in the waiting area post vaccine. 11:29AM layed patient down in cot with an ice pack. 11:36 Patients color returned in her face. B/P 99/58, pulse 67, O2 98% and patient states feeling better. 11:38 BP 100/57 Pulse 66, and O2 98. 11:42 Patient sitting position now, and denies dizziness. Drank some water. B/P 100/57. 11:50 Patient stood up and denies any complaints. Patient states she passed out as a young child after an injection. Patient had no food this morning before her appointment. Advised to eat and hydrate before next vaccine, and to lay down for injection. |
| 1358134 | 5/28/2021 | IN | 29 | M | 5/27/2021 | 5/28/2021 | Fever, extreme weakness, fainting, nausea, muscle pain, injection site pain, chills, swollen lymph nodes, headache, arm pain, cannot stand for more than 30 seconds. All symptoms have lasted many hours after onset (>6 hours) |

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| 1358138 | 5/28/2021 | IA | 13 | F | 5/28/2021 | 5/28/2021 | RN reported that patient became flaccid after her vaccination, then became rigid, crossed her legs, and lightly slammed her head back against the wall. He reports that she fainted but had some seizure-type activity, but minimalized. She was monitored by both RN and myself. She was lowered to the floor to lay on the floor, was fanned, and her BP and pulse were monitored by RN. She was accompanied by her mother, and her mother declined having EMS contacted. Once patient regained consciousness, she was alert, laughed and talked to us, and regained a sitting position. We then gave her cold water to drink, and she was able to get up into a chair. After sitting for several minutes, she was able to walk out of the room and into one of our monitoring cubicles for an extended monitoring timeframe. We kept her here for 30 minutes for further observation, then left accompanied by her mother. Due to RN's report of the seizure-type activity, mom is going to contact patient's pediatrician to see if further treatment is needed. |
| 1358161 | 5/28/2021 | NM | 38 | M | 5/27/2021 | 5/27/2021 | I nearly fainted. Had about 3 different moments of heart flutters (not sure how else to describe it) My vision was half blackened. I was light headed and had a little bit of breathing weirdness. It probably only lasted about 2 minutes. I laid down and all symptoms went away in about a minute. The only other time I fainted in my life it was from seeing blood shoot out of my body but it wasn't accompanied by heart flutters. |
| 1358171 | 5/28/2021 | NV | 28 | M | 4/7/2021 | 4/8/2021 | Fatigue w/in 12 hrs that lasted more than 2 days, after which fatigue continues even now. We believe he fainted while operating a scooter which resulted in an emergency room visit. Complains of chest pain. Concerned this could be myocarditis- he?s on government insurance so medical access is limited. |
| 1356521 | 5/28/2021 | TX | 44 | F | 5/24/2021 | 5/25/2021 | DIZZINES, SYNCOPE WHILE SEATED, FELL INTO COFFE TABLE, RANDOM ABNORMAL BRUISING ON ABDOMINAL WALL AND LEGS. |
| 1357967 | 5/28/2021 | MD | 41 | F | 5/28/2021 | 5/28/2021 | pt fainted after vaccination and recovered right away |

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| 1357360 | 5/28/2021 | | | F | | | faint; This is a spontaneous report from a contactable consumer or other non hcp. This consumer (caregiver) reported for a 13-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Batch/Lot Number: Unknown), via an unspecified route of administration on an unspecified date as single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On an unspecified date, the patient got fainted (syncope) (medically significant). Reporter considered the event as serious. Caller is asking if there would be a component that would cause her daughter to faint a few minutes after getting the first dose of the Pfizer BioNTech Covid-19 Vaccine. Caller wanted to know if fainting is a reported side effect after getting the first shot of the Pfizer BioNTech Covid-19 Vaccine. The outcome of the event was unknown. Information about lot/batch number has been requested. |
| 1357093 | 5/28/2021 | NJ | | F | | 5/1/2021 | LEG CRAMPS; STOMACH PAIN; ALMOST FAINTED AT WORK; This spontaneous report received from a patient concerned a female of unspecified age. The patient's height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine (suspension for injection, route of admin not reported, batch number: 1808609 and expiry: UNKNOWN) dose was not reported, administered on 20-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On MAY-2021, the subject experienced leg cramps. On MAY-2021, the subject experienced stomach pain. On MAY-2021, the subject experienced almost fainted at work. The action taken with covid-19 vaccine was not applicable. The outcome of the leg cramps, stomach pain and almost fainted at work was not reported. This report was non-serious. |

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| 1357110 | 5/28/2021 | MI | 24 | M | 5/11/2021 | 5/11/2021 | <p>passed out; dizzy; moaning; gasping; foaming in the mouth; headache; tired; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (passed out) in a 24-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 002C21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 11-May-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 11-May-2021, the patient experienced LOSS OF CONSCIOUSNESS (passed out) (seriousness criterion medically significant), DIZZINESS (dizzy), MOANING (moaning), DYSPNOEA (gasping), FOAMING AT MOUTH (foaming in the mouth), HEADACHE (headache) and FATIGUE (tired). At the time of the report, LOSS OF CONSCIOUSNESS (passed out), DIZZINESS (dizzy), MOANING (moaning), DYSPNOEA (gasping), FOAMING AT MOUTH (foaming in the mouth), HEADACHE (headache) and FATIGUE (tired) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 11-May-2021, Vital signs measurement: normal (normal) normal. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. The patient had a severe reaction when he was getting in the car to leave. He was dizzy first then had a blank stare. After that he started moaning and gasping and foaming in the mouth then passed out. They called the paramedics. Vitals were normal and the patient was given the choice to go to the hospital but declined. Patient felt very tired and had a headache later. No concomitant medications were reported. No corrective treatment was provided. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. However, medical history and concomitant medication details are required for further evaluation. Most recent FOLLOW-UP information incorporated above includes: On 18-May-2021: Follow up included correct DOB was confirmed; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start</p> |

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date of the event, a causal relationship cannot be excluded. However, medical history and concomitant medication details are required for further evaluation.

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| 1357221 | 5/28/2021 | IL | 57 | M | 4/22/2021 | 4/1/2021 | <p>passed out; blood pressure is low/blood pressure was 80 something over 50 something; white blood count is high; dehydrated; not feeling well; This is a spontaneous report from a contactable consumer (patient). A 57-years-old male patient received bnt162b2 (PFIZER COVID 19 VACCINE, Batch/Lot Number: EW0169), via an unspecified route of administration, administered in Arm Left on 22Apr2021 08:00 (57-years-old) as 1st dose, single for COVID-19 immunization (his cardiologist recommended him to get it and signed him up for it). Medical history included ongoing coronary stents (Has 18 coronary stents in total. The last three stents were put in 2018), burning of nerves in the back from Apr2021 (The burning of nerves was done through injection), underlying heart issue, neuropathy, diabetes, blood pressure, Cholesterol. Concomitant medications included metformin taken for diabetes from an unspecified start date and ongoing; pantoprazole from an unspecified start date and ongoing; lorazepam from an unspecified start date and ongoing; gabapentin like a nerve block for neuropathy and diabetes from an unspecified start date and ongoing; isosorbide taken for slow release nitro for heart from an unspecified start date and ongoing; carvedilol taken as beta blocker and helps blood pressure and stuff from an unspecified start date to 10May2021; rosuvastatin taken for cholesterol from an unspecified start date and ongoing; ticagrelor (BRILINTA) taken as blood thinner; losartan taken for blood pressure from an unspecified date and unspecified date; acetylsalicylic acid (ASPRIN, Bayer) from an unspecified start date and ongoing; magnesium from an unspecified start date and ongoing; furosemide taken as water pill from an unspecified date and unspecified date; metoprolol from 10May2021 to an unspecified stop date; amlodipine from an unspecified date and from May2021; chlorthalid tabniva taken as water pill (25mg at night at the time of the shot, couple of days ago he had to start cutting it in half, now he is only taking 12.5mg at night). The patient previously took Plavix (Brilinta replaced Plavix to keep his stents open. He was on Plavix over 6 years ago), Fentanyl, and Versed. The patient experienced passed out (hospitalization) on 04May2021, blood pressure is low/blood pressure was 80 something over 50 something (hospitalization) on 01May2021, not feeling well on Apr2021, white blood count is high on an</p> |

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unspecified date, dehydrated on an unspecified date. The patient was hospitalized for passed out and blood pressure is low/blood pressure was 80 something over 50 something from 04May2021 to 05May2021. The patient underwent lab tests and procedures which included blood count: 13 on 12May2021. The patient received Pfizer COVID vaccine and reported after 1st dose received on 22Apr2021 he is not feeling well, he has an underlying heart issue and a history of stents placed, white blood cells are high and has a low blood pressure. His Dr. asked him to call Pfizer to ask if this could have been reported as side effects from vaccination. He was asking if he should get the second dose. He had Pfizer shot and has got to get the second one on Saturday. He doesn't know if it is related or not. He has been going to the doctor. He has underlying conditions and takes heart medications and has stents. He has not been feeling good since getting the shot. He is not sure if it is affiliated. His white blood count is high and he has to go to the doctor. His doctor is advising him to hold off on getting the second one and told him to call and ask if anyone else has had side effects like that. He clarified shot as COVID19 Vaccine. He saw his cardiologist yesterday and they thought it was interesting that he started having problems. They wanted him to call the phone number and see if he can postpone the second one. He is not sure if it is related to the shot. His blood pressure has been really low (01May2021) since taking the shot. He takes a ton of medications and they are having to adjust his medications since. Not been feeling good is ongoing. It started 3 to 4 days after getting shot. White blood count is high information reported as he was in the hospital and they didn't say anything about his white count. They did his blood count yesterday and they said it was 13 and want him to see his primary care. He just found out about that yesterday. He is going to see his primary care today. He was in the hospital from 04May2021 to 05May2021 because he passed out because his blood pressure was 80 something over 50 something. Blood pressure is low has improved but they have adjusted his medications to help it improve. COVID19 Vaccination Card: it says first dose COVID19. It doesn't have how much was administered. There is a number 42221 on the vaccination card, but he is not sure what it is. At first caller had said he got the vaccine on

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24Apr2021, but then clarified that he got the vaccine on 22Apr2021. The patient went to Emergency Room. His wife had to call the ambulance because his wife thought it was his heart. They took him to the ER. They were treating him for his heart and then realized it was his blood pressure was extremely low. Prior Vaccinations (within 4 weeks): No vaccine, but he did have burning of nerves in the back at Pain Clinic done in Apr2021. The burning of nerves was done through injection. He has had it done many times. They give him a local anesthetic when they do it and also Fentanyl and Versed. He has had Fentanyl and Versed many times, due to having stents. Family Medical History Relevant to AE: No. His sisters have gotten it and they are fine. His brother has gotten it and he is fine. Patient did not wish to do a report about his siblings experience with the vaccine. His brother has issues like caller and takes medications, but he hasn't had any side effects from the vaccine. The outcome of the event blood pressure is low/blood pressure was 80 something over 50 something was recovering, not feeling well was not recovered, while for other events was unknown.

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| 1357282 | 5/28/2021 | NY | 52 | F | 4/26/2021 | 4/26/2021 | <p>couldn't even function; I have been having really bad breathing problem; Loss of appetite; I just got bruised; double vision; couldn't stand; couldn't even focus; her eyes could not focus; could not see to drive, all of sudden my vision was gone away; diarrhea; blurred vision; vertigo; continuous dizziness; This is a spontaneous report from a contactable consumer. A 53-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 2 via an unspecified route of administration on 26Apr2021 (at the age of 52 years-old) (Batch/Lot Number: EW0169; Expiration Date: Aug2021) as 2ND DOSE, SINGLE for covid-19 immunisation. Medical history included syncope Unspecified syncope, migraine Chronic Migraines, concussion history of severe chronic migraines and unspecified syncope due to have a concussion 3 times. The patient received first dose BNT162B2 for COVID-19 immunization on 06Apr2021 at the age of 52 years old. Caller said that since the second dose she has diarrhea that is coming and going, but she has been having it for 2 weeks and is treating it with Imodium AD. She has been having blurred vision, vertigo, and dizziness continuously. She has never had this before. She said that within an hour of getting the second dose, she was taking her dog for a walk and only made it a block before she had to come home because she thought she was going to fall. She states on Mothers Day she felt like she could not get her bearings and states it was "very, very scary." She said that she cant even walk down her staircase or drive her vehicle. Consumer further stated, I have been having a loss of appetite too not feverish or anything and you know I had the shot, I had no reaction there. I just got bruised and I had no hurt or anything. I have been having symptoms. I had several symptoms from Pfizer but the second vaccine I had been having sever symptoms, they haven't gone away. I was vaccinated for second vaccination on second dose was on 26Apr2021. I am pulling it on my screen here because I have a V-safe. I have been having really bad breathing problem. I have brain situation that my neurology check. I have underlying medical conditions. My pulmonologist asked me to get the Pfizer so that's what I did. I had the first dose 06Apr2021, I had the second dose 26Apr2021. Now basically just the second dose, I started having visions problem really bad and dizziness, it's kind of little</p> |

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vertigo. I had severe diarrhea for at least I guess I am still having it little bit. So it was really severe for about a week or so. But I have it, I am having it still couple of days, 3 weeks still, 3 and a half days and week. The vision on modern days I had like double vision and dizziness and I got vertigo, the whole day. So my brother left with my granddaughter. I had to hold on to the banished couldn't stand. I couldn't even focus. I have unspecified think to the give more and I have a severe chronic migraine (Intent: History) since I am 4 years old but I have never had this happened to me until after I took the Pfizer second vaccine. The day that I took the Pfizer second vaccine, I went with my dog outside I only was able to walk a block and a half and then I had to walk back home because I felt dizzy. Now this is about an hour after I took the second vaccine. Also the next day I drove my car to the park, this is about maybe 10 minutes away and I was getting home run around the park and about an hour after that I had going to car and and surrounded and could not even get my barrig's. She states the next day she took her dog to the dog park and experienced the same thing so she had to lay down in her car and states she "couldn't even function." She states that when she was driving later, she states her eyes could not focus and she could not see to drive. As she was driving home, all of sudden my vision was gone away, from what happen was is I had to call my son. Then I started to cry because I couldn't able to see. Now this has been continuing since the vaccine. Therapeutic measures were taken as a result of diarrhea. The outcome of the events was not recovered. No follow-up attempts are needed; information about lot/batch number cannot be obtained.

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| 1357294 | 5/28/2021 | CA | 39 | F | 5/7/2021 | 5/7/2021 | <p>Passed out if upright for too long; Nausea; Severe abdominal pains; Racing heart; Feeling like I was going to pass out; This is a spontaneous report from a contactable Other HCP (patient). A 39-year-old female patient (not pregnant) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), first dose via an unspecified route of administration, administered in arm left, on 07May2021 16:00 (at the age of 39-year-old, not pregnant at time of vaccination) (Batch/Lot number was not reported) as single dose for covid-19 immunisation. Medical history included migraine, hypothyroidism. Concomitant medications included escitalopram oxalate (LEXAPRO); imipramine; levothyroxine; meloxicam. The patient received them within 2 weeks of vaccination. The patient previously took topiramate (TOPAMAX), rizatriptan benzoate (MAXALT), flu vaccine, nitrofluorontin, neomycin, and had known allergies. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. On 07May2021 16:15 (as reported), the patient experienced nausea, severe abdominal pains, racing heart and feeling like she was going to pass out when upright in the first 24hours post shot. Passed out if upright for too long. Racing heart would calm down after laying back down. No treatment received for all events. Events outcome was recovered in May2021. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information available and a close temporal association, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported events of loss of consciousness and other. The case will be reassessed once new information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Committees, and Investigators, as appropriate</p> |

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| 1357296 | 5/28/2021 | CA | 12 | F | 5/14/2021 | 5/14/2021 | fainted; Nausea; lips white; Really pale; 12 year old daughter; This is a spontaneous report from a contactable consumer (patient's mother). A 12-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in Arm Left on 14May2021 got it closer to 12:00 (Batch/Lot number was reported: First letter was R, W or B, followed by A6256) at the age of 12-years-old as SINGLE DOSE for covid-19 immunization. The COVID-19 vaccine was administered at Pharmacy/Drug Store. Medical history reported as none. No family medical history relevant to adverse event, reporter who was the patients mother, is a fainter, who fainted a lot when she saw blood. The patient's concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. As they were driving away, her daughter started feeling really nauseous, then fainted, was super pale, lips were white and she was really pale. It all occurred at the same time all started 10 minutes after vaccine on 14May2021. Then the ambulance came. Her daughter looked really bad and it freaked reporter out. Her daughter sat for a little while and was feeling better now. Her daughter was no longer pale, it went away. They checked her and everything was normal. No Emergency Room and no Physician Office visit required. Ambulance was called, they checked her and she was fine. Told her to keep any eye on her at home. The outcome of the events pale, lips were white was recovered on 14May2021, the outcome of the events nauseous, and fainted was recovering. Information about Lot/Batch number has been requested. |

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| 1357320 | 5/28/2021 | | | F | | 5/14/2021 | She fainted; Chills; Fever; Body ache; This is a spontaneous report from a contactable consumer. A female patient of unspecified age received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Batch/Lot number was not reported), via an unspecified route of administration on an unspecified date (at unknown age) as single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient previously took first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Batch/Lot number was not reported) as single dose for COVID-19 immunisation. Reporter stated, "One of my family members had the vaccine, her second dose of vaccine and she today (14May2021) at 4:00 in the morning she started having chills and fever and body ache and then took like, like in less than an hour she fainted. Is that normal or she has to go to the, her doctor or the emergency room?" Reporter confirmed it was the Pfizer Covid19 vaccine. The outcome of the events was unknown. information on the lot/batch number has been requested. |
| 1357755 | 5/28/2021 | MA | 36 | F | 5/27/2021 | 5/27/2021 | Site: Pain at Injection Site-Mild, Systemic: Fainting / Unresponsive-Severe |

VAERS_ID RECVDATE STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

1357353 5/28/2021

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she would faint; sick and she thought that she was going to die; hit her head and injured her head; could of fell and hit her head on the floor that is hard; dizzy; didn't feel good / horrible feeling; weak; diarrhea; feeling of vomiting; arm pain; feeling unwell; severe allergic reaction; This is a spontaneous report from a contactable consumer (patient). A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), dose 1 via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as 1ST DOSE, SINGLE DOSE for covid-19 immunisation. The patient's medical history and concomitant medications was not reported. Patient says that on Monday she went to go get the COVID vaccine and then Tuesday she called Pfizer and told them that she had a severe reaction and she told them all of her symptoms. But then on Wednesday, yesterday, she went to work and she was fine and then all of a sudden she was in the gallery, she is a security officer, and everything went dark and she was getting dizzy. It was a horrible feeling. She called her supervisor who came and the Patient said that she didn't feel good and she thought that she would faint. Her supervisor told her to sit down and put her head down so she did and that had calmed her down but she was still so weak. She said that she has got to go home and they asked her if she needed an ambulance and she said no and she walked to her car. She probably should of asked for someone to go with her for her to lean on but she guesses that she was so involved with what was going on that she didn't tell them that she needed that help. That is the reaction that she got yesterday so she called right away to her provider and told them what happened and she talked to the registered nurse there who said that the Patient didn't need to go to work today either because the side effects usually last 3 days. She also informed the Patient that if she is still feeling like this the next day, Friday, then she needs to go to the emergency hospital. The Patient mentioned that someone else called her yesterday but she doesn't remember the phone call because she was so out of it. So she went through all of that. After her COVID vaccine, she had diarrhea as soon as she got home 2 hours later. She has also had the feeling of vomiting the day before yesterday and she had arm pain, she was feeling unwell and she had that severe allergic

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reaction. She just wanted to let Pfizer know all of this because the COVID vaccine got her sick and she thought that she was going to die. She could of fell and hit her head on the floor that is hard and something could of happened but God took care of her and put an angel there and she had reacted so fast but she could of hit the floor. She wanted Pfizer to know that because she needs money and she shouldn't of even gotten the COVID vaccine. Now she has got to get the second one since she had the first and she is scared to get the second one thinking that the same thing may happen. Also, as she was reading about it and this vaccine doesn't even help you, you can still have the virus from what she is reading and this vaccine is also unapproved. She says that she think that she has already spoke to someone about this, but as she was reading it she saw that really it is saying that it is an unapproved vaccine. She has to go Monday and Tuesday to her doctor, a specialist, and tell them what she went though which was horrible. She did have a severe reaction to this because she got so sick and she could of hit her head and injured her head but God put an angel there. She said she felt like she was fainting and that is why she called her supervisor right away. She said that when she woke up she said she wasn't going to come in to work today because the registered nurse said to go home and relax because it can take 3 days for the side effects to go away. She has been okay for right now. She has had a lot of fluids to drink since the nurse told her to do that and she has chicken noodles because she feels so weak. She is just concerned about the second one, it scares her. Why are they giving this Pfizer COVID vaccine. Is that the only one in the world. She is just curious. Patient declined to complete a full follow up report and said that she just wanted to let Pfizer know what she went though and if she would of gotten hurt then who knows what, but thank God nothing happened and an angel was there protecting her. Right now she just feels so weak. The outcome of event weak was not recovered. The outcome of other events was unknown. Information on the batch/Lot number has been requested.

Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium

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| 1357451 | 5/28/2021 | CO | 33 | M | 4/10/2021 | 4/10/2021 | <p>~~Pt received first Pfizer vaccine at 0920. At 0922 he became lightheaded and fainted. He fell out of his chair onto the floor. RRT was called at 0922.He regained consciousness and was alert to person and place. VS 02- 98% BP 86/36 House supervisor and Pharmacist arrived at 0923. Pt was conscious and talking. He did not report any injury to his head or neck. He states he hit his shoulder and may have bitten his tongue. Observed a small contusion on his tongue. No bleeding at this time. He denies being diabetic. 0927-Vital signs O2 97% BP-104/64 Pt sat up and was given juice. He states he feels better and has fainted before with blood draws. 0931 Vital Signs-BP 97/82 O2 96% 0945 Vital signs BP 96/77 O2 98% Pt standing up and able to walk to hallway. Given water and a granola bar. 0949- Pt called his wife. 1002 BP 108/73. He states he is feeling better, and standing. 1005-BP 123/80 1010 Pt escorted to elevator and to Cafeteria. Reports no pain. He states he feels well and will eat something more and go home. ~~</p> |
| 1357463 | 5/28/2021 | DC | 43 | F | 5/27/2021 | 5/27/2021 | <p>Systemic: Abdominal Pain-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Severe, Systemic: Hypotension-Medium, Systemic: Nausea-Medium</p> |

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1357471 | 5/28/2021 | OH | 60 | M | 3/3/2021 | 4/7/2021 | <p>Passed out in traffic; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out in traffic) in a 61-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 025D21A) for COVID-19 vaccination. No Medical History information was reported. On 03-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 07-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 07-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (Passed out in traffic) (seriousness criteria hospitalization and medically significant). The patient was hospitalized from 07-Apr-2021 to 09-Apr-2021 due to LOSS OF CONSCIOUSNESS. At the time of the report, LOSS OF CONSCIOUSNESS (Passed out in traffic) had resolved. No relevant concomitant medications were provided. No treatment medication was provided. Patient also went to emergency room on 10 Apr 2021 and was examined for stroke and heart which came normal. No treatment information was provided. He wanted to know if Moderna can pay bills for the incurred loss. Company comment: Based on current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded. This case was linked to MOD-2021-142984 (E2B Linked Report).; Sender's Comments: Based on current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded. MOD-2021-142984:dose 1 case</p> |
| 1357617 | 5/28/2021 | CA | 19 | F | 5/25/2021 | 5/25/2021 | <p>Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Headache-Mild, Systemic: Hypotension-Mild, Systemic: Nausea-Mild</p> |

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1357627 | 5/28/2021 | NE | 53 | F | 5/27/2021 | 5/27/2021 | Systemic: Fainting / Unresponsive-Medium, Additional Details: Patient lost consciousness within one minute of receiving covid-19 vaccine. Regained consciousness within a few seconds. Checked vitals which were stable and had patient lie on floor with feet up. Monitored patient for at least 30 minutes and rechecked vitals which were stable. Patient reported no further issues upon follow-up a few hours later |
| 1357652 | 5/28/2021 | SC | 31 | M | 5/27/2021 | 5/27/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Hypotension-Severe |
| 1357666 | 5/28/2021 | TX | 20 | M | 5/17/2021 | 5/17/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Seizure-Mild, Additional Details: While sitting on the chair, patient fainted and started to have seizure for 1-2 second then recovered completely by himself. Called 911 but patient did not want to have any medical attention. After that, patient sit for more than 30 minutes before going home. |
| 1358268 | 5/28/2021 | MD | 18 | F | 5/28/2021 | 5/28/2021 | AFTER ADMINISTRATION PATIENT FELT PASSING OUT. ANXIOUS, TURNED EXTREME PALE, SWEATING, SHAKING, NOT ALERT, SHOWED SIGNS OF FAINTING, CALLED 911. OBSERVED ALL TIME . PATIENT STARTED FEELING BETTER AFTER 10 MINUTES . ALL VITAL WERE NORMAL EXCEPT BP WAS LO W. PATIENT DID NOT REMEMBER WHOLE EPISODE WHEN GOT BACK TO NORMAL. |

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| 1357348 | 5/28/2021 | GA | | M | | | <p>Passed out; This is a spontaneous report from a contactable consumer. This consumer reported for a male patient (nephew) reported that. A 30-years-old male patient received first dose of bnt162b2 (Pfizer covid vaccine, Solution for injection, Lot number was not reported), via an unspecified route of administration, administered in Arm on an unspecified date as 1st dose, single for covid-19 immunization. Medical history included allergy (to an unknown medication). The patient's concomitant medications were not reported. On an unknown date the patient experienced passed out. It was reported that the patient suddenly passed out and was rushed to the hospital after the first dose of the Pfizer covid vaccine. The patient is healthy and has an allergy to an unknown medication. The patient went to get the shot and then passed out. The patient passed out at the facility where he received the vaccine and was then rushed to the hospital and hospitalized. The caller is unsure when this event happened or the dates that the patient was hospitalized. The patient was released from the hospital the same day he was admitted. The caller mentions that the patient did not eat anything the day of the vaccine, prior to receiving the vaccine. The reporter asked Should the patient get the second dose of the vaccine. Is there any data on not eating all day and if that was an issue. The hospital ran all sorts of test on the patient and everything was fine. He had one shot he had one. And reporter wondering about getting the second one. The reporter stated, Okay, so I have a question about the Pfizer vaccine, so his 30 year old pretty much healthy nephew took the Pfizer vaccine and he passed out and they took him to the hospital (not clarified further if hospitalized or not, hence not captured in event tab) and ran bunch of test, he was fine, but he didn't eat all day. Do they have any data that shows if you don't eat all day you could have that kind of a reaction? Because the thing you know if is going to end up in the hospital I hate for him to have a second one you know what I mean, but if it is related to him not eating then that's another story. Well, I am wondering if they had data on anyone who had not eaten all day and whether or not there were reactions of that. Reporter was sure they tested every possibility when they tested this Pfizer vaccine. The patient underwent lab tests and procedures which included investigation: everything was fine. The event's</p> |

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| 1359020 | 5/28/2021 | CA | 34 | F | 5/28/2021 | 5/28/2021 | seriousness was captured as hospitalized and medically significant. The clinical outcome of the event was unknown. |
| 1358721 | 5/28/2021 | NY | 29 | M | 5/25/2021 | 5/25/2021 | Patient has phobia of needles and had a syncope episode. Vital signs are stable. Ammonia capsule used patient reacted well and recovered fully. |
| | | | | | | | Moderna COVID-19 Vaccine EUA Per EMT Chief Complaint: Dizziness 10:23 AM B/P 128/82 Pulse 46 Respirations 18 10:33 AM B/P 126/80 Pulse 48 Respirations 16 Patient CAO X 4, complaining of dizziness, pupils dilated, fisting with hands, appears nervous, vitals stable, pulse rate low but patient states he is a runner/soccer player. BLS assessment conducted, no issues noted, had breakfast, denies diabetic or similar history. Physician on site evaluated patient, appears to be anxiety, patient declined EMS, released when dizziness subsided. Instructed to monitor symptoms, seek medical attention for anaphylaxis or near syncope symptoms. |

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| 1358728 | 5/28/2021 | CA | 35 | M | 5/28/2021 | 5/28/2021 | Patient had fainted after receiving the vaccine and when I came to see him, he was back on the chair. He said he felt faint. I asked if his breathing was alright, his sight and hearing was ok; he said everything was fine, but he still felt faint. Then I saw his eyes closing again and he slouched down on the chair and became unconscious. I helped him onto the ground, where he started shaking, so I rolled him onto his side. He felt clammy. It was a few seconds before he stopped shaking and opened his eyes again. I asked him to stay laying on the ground and asked him again regarding his breathing, hear rate, vision, how he felt. He asked if he passed out again and I told him yes and we're going to keep him on the ground until paramedics arrive. He said he felt better; his breathing and speech was fine, there wasn't any sound of shortness of breath, but he was sweating in cold sweats and he asked us to fan him. He said that he felt better and that he has a big phobia of needles, which his wife who was there, confirmed. He informed me that he's fainted several times at doctor's office and hospitals when they stick a needle in him. When the fire fighters arrived, they spoke to him prepared to get a EKG on him, to which he immediately told them that he doesn't want them to stick any needles in him and he became frightened that the EKG pads were needles. When paramedics came, they determined that they had to take him to the hospital because they said he wasn't able to stand up on his own without falling over and his heart rate was increasing. |
| 1358736 | 5/28/2021 | MA | 29 | F | 5/25/2021 | 5/26/2021 | patient called a couple of days later, explained to me she passed out, her eyes rolling in the back of her head, was unconscious and husband was scared, called 911 ambulance took her to ER , patient is home and appears to be doing well |
| 1358751 | 5/28/2021 | FL | 44 | M | 5/28/2021 | 5/28/2021 | Patient received his vaccine and sat down in an alternate chair. He stated that he started to feel dizzy and then passed out. The patient regained consciousness fairly quickly. He did fall on the ground out of the chair, but did not hit his head. EMTs were called and he was checked out. He was able to leave saying he felt much better. |

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| 1358757 | 5/28/2021 | CA | 15 | F | 5/28/2021 | 5/28/2021 | Approximately 10 minutes after the 1st dose, the patient fainted in the store and hit the back of her head. She regained consciousness immediately. She was alert but pale and complained of pain on the back of her head. |
| 1358779 | 5/28/2021 | AL | 14 | M | 5/28/2021 | 5/28/2021 | patient received vaccine and immediately passed out and hit the floor. he woke up soon after and we gave him some water and crackers and he felt better. we called the ambulance and they came and checked him out and he was fine so he and his mom went home. he walked out on his own and was fine. no issue at the injection site, etc. i think he just passed out from nerves and not eating all day. |
| 1358795 | 5/28/2021 | TN | 22 | M | 4/1/2021 | 4/5/2021 | A few days after being vaccinated, I had experienced dizziness, fainting while at physical therapy. When laid on the table, I noticed I had tightness in my chest, like I couldn't catch my breath. They took my blood pressure, and it was 136/88 pulse rate of 88. These issues continued to persist. I went to the doctors to discuss the issue with a PA. She took an EKG, and found no abnormalities, although I wasn't having an episode at the time. I later felt palpitations in my chest. (my heart would race spontaneously at times for no longer than a few seconds.) The PA as well as my Doctor, had confirmed I had high blood pressure. I began to eat healthier and lose weight in order to change the blood pressure issues. The first appointment, I was 284. The second appointment which was in late April, I was 264, and my blood pressure was in the mid 120's over upper 70's, with my pulse rate in the 70's. The most recent appointment, I became more liberal with my diet and gained weight, weighing 268, but my heart rate continued to lower to a normal point, regardless (low 120's over 68, Pulse rate in the 60's.) Dr. and I had discussed possible causes, and I still have a cardiology appointment to follow up with, and we agreed that with the recent notice of myocarditis in vaccinated young adults and kids, it's a strong possibility the vaccine may have caused my issues, although I am to follow through with the cardiologist to confirm these suspicions. |
| 1358172 | 5/28/2021 | OH | 25 | M | 5/28/2021 | 5/28/2021 | syncope |

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| 1358818 | 5/28/2021 | | 24 | M | 5/28/2021 | 5/28/2021 | patient experienced syncope within 5 minutes of vaccine |
| 1358603 | 5/28/2021 | CA | 14 | F | 5/13/2021 | 5/13/2021 | Participant's mother states her daughter received the vaccine around 3:30pm. PT mother states her daughter felt a headache, felt dizzy and then had a syncope at around 6:00pm. 911 was called. PT mother states they went to the hospital where lab work was done. They told her that her daughter's potassium, iron and sodium was low. The medical staff said she was excessively dehydrated. Her mother states as for today her daughter gets easily dizzy after she eats, and gets headaches, feels light headiness and I have been IV liquids to give her levels up. |
| 1359265 | 5/28/2021 | CA | 33 | M | 5/28/2021 | 5/28/2021 | Patient fainted approximately 5 minutes after receiving his first Covid vaccine. Patient regained consciousness with the smell of an alcohol pad, but our pharmacy staff did call 9-1-1. EMT's arrived within a few minutes and ensure patient was healthy to leave the pharmacy/store. |
| 1359272 | 5/28/2021 | CA | 39 | M | 5/18/2021 | 5/28/2021 | PER PT - FAINTED, PER RPH SEEMS LIKE A SMALL SEIZURE FOR 3-5 MINUTES. CLIENT DID NOT RESPOND BUT WAS BREATHING THE WHOLE TIME - UNRESPONSIVE ON THE COUCH LAYING DOWN. RPH CONTINUE TO MONITOR BREATHING AND AFTER A FEW MINUTES THE PATIENT GAIN CONSCIOUSNESS. THE PATIENT BECAME FULLY AWARE OF LOCATION AND WHAT HAPPENED. STAFF CALLED 911 BUT WHEN THEY ARRIVED PATIENT REFUSED HELP. |
| 1359298 | 5/28/2021 | CO | 25 | M | 5/28/2021 | 5/28/2021 | After 2 minutes of vaccination, patient passed out and had an absent seizure. However, it lasted about 1 to 2 minutes, he was able to wake up by himself. |

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| 1359307 | 5/28/2021 | CA | 50 | F | 5/23/2021 | 5/24/2021 | ~~Pfizer-BioNTech Covid 19 vaccine EUA": About 24 hours after my second shot, I felt strong nausea, losing control of the environment, feeling very unwell, weak, blood pressure must have dropped, my vision had darkened, I was about to collapse on the floor had I not reached my bed quickly. Couple of minutes later I had the urge to vomit but nothing came out, and then I had a normal bowel movement. After all that, I felt like the pressure had been released, took 1 tylenol, and went back to bed to rest. It's been 4 days now since the fainting symptoms, and I've been fine so far. The scary part was really the fainting symptoms, I wasn't expecting that. |
| 1359529 | 5/28/2021 | WA | 20 | F | 5/26/2021 | 5/26/2021 | About 5 min after giving the vaccine, patient complained of not feeling well. Symptoms included headache, loss of sensation in arms, light headedness. Patient appeared pale, and confused. Attempted to have patient stand up and walk to counsel room opposite where she was sat. After standing, she immediately sat down, and fainted while she was seated. Pharmacist supported her head, and her boyfriend/significant other prevented her from falling off the chair. Patient was momentarily unresponsive for about 3 seconds. During this time her eyes remained open. Once patient regained consciousness, walked her to counsel room and had her lie down on her back with her legs elevated on a chair. Blood pressure was within normal limits. Patient was feeling better in about 10 minutes, and continued to monitor for another 5. Gave water to sip on, and no additional adverse effects noted. |
| 1359534 | 5/28/2021 | NM | 64 | F | 5/28/2021 | 5/28/2021 | Patient Fainted for few minutes and looked like she was seizing. Few minutes she was back up to normal and stated that she fainted every time after a shot |
| 1359541 | 5/28/2021 | TX | 16 | M | 5/28/2021 | 5/28/2021 | About 10 mins after shot, fainted with eyes rolling back in head, convulsions for a few seconds. Patient helped to lay on floor. Showed confusion for a few seconds and then came to. EMTs checked vitals and blood sugar levels and said things were normal. Visited urgent care facility a few hours later where physician said episode was likely vasovagal syncope. |

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| 1359730 | 5/28/2021 | | 22 | M | 3/25/2021 | 5/27/2021 | Sitting In a hot tub and started feeling faint and then climbed out and passed out |
| 1358817 | 5/28/2021 | AK | 18 | F | 5/28/2021 | 5/28/2021 | Patient passed out a couple minutes after vaccine was administered. She was disoriented when she came to. I give her some Gatorade and she seemed ok for a couple minutes then she passed out again for 30 or 40 seconds. She was disoriented and confused when she came to. She laid on floor for 15 minutes with her elevated and then sat in waiting area with her dad for 20 minutes. She said she felt fine and color returned to her face. |
| 1358374 | 5/28/2021 | IN | 18 | M | 5/28/2021 | 5/28/2021 | After receipt of vaccine, patient felt faint as he was sitting down in waiting area. Subsequently fainted and was taken to the emergency department for evaluation |
| 1358288 | 5/28/2021 | WI | 18 | F | 5/28/2021 | 5/28/2021 | After about 2 minutes of getting her shot she passed out and fell onto the floor. She became conscious again within a minute we gave her some water. I had somebody call 911 and an ambulance came. While the ambulance was here she seemed to be turning pale in the face. The ambulance ended up taking her to the hospital for further evaluation |
| 1358291 | 5/28/2021 | NJ | 33 | F | 5/21/2021 | 5/22/2021 | I got dizzy, passed out, and threw up twice. |
| 1358299 | 5/28/2021 | NJ | 32 | F | 5/27/2021 | 5/27/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Nausea-Mild, Systemic: Seizure-Mild, Systemic: Vomiting-Mild, Additional Details: PATIENT STARTED FELLING DIZZY SOON AFTER THE VACCINE. KEPT LOOSING CONSIUSNESS. STARTED THROWING UP SOON AFTER. |

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| 1358311 | 5/28/2021 | MI | 16 | F | 5/27/2021 | 5/27/2021 | Patient received the Pfizer vaccine. Patient left to sit in out waiting room after vaccine. Patient's mother informed in a few minutes that the patient was not feeling well. She stated that the patient felt hot. I grabbed an ice pack on my way out to her. I put the ice pack behind her neck. Patient passed out within a minute of me getting to the patient. She came back to quickly and stated that she was having a hard time seeing and hearing. She then again passes out. At this point I made the decision to call 911. I delegated to my tech to call 911. She called 911. I asked my other tech to come help me thinking the patient my have needed to be lower to the ground. The patient again regained consciousness. At this point I asked tech to call our Store Director and inform them. I also asked that she get me a water for the patient. The patient was feeling better and drank some water. She then again passes out. This time we were struggling to get her to regain consciousness. I used sternal rubs to help the patient regain consciousness. I was having a hard time finding her pulse. This lasted for a minute or two and then she started responding. Right then EMS arrived and took over. I gave them the information I had and they took her vitals. EMS decided that she was stable and could go home to be monitored by mom. I did call the Mother the next morning to check on the patient. The patient did well last night and was feeling good this morning. |
| 1358328 | 5/28/2021 | MA | 12 | F | 5/14/2021 | 5/14/2021 | Within 3-5 minutes, she was asking for water and feeling hot. Her back was sweaty. Her eyes looked like they were glazed- not responding; didn't look bright. She got some water and an ice pack on her back and removed her shoes and put her feet up. After drinking the water and keeping the ice pack on for the rest of those 15 minutes. Nurses were there watching her. And she was able to walk out of the clinic on her own power. It had looked like she maybe would have passed out without the intervention of water, ice pack and getting her feet up. She had muscle pain in her arm (of injection site) that day and into the next day. The muscle pain in her arm lasted for about 24 hours. |

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| 1358342 | 5/28/2021 | IL | 59 | M | 5/27/2021 | 5/27/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Nausea-Medium, Additional Details: Patient became unresponsive with gasping but remained with normal pulse, pt came to within a minute |
| 1358363 | 5/28/2021 | CA | 17 | F | 5/27/2021 | 5/27/2021 | at 2:30pm pt had temporary loss of consciousness for approx. 15 seconds pt. was safely assisted to gurney and placed in supine position with BLE elevated. vitals monitored VS BP 97/67 P-65 RR-17 o2SAT 97% RA pt offered fluids and snacks pt refused snacks pt had water. 230pm pt denies dizziness no headache no SOB no lightheadness vitals BP80-/50 17,69, 98%RA 245pm pt bp still cont. to be below normal. bp 87/57 P-63 RR-18 o2SAT 97% RA pt was recommended to sent to hospital for further eval. 255pm 911 came and elaluated pt per paramedics based in theri eval. pt. &mother was made to choose to go to the hospital or go home pt. and mom choose to go home. #23 Syncope #21 went home against med advice |
| 1358365 | 5/28/2021 | AZ | 21 | F | 5/28/2021 | 5/28/2021 | Patient fainted less than five minutes after receiving the vaccine, and was unconscious for less than 60 seconds before waking up and sitting up. Complained of ankle pain and that she was feeling hot. Paramedics were called to assess vital signs. Patient walked out of the store after finishing with paramedics. |

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| 1358643 | 5/28/2021 | FL | 31 | F | 5/3/2021 | 5/4/2021 | On May 4th, I fainted shortly after waking up. Light headed and unable to sit upright, stand, or walk. Had a fever. Called out of work. Headaches, chills, nausea, pain at injection sight, bedridden for most of the day. Around 3/4 in the afternoon I called the doctor's office (phone kept ringing) so I called the nurse through the insurance company. Nurse advised me to stay home for now but to seek medical care if symptoms persisted for more than 3 days. Symptoms continued but were less severe on Wednesday May 5th causing me to miss another day of school. On Friday May 7th at about 12:50 AM I awoke to severe abdominal pain-the kind the pharmacist had warned me of when getting my vaccine. I could not stand or move. I never take aspirin and yelled for a family member to give me Tylenol. I called the nurse from my insurance company and she asked me a series of questions and advised me to seek immediate medical attention. My family called 911 and an ambulance was sent to the house. They checked my vitals and suggested a family member take me to the ER. My family took me to the Emergency Center. I was wheeled into the ER. ER did test but put "Abdominal Pain, Unknown Cause, (Female) on my paperwork. I missed another day of work due to my ER visit. Symptoms lessened but persisted for several days. |
| 1358367 | 5/28/2021 | CA | 19 | M | 5/28/2021 | 5/28/2021 | Pt has syncopal episode 14-15 minutes after vaccine. Pt sitting in chair during observation and suddenly passed out. Pt was able to come out of syncopal episode within a few seconds (10-15 s) after RN approached him. Pt states he felt dizzy for 30 seconds and passed out. Pt was dazed /confused and pale when awoken. Pt states he did not have breakfast this morning and last had a meal yesterday evening. Pt denies having syncopal episode in the past related to blood draw or vaccines. Vital signs taken initially (at 1041) after syncopal episode were as followed: BP 84/47, HR57, SpO2 97%, pt given granola bar, ice water, and ice pack applied in back of head. After patient was able to regain skin color back, drink full cup of ice water, and eat whole granola bar, vital signs were taken again as followed at 1052 105/50BP, HR71, spO2 97%. Pt placed in gurney to be taken to treatment room. RN gave report to treatment room RN. Pt AOX4 when, able to follow commands. |

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| 1358613 | 5/28/2021 | WA | 21 | M | 5/28/2021 | 5/28/2021 | Patient got vaccinated and was walking over to observation area. Before he sat down, he passed out, hitting his face on the ground. |
| 1358396 | 5/28/2021 | IL | 67 | F | 3/16/2021 | 3/18/2021 | On Thursday, 3/18, I woke up at 3:30 am extremely dizzy with everything moving around me. Sitting up was better but upon laying down, the extreme dizziness returned. I was still dizzy when I finally fell back asleep. In the morning, I nearly passed out & was in a cold sweat when I got up. Gatorade helped. My PCP's office said it was probably a vaccine reaction. I continued to feel rather light headed & neck pressure & by Tuesday, 3/23, I had a lot of body aches, diarrhea, I was definitely light headed & felt like I could pass out. Over the next days, my blood pressure was very unstable. This random blood pressure issue continued & then the Premature Ventricular Contractions (PVC's) began to increase in spite of the Metropolol. They became very frequent causing light headedness & neck pressure. On 4/12, I went to the ER because my blood pressure was 185/50, heart rate 92. Every 3rd beat was a PVC. The cardiologist changed me to Verapamil 120 mg/day. My condition deteriorated especially in the 3 days prior to the ablation. I was short of breath with weak extremities. The ablation was done on 5/25 & the Cardiologist said I was having PVC's every 2 seconds. I am currently recovering from the procedure. Prior to the 2nd vaccine shot, my PVC's were well controlled by Metropolol to 18% from the 21% in February 2019 prior to taking Metropolol. My blood pressure was consistently normal as well. |
| 1358440 | 5/28/2021 | VA | 12 | M | 5/28/2021 | 5/28/2021 | Systemic: Dizziness / Lighthadness-Medium, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Hypotension-Medium |

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| 1358443 | 5/28/2021 | PA | 19 | F | 5/28/2021 | 5/28/2021 | Mother alerted pharmacists before administration that their daughter experiences syncope with needles. The mother sat by her side as I administered the vaccine. The patient said that the vaccine hurt and sat there for about 5 minutes. At that time the patient said she did not feel well and laid on the ground. It is unclear if patient passed out for a few seconds. I spoke with patient to make sure she was conscious and then monitored her to look for signs of anaphylaxis. Her symptoms appeared to be related to anxiety rather than anaphylaxis. The pharmacy did call 911, but the patient and her family turned down the emergency service. I sat with patient for about 45 minutes to monitor her condition. When she improved they decided to leave that pharmacy. I did suggest they be looked at by a physician. We also called and check on patients well being and she seems to be doing fine. |
| 1358480 | 5/28/2021 | VA | 31 | F | 5/17/2021 | 5/17/2021 | passed out in my car while i was driving on the highway. woke up in my car in the ditch |
| 1358513 | 5/28/2021 | NY | 17 | F | 5/18/2021 | 5/19/2021 | She had been bleeding since May 2. We took her to Hospital Pediatric ER on Thursday, the ambulance took her in because she had a seizure on Wednesday (the Ambulance - they stabilized her that day and took her vitals and was sure she was okay - they knew we had an appt to go in the next day at 10:00 am for tests (previously scheduled); Thursday morning she had another seizure - we gave her seizure meds and she came out that - she ate breakfast after and then took her regular meds and the next thing we know, 50 minutes later, her head drop forward and her arms go completely limp and there was no response. She was breathing but she was out. I called the ambulance. And they took her in to ER. What they put in the paperwork was that she had a seizure and they wrote that she had had syncope episode - it took 20 minutes to come out of it. Which she has never had anything like that. We were in the ER for 7 hours. Was admitted to Hospital -from 24th -28th. |

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| 1358551 | 5/28/2021 | AZ | 24 | M | 5/28/2021 | 5/28/2021 | Patient reported dizziness 5 minutes after he was administered the vaccine and then was reported by his sister he was fainting. Call 911, patient was monitored while waiting for EMS arriving to the store. Patient get his consciousness back, response to our questions. His breathing was normal, skin looked pale. Patient felt better after EMS came, got monitoring for more than 30 minutes and then went home. |
| 1358559 | 5/28/2021 | PA | 58 | M | 5/18/2021 | 5/19/2021 | Hx of COVID in Feb 2021. Hospitalized Days 8-10 (No vent). Day 8 had high fever, dehydration, syncope and delirium. Vaccinated with dose 1 of Moderna on 5/18/2021. Next day had high fever (102.8), dehydration and altered level of consciousness. Taken to ER. Improved with IV fluid, observed and discharged. Physician does not recommend dose 2. |
| 1356510 | 5/28/2021 | WA | 47 | F | 5/17/2021 | 5/17/2021 | During shot administration (which was angled from the bottom, up rather than straight in), I felt burning. The injection site bled, and the nurse had to staunch it a bit. Injection site burned/stung as I drove away to wait in line in the parking lot and for a few more minutes. Then my arm swole up around the injection site to a size of about a silver dollar and maybe 1 cm high. Four nurses monitored me, including the one who gave the shot, but she did not talk and stood slightly behind my driver's side window. They let me go after maybe 25 minutes of monitoring and making sure I was OK, and what seemed like the head nurse gave me her phone number and asked me to report in in 24 and 48 hours to let them know how I was doing. I reported 24 hours later that I developed a 99* to 100* fever, chills, and slightly achy joints over night and experienced that for one day. I texted again around 48 hours to let her know those symptoms were gone, I felt a little dizzy now and again, and I developed a bruise around the injection site. I took a photo and texted that to her. She was very kind in asking me to report my adverse effects and get care if needed. As of this typing, 10 days later, I still have a slight bruise, and I have experienced heartbeat lapses once or twice a day. Yesterday (9 days after shot), I was sitting on the toilet resting (not exerting) and felt my heart beat hard four times slightly faster than it was at resting pace. I've experienced minor dizziness off and on but not fainted or blacked out. |

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| 1358366 | 5/28/2021 | VA | 24 | M | 5/27/2021 | 5/27/2021 | Patient became light headed and passed out. Lost consciousness for less than 5 seconds and then sat up. Was sweaty but quickly felt better. Gave patient orange juice as he had had nothing to eat or drink since last night. He would not allow us to call the ambulance for him. told him to wait around for 30 minutes after he stated he as feeling normal allowed him to leave. Spoke with patient today and said he was feeling fine. |
| 1357030 | 5/28/2021 | NY | | M | | 5/21/2021 | SEIZURE (PASSED OUT); WEAK; This spontaneous report received from a consumer concerned a male of unspecified age. The patient's height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, administered on 21-MAY-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 21-May-2021, the patient got the vaccine and passed out, patient had 2 seizures. patient had not eaten much during day so patient might have been weak. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the seizure (passed out) and weak was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: covid-19 vaccine ad26.cov2.s-seizure (passed out). This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s). |

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| 1355009 | 5/27/2021 | | 42 | F | 5/23/2021 | 5/23/2021 | Charge nurse called to attend to patient after receiving her second Pfizer vaccine. Family members reported she was anxious since yesterday about receiving her second Pfizer vaccine today. It was reported by patient that she had symptoms of nausea, dizziness and anxiousness today. As per her family same thing occurred with her 1st Pfizer vaccine. She denied any significant Medical hx , other than decreased vision, which she does not take any medication for. Charge nurse and vaccinating nurse, moved her to a private tent to vaccinate her and to be monitored. Charge nurse and myself elevated her feet, and had her take sips of water. Wet cool cloth was applied to the back of her neck. She confirmed she felt better after the cloth. She was left in stable condition with vaccinating nurse. I was called back at 1330, because she felt with SOB and more anxious. She did not have any emesis at any point while she was at vaccination site, and no syncope occurred. She was more relaxed after breathing exercises. She was walked over in stable condition closer to EMT to be monitored closely. Vitals were taken. At this time, she was more relaxed and denied any nausea, headaches, SOB or any other symptoms. Family members continued to give her water and she was able to sustain without any emesis. Pt left with family members at 1400, in stable condition. |
| 1354771 | 5/27/2021 | CA | 30 | M | 5/26/2021 | 5/26/2021 | Per patient, he has a history of fainting with immunization. Pt felt dizzy after shot was given. Pt was given water and snack to eat while being monitored. Heat may have been on contributing factor. Patient felt nauseous and threw up about 15 minutes after shot was given. Patient stated he felt better as soon as he threw up. Patient was accompanied by spouse. After more than 30 minutes of being monitored, patient was able to go home to rest. |
| 1354847 | 5/27/2021 | CA | 55 | F | 5/22/2021 | 5/23/2021 | 24 hours after receiving the 2nd dose of Moderna, Patient passed out and fell to the floor, unresponsive for about 10 minutes. |
| 1354865 | 5/27/2021 | FL | 24 | M | 5/27/2021 | 5/27/2021 | PATIENT REMAINED SEATE AFTER VACCINATION, AND ALERTED US AFTER THAT HE HAD JUST PASSED OUT. HE WAS SWEATY AND SEEMED PALE AND LIKE HE WAS LIGHT HEADED. |

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| 1354897 | 5/27/2021 | NY | 45 | F | 5/24/2021 | 5/24/2021 | Massive pulmonary embolism resulting in syncope and hypoxia |
| 1354933 | 5/27/2021 | OH | 47 | M | 4/29/2021 | 4/30/2021 | Around 2 AM the (approx. 12 hours after he received the vaccine) patient got out of bed to use the restroom, felt dizzy, and fainted. |
| 1354940 | 5/27/2021 | DC | 47 | F | 4/14/2021 | 4/16/2021 | I experienced dizziness, nausea, disorientation and fainted while standing. I hurt my head, knee and thumb, but was otherwise ok. I don't know how long I was out and woke up on the floor. :(|
| 1354952 | 5/27/2021 | | 21 | M | 5/26/2021 | 5/26/2021 | Pt w/ allergies to shrimp. Pt w/hx of fainting when getting vaccinated. Pt c/o blurry vision, dizziness. BP 94/49, HR 60, RR 18. Pt A&Ox4. VS Stable. Cleared to go home by NP. Recommended pt to get second dose while lying down. Pt stable and released from the vaccination site. |
| 1355000 | 5/27/2021 | CA | 12 | M | 5/26/2021 | 5/26/2021 | sees black, dizzy, blurriness, clammy skin, diaphoretic 84,16, 82/42 86/58, 99, 16, 98% given juice, icepack-- felt better no meds, no previous fainting episode |
| 1354731 | 5/27/2021 | TN | 12 | M | 5/26/2021 | 5/26/2021 | Called out to vehicle by Covid staff that a patient had passed out. Upon approaching vehicle, patient is in passenger side of his mothers van, with mother in driver seat, and is awake. Patient is very pale and is sipping on Powerade. Mother reports that patient passed out for about 10 seconds about 3 minutes after receiving Covid vaccine. She also reports that patient does this every time he gets any type of injection. Blood pressure at this time 118/60. Patient is becoming less pale and reports he is starting to feel better. Patient reports that he hasn't had anything to eat or drink all day. Patient and mother deny the need to call the ambulance for evaluation. Patient continues to be less pale and feeling better. Encouraged patient and mother to always eat and drink before receiving an injection and to wait at least 15 minutes and to make sure he is feeling completely back to normal before leaving. Patient and mother report good understanding. |

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| 1355027 | 5/27/2021 | WA | 32 | M | 5/22/2021 | 5/22/2021 | Patient was waiting in a chair after the vaccine and bent over to pick up a phone off of the ground. He got lightheaded and passed out as he was bending over. The patient hit his head and briefly passed out. We got him to the ground slowly and provided him with an ice pack and bottle of water. He was breathing quickly and shallowly for about 30 seconds but returned to normal shortly after. |
| 1355054 | 5/27/2021 | CA | 12 | M | 5/26/2021 | 5/26/2021 | sees black, was dizzy, blurriness, clammy skin, diaphoretic. Apple juice, Graham crackers, icepack, fan air-- felt better, having whole conversation, no complaints 18: 50 --84,16, 82/42, 18: 58-- 86/58, 99, 16, 98% monitored for 30 minutes, walked out of clinic with parent in stable condition give juice, icepack-- better no meds, no previous fainting episode |
| 1355062 | 5/27/2021 | FL | 27 | M | 5/27/2021 | 5/27/2021 | Patient stood up and walked over to register and said he didn't feel so well. I came around the pharmacy and he was fainting as I got to him. Technician called paramedics, store manager was called and when I asked him his name and if he knew where he was he said yes. We sat him up per his request. When he was well enough we sat him on a chair, I took his blood pressure and we got him water. He was on the phone with his dad who is a physician and dad said it sounded like a syncope and asked we give him gator aid. Paramedics arrived and they took his vitals and ran some tests. |
| 1355065 | 5/27/2021 | | 31 | M | 5/26/2021 | 5/26/2021 | pt got dizziness, fainted, shaking after 5 minutes of vaccine administration. His heart rate dropped to 60 and his blood pressure 105//70. pt was conscious and breathing on his own and felt normal after 30 minutes and went home with his family members. |
| 1355080 | 5/27/2021 | CA | 31 | M | 5/27/2021 | 5/27/2021 | PATIENT RECIVED VACCINE AND PASSED OUT WITHIN 5 MINUTES AND REGAINED CONSCIOUSNESS, EMTs responded and patient was released, patient's alternative domestic number listed above |
| 1355090 | 5/27/2021 | CA | 30 | M | 5/26/2021 | 5/26/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient regained consciousness in about 20 seconds after lying him on his back with leg elevated. |

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| 1355097 | 5/27/2021 | IN | 71 | M | 5/21/2021 | 5/22/2021 | 1st dose of Moderna was patient reported that he had decrease in appetite, was fatigued and sat in chair for days after his vaccination. Had no allergic reactions. Second dose was 5/21/21 at 11:10 AM. The next morning 5/22/21 passed out and fell on the floor when walking to the bathroom. Back pain and injured skin on both legs. Saw his PCP on Monday 5/24/21 for evaluation. |
| 1355101 | 5/27/2021 | MA | 37 | M | 5/27/2021 | 5/27/2021 | Patient received vaccine and then passed out about 10 minutes after, was taken to hospital |
| 1354983 | 5/27/2021 | IL | 14 | M | 5/27/2021 | 5/27/2021 | passed out in aisle of store 5 min after receiving vaccine. mother and sister have history of passing out (vaso-vagal rxn). mother, neighbor and pharmacist sat him up in chair in aisle while 911 was called. all stayed with patient until emt arrived and patient left with them. |
| 1354695 | 5/27/2021 | OH | 19 | M | 5/27/2021 | 5/27/2021 | Patient passed out within 45 seconds of vaccine, convulsed for 5 secs while unconscious. woke up with in a minute, vomited after 3 minutes. He was able to say his name and address. BP 116/69 Pulse 68. patient said that this has happened before after an unknown booster at age 17. Only ate french fries earlier today. Was able to stand after 5 minutes. Put cool paper towel on neck, ate fruit bar and drank water before leaving |
| 1354502 | 5/27/2021 | IL | 13 | M | 5/26/2021 | 5/26/2021 | Systemic: Allergic: Anaphylaxis-Severe, Systemic: Allergic: Difficulty Breathing-Severe, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Headache-Medium, Systemic: Weakness-Severe, Additional Details: pt was mostly unresponsive and turning white and motionless; throat closing up; no other choice but to give the epi-jr shot; after administering the shot the patient started to feel better but we decided to still call 911 to be on the safe side |

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| 1354533 | 5/27/2021 | NJ | 23 | F | 5/26/2021 | 5/26/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Nausea-Mild, Systemic: Tingling (specify: facial area, extremities)-Mild, Systemic: Visual Changes/Disturbances-Medium, Systemic: Weakness-Mild, Additional Details: Pt has history of fainting from needles that was not reported prior to vaccine administration. Patient began experiencing dizziness/nausea/blurry vision immediately after vaccine administration but did not have difficulty breathing or signs of swelling, no injection site reaction. Patient was laid down on her back with feet propped up and she began to feel better. She was evaluated by EMT and all vital signs were stable/normal, she had recovered by the time of emt arrival. |
| 1354541 | 5/27/2021 | TN | 18 | F | 4/9/2021 | 4/10/2021 | I started having chills and a fever and went to bed. I woke up the next morning brushed my teeth and i passed out and hit my head and was dehydrated. I stayed in the ER for about 5 hours. |
| 1354566 | 5/27/2021 | | 22 | F | 5/19/2021 | 5/19/2021 | Patient reports having a history of allergic reaction with first vaccine. Per patient she reports symptoms of hives, itching and syncope. Patient Pulse ox 98%, Hr 97, BP 114/68. Patient does have a history of allergies, POTTS. Patient felt itching, throat tightness, and cough after second vaccination (similar to first. Patient did not require EPI with first vaccin. On evaluation lungs sound clear, no edema. Patient took Benadryl 50mg and was provided Pepcid 20mg. Patient was observed for 30 minutes. Patient was discharged home with parent. |
| 1354597 | 5/27/2021 | MI | 63 | F | 5/20/2021 | 5/21/2021 | Began with headache, body aches, and feeling tired. Progressed to hives on stomach - called ER recommended I take Benedryl, I did. Hives progressed and worsened, I passed out and my husband had to call 911. I was taken by ambulance to the ER and admitted to the hospital. I stayed until on Monday 5/24/2021. I was released 1:30pm. Wednesday 5/27/2021 I felt jittery I called my PCP they could not get me in and recommended I go to the walk in clinic, I did and they reduced some of the medications I was put on from the hospital. I have a follow up appointment with my PCP 6/2/2021. |

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| 1354643 | 5/27/2021 | CA | 39 | F | 5/18/2021 | 5/18/2021 | Immediately after receiving the second dose of Pfizer on Tues May 18, I felt prickly sensations throughout my body. After sitting for the recommended 30 minutes (due to known allergies to previous medications), I began to feel dizzy. They monitored me in the tent for several minutes and checked my vitals, which were fine. The nurse thought I may have hyperventilated. I thought I must have just had a mild panic attack. But the attacks did not stop. Rather, the first three days post vaccine, I had several panic attacks a day, even being woken from sleep because of them. It's not fear or a racing mind but a constant racing heart, weakness, feeling faint. I feel prickly sensations and sensation of heat, which are common in panic attacks. But even after three days, they were not letting up. In addition to the attacks, I felt lightheaded, weak and extremely fatigued, even at rest. There is also constant pain and tightness in my neck and jaws. Thursday evening (May 20), I had an episode where I nearly passed out. Once I got seated, my body froze. I was unable to get my words out clearly. Instead of saying the full sentence in my head, I could only get a word or two out. Instead of being able to lift my arm to eat, I couldn't move. The episode lasted about 15-20 minutes. I had several of these episodes on Saturday, two on Sunday and one on Monday. Thinking it was purely anxiety, I reached out to my psychiatrist who prescribed Klonopin to ease the symptoms. I took 0.5mg on Friday afternoon (5/21) and 0.5mg on Saturday morning (5/22). Realizing the Klonopin was likely making my symptoms worse, I have not taken any since Saturday morning (05/22). Most of the day I am breathless, weak, feel faint doing nearly nothing. I have an hour or so a couple of times of day where I'm more functional but still have to move very slowly. Otherwise, I'm either like a zombie or unable to speak clearly, stuttering when I speak, and unable to operate without feeling faint. |

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| 1354651 | 5/27/2021 | OR | 63 | F | 4/2/2021 | 5/13/2021 | <p>H&P: Patient is a 63 y.o. female who presents for chest pain found to have NSTEMI. No prior cardiac history who presents with acute onset left sided arm, and jaw pain. Associated with diaphoresis. Looked up "heart attack signs in women" and came to the ER after reading this. In the days/weeks leading up denies any chest pain or pressure, LH, dizziness or syncope. No exertional dyspnea, orthopnea, PND or LE edema. BP at home are usually 130-150s. BP in the hospital is always higher because of white coat hypertension. ER course BP 170-190s systolic, HR in the 90s, AF. EKG Q waves in the inferior lead with no significant ischemia or ST elevations. Labs notable for a troponin ~ 2000. CXR within normal limits. Given aspirin, statin, nitro and heparin. Currently feels pain free. No other acute issues or complaints/ Smoked 3 mos after a divorce, otherwise no smoking history. No significant family history of CAD. " D/C summary: "Principal Diagnosis: o Myocarditis Secondary Diagnoses: o Type II MI o Hypertension o Hypercholesterolemia o Prediabetes mellitus o Obesity Procedures/Diagnostics: 5/13/2021. Coronary angiogram. o Normal left ventricular function o Normal coronary anatomy o Right radial loop Note: A right radial loop was encountered requiring a femoral access. 5/13/2021. Echocardiogram. ? Left ventricle size is normal. Mildly increased wall thickness. Normal wall motion. Normal systolic function. LV EF is 75 % , ? Nrrmal valve function. 5/13/2021. Cardiac MRI. Evidence of myocarditis, with subepicardial late enhancement at the mid chamber and apical lateral wall with associated regional edema and mild native T1 signal elevation. Normal right and left ventricular size. Hyperdynamic LV. No significant valvular abnormality. Hospital Course: In brief, this is a 63 y.o. year old female admitted on 5/13/2021 with chest pain, troponin elevation and found to have normal coronary arteries. Preserved LV systolic function by echocardiogram. She underwent an cMRI demonstrating myocarditis. She was started on colchicine and remained pain free for the rest of the admission. Myocarditis: Presented with acute onset chest pain and troponin of ~2000. Diagnosed via MRI after normal coronary angiogram. Normal biventricular function. Etiology is likely idiopathic as she had no other obvious inciting events. Pain free prior to discharge. o Colchicine 0.6 mg twice daily. o Follow-up with Dr. on</p> |

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| | | | | | | | 6/8 arrival time 12:40 PM Hyertension: well controlled today. Management per PCP o Metoprolol succinate 25 mg daily o Hyzaar 100-12.5 mg daily o Amlodipine 10 mg daily Hyperlipidemia: tolerating atorvastatin 20 mg daily. ~~ |
| 1354653 | 5/27/2021 | OH | 23 | M | 5/27/2021 | 5/27/2021 | Pt fainted during the 15 minute waiting period. Hit head. Recovered quickly. Was evaluated by rescue squad. |
| 1354742 | 5/27/2021 | | 15 | M | 5/24/2021 | 5/24/2021 | Patient had syncope and dizziness after 1st pfizer vaccine dose at another facility. Patient has previous history of syncope approximately 2 months ago after blood donation was seen and evaluated by cardiologist. Initially skin on face slightly pale, sweaty arms -improved after lying down on bed. Oriented X3, BP 95/57 O2 sat 99% HR 61, was offered apple juice and peanut butter crackers, left ambulatory with his mom, asymptomatic at time of discharge. |
| 1354683 | 5/27/2021 | MN | 15 | F | 5/27/2021 | 5/27/2021 | Patient fainted at check out desk. All necessary precautions were utilized. Patient walked to check out desk and started to fall forward. Desk staff and mom caught patient and lowered her to the floor. Patient became conscious and sent over to observation area and was monitored for 30 minutes. No injuries sustained during fall and was able to leave with mom. |
| 1354739 | 5/27/2021 | | 17 | M | 5/22/2021 | 5/22/2021 | After 10 minutes of administration the patient fainted. He was lowered to the floor and awakened almost immediately. BP was 127/65, pulse was 63. He was pale. A physician was in attendance the entire time. Once he was better he was transferred to a stretcher. Mother stated he had been at an overnight sleep over, she had picked him up from there and came directly to the clinic. He stated he had nothing to eat or drink that morning. he was given water and some snacks.. MD released him when he appeared to be back to baseline. He was seen in the pediatician's office on the 5/24/21 as a followup at the parent's request at which time no issues were found. Patient's father had asked the pediatician's office to see the patient following the innoculation that day which the office deferred as an MD was attending this patient in the clinic. |

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| 1354697 | 5/27/2021 | DC | 38 | M | 5/17/2021 | 5/20/2021 | Unexplained fainting at approximately 9:00 pm on 5/20/2021; unexplained persistent bruising possibly indicative of low platelet count, first noticed on 5/22/21 at approximately 4:00 pm and continuing to the present |
| 1354703 | 5/27/2021 | NJ | 19 | F | 5/25/2021 | 5/25/2021 | Patient fainted after receiving covid19 Pfizer 1st dose vaccination |
| 1354706 | 5/27/2021 | CA | 18 | F | 5/27/2021 | 5/27/2021 | Patient passed out a couple minutes post vaccination and recovered quickly. Patient's face was pale, feeling nauseous, no EPIpen was given as this doesn't manifest allergic reaction. Patient was given alcohol pad to smell on to reduce nauseous feeling and bottle of ice water. Patient recovered quickly after 10 minutes and was observed for additional 10 minutes, she was alert and was walking around the store. |
| 1354708 | 5/27/2021 | WA | 14 | M | 5/22/2021 | 5/22/2021 | Fainted 20 min after vaccine, after the waiting period waiting to check out. Vitals were taken and observed for another 20 min. Has been ok since. No additional symptoms. |
| 1354713 | 5/27/2021 | KS | 21 | M | 5/27/2021 | 5/27/2021 | Fainted approximately 5 minutes after administration of second vaccination. Time of unconsciousness was approximately 2 minutes. Patient stated no previous history of fainting. |
| 1354719 | 5/27/2021 | NC | 31 | F | 4/8/2021 | 4/8/2021 | passed out, later had chest pains, high blood pressure, high heart rate and was checked for a PE via catscan. Still experience racing heart periodically almost 2 months later. |
| 1354721 | 5/27/2021 | NY | 24 | F | 5/27/2021 | 5/27/2021 | Patient fainted at 10.15 when she was waiting in the waiting area after the vaccine. She quickly came about. PA and EMT treated for Vasovagal Episode. Patient mentioned she fainted previously at a flu shot y ears ago and that she hadn't eaten all day. Pulse ox and blood pressure was ok, blood sugar was low. She was given 15 mg liquid glucose. |

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| 1355128 | 5/27/2021 | MA | 70 | M | 4/1/2021 | 4/3/2021 | Fainted in apartment parking lot, on morning of April 3; transported to ER,, via ambulance. Hospital stay for several days, moved to Rehab, sent back to ER with a cough, trouble breathing, and swallowing. Diagnosed with pneumonia. Went into coma on 4/18. Passed away on 4/22/2021. |
| 1354678 | 5/27/2021 | TX | 44 | F | 5/25/2021 | 5/26/2021 | Fever 101.1, Fatigued, Dizzy, Disoriented, Fainted and fell off couch, hit head and knee |
| 1355813 | 5/27/2021 | CA | 15 | F | 5/26/2021 | 5/26/2021 | patient received the fist dose of Pfizer and started to experience syncope during her 15 minutes post-monitoring. EMT was called per mom's request because patient wasn't feeling good. Patient was escorted out with EMT. |
| 1355107 | 5/27/2021 | RI | 26 | M | 5/27/2021 | 5/27/2021 | Systemic: Fainting / Unresponsive-Medium, Additional Details: Patient was very nervous/anxious upon arrival. Shortly after the vaccine was given he became unresponsive and unconscious. 911 was called. Patient became responsive minutes later. Patient became unconscious for a second time while EMT was present. Patient was taken to the hospital. |
| 1355583 | 5/27/2021 | SC | 16 | U | 5/27/2021 | 5/27/2021 | passed out for at least 30 seconds, dizziness, lightheaded, black out, hot/clammy skin, sweating, ringing in the ears, disoriented 911 was called and responded to by both fire and medical paramedics vitals were taken and patient was observed for an additional 20 minutes before leaving when he had returned to a stable condition |
| 1355585 | 5/27/2021 | SC | 16 | U | 5/27/2021 | 5/27/2021 | passed out for at least 30 seconds, dizziness, lightheaded, black out, hot/clammy skin, sweating, ringing in the ears, disoriented 911 was called and responded to by both fire and medical paramedics vitals were taken and patient was observed for an additional 20 minutes before leaving when he had returned to a stable condition |
| 1355592 | 5/27/2021 | | 27 | F | 5/5/2021 | 5/5/2021 | patient fainted. |
| 1355600 | 5/27/2021 | MI | 17 | F | 5/27/2021 | 5/27/2021 | Fainted shortly after vaccination, patient was seated and assisted |

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| 1355604 | 5/27/2021 | CO | 28 | M | 5/27/2021 | 5/27/2021 | Administered 1st Pfizer dose to patient. Requested that patient wait 15-20 minutes in waiting area after vaccine. After 10 min, Patient signled me (the pharmacist) that he wasn't feeling well. As I approached, he stood up and started walking towards me. I took his arm, we took two steps and he fainted. I laid him to the ground while supporting his head. He regained consciousness quickly, but was disoriented. NP assisted by taking vitals/911 called. Paramedics arrived and then took over evaluation. Pt was taken to ambulance for further evaluation, as he still could not walk to diziness. |
| 1355765 | 5/27/2021 | MD | 13 | F | 5/20/2021 | 5/20/2021 | Before I administered the vaccine, the mother stated that she sometimes has an issue with fainting, but mainly at the doctor's office out of fear. She assumed that since this was a different environment, she would be okay. After giving her the shot , she fainted. The mom called 911. I waved an ammonia inhalant under her nose, and she was revived. Her twin brother informed me that she has been in an ambulance 4 times prior after getting shots. Had I known she had a history of fainting, I would have suggested that she receive the vaccine at the pediatrician's office once it becomes available. The mom refused to go to the hospital once paramedics arrived. She sat for 15 minutes, I applied a cool cloth, she drank water and was able to walk out on her own. |
| 1355777 | 5/27/2021 | CA | 14 | F | 5/27/2021 | 5/27/2021 | Pt fainted/syncope s/p vaccination. No head injury. Experience nausea. symptoms self-resolved and pt discharged home in stable condition with family. BP 93/56 HR 76 RR 16, unlabored SpO2 99% RA |
| 1355575 | 5/27/2021 | MA | 26 | F | 5/27/2021 | 5/27/2021 | syncope for few minutes, was able to communicate and was taken to Er for observation |
| 1355807 | 5/27/2021 | OH | 18 | F | 5/27/2021 | 5/27/2021 | Patient was administered Pfizer COVID-19 vaccine and fainted during her 15 minute observation time. Mother alerted pharmacy staff. Pharmacist observed patient regain consciousness. Patient reported feeling warm, was sweating, and saw spots of light. Patient was given a bottle of water and and instant cold ice pack. Patient observation time was continued. After fifteen minutes patient was feeling better and left pharmacy with mother. |

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| 1355569 | 5/27/2021 | CA | 18 | M | 5/26/2021 | 5/26/2021 | Patient is a 18 y.o. male who witnessed syncopal episode at 1605 yesterday s/p COVID vaccine. Patient says that he received a COVID vaccination yesterday at 1601. Per mother, the patient had a syncopal episode at 1605, he was sitting down and slid out of his chair with full extension of bilateral arms and legs, lasting about 30 seconds. Witnesses deny headstrike or shaking during syncopal episode. The patient denies pain. He states that he only ate cereal yesterday morning and has experienced similar symptoms in the past while receiving other shots. Patient denies recent trauma or fall. HA, confusion, changes in vision/speech, changes in gait, fever, chills, n/v, abdominal pain, chest pain, SOB, palpitations, cough, hemoptysis, back pain, neck pain, dysuria, hematuria, recent sick contact or travel. Otherwise has no complaints at this time. Patient was discharged at 16:54 and given educational materials on understanding vasovagal syncope |
| 1356047 | 5/27/2021 | NM | 26 | F | 5/27/2021 | 5/27/2021 | Pt had reported to us that she once fainted in her doctor's office when she was pregnant and receiving the Tdap vaccine. We watched her closely, encouraged her sit in pharmacy waiting area and eat and drink. Pt reported that she felt dizzy even after eating a sandwich and drinking some. I gave her an ice pack to put on her head. When I came back to check on her, her brother who came with her, had laid her down on the floor. She had fainted but did not fall or injure herself. We called 911 and for management. EMTs arrived on scene and took vitals, offered to take her to the hospital but she declined. EMTs walked with her to her car. I called the patient this evening before the closed but she didn't answer so I wasn't able to confirm how she was doing. |
| 1356062 | 5/27/2021 | CO | 17 | F | 5/27/2021 | 5/27/2021 | Patient fainted and felt hot. Patient fainted within 10 seconds of receiving vaccine. Once patient came to, she sat down for about 15 minutes and felt better. Patient stated she did not eat anything before. |
| 1356064 | 5/27/2021 | CO | 18 | M | 5/27/2021 | 5/27/2021 | Patient experienced syncope episode 6 minutes after vaccination and lost consciousness for a few seconds. Patient was taken to the hospital for further evaluations. |

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| 1356065 | 5/27/2021 | PA | 19 | F | 5/27/2021 | 5/27/2021 | After administration the patient stated that "it felt weird". She moved her arm around a little and said she was afraid to move it too much. A minute later she said she felt like she was going to pass out. She leaned against the wall and her eyes started to close. I noticed that she was starting to break out into a sweat. I asked if she was having trouble breathing, if her throat felt like it was swelling or if she felt nauseous. She said no, just dizzy and really thirsty and asked for some water. I asked again if she was having trouble breathing or was nauseous and she said no, then passed out. I took her blood pressure, which was normal. After a couple of minutes she started to wake up, although not fully, and asked what happened. I told her I had given her a COVID vaccine and asked if she remembered that. She said yes then seemed to pass out again. I then decided to call 911. A minute later the patient woke up. I asked how she was feeling and she said better. After a minute she asked if she could sit up and I said yes, as long as she felt she could. I took her blood pressure a second time. By the time EMS arrived the patient was fully alert, we were having a conversation and she said she felt fine. EMS checked her over but she refused to go to the hospital. I had her sit a few more minutes while I filled out her immunization card. When she left she said she felt completely fine. |
| 1356074 | 5/27/2021 | WA | 18 | M | 5/26/2021 | 5/26/2021 | Patient experienced syncope upon exiting pharmacy after vaccination. He was assisted to a nearby chair before falling and sustained no injury. Patient and father declined emergency medical services to be requested. After an additional 15 minutes of monitoring, patient reported feeling well and was permitted to leave. |
| 1356311 | 5/27/2021 | MI | 21 | F | 5/22/2021 | 5/22/2021 | Was extremely lightheaded right afterwards. Passed out during the 15-minute observation. Was lightheaded the next couple of days, passed out twice more that day. Was really sick to my stomach for 3 days after, with on and off dizzy spells and lightheadedness. |

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| 1356328 | 5/27/2021 | CA | 24 | F | 4/29/2021 | 4/29/2021 | Client stated syncope episode 1hr after receiving vaccine at home. Since first dose, client reported 4 additional syncope episodes. Per client went to urgent care emergency room where she had a normal head CT, normal EKG and normal chest X-ray. No medications given. Client states currently following up closely with primary doctor. Recently diagnosed with type 2 diabetes and takes Metformin. Allergy to Oxycodone. |
| 1367565 | 5/27/2021 | OR | 25 | F | 5/26/2021 | 5/26/2021 | Patient fainted after the shot. Her chin hit the carpet and started bleeding. Friend was in the room when it happened. We cleaned up her wound and she felt better. Patient then went to get stitchings. |
| 1355801 | 5/27/2021 | MI | 27 | F | 5/27/2021 | 5/27/2021 | Patient fainted after sitting down in observation. Disoriented and scared once alert. Complained of nausea and headache. EMS called. Patient alert and agreed to go to hospital. Vitals @ 12:11p: 110/80 BP, 84 Pulse, 98% O2. |
| 1355311 | 5/27/2021 | IL | 28 | F | 5/3/2021 | 5/5/2021 | Fatigue, weakness, Acute kidney injury, shock liver, thrombocytopenia, pneumonia, syncope, wide complex tachycardia over last 2 weeks |
| 1354483 | 5/27/2021 | RI | 16 | F | 5/27/2021 | 5/27/2021 | patient became pale white ; lightheaded, had to lay her down to prevent full fainting episode |
| 1355137 | 5/27/2021 | | 34 | F | 5/26/2021 | 5/26/2021 | Pt received Janssen J&J vaccine lot 1808980 on May 26, 2021 and was sent to the 15 minute observation lot. Pt then had a syncopal episode and hit the vehicle in front of her. Zero damage noted. Pt has hx of syncope with injections. Pt was assessed by medics, vitals stable 88/62, HR 68, R 12, Skin: PWD. Pt has no other s/sx. Pt denies any other issues. Pt states she feels fine now. Pt's husband was called and he drove her home. No further action needed. |
| 1355166 | 5/27/2021 | VA | 31 | F | 5/26/2021 | 5/26/2021 | Systemic: Patient fainted 2 times due to feeling dizzy and on one occasion for 5-8 seconds was shaking like a mini seizure. EMS came and cleared her, she refused the trip to hospital-Medium, Systemic: Seizure-Mild, Additional Details: As described above |

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| 1355178 | 5/27/2021 | NJ | 34 | M | 5/23/2021 | 5/23/2021 | Systemic: Confusion-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Nausea-Medium, Additional Details: pt fell from chair and landed on floor. scraped his face on the way on the floor. i ran to the patient and asked him if he is okay and checked to see if he was breathing, 911 was called, and after about 3 seconds, the patient regains conciousness and explains he has no idea how he ended up on the floor but remembers getting the vaccine and sitting. this occured about 5 minutes into the 15 minute post vaccination observation. pt states he gets squeamish and nauseus at the thought of needles |
| 1355192 | 5/27/2021 | KS | 18 | F | 5/26/2021 | 5/26/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Weakness-Mild |
| 1355213 | 5/27/2021 | PA | 21 | M | 5/27/2021 | 5/27/2021 | Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Mild, Systemic: Hypotension-Medium, Systemic: Shakiness-Medium |
| 1355237 | 5/27/2021 | VA | 32 | F | 5/27/2021 | 5/27/2021 | Patient received vaccine and did not got and sit down, was watching her husband get his and about 5 minutes after giving the shot, she fainted and fell backwards, was alert in about 10 seconds after hitting the ground, ems was called, vitals monitored until they arrived, no anaphylaxis |
| 1355252 | 5/27/2021 | RI | 15 | F | 5/26/2021 | 5/26/2021 | After the vaccine within second my child was sweating was taken out the waiting area before the 15 minutes and passed out on the floor .we have a broken jaw missing teeth and concussion there no protocol being followed my family is going through the worst right now this could have been avoided if guidelines were followed |

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| 1355579 | 5/27/2021 | NY | 23 | M | 5/27/2021 | 5/27/2021 | Patient was administered the pfizer covid-19 vaccine 1:24pm. After the vaccine was administered patient went to a designated chair to wait for 15 minutes post-vaccine. Pharmacist monitored patient, noticed patient sitting talking on the phone shortly after vaccine. However, after a couple minutes patient passed out and fell off of chair. After yelling patient's name he came to and did not lose consciousness again. Patient suffered injury on head with a substantial laceration on forehead above eye. Code white was called and patient was given an ice pack and advised to sit for 30 minutes following incident. Asked patient if he would like us to call 911, he refused. He sat with management while an incident report was filled out and while he didn't want us to call an ambulance it did seem as though his mom was going to take him to urgent care to have his cut examined. |
| 1355299 | 5/27/2021 | CA | 24 | F | 5/27/2021 | 5/27/2021 | FELT FAINT, DIFFICULTY BREATHING, CHEST TIGHTNESS. PARAMEDICS CAME, VSS, HX OF FAINTING WITH BLOOD DRAWN. DID NOT EAT OR DRINK PRIOR TO VACCINATION. PROVIDED HYDRATION, SX RESOLVED. NO TRANSPORT. |
| 1355109 | 5/27/2021 | MI | 25 | F | 5/5/2021 | 5/6/2021 | High heart rate, fainting, convulsing or seizure, vomiting |
| 1355326 | 5/27/2021 | | 17 | F | 5/27/2021 | 5/27/2021 | An attendee fainted after receiving vaccine Pfizer 1st dose. She didn't lose her airway. The business called 911 they assessed the situation and said she was ok. Patient up walking around. |
| 1355375 | 5/27/2021 | IL | 23 | M | 5/27/2021 | 5/27/2021 | After patient received the shot and was getting up to leave, he passed out. It took a moment to wake up. |

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| 1355390 | 5/27/2021 | IL | 15 | F | 5/26/2021 | 5/26/2021 | Pt came in to pharmacy with her mom for her 1st dose Pfizer vaccine appointment at 2pm on 5/26/21. We checked her in and (pharmacist) gave her shot with her mom present at 2 10pm and she was fine with no issues. Within 2 minutes in of her observation period, she started fainting and having seizure like for about 10 seconds, and regained conscious and said she felt dizzy and then blacked out. She was pale and sweating and asked for water. Our shift lead happened to be closed by her chair where she was sitting so she prevented pt from falling down from the chair and called pharmacist for help from inside the pharmacy. Pharmacist rushed to the patient and asked shift lead to call 911. Pt was conscious, but lethargic, she could breath normally, no sign of obstruction airway. Pharmacist lift her legs up to opposite chair and started to take BP. Paramedic arrived within minutes and took her vitals which was normal. Mom agreed for paramedic took her out in stretcher to hospital for check up. |
| 1355403 | 5/27/2021 | NE | 26 | F | 5/27/2021 | 5/27/2021 | Pt feeling faint and dizzy. Pt felt nasal congestion Pt felt chest heaviness for a short period of time. Pharmacist tried to get her to lay down with her feet up but pt refused. Pt was given water and Sprite to drink due to dizziness and feeling "off". Was sitting on a chair for fifteen minutes after vaccination and said she was dizzy and about to fall off the chair. Had the patient sit on the floor. Pt currently awake and talking fine. No fainting episode of any sort. No s/s of allergic reaction. For treatment pt held cold compress instant packs on neck and wrists. |
| 1355527 | 5/27/2021 | OR | 40 | F | 5/27/2021 | 5/27/2021 | After receiving vaccination, patient was reported to have fainted, with a potential seizure, and fallen over resulting in injury to head and laceration to forehead. Pharmacist was notified in which patient was immediately placed in laying position with elevation to her head and support to neck. Patient reported nausea, confusion, attempted to vomit without success. Patient was able to report name when prompted. 911 was called, fire service and ambulatory service arrived for further assessment. Patient was deemed safe without necessity of going to emergency room. |

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| 1355529 | 5/27/2021 | NJ | 28 | F | 5/24/2021 | 5/24/2021 | patient fainted after receiving COVID 19 vaccine Pfizer-biontech 1st dose vaccination. Ambulance arrived and patient was evaluated. Patient didn't need to be transported to the hospital. patient stayed 30-40 minutes at the vaccination area after vaccine was administered |
| 1355556 | 5/27/2021 | | 16 | F | 5/27/2021 | 5/27/2021 | PATIENT'S FATHER REPORTED AFTER PATIENT SAT DOWN IN OBSERVATION AREA, SHE REQUESTED A WATER. PATIENT AND MOTHER WALKED TO RETRIEVE WATER AND AS SHE ENTERED THE TENT PATIENT REPORTED DIZZINESS AND VISION DISTURBANCE. PATIENT STATED SHE BEGAN TO SEE BLACK AS SHE WAS SEATED. NURSE WAS CALLED OVER. DAD STATED PATIENT'S BODY SLUMPED OVER AND HE SUPPORTED HER IN THE CHAIR. THE NURSE WITNESSED FULL BODY UNCONTROLLABLE SHAKING FOR LESS THAN 20 SECS. LOC ASSESSED AND PATIENT WAS AOX4 IMMEDIATELY FOLLOWING THE SHAKING. NURSE ALSO OBSERVED PALE LIPS. FLUIDS OFFERED AND CONSUMED. MD & EMS PAGED. DAD REPORTED TO MD, PATIENT HX OF FAINTING. PATIENT BECAME PALER. MD ADVISED AGAINST PLACING PATIENT ON GROUND. GURNEY PROVIDED. PATIENT FEET ELEVATED. VS OBTAINED #1 BP: 76/48; #2 83/52, p: 60, RR: 16; O2: 98%; #3 BP: 85/53, P: 81 at 1540. PATIENT OBSERVED WITH FEET ELEVATED FOR LESS THAN 10 MINS. MD RECOMMENDED PATIENT REMAIN IN OBSERVATION FOR 15 MINS PRIOR TO LEAVING. PATIENT MOVED TO CHAIR SEATED UPRIGHT POSITION WITHOUT ASSISTANCE FOR 15 MINS. 15 MINS ELAPSED, MD MADE AWARE AND DECLINED TO REEVALUATE PATIENT AT 1555. PATIENT EXITED OBSERVATION AREA ACCOMPANIED BY PARENTS AND BROTHER WITH FLUID IN HAND IN STABLE CONDITION. |
| 1355561 | 5/27/2021 | MD | 38 | F | 5/3/2021 | 5/9/2021 | Fainting spell/syncope, pulsatile tinnitus in the right ear & migraine with neurological symptoms - burning, tingling and pain in head, neck, face, left arm and left leg - for 3 weeks now. 1st Moderna shot was on 5/3. Symptoms started 5/9 and have not reduced or gone away. Been to the ER 3 times now in 3 weeks. Seen ENT, Neurologist, Primary and ER physicians. This came on abruptly with no prior history of migraines. Status migrainosus. |

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| 1355254 | 5/27/2021 | MN | 51 | M | 5/27/2021 | 5/27/2021 | Patient had syncopal fainting and profuse sweating, no difficulty breathing. Ambulance called, assessed patient, transported from pharmacy after about 10 minutes. Patient remained sweating, light headed while still in pharmacy |
| 1353106 | 5/27/2021 | MD | | F | 4/1/2021 | 4/1/2021 | fainted; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of SYNCOPE (fainted) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 01-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 01-Apr-2021, the patient experienced SYNCOPE (fainted) (seriousness criterion medically significant). At the time of the report, SYNCOPE (fainted) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No relevant concomitant medications were reported. The reporter stated that patient fainted and was taken to the hospital emergency room. No treatment information was provided. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. This case was linked to MOD-2021-089124, MOD-2021-089511 (E2B Linked Report).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. MOD-2021-089124:Reporter's husband MOD-2021-089511:Same Reporter_Invalid Case_No patient identifier |

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1353545 5/27/2021 TN

M

his chin, the left upper and lower jaw wet numb as well as his left ear, which was the same side as his injection; he almost passed out; felt a lump on the bone of the upper jaw on the inside; upset; This is a spontaneous report from a contactable consumer (parent). A 40-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Solution for injection, lot number and expiry date not reported), via an unspecified route of administration on an unspecified date in 2021 as first dose, single for covid-19 immunization. The patient's medical history and concomitant medications were not reported. Patient previously took procaine hydrochloride (NOVOCAIN) and experienced numb. Patient previously had a flu shot last fall (28Sep2020) which was influenza, inactivated split 4V (QUADRIVALENT INFLUENZA VACCINE; Lot number PLOOZZ9091 or PLOOZZ7091. Manufacturer), and experienced face went numb. Patient received the vaccine yesterday (date unspecified in 2021) at 6pm. He waited for 30 minutes at the vaccination site and then left. An hour to an hour and a half later his chin, the left upper and lower jaw wet numb as well as his left ear, which was the same side as his injection. His hearing was okay. He said it was like getting Novocain. He went back to the ER and was told since the vaccine people were already gone they couldn't help him unless he wanted to be checked into the ER or he could go home. He hung out in the waiting room for 3 hours incase something else went wrong and then went home. This morning he felt a lump on the bone of the upper jaw on the inside, way above the cheek and he was still numb. Patient told that he almost passed out-because he freaked himself out, not from the vaccine. She said he had a similar experience with a flu shot last fall - face went numb on the same side for four hours Quadrivalent Influenza vaccine on 28Sep2020. Reporter wanted to know what ingredients could be causing this reaction. Reporter asked if there was something in this like sulfur/nickel, mercury, sulfur, sulfates, sulfites, nickel, thimerosal that could cause this reaction. She wanted to know if the company had anyone else that has had these symptoms. It was reported that when patient got the flu shot he also had the numbness in his jaw, with the flu shot it lasted for about 4-5 hours but now he has had the same experience this time with the COVID 19 vaccine but it was worse and now he also fekt a lump in his upper

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jaw on the inside. They were trying to figure out what is in the vaccines that could make his jaw go numb. He reported through the thing, she told him to scan the paper, he scanned it and he put in his symptoms yesterday so he should be starting to get text messages about it. The lump was in the inside of his jaw, it did not hurt but there was a lump on the bone and he was upset (2021), he almost passed out and he was going to go to the doctor and he just wanted to find out if he was the only one getting these symptoms and what he needed to be aware so he does not go and do it again next flu season like he can go with different brand or something because his jaw was going numb. The outcome of the events was unknown. Information about lot/batch number has been requested.

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| 1353541 | 5/27/2021 | NM | 56 | M | 4/7/2021 | 4/1/2021 | couple pains in the left chest area behind the breast; his stomach was feeling sick and his body was hurting; His whole torso hurt and his stomach; The pain now is not like where it hit him with the back. He has back pain every day but more than he used to. the back pain was just the one day.; his arm was a little sore; He was lethargic and had no energy; He was lethargic and had no energy/weakness; diarrhea; Responding strangely to people/but is still there and is so weird; dizzy; getting really irritable; Slept all day for several days; Arm started hurting where he got the shot; been sick pretty much everyday; not feeling good in his stomach; he passed out for 2 days; breathing hard; wouldn't feel good; a fast heartbeat; chills; nausea; headache; he gets really short and impatient; forget a little something still, but just once in a while; This is a spontaneous report from a contactable consumer (patient). A 56-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in Arm Left on 07Apr2021 14:30 (Lot Number: WR8783) as 1ST DOSE SINGLE for covid-19 immunisation. Medical history included ongoing sciatica, back problems, stomach was sensitive, lower back pain, bone spurs down his spine. He was a medical marijuana patient, he had Shigella when he was a baby. He was 2 or 3 and almost died but came out of it; His mom had cancer from smoking, he got the worse flu sick of his life. His stomach was sensitive all of the time. If he was too happy or too nervous get upset. He can eat spicy food, not super hot, but he can eat anything and it doesn't go crazy. He has a little bit of a sensitive stomach sometimes. He can't take a multivitamin or supplements because he would get sick to his stomach, this was before the vaccine. He was getting that same sick feeling now that he would get if he was taking a multivitamin. He had his blood drawn a week before he had the vaccine to check his kidneys with the pills he is on. It was perfect and normal, and he has had nothing since then. In his 20s he had the flu vaccine, and he had never had the flu in his life. That year he got the worse flu sick of his life. He never got the flu vaccine or other vaccines after that. That was probably between 1987 to 1990. His folks passed away. He had been in the hospital when he was little. Concomitant medications included acetaminophen taken for back pain, sciatica from an unspecified start |

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date and ongoing; nabumetone taken for sciatica, back pain from an unspecified start date and ongoing. The patient experienced he passed out for 2 days (medically significant) on Apr2021 with outcome of unknown, been sick pretty much everyday (non-serious) on 07Apr2021 22:00 with outcome of not recovered, not feeling good in his stomach (non-serious) on 07Apr2021 with outcome of not recovered, slept all day for several days (non-serious) on 08Apr2021 with outcome of unknown, responding strangely to people/but is still there and is so weird (non-serious) on 12Apr2021 with outcome of not recovered, his stomach was feeling sick and his body was hurting (non-serious) on 15Apr2021 with outcome of not recovered, his whole torso hurt and his stomach (non-serious) on 15Apr2021 with outcome of unknown, diarrhea (non-serious) on 12Apr2021 with outcome of not recovered, getting really irritable (non-serious) on 09Apr2021 with outcome of not recovered, he had no energy (non-serious) on 12Apr2021 with outcome of recovering, he was lethargic/weakness (asthenia) (non-serious) on 12Apr2021 with outcome of not recovered, dizzy (non-serious) on 10Apr2021 with outcome of not recovered, couple pains in the left chest area behind the breast (non-serious) on 17Apr2021 with outcome of not recovered, breathing hard (non-serious) on Apr2021 with outcome of not recovered, wouldn't feel good (non-serious) on Apr2021 with outcome of not recovered, arm started hurting where he got the shot (non-serious) on 08Apr2021 with outcome of not recovered, headache (non-serious) on Apr2021 with outcome of unknown, his arm was a little sore (non-serious) on 13Apr2021 with outcome of unknown, a fast heartbeat (non-serious) on Apr2021 with outcome of unknown, chills (non-serious) on Apr2021 with outcome of unknown. Patient got sick around 10:00 at night. He was supposed to get his second dose but he was so sick and they said lets give it a week. Then he talked to his doctor and he said to wait 2-3 weeks to make sure he is back to normal. So he is scheduled for the second dose next week at 6 weeks. He asked if it was okay that the shot was given in the sunlight. He stated that he saw that it was in an ice chest but the person had to walk it over to him 20 feet and deal with his sleeve for a second or two so it was in the sun. He said all that walking it was 100% in the sun and he has read that it should not be in the sun. He asked if this

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could have caused bacteria and caused his symptoms. He stated his doctor was only concerned about giving him antibiotics for bacteria if it was in the sun and if that was a problem. He just read from CDC, once mixed the vaccine can be left at room temp for 6 hours and mixed vaccine does not need to be protected from light. So it sounds like his first shot was good. He had gotten the shot at about 1430 in the afternoon. He was like he is going to get the shot and everything will be great. He didn't think there would be an effect. Then strangely enough at about 2200 he was about to eat dinner and he got to not feeling good in his stomach. It had been close to 8 hours. The next day he slept all day, got up and had coffee, and Saturday he was in the chair in the living room. He is never in the chair during the day because he works. He slept all day and all night and the next day. He was responding strangely to people, and he was in and out of it. He had the shot on Wednesday and then his stomach was feeling sick and his body was hurting. He has back pain anyway and bone spurs on his spine. He was telling his wife whatever pain he is normally in was enhanced. His whole torso hurt and his stomach. The following Monday he had diarrhea. Then he started getting really irritable and didn't want to talk and was impatient. He was lethargic and had no energy. That was the second week. By the end of the second week he had a couple pains in the left chest area behind the breast. He thought it was a heart attack, then thought it was just pain not a heart attack. Every time he wouldn't feel good he would start breathing hard. Once in a while he gets pain through his chest area. His stomach would start and he would breath hard every time he didn't feel good. The third week he was supposed to get the second shot. He called the department of health for New Mexico. The nurse called back and said not to do the shot that week but to wait a week. He rescheduled for a week later. By the third week he was still not feeling good and called the doctor. He asked about the pain in his chest 3 times and he said it seemed to be okay. His arm started hurting where he got the shot in the second week. He still had no energy and he told the doctor this. Patient started taking 2 extra Tylenol during the day for pain. Lately he has been good until one little thing and then all of a sudden his stomach is hurting and he is holding his stomach. He was good today, all he did was eat a cookie and he didn't

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get sick. He was worse for a little while in the first or second week, he was really bad. It came and went over the next 2 weeks and now it is coming and going less frequently. He slept through 2 or 3 days. Thursday, Friday, and then Saturday he was in and out. He woke up to take the garbage out on Friday then saw he already took it out and forgot it was out there. And it was Saturday. He was kind of out of it. When he would respond strangely he would respond with a question he just asked and someone answered. It is like brain fog or like he is on something. It started after the weekend, more on 12Apr2021. Once in a while he will forget a little something still, but just once in a while. He would walk and hold his rib cage with both arms when he was hurting. He wrote down that it felt like somebody had hit him in the back with a bat in the lower back. One day it was that bad. His back pain was on Thursday 15Apr2021. The pain now is not like where it hit him with the back. He has back pain every day but more than he used to. The sore like he was hit in the back pain was just the one day. He had diarrhea 12Apr2021, 13Apr2021, and 14Apr2021 then it left for probably a week. Then it came back last week one day. Instead of every day it was every 3 or 4 days. He has not had it in the last 4 days. He hopes it is done. He noticed any time he has salad or lettuce he feels bad in the morning so he stopped eating those. He felt irritable more when he started not feeling good. The last 5 days or so more towards the evening at 1800 or 1900 he starts not feeling good and gets irritated. His wife will ask him something and he gets really short and impatient. He felt irritable more when he started not feeling good. The last 5 days or so more towards the evening at 1800 or 1900 he starts not feeling good and gets irritated. His wife will ask him something and he gets really short and impatient. The irritable feeling started right away the Friday of the week he got the shot. He is still struggling some, it will come and go. Yesterday he was zonked. With having no energy it is a big thing. He has to do something instead of what he would be doing. He works all day and takes long orders and stuff. Now he does like one order when normally he did 10. One for him is a huge little sore so he will lay on his right side. His left arm still hurts like a pulling hurt from his neck to his arm. It has been every day from 13Apr2021. It is much better and he will move

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and it will relax a little bit. It was really weird. The whole time he held the phone with his left hand up until one second he moved his phone and it was the same pain. At night the left side where he had the injection pulls on his neck muscle coming from his arm. He was actually taking two Tylenol in the morning and two at night when he went to bed. With the pain he takes 2 during the day, 650mg each. He was just taking 500mg and then his wife said take these. It seems to have gotten a little better. He always took them 2 times a day and now he takes them 3 times a day. After the first dose he experienced difficulty breathing dizziness, weakness, a fast heartbeat, chills, nausea, headache, he passed out for 2 days and has been sick for 5 weeks. He started having some dizziness a couple of days later and reports, it's like I would stand up too quickly and get a head rush, that kind of dizzy feeling. He confirmed that his dizziness did not start until a couple of days after he received his first dose.

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| 1353523 | 5/27/2021 | FL | 28 | F | 5/7/2021 | 5/7/2021 | After leaving the facility ended up passing out in the car; caller's arm was bleeding; feeling kind of dizzy; the administering person didn't check the syringe before administering; This is a spontaneous report from a contactable consumer (patient). A 28-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration, administered in left arm on 07May2021 (Between 1830 and 1900) (Lot Number: EW0182) as single dose for COVID-19 immunization. Medical history included Covid Virus in Dec2020 (had the Covid Virus but received the vaccines to prevent if it were to happen again). The patient's concomitant medications were not reported. The patient previously received the first dose of BNT162B2 (lot number: EW0161) on 16Apr2021 (Between 1830 and 1900) in left arm for COVID-19 immunization. Patient went to Pharmacy to receive her second dose Pfizer Covid Vaccine. Thought there was a mistake coming from the person who gave the vaccine. After the administering person supposedly gave the patient her second dose Pfizer Covid Vaccine, the administering person started making some faces like she was concerned. The patient asked three times, what was going on and the administering person would not tell the patient. The patient asked to please tell her what was going on, the administering person's face was very concerned. The administering person finally told the patient, she wasn't sure, it just felt weird when injecting the second dose Pfizer Covid Vaccine. Patient asked the administering person what she meant by it felt weird and the administering person stated she thought the syringe was empty. The patient stated the administering person was scared. The patient looked at her arm and it was bleeding quite a bit. Patient thought the injection was weird, usually injections in muscles can hurt but this just felt different. Patient stated it felt like the injecting needle was dull, like it had already been used. The administering person thought the syringe was empty so the patient thought was that someone else's syringe that had already been used and the administering person didn't pay attention. Patient is not sure if she received the second dose Pfizer Covid Vaccine. The administering person got up and was about to walk out the door and saw the patient's arm was bleeding. The person said she would clean it up and she did. The administering person |

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stepped outside and asked whoever pulled the vaccine to see if the syringe had the vaccine in it prior to administering to the patient. The patient stated the administering person didn't check the syringe before administering the second dose Pfizer Covid Vaccine to the patient. Otherwise, the administering person would have known if the syringe was full or not. The administering person came back in after she had stepped out for two or three minutes. The administering person told the patient she was good and did receive the second dose Pfizer Covid Vaccine. Patient asked how did the person know, if the administering person had said the syringe felt empty. The administering person said no, the patient did receive the second dose Pfizer Covid Vaccine. The administering person sat next to the patient and the patient asked are you sure, administering person said yes. At this time, the administering person had a 3cc syringe in her hand with something in it and she threw this syringe away. Patient asked the administering person again if she was certain patient received second dose Pfizer Covid vaccine and the administering person said yes. The administering person was still playing around with the syringe the patient supposedly received the second dose Pfizer Covid Vaccine with, like the administering person was doubting herself. Patient was concerned now, if the administering person did in fact use a syringe that was previously used by someone else. Patient didn't know if the person who previously utilized the syringe had something or not. After leaving facility the patient ended up passing out in the car. Some random person in the parking lot got someone from inside the facility. The facility cashier came to see the patient. The patient stated no Pharmacist came outside, just the cashier. After 20 minutes or so, patient 's parents ended up showing up to make sure the patient was okay. The patient got home and a Pharmacist called and basically said how the patient probably passed out because she hadn't eaten. The patient stated she had eaten just not within an hour or two prior to receiving the second dose Pfizer Covid Vaccine. The patient stated the pharmacist was giving a lot of excuses and saying that the patient passed out probably because she didn't eat. Patient asked the pharmacist why no one came out to make sure the patient was fine. The pharmacist said they were changing persons in rotation. Patient stated this hasn't

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happened before. This may have occurred due to stress and patient getting scared due to the administering persons concern and facial expression and what the administering person said to the patient. The patient got really scared. The patient didn't know if that had anything to do with passing out. Patient didn't think the administering person gave the patient the second dose Pfizer Covid Vaccine at all. As the patient was leaving the facility, patient was getting closer to the car and started feeling kind of dizzy. Patient opened the car door and ended up passing out. Patient stated this occurred this one time, patient was recovered completely. Right before patient was almost passed out entirely, patient had gone to get somebody in the parking lot and asked the person to get someone from inside. Patient asked the Pharmacist if the person who administered the second dose Pfizer Covid Vaccine to the patient, was the person who drew up the patient's vaccination into the syringe. The pharmacist said yes, (name) drew up the vaccine into the patient's syringe. Patient stated the Pharmacist was lying to the patient, (name) told the patient she was not the person who drew up the vaccine into the syringe and went to check to see who had drawn up the vaccine into the syringe after the patient received the second dose Pfizer Covid Vaccine. The Pharmacist changed the subject entirely. The patient underwent lab tests and procedures which included Covid Virus: present in Dec2020. Outcome of the event passed out was recovered on 07May2021, of the other events was recovered on an unspecified date.

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| 1353519 | 5/27/2021 | PA | | M | | | passed out; This is a spontaneous report from a contactable consumer. A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot number and expiration date not provided) via an unspecified route of administration on an unspecified date, at single dose, for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. Caller reported that someone he knew, the patient, who did not wait the recommended 15 minutes after receiving the Covid-19 vaccine. Caller reported that after leaving the vaccination facility, the patient passed out in his car and hit 2 parked cars. The outcome of the event was unknown. Information on the Lot/Batch number has been requested. |

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| 1353497 | 5/27/2021 | AL | 70 | F | 5/7/2021 | 5/7/2021 | she passed out; diarrhea; stools are black in color; This is a spontaneous report from a contactable consumer(patient). A 70-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 in Arm Left on 07May2021 (Lot Number: EVL8737) as 1ST DOSE, SINGLE for covid-19 immunisation. The patient medical history and the concomitant medications were not reported. She had her first dose of Pfizer COVID vaccine on 07May2021, between 11 and noon, after receiving the vaccine, she experienced diarrhea, stools are black in color; as well as that same night she passed out and it's the first time this happens to her. The outcome of Diarrhea was recovered on 08May2021, of Black stools was not recovered, of Passed out was unknown. The Diarrhea started right after when she got home that evening. For the diarrhea, it started last Friday to early Saturday morning. Saturday 08May2021 morning she had about 2 bowel but its now checked itself (means it stopped). She had the Kaopectate. Then Sunday 09May2021and Monday 10May2021 she had no Diarrhea, no bowel movement but then today 11May2021, she had one bowel movement, there was no diarrhea but her stool was black. Her stools have been black in color since Friday 07May2021. She has never had black stools. The Kaopectate was started after the vaccine. Kaopectate is over the counter. She bought it for the diarrhea and upset stomach. Friday night she also passed out and that has never happened before. She is concerned about Friday night because she went to the bathroom at 2-3 at night and she passed out in the bathroom, she didn't feel faint or anything, she just passed out, she woke up on the bathroom floor. It happened just the one time on Friday night. She was scheduled for the second dose on 01Jun2021. |

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| 1353492 | 5/27/2021 | PA | 64 | M | 3/31/2021 | 4/7/2021 | <p>passed out; dizzy; cannot raise my arms above my waist; neck is stiff; limited rotation of my head; tired; aches and pains and severe reduction in range of motion in all of my joints and muscles; aches and pains and severe reduction in range of motion in all of my joints and muscles; aches and pains and severe reduction in range of motion in all of my joints and muscles; This is a spontaneous report from a contactable consumer. This consumer reported for herself that the 64-year-old male patient received second dose of bnt162b2 (BNT162B2, Pfizer COVID 19), via an unspecified route of administration, administered in Arm Left on 31Mar2021 12:30 PM (Batch/Lot Number: ER8730) as 2nd dose, single for covid-19 immunisation. Medical history included high blood pressure from an unknown date and unknown if ongoing , drug hypersensitivity from an unknown date and unknown if ongoing. The patient's concomitant medications were not reported. The patient previously took first dose of bnt162b2 (BNT162B2, Pfizer COVID 19), via an unspecified route of administration, administered in Arm Left on 03Mar2021 11:30 AM (Batch/Lot Number: EN6202) for covid-19 immunization. The patient experienced passed out (medically significant) on an unspecified date with outcome of unknown, aches and pains and severe reduction in range of motion in all of my joints and muscles on 07Apr2021 with outcome of not recovered , aches and pains and severe reduction in range of motion in all of my joints and muscles on 07Apr2021 with outcome of not recovered , aches and pains and severe reduction in range of motion in all of my joints and muscles on 07Apr2021 with outcome of not recovered , dizzy on an unspecified date with outcome of not recovered , cannot raise my arms above my waist on an unspecified date with outcome of not recovered , neck is stiff on an unspecified date with outcome of not recovered , limited rotation of my head on an unspecified date with outcome of not recovered , tired on an unspecified date with outcome of not recovered. The patient underwent lab tests and procedures which included blood pressure measurement: unknown results on unknown date, electrocardiogram: unknown results on unknown date, sars-cov-2 test: negative on 21Apr2021. Therapeutic measures were taken as a result of the events. Facility where the most recent COVID-19 vaccine was administered was Clinic. The patient did not receive</p> |

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any other vaccines within 4 weeks prior to the COVID vaccine. List of any other medications the patient received within 2 weeks of vaccination. The clinical course was reported as follows: I have aches and pains and severe reduction in range of motion in all of my joints and muscles. I also got dizzy one day and passed out. I have been put on a 6 -day steroid pack twice already. The steroids help greatly but once the pill pack was complete the symptoms came back. I cannot raise my arms above my waist. My neck is stiff and I have limited rotation of my head. I'm tired most of the time. I have had many blood tests, (2) EKG tests and my blood pressure is being monitored. So far nothing. My doctor is going to send me to see a rheumatologist. I was very healthy before receiving my 2nd shot of the vaccine. The adverse event result in Doctor or other healthcare professional office/clinic visit. The adverse event resulted in Emergency room/department or urgent care. Treatment was received for the adverse event included Put on a 6-day steroid pack twice so far. Prior to vaccination, was the patient was not diagnosed with COVID-19. Since the vaccination, the patient has been tested for COVID-19. Batch/Lot number has been obtained. Further information has been requested

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| 1353458 | 5/27/2021 | IL | 50 | F | 4/18/2021 | 4/1/2021 | <p>pain in her arm in the muscle where the needle was placed; pain in her arm in the muscle where the needle was placed; she almost fainted; had so much tightness in her throat; couldn't swallow; the other arm pain; 8-10 days late for her period; This is a spontaneous report from a contactable consumer (patient). A 50-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: ER8731 and expiration date not provided), via an unspecified route of administration, in arm left, on 18Apr2021 09:30 (at the age of 50-year-old), at single dose, for COVID-19 immunization. Medical history reported as no. Concomitant medications were not reported. No prior vaccinations within 4 weeks. Patient was scheduled for the second dose on 09May2021 but she had doubts because of her reaction to the first dose. The patient experienced 8-10 days late for her period in Apr2021; pain in her arm in the muscle where the needle was placed on 18Apr2021; almost fainted on 18Apr2021; had so much tightness in her throat on 18Apr2021;couldn't swallow on 18Apr2021; and the other arm pain on 18Apr2021. Patient stated this was not an allergic reaction and the vaccination provider was about to administer the epi-pen but then she did not. Patient would like to know if her side effects are normal and if she should receive the second dose. Patient got the first shot on 18Apr2021 and she was scared of needles so she just didn't look at them but this one... Patient stated as soon as she got the shot, she had pain in her arm in the muscle where the needle was placed. Patient stated it's not a big deal. Patient stated the pharmacy said it's ok to feel pain and told caller to go sit down and they would be with her in half an hour or so. Patient stated she didn't even make it through the door, she almost fainted and could not hear what she was saying, she had so much tightness in her throat and she couldn't swallow. Patient stated it lasted about 2 to 3 minutes (also reported "lasted for 3-4 minutes"). Patient stated they called an ambulance but it took them 15 minutes to get there and she felt better by then. Patient stated because they told her to wait and she couldn't even get through the door so she just laid on the floor and her throat got so tight, she was frightened. Patient stated it lasted about 5 minutes, actually. Patient confirmed her symptoms began and ended on 18Apr2021. As for "hurting in her muscle; arm</p> |

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pain", patient stated she had the arm pain for two days but then her whole arm started hurting in that arm, but that was a different pain. Patient stated she got the shot at 09:30 in the morning and by 16:00 afternoon she started feeling the pain. Patient stated the pain from the needle when she got the shot, that pain lasted 5 to 6 hours or maybe she would say less. Patient stated after 16:00, then the other arm pain started. Patient stated she was putting ice on and off it for arm soreness overnight and into the next day. Patient confirmed her arm pain ended 19Apr2021. Patient confirmed she had recovered completely from all symptoms. Patient stated she didn't have any pains or anything so she would think she has recovered. Patient stated she went to her physician and the doctor suggested that she should take the second shot. Patient stated she also was 8-10 days late for her period. Patient stated something happened and she said she couldn't do it because she was going to get her period and then it didn't come and days passed by. Patient stated she was supposed to get it 21Apr2021 or 22Apr2021, supposed to get it between 21Apr2021 and 25Apr2021 and she got it yesterday, 04May2021. Patient stated as soon as it passed 26Apr2021, but she was also 51 and menopausal so it might be that, but she doubts it. No emergency room or physician office require for events. Treatment received for event "the other arm pain" included putting ice on and off. The outcome of the event "8-10 days late for her period" was recovered on 04May2021; of "pain in her arm in the muscle where the needle was placed/ almost fainted/ had so much tightness in her throat/ couldn't swallow" was recovered on 18Apr2021, of "arm pain" was recovered on 19Apr2021. No follow-up attempts are possible. No further information is expected.

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| 1353322 | 5/27/2021 | | | F | | | This is a spontaneous report from a contactable consumer (patient herself). A female patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, Batch/Lot number was not reported), via an unspecified route of administration on an unspecified date as 1ST DOSE, SINGLE for covid-19 immunization. The Patient's medical history included anxiety and is also under doctor supervision for anti-anxiety meds. On an unspecified date, the patient experienced heart racing after first dose of COVID-19 vaccine, heart racing lasted for 3-4 days, slow at first and more at night that woke her up at night, feeling of almost fainting because she felt out of control and feeling out of breath. It was reported that, event took place after use of product. The patient underwent lab tests and procedures which included EKG (electrocardiogram): normal on 24Feb2021, heart rate: racing lasted for 3-4 days, slow at first and more on at night on an unspecified date. The outcome of the events was recovered on 24Feb2021. No follow-up attempts are possible; information about lot/batch number cannot be obtained. |
| 1353753 | 5/27/2021 | MN | 26 | F | 5/26/2021 | 5/27/2021 | After standing up from the toilet early in the morning, fainted and fell on bathroom floor. No injuries were sustained. After regaining consciousness less than 1 minute later, sat up and breathed and focused for about 2 minutes until mentally clear. Relocated with assistance to couch, drank water, ate a slice of toast. |

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| 1353115 | 5/27/2021 | IN | 28 | M | 3/24/2021 | 4/24/2021 | I passed out and then I hit my head on floor and chin; Hit my head on floor and chin; I hurt my neck and put neck braces on me in hospital; My wife jumped up and came to me and put me up on floor and heard gargling noise; I have 2 provoked seizures from Moderna shot; Doctors found every thing normal in result except sinus; I woke up with slight headache; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of LOSS OF CONSCIOUSNESS (I passed out and then I hit my head on floor and chin), HEAD INJURY (Hit my head on floor and chin), NECK INJURY (I hurt my neck and put neck braces on me in hospital), GASTROINTESTINAL SOUNDS ABNORMAL (My wife jumped up and came to me and put me up on floor and heard gargling noise) and SEIZURE (I have 2 provoked seizures from Moderna shot) in a 28-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 043B21A and 040A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 24-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 23-Apr-2021 at 5:30 PM, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 24-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (I passed out and then I hit my head on floor and chin) (seriousness criteria hospitalization and medically significant), HEAD INJURY (Hit my head on floor and chin) (seriousness criterion hospitalization), NECK INJURY (I hurt my neck and put neck braces on me in hospital) (seriousness criterion hospitalization), GASTROINTESTINAL SOUNDS ABNORMAL (My wife jumped up and came to me and put me up on floor and heard gargling noise) (seriousness criterion hospitalization) and HEADACHE (I woke up with slight headache). On an unknown date, the patient experienced SEIZURE (I have 2 provoked seizures from Moderna shot) (seriousness criterion medically significant) and SINUS DISORDER (Doctors found every thing normal in result except sinus). The patient was hospitalized on 24-Apr-2021 due to GASTROINTESTINAL SOUNDS ABNORMAL, HEAD INJURY, LOSS OF CONSCIOUSNESS and NECK |

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INJURY. At the time of the report, LOSS OF CONSCIOUSNESS (I passed out and then I hit my head on floor and chin), HEAD INJURY (Hit my head on floor and chin), NECK INJURY (I hurt my neck and put neck braces on me in hospital), GASTROINTESTINAL SOUNDS ABNORMAL (My wife jumped up and came to me and put me up on floor and heard gargling noise), SEIZURE (I have 2 provoked seizures from Moderna shot), SINUS DISORDER (Doctors found every thing normal in result except sinus) and HEADACHE (I woke up with slight headache) outcome was unknown. Concomitant medication use was not reported. It was reported that the patient was not taking any medication on regular basis. The patient reported that they did bunch of tests like CAT scan, EEG test, they monitor my heart for 30 days. Results were not reported. For treatment the patient reported they gave him IV and seizure medication which he was not taking right now. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

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| 1353092 | 5/27/2021 | IL | 51 | F | 2/26/2021 | 4/1/2021 | <p>anxiety aggravated; swelling of fingers; local swelling; Symptoms of psoriasis got worse on scalp; Could not move; Some problems walking; Moderate pain or discomfort; When she stood up she would faint; Orthostatic hypertension; This spontaneous case was reported by a physician (subsequently medically confirmed) and describes the occurrence of SYNCOPE (When she stood up she would faint), ORTHOSTATIC HYPERTENSION (Orthostatic hypertension), PSORIASIS (Symptoms of psoriasis got worse on scalp), MOBILITY DECREASED (Could not move), GAIT DISTURBANCE (Some problems walking), PAIN (Moderate pain or discomfort), ANXIETY (anxiety aggravated), PERIPHERAL SWELLING (swelling of fingers) and SWELLING (local swelling) in a 52-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Co-suspect product included non-company product ADALIMUMAB (HUMIRA) for Psoriatic arthritis. The patient's past medical history included Back disorder NOS (could not lay down on back). Concurrent medical conditions included Swollen joints (swollen joints in hands, wrist, finger, spine), Gait disturbance (some problems walking), Loss of personal independence in daily activities (some problems with usual activities/ sometimes problems with buttons when getting dressed), Pain, Discomfort, Anxiety, Hypertension, Diabetes, Psoriatic arthritis (swollen and tender joints in hands, wrist, finger, spine) and Joint tenderness. On 26-Feb-2021, the patient started ADALIMUMAB (HUMIRA) (Subcutaneous) 40 milligram every two weeks. On 22-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. In April 2021, the patient experienced SYNCOPE (When she stood up she would faint) (seriousness criteria hospitalization and medically significant), ORTHOSTATIC HYPERTENSION (Orthostatic hypertension) (seriousness criterion hospitalization), PSORIASIS (Symptoms of psoriasis got worse on scalp) (seriousness criterion hospitalization), MOBILITY DECREASED (Could not move) (seriousness criterion hospitalization), GAIT DISTURBANCE (Some problems walking) (seriousness criterion hospitalization) and PAIN (Moderate pain or discomfort) (seriousness criterion hospitalization). On an unknown date, the patient</p> |

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experienced ANXIETY (anxiety aggravated) (seriousness criterion hospitalization), PERIPHERAL SWELLING (swelling of fingers) (seriousness criterion hospitalization) and SWELLING (local swelling) (seriousness criterion hospitalization). The patient was hospitalized from 28-Apr-2021 to 30-Apr-2021 due to ORTHOSTATIC HYPERTENSION and SYNCOPE. At the time of the report, SYNCOPE (When she stood up she would faint), ORTHOSTATIC HYPERTENSION (Orthostatic hypertension), MOBILITY DECREASED (Could not move), GAIT DISTURBANCE (Some problems walking) and PAIN (Moderate pain or discomfort) outcome was unknown, PSORIASIS (Symptoms of psoriasis got worse on scalp) and ANXIETY (anxiety aggravated) had not resolved and PERIPHERAL SWELLING (swelling of fingers) and SWELLING (local swelling) was resolving. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. The patient's current blood pressure and insulin doses were both decreased after the diagnosis of orthostatic hypertension. Additional treatments were not provided. In 2021, the patient reported pain of 4 out of 10 on 1 occasion, and 7 out of 10 on a separate occasion. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

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| 1353085 | 5/27/2021 | NC | 78 | F | 3/31/2021 | 3/31/2021 | <p>Passed out; Does not want to get 2nd dose; Head was hurting; Mini stroke; Speech difficulties; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out) and CEREBROVASCULAR ACCIDENT (Mini stroke) in a 78-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 028A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No relevant medical history was reported. Concomitant products included LOSARTAN, LEVOCETIRIZINE, TEMAZEPAM, ATORVASTATIN CALCIUM (LIPITOR), BISOPROLOL and BUSPIRONE for an unknown indication. On 31-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 31-Mar-2021, the patient experienced LOSS OF CONSCIOUSNESS (Passed out) (seriousness criteria hospitalization and medically significant). On 01-Apr-2021, the patient experienced CEREBROVASCULAR ACCIDENT (Mini stroke) (seriousness criteria hospitalization and medically significant), SPEECH DISORDER (Speech difficulties) and HEADACHE (Head was hurting). On an unknown date, the patient experienced PRODUCT DOSE OMISSION ISSUE (Does not want to get 2nd dose). The patient was hospitalized from 01-Apr-2021 to 04-Apr-2021 due to CEREBROVASCULAR ACCIDENT and LOSS OF CONSCIOUSNESS. At the time of the report, LOSS OF CONSCIOUSNESS (Passed out), CEREBROVASCULAR ACCIDENT (Mini stroke), SPEECH DISORDER (Speech difficulties) and HEADACHE (Head was hurting) outcome was unknown and PRODUCT DOSE OMISSION ISSUE (Does not want to get 2nd dose) had resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Treatment details included generic Plavix and blood thinner. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p> |

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| 1353075 | 5/27/2021 | NV | 34 | F | 5/6/2021 | | fainted many times; ongoing diarrhea; This spontaneous case was reported by a non-health professional and describes the occurrence of SYNCOPE (fainted many times) in a 34-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 001c21a) for COVID-19 immunisation. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 06-May-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 2 dosage form. On an unknown date, the patient experienced SYNCOPE (fainted many times) (seriousness criterion medically significant) and DIARRHOEA (ongoing diarrhea). At the time of the report, SYNCOPE (fainted many times) outcome was unknown and DIARRHOEA (ongoing diarrhea) had not resolved. Action taken with mRNA-1273 in response to the events was not applicable. Concomitant and treatment information were not provided. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |

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| 1353073 | 5/27/2021 | CA | | F | 2/5/2021 | | <p>I was like I had I ke passed out; I couldn't feel hungry anymore, I didn't have appetite; It was the first time I was feeling so unable to even; I would get like dizzy and just fall in my bed again; Fever; Muscle Pain; Horribly exhausted for 5 days, I was in bed; I couldn't even lift up my arm to get up and go and eat; This spontaneous case was reported by a non-health professional and describes the occurrence of LOSS OF CONSCIOUSNESS (I was like I had I ke passed out) in a 57-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 013M204) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 05-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 05-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient experienced LOSS OF CONSCIOUSNESS (I was like I had I ke passed out) (seriousness criterion medically significant), DECREASED APPETITE (I couldn't feel hungry anymore, I didn't have appetite), HYPOKINESIA (It was the first time I was feeling so unable to even), DIZZINESS (I would get like dizzy and just fall in my bed again), PYREXIA (Fever), MYALGIA (Muscle Pain), FATIGUE (Horribly exhausted for 5 days, I was in bed) and VACCINATION SITE PAIN (I couldn't even lift up my arm to get up and go and eat). At the time of the report, LOSS OF CONSCIOUSNESS (I was like I had I ke passed out), DECREASED APPETITE (I couldn't feel hungry anymore, I didn't have appetite), HYPOKINESIA (It was the first time I was feeling so unable to even), DIZZINESS (I would get like dizzy and just fall in my bed again), PYREXIA (Fever), MYALGIA (Muscle Pain), FATIGUE (Horribly exhausted for 5 days, I was in bed) and VACCINATION SITE PAIN (I couldn't even lift up my arm to get up and go and eat) outcome was unknown. No concomitant medication reported. The patient stated having similar symptoms following the first dose of the Moderna COVID-19 Vaccine. Very limited information regarding the events has been provided at this time. Further information has been requested.; Sender's Comments: Very limited information regarding the events has been provided at this time.</p> |

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| 1353068 | 5/27/2021 | | 32 | M | 3/22/2021 | 3/31/2021 | Further information has been requested. Passed out multiple times; Blood clots; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out multiple times) and THROMBOSIS (Blood clots) in a 32-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 047a21a) for COVID-19 vaccination. No Medical History information was reported. On 22-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 31-Mar-2021, the patient experienced LOSS OF CONSCIOUSNESS (Passed out multiple times) (seriousness criterion medically significant) and THROMBOSIS (Blood clots) (seriousness criterion medically significant). At the time of the report, LOSS OF CONSCIOUSNESS (Passed out multiple times) and THROMBOSIS (Blood clots) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Concomitant product use was not provided by the reporter. Treatment information was not provided. Patient was taken to hospital where it was discovered that he had blood clots that needed to be removed. Very limited information regarding the events has been provided at this time. Further information has been requested.; Sender's Comments: Very limited information regarding the events has been provided at this time. Further information has been requested. |
| 1354530 | 5/27/2021 | CA | 22 | F | 5/26/2021 | 5/26/2021 | DIAPHOERTIC, DIZZY, SYNCOPE, ALTERED after 7-8 minutes of vaccine administration legs raised on chair across, fan air, v/s monitored, apple juice, crackers, icepacks to neck. EMS called but by the time they arrived patient was smiling and talking, refused to go to hospital. was discharged in stable condition after monitoring for additional 30 minutes 1322-60,16.110/84. 99% RA 1330-69, 18, 110/78.97% |

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| 1353092 | 5/27/2021 | IL | 51 | F | 2/26/2021 | 4/1/2021 | <p>anxiety aggravated; swelling of fingers; local swelling; Symptoms of psoriasis got worse on scalp; Could not move; Some problems walking; Moderate pain or discomfort; When she stood up she would faint; Orthostatic hypertension; This spontaneous case was reported by a physician (subsequently medically confirmed) and describes the occurrence of SYNCOPE (When she stood up she would faint), ORTHOSTATIC HYPERTENSION (Orthostatic hypertension), PSORIASIS (Symptoms of psoriasis got worse on scalp), MOBILITY DECREASED (Could not move), GAIT DISTURBANCE (Some problems walking), PAIN (Moderate pain or discomfort), ANXIETY (anxiety aggravated), PERIPHERAL SWELLING (swelling of fingers) and SWELLING (local swelling) in a 52-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Co-suspect product included non-company product ADALIMUMAB (HUMIRA) for Psoriatic arthritis. The patient's past medical history included Back disorder NOS (could not lay down on back). Concurrent medical conditions included Swollen joints (swollen joints in hands, wrist, finger, spine), Gait disturbance (some problems walking), Loss of personal independence in daily activities (some problems with usual activities/ sometimes problems with buttons when getting dressed), Pain, Discomfort, Anxiety, Hypertension, Diabetes, Psoriatic arthritis (swollen and tender joints in hands, wrist, finger, spine) and Joint tenderness. On 26-Feb-2021, the patient started ADALIMUMAB (HUMIRA) (Subcutaneous) 40 milligram every two weeks. On 22-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. In April 2021, the patient experienced SYNCOPE (When she stood up she would faint) (seriousness criteria hospitalization and medically significant), ORTHOSTATIC HYPERTENSION (Orthostatic hypertension) (seriousness criterion hospitalization), PSORIASIS (Symptoms of psoriasis got worse on scalp) (seriousness criterion hospitalization), MOBILITY DECREASED (Could not move) (seriousness criterion hospitalization), GAIT DISTURBANCE (Some problems walking) (seriousness criterion hospitalization) and PAIN (Moderate pain or discomfort) (seriousness criterion hospitalization). On an unknown date, the patient</p> |

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experienced ANXIETY (anxiety aggravated) (seriousness criterion hospitalization), PERIPHERAL SWELLING (swelling of fingers) (seriousness criterion hospitalization) and SWELLING (local swelling) (seriousness criterion hospitalization). The patient was hospitalized from 28-Apr-2021 to 30-Apr-2021 due to ORTHOSTATIC HYPERTENSION and SYNCOPE. At the time of the report, SYNCOPE (When she stood up she would faint), ORTHOSTATIC HYPERTENSION (Orthostatic hypertension), MOBILITY DECREASED (Could not move), GAIT DISTURBANCE (Some problems walking) and PAIN (Moderate pain or discomfort) outcome was unknown, PSORIASIS (Symptoms of psoriasis got worse on scalp) and ANXIETY (anxiety aggravated) had not resolved and PERIPHERAL SWELLING (swelling of fingers) and SWELLING (local swelling) was resolving. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. The patient's current blood pressure and insulin doses were both decreased after the diagnosis of orthostatic hypertension. Additional treatments were not provided. In 2021, the patient reported pain of 4 out of 10 on 1 occasion, and 7 out of 10 on a separate occasion. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

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| 1354494 | 5/27/2021 | OR | 78 | M | 3/21/2021 | 3/21/2021 | HPI/Subjective: 78 yo with above PMH who presents for new patient evaluation. He was admitted to hospital on 4/3-4/5 for acute episode of dizziness jaw pain found to be hypertensive with elevated troponin. Troponin peaked at 10K. Echo showed no WMAs. Angiogram showed mild distal PLA disease but no other obstructive disease. Cardiac MRI showed a focal area of mid wall LGE consistent with myocarditis. Supportive treatment. Additionally during this admission was found to have small acute L occipital infarcts and tiny infarcts vs artifact in the left thalamus and medulla. Lipid panel and HbA1c unrevealing. ECHO unrevealing. CTA was unrevealing. Patient will D/C with zio patch. Long term blood pressure goal is <130/80. Today, reports feeling OK. No recurrence of the dizziness or jaw pain that brought him into the hospital. No chest pain or pressure or syncope or dyspnea on exertion. No orthopnea, PND or LE edema. Walking 2 miles fast pace without any symptoms. Blood pressures are 130-200s (pre increase in Lisinopril) lower in the morning and worse in the afternoon/evening. Former smoker (quit in '85). Family history - Mom had a AVR in 70s |

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| 1354485 | 5/27/2021 | CA | 38 | F | 5/25/2021 | 5/25/2021 | Client stating she was dizzy and turning pale. EMT and Lead RN made contact with client who stated she was feeling dizzy and nauseous, client denied any other symptoms such as chest pain, shortness of breath, and tingling of mouth, tongue or lips. EMT provided client with an emesis bag and bottle of water. Client's skin turned ashen and then client had a loss of responsiveness. RN applied a sternal rub to client who regained responsiveness in <30 seconds. Lead RN applied an instant ice pack to the back of client's neck and instructed client to take deep breaths. Client was Alert & oriented x4 following loss of responsiveness. At 1230 baseline vitals taken with client sitting in folding chair at vaccination table: blood pressure (BP) 138/78, heart rate (HR) 44, Respiratory rate (RR) 14, skins pale, cool and clammy. Client stated she has a history of fainting with every injection or blood draw and that she failed to mention this to RN when she was asked how she does with shots. Ancillary brought the zero gravity chair to the table for client to recover in. Client denied any history of allergic reaction to meds/foods/environment. Denied any other medical conditions or medications taken. Continued complaint of lightheaded/dizziness and nausea. Clients skins remained pale, cool and clammy. At 1235 HR 76, RR 16 client was given a juice box. At 1240 client's skins returned to normal color for ethnicity and were warm and dry, she was alert and oriented x4, she was able to walk to observation area on her own where she was placed in the zero gravity chair and a second set of vitals were taken while sitting: BP 120/88, RR 16, HR 80. At 1250 EMT took a third BP 118/70. Client stated symptoms were fully resolved, skins normal for ethnicity, warm and dry, alert and oriented x4. At 1325 client was finished with observation, denied any other symptoms and walked away from the observation site with a steady gait |
| 1354507 | 5/27/2021 | MO | 52 | F | 4/9/2021 | 4/21/2021 | I broke out in hives from head to toe, couldn't breathe, fainted, couldn't walk or move. Went to ER, BP was 60/40. Was given epi shot and Benadryl and some other meds I don't have the names of. |

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| 1353223 | 5/27/2021 | | | F | | | Severe headache; This is a spontaneous report from a contactable consumer. This consumer reported for a female patient (reporter's sister-in-law). A female patient of an unspecified age received first and second dose of BNT162B2 (PFIZER-BIONTEC COVID-19 mRNA VACCINE, Solution for injection, lot number and expiry date were not reported), via an unspecified route of administration, on an unknown date, as a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The reporter (67-year-old) reported that the reporter received the first dose of the Pfizer COVID vaccine on 28Jan2021 at 10:45 am. Yesterday at 3:15 pm the reporter practically passed out and couldn't stand up. The reporter was pretty healthy and didn't drink anymore. Things like that used to happen when the reporter drank but not now. The reporter hope it wasn't something neurologic going on with the reporter's body. The reporter also reported that the patient (reporter's sister-in-law) just got her second shot yesterday. On an unknown date, she had a severe headache 5 days after getting the first dose of the vaccine. The reporter asked was it possible to have a side effect from the vaccine that many days later. The reporter just wanted to thank Pfizer for coming up with this medication to help millions of people and was looking forward to getting second dose. Outcome of the event was unknown. Information on lot/batch number has been requested. Follow-up attempts are completed. No further information is expected. |
| 1354428 | 5/27/2021 | NY | 43 | F | 5/27/2021 | 5/27/2021 | Patient received vaccine and was in the pharmacy waiting area for observation. Within minutes (~7min), patient came to counter to let the staff know that she wasn't feeling good. Staff told her to go sit back down and the pharmacist will be right out. She explained that she felt very nausea and wanted to vomit. She also explained that she felt lightheaded and faint. We made sure she was sitting down and protecting her in case of fainting. Other symptoms were shaking, sweating and difficulty swallowing. She was breathing fine but explained that it felt like there was something in her throat that was making it difficult to swallow. Ambulance was called (~9min) and she went to the emergency room for observation (~16m). |

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| 1354466 | 5/27/2021 | OR | 13 | F | 5/26/2021 | 5/26/2021 | Patient experienced vasovagal syncope within a minute of her vaccination. Helped patient lie down on the floor and explained situation to her. Assisted patient to cot, and provided apple juice. Encouraged patient to call her mom and continued to monitor patient's status. |
| 1354457 | 5/27/2021 | WI | 17 | F | 5/27/2021 | 5/27/2021 | Patient fainted in a chair in the waiting area during observation period (~10 minutes after vaccination). Patients guardian said the patient has a history of vasovagal syncope in medical environments. Patient recovered in a few minutes. Patient remained in the chair for 15 minutes until her guardian and her were able to leave the store on their own accord. |
| 1354471 | 5/27/2021 | WA | 14 | F | 5/25/2021 | 5/25/2021 | Patient received her first dose of the vaccine then fainted shortly after.. She appeared unresponsive and her cheeks were flushed. Patient only responded to verbal command with confusion. Permission was obtained from ER Dr on duty to administer EpiPen at 0.3 mg Patient was then transported to ER |

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| 1353077 | 5/27/2021 | IN | 66 | F | 5/4/2021 | 5/4/2021 | passed out; very bad infection from the Diverticulitis in the bowel; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of LOSS OF CONSCIOUSNESS (passed out) and DIVERTICULITIS (very bad infection from the Diverticulitis in the bowel) in a 66-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No medical history reported by the reporter. Concomitant products included LISINAPRIL for Blood pressure, POTASSIUM and OMEPRAZOLE for an unknown indication. On 04-May-2021, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 04-May-2021, the patient experienced LOSS OF CONSCIOUSNESS (passed out) (seriousness criterion medically significant) and DIVERTICULITIS (very bad infection from the Diverticulitis in the bowel) (seriousness criterion medically significant). On 04-May-2021, LOSS OF CONSCIOUSNESS (passed out) had resolved. At the time of the report, DIVERTICULITIS (very bad infection from the Diverticulitis in the bowel) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 04-May-2021, Blood potassium: Low. On 04-May-2021, Blood pressure measurement: Low. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. Events included some other issues. Patient was treated with 2 unspecified antibiotics. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |
| 1353757 | 5/27/2021 | CA | 23 | M | 5/26/2021 | 5/26/2021 | Systemic: Fainting / Unresponsive-Mild |

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| 1354445 | 5/27/2021 | MN | 22 | F | 5/22/2021 | 5/23/2021 | Patient obtained her 1st dose of the Moderna vaccine on May 22nd subsequent development erythema roughly 4 fingers below the injection site, roughly 24 hours after the injection. Notes associated swelling, warmth and discomfort. Denies any open wound, fevers, chills or malaise. Since then, erythema and swelling have progressed by increasing roughly 1 cm in diameter. Notes pruritus and discomfort have improved by the time of today's (5/27/21) clinic visit. She has tried no medications or topicals to treat the rash. No additional sites of rash. She denies syncope, lightheadedness, dizziness, lip swelling, tongue swelling, shortness of breath, wheezing, abdominal pain, nausea, vomiting. No PEG allergy history. No documented vaccine allergies. No allergies causing anaphylaxis. |
| 1354451 | 5/27/2021 | MO | 18 | M | 5/26/2021 | 5/26/2021 | Patient fainted approximately 30 seconds after vaccine. Eyes closed and patient did not respond for approximately 30 seconds but still had pulse. When patient's eyes opened he stated his vision was slightly blurred; also pale and sweating. After elevating feet and providing ice packs patient began to feel better. Blood pressure and pulse stable 30 minutes following. Patient felt fatigued but otherwise back to normal when leaving pharmacy. |

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| 1354426 | 5/27/2021 | OR | 47 | M | 5/13/2021 | 5/16/2021 | HPI/Subjective: is a 47 year old male with minimal past medical history who presents in consultation. He was hospitalized with myocarditis. The patient presented to PWF 5/16 with CP, fatigue and elevated HR. He had received his second dose of the Moderna COVID-19 vaccine 3 days prior. The initial ECG showed nonspecific ST abnormalities. HS-troponin 1,438 -- > 5,951. Echo showed ejection fraction of 35% with global hypokinesis, akinesis in inferior and inferoapical segments, and mild right ventricular hypokinesis. He was subsequently transferred to PPMC and underwent coronary angiogram on 5/18/21 which demonstrated normal coronary arteries. In consultation with Dr. , he was discharged on losartan 25 mg/day and metoprolol succinate 50 mg BID for outpatient follow-up. Cardiac MRI 5/19 showed T2 signal abnormality and LGE involving the subepicardium of the lateral wall, inferior wall, as well as septum c/w acute myocarditis. LVEF 53%. Dr. submitted his case to the VAERS site. reports feeling much improved. He denies fatigue, dyspnea, palpitation, or presyncope. He has noted fleeting chest discomfort. No fevers or chills. |
| 1354364 | 5/27/2021 | CA | 41 | M | 5/22/2021 | 5/22/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Pt recovered in less than 1/2 hr. Checked his BP and pulse- normal. Pt and his cousin said he fainted after getting the first dose on 4/24/2021. He promised he'll see his PCP. |

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| 1354352 | 5/27/2021 | NJ | 17 | F | 5/26/2021 | 5/26/2021 | Patient upon seated for the 15 minutes post-vaccination fainted. When she was coming through, she started shaking as if she was having a seizure. When I reached the patient, she was shaking and then came through and stopped shaking. Patient was still pale, sweating, and didn't feel okay. 911 was already called once the patient was shaking. As I am checking in on the patient, the mom discloses that she has fainted at least twice before and when she comes through she shakes but it is not seizures. However, during the screening process, patient and mom stated the patient never had any problems when getting vaccinated. I got her BP checked and it was 102/61 and HR of 92. We had the patient sit still and drink water. When EMS arrived within 5-10 mins, they took her vitals and it was 112/70s and HR of 84 with 98% O2 sat. Patient and mom decided to be taken to the ED to make sure she is okay. |
| 1354328 | 5/27/2021 | PA | 17 | F | 5/25/2021 | 5/25/2021 | Site: Pain at Injection Site-Medium, Systemic: Chills-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Fever-Medium, Systemic: JAW AND THROAT PAIN-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Hypotension-Medium |
| 1354137 | 5/27/2021 | CT | 58 | M | 5/27/2021 | 5/27/2021 | Approx 5 min after receiving the 2nd Pfizer COVID vaccine the patient fainted hitting head against wall, scraping knee from falling and biting his lip. Pt was unconscious for approx 45 secs to 1 min. Vitals remained within normal limits during entire encounter except for increase in respiration rate of about 26-28. After regaining consciousness the pt was confused, nauseas, vomiting, diaphoretic and clammy to the touch. EMS arrived un scene approx 5-10 minutes after pt hitting his head and was transported to Hospital |
| 1354286 | 5/27/2021 | NJ | 17 | F | 5/26/2021 | 5/26/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Additional Details: Patient recovered in about 20 to 25 minutes. |

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| 1354278 | 5/27/2021 | NJ | 23 | F | 5/26/2021 | 5/26/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Flushed / Sweating-Mild, Systemic: Nausea-Mild, Systemic: Tingling (specify: facial area, extremities)-Mild, Systemic: Visual Changes/Disturbances-Medium, Systemic: Weakness-Medium, Additional Details: Pt has history of fainting from needles that was not reported prior to vaccine administration. Pt began feeling dizzy/nauseous/blurry vision immediately after administration, no difficulty breathing or signs of swelling, epipen not administered. pt was laid down on back and feet were propped up, began to feel better. She was evaluated by EMT, all vital signs stable and she had recovered by the time of their arrival, did not go to hospital. Symptoms likely from needle anxiety, not vaccine itself |
| 1354157 | 5/27/2021 | RI | 21 | M | 5/27/2021 | 5/27/2021 | after administration patient showed immediate signs of dizziness and fainted. they came to almost immediately and seized for a moment, no longer than 30 seconds from the moment they fainted and revived. |
| 1354165 | 5/27/2021 | NY | 21 | F | 5/26/2021 | 5/26/2021 | Patient apparently passed out while waiting after receiving vaccine. She was sitting in a chair and fell over to her right side. She appears to have had a petit mal seizure. Her pupils were very dilated and it took her several minutes to become fully responsive, although she was unresponsive for just a short period of time. She is a student and the EMS staff who responded to the 911 call reports that she is well known to them, as she has a history of "pseudo-seizures". Patient's BP was 138/84 and SPO2 was 98%. Pt was transported to ED around noon, and was back to the clinic by 1:15 to collect her eyeglasses that had been left where she was sitting. |
| 1354355 | 5/27/2021 | MD | 37 | M | 5/27/2021 | 5/27/2021 | 0847 patient, looked pale, stated do not feel good, passed out in chair, did not fall. Called MET. syncope for 30 seconds. When awake slightly confused but reorienting easily. Unable to get a blood pressure. Diaphoretic and pale. METS placed patient on stretcher, BP 107/53 at 0855. Transported to ED. |

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| 1354446 | 5/27/2021 | OR | 37 | M | 3/29/2021 | 3/31/2021 | From f/u note 5/18/21: HPI/Subjective: patient is a 37 y.o. male with above past cardiovascular history who presents today for follow-up. He was hospitalized at hospital from 4/1/21 to 4/2/21 after presenting to ED with 12 hours of chest pain, found to have markedly elevated troponin (9,142). Of note, he received 2nd COVID vaccine a day before symptoms began. CT coronary scan showed calcium score of 0. Cardiac MRI on 4/2 showed myocarditis, with anterior and lateral subepicardial enhancement as well as abnormal T1 and T2 signal. He was started on colchicine x 6 months. Today, patient reports improvement in chest pain since discharge. He reports rare episode of chest pain with last episode ~3 weeks ago. He denies participating in very rigorous exercise, but did complete 20 mile bike ride recently. Denies palpitations, dyspnea, orthopnea, PND, abdominal distention, LE edema, fatigue, lightheadedness, dizziness, syncope or near syncope. Cardiovascular Problem List: #Myocarditis o 4/1/21. Echocardiogram: EF 60% o 4/1/21. CT coronary: Calcium score 0 o 4/2/21. Cardiac MRI: myocarditis, with anterior and lateral subepicardial enhancement as well as abnormal T1 and T2 signal. Assessment/Plan: #Myocarditis: During admission, echocardiogram was normal with EF 60% and CT coronary angiogram showed Agatston score of 0. Cardiac MRI showed myocarditis, with anterior and lateral subepicardial enhancement as well as abnormal T1 and T2 signal. Of note, he received the second Moderna COVID-19 vaccine the day prior, so - Monitor, will consider repeat MRI at follow up (more for activity recommendations given age) - Continue colchicine for total of 6 months (until Oct 2021) |
| 1354269 | 5/27/2021 | TX | 13 | M | 5/26/2021 | 5/26/2021 | Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild |

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| 1354203 | 5/27/2021 | IN | 27 | M | 5/27/2021 | 5/27/2021 | APPROXIMATELY 5 MINUTES AFTER RECEIVING SHOT, PATIENT WAS SITTING IN A CHAIR AND FAINTED ONTO THE FLOOR. WE SAW HIM IMMEDIATELY AND RESPONDED. HE WAS VISIBLY BREATHING AND SOUNDED LIKE HE WAS SNORING AND AFTER ABOUT 20-30 SECONDS HE WOKE UP AND SAID, "OH, DID I PASS OUT?" HE THEN EXPLAINED THAT THIS HAS HAPPENED TO HIM SEVERAL TIMES BEFORE, BUT NOT IN RECENT YEARS. HE HAD ANSWERED "NO" ON HIS QUESTIONNAIRE TO THE QUESTION ABOUT PREVIOUSLY FAINTING AFTER A VACCINE. HE SAT FOR A FEW MORE MINUTES, AND THEN LEFT STATING HE WAS FINE. |
| 1350485 | 5/26/2021 | | 33 | F | 5/23/2021 | 5/23/2021 | AE: Syncope Tx: no medication given, monitored symptoms and checked vitals. Juice and water resolved the symptoms Outcome: Patient was discharged to POV/Home. |
| 1350658 | 5/26/2021 | MI | 19 | F | 5/19/2021 | 5/19/2021 | Pt brought to ED w/concerns for allergic rxn immediately following COVID-19 vaccine at PCP office (5/19) where w/in 15 mins, experienced significant lightheadedness, dizziness & throat swelling & itch w/wheezing. In ED, developed brief episodes of syncope and was administered EpiPen, IV fluids, solu-medrol and famotidine w/improvement. After multi doses of epi IM for recurrent symptoms throughout observation, was started on epi drip. Ultimately discharged, however, returned same night with recurrent anaphylactic rxn and was again started on an epinephrine drip and claritin. Of note, pt had previously had COVID on 1/22/2021. Pt discharged w/plans to f/u w/ allergy and immunology at Hospital. |

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| 1350637 | 5/26/2021 | VA | 16 | M | 5/23/2021 | 5/24/2021 | <p>Previously healthy 16 year old male presenting to hospital as a transfer for chest pain and elevated Troponin levels concerning for myocarditis. Patient has otherwise been healthy. Two days ago he received his second dose of COVID vaccination. He initially felt fine, but later that day had some body aches. The next day he felt feverish off and on and had dull left upper sternal border chest pain intermittently. Today, he reports sharp 7/10 mid sternal chest pain, lightheadedness, sweating, chills, and intermittent non-productive cough. He presented to original hospital for evaluation. The patient admits to tactile warmth since Sunday with no documented temperatures. He recently received his second dose of Pfizer just before onset of these symptoms. He reports difficulty sleeping since Sunday, but no shortness of breath, rashes, syncope, nausea, or vomiting. He has not had any other recent illness, fevers, or known COVID-19 exposures. He denies any history of prior cardiac disease and there is no known family history of cardiac disease, arrhythmias, or sudden death in the child or adolescent period. He denies illicit or recreational drug use. In the ED, he was well appearing with pain now 1 out of 10. POC troponin was 16.8 ng/mL. He had labs pertinent for ESR 10, CRP 3.0, BNP 24. RP2 PCR was negative. UDS was negative except for opiates (s/p morphine). IV was placed and patient was started on IV fluids. EKG was obtained and showed questionable left atrial enlargement per ED read. Cardiology was consulted and performed Echocardiogram in the ED at bedside and was within normal limits. Cardiology resident team contacted for admission. Past Medical History: No major medical diagnoses Past Surgical History: Orchiopexy, T&A Family History: No cardiac family history Social History: Lives at home with mother. Has two healthy siblings not living at home Immunizations: Up to date Medications: None Allergies: NKDA Etiology of likely myocarditis remains unclear at this time. In his age group, this would most likely represent a viral myocarditis. He would likely benefit from cardiac MRI during this admission for further evaluation of myocarditis. His EKG findings with his age group are unlikely to be secondary to myocardial infarct. No arrhythmias or heart block noted on EKG at time of admission or telemetry in ED. There is no family history of autoimmune disease or cardiac disease to suggest an</p> |

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| 1350634 | 5/26/2021 | MI | 16 | F | 5/17/2021 | 5/17/2021 | autoimmune component or genetic etiology. Patient sat about 2 minutes after getting vaccine and started to walk away to sit in our designated area. She immediately turned around to sit down again. She then proceeded to start falling to her right and passed out. I was able to catch her and then she started shaking as if having a seizure. This lasted about 5 seconds. She stopped and then it happened again for about 5 seconds. When she came to, she tried to walk away again and had to return to sitting. Then she vomited twice. Upon checking her blood pressure after about 30 minutes, it was 97/66. She sat for a total of about an hour before feeling good enough to leave. She was nauseous for the remainder of the day and the next day as well. |
| 1350576 | 5/26/2021 | MA | 41 | F | 5/17/2021 | 5/17/2021 | Within 2 mins of receiving injection, I experienced full body sweats, deadening of sound, blackness in eyes, lightheaded, unable to hold things in my hands, uneasy stomach, very pale all over, especially face. Talked/deep breathed my way out of fainting. Within 10 minutes all the above symptoms started to lessen. 15 minutes after receiving the injection, the near fainting experience was over and I was comfortable leaving and driving. But the 10 minutes were terrible and I came very close to passing out. My husband experienced the exact same symptoms 2 days later. I will be reporting that immediately following this submission. |

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| 1350516 | 5/26/2021 | MI | 71 | F | 3/13/2021 | 5/11/2021 | This is a 71y.o. female hx of HTN, HLD, and breast cancer dx in 2018 with lumpectomy/radiation in 2018 taking Arimidex since presenting secondary to DIB. The patient states she had her covid vaccine Pfizer completed in March. She then decided to go to her timeshare and had flown there last week. She states that they had done multiple driving trips and had only gone to one casino that was low crowds. She states starting on Tuesday prior to flying home she developed shortness of breath with exertion to where she needed a wheelchair for transport. She denies any syncope or chest pain. She denies any history of blood clots. She denies any fever or COVID exposure. In emergency department patient is found to be Covid positive as well as have acute PE. ID consulted and pt on Heparin. seen this morning. No tobacco history, resides with her husband. To check lower extremity venous Doppler studies for completeness. Plan of care discussed with patient. To coordinate outpatient follow-up with her primary care physician, Doctor. Anticipate 6mos of anticoag ID following, on decadron and Remdesivir |
| 1350483 | 5/26/2021 | FL | 16 | F | 5/25/2021 | 5/25/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Medium, Systemic: Nausea-Severe, Systemic: Vomiting-Mild, Additional Details: Patient temp at time of incident was 96.8. About 8 mintues after vaccination was given patient became pale and passed out for several seconds. Patient was dizzy and vomited. No other symptoms. Called paramedics to make sure patient was okay. Gave patient some water and spoke to patient until the paramedics arrived. Paramedics took her vitals and after while they cleared her. She was able to walk out on her own and went home with her father and brother. |

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| 1350482 | 5/26/2021 | FL | 27 | M | 5/25/2021 | 5/25/2021 | Patient started to feel dizzy , skin color getting pale , cold hands , sweat , and was about to faint 5 minutes after administering the vaccine . pharmacist on duty grabbed the Epipen and blood pressure machine . patient blood pressure was 65/40 , patient started to feel better for couple minutes then he start to feel dizzy and to get same symptoms again , at this moment pharmacist injected the patient with Epipen as he stated he iwas fainting .patient denied to have any allergies , fear for needles or any health conditions . pharmacist kept watching and monitoring the patient till his blood pressure came back to 118/69. patient family came to pick him up . |
| 1350688 | 5/26/2021 | NJ | 65 | F | 5/26/2021 | 5/26/2021 | PATIENT FELT ODD AFTER APPROX 10 MINS. HER EYES GLAZED OVER AND IT SEEMED AS IF SHE PASSED OUT FOR A FEW MOMENTS. WE DETERMINED SHE WAS DIABETIC AND HAS HTN. WE ALSO DETERMINED SHE DID NOT TAKE HER MEDS IN THE MORNING PRIOR TO VACCINATION. EMTs WERE CALLED |
| 1351048 | 5/26/2021 | FL | 42 | F | 5/25/2021 | 5/25/2021 | Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Severe, Additional Details: Patient had began feeling anxiety during check in , reported fear of needles, after injection she became pale, sweating, and lost consciousness in a seated position, there was no fall associated with this event. She was not responding to her husband or pharmacist, pharmacist checked pulse and breathing, both were fine, prompted student to call 911. After a few minutes she regained consciousness and therefore no response from ems.After observation of 30 minutes was fine and left with her husband. |
| 1350477 | 5/26/2021 | TX | 17 | M | 5/25/2021 | 5/25/2021 | Site: Bruising at Injection Site-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe |
| 1350575 | 5/26/2021 | MN | 35 | F | 5/26/2021 | 5/26/2021 | Patient became dizzy and unconscious. She has a history of fear of needles and reported that she passed out before when receiving vaccines and doing blood work. She is pregnant at the time of the vaccinated. |

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| 1351928 | 5/26/2021 | CA | 31 | M | 5/25/2021 | 5/25/2021 | I experienced a fever going to sleep at 05/25/21 at 2300h. My temperature reading was 97 F. I woke up on 05/26/21 at approximately 0120h feeling the need to urinate and was very sweaty, hot and thirsty. I sat down to urinate, and I felt dizzy standing back up. I was feeling very thirsty so proceeded to walk to get some water. I fainted after walking about 10 feet. I regained consciousness, and I drank water and ingested an Advil with the help of my wife. I felt a lot better after drinking the water, but still had a mild throbbing headache. I went back to sleep, and the fever symptoms came and went which affected my sleep quality. I drank more water any time I woke up. I took 2 more Advil as well at one time waking up. I woke up around 1300h on 05/26/21 feeling a lot better and a little more well rested. My fever symptoms are gone, but I am still a little sensitive to cold and feeling a little weak. |

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| 1349493 | 5/26/2021 | MO | 45 | F | 5/3/2021 | 5/3/2021 | nausea; vomiting/almost threw up with severe; almost threw up with severe,frightening, severe, heartburn, felt like esophagus was going to burst it hurt so bad; almost threw up with severe,frightening, severe, heartburn, felt like esophagus was going to burst it hurt so bad; fever of 101 all day; Caller almost passed out at one point; feeling terrible; dizzy; weak after second dose; chills/got really bad chills; arm started hurting all at once; This is a spontaneous report from a contactable consumer (patient). A 45-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in left arm on 03May2021 10:00 (Batch/Lot Number: ER8731) as 2nd dose, single for covid-19 immunisation. Medical history included she was very sensitive to medications and had a heart burn before. The patient's concomitant medications were not reported. The patient previously had a flu shot more than a month ago and experienced pain in joints for like a couple of weeks. The patient received first dose of bnt162b2 on 12Apr2021 (Lot: ER8734; left shoulder at 10:00) for COVID-19 immunization and experienced chills for like a week after the first dose, arm was sore and numbness inside mouth and face. Patient reported that she had no side effects occurred after second dose of the vaccine until about 2300, 12 hours after caller received the second dose. On 03May2021, 23:30, she was dizzy, and was weak after second dose. What started it was she got really bad chills, she tried to get up and was dizzy, felt like she couldn't stand up without holding onto something. The dizziness was ongoing maybe a little bit, probably related to the fact she can't eat more than the vaccination itself. She stated the dizziness was probably a lot less, and she was able to walk around now. Her bad chills were not ongoing and didn't last all that long. It lasted an hour that night of 03May2021 and she had chills again yesterday, 04May2021, when fever was going back up. They were really not that bad and stated that chills were gone now and recovered completely. On 03May2021, 23:30, her arm was sore; she reported that it started hurting all at once 23:30 on 03May2021. It was pretty severe, felt like entire arm it went through, it wasn't just like it went through to inside of her arm. It was where lymph nodes were and partially across chest. It was still sore but definitely not anywhere near the degree it was Monday |

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night, 03May2021. She stated that it has improved. On 04May2021, around 18:00, the patient experienced nausea and vomiting but this was different, hasn't thrown up, almost threw up with severe, frightening, severe, heartburn, felt like esophagus was going to burst it hurt so bad. Patient reported that she has had heart burn before but she doesn't typically suffer from it and this was beyond, extremely painful. The events lasted about an hour. She immediately took some antacid tablets, but they did not work. Her husband got her Tagamet, by the time she took it she felt a lot better. The patient guessed that she recovered with lasting effects. She tried to drink plain broth with nothing, no noodles. This was why she called because acid started jumping up into her throat from drinking that. She was afraid to eat, and she was going to have to eat at some point. On 04May2021, the patient almost passed out at one point, felt like she was going to pee her pants because of the pain, and it hurts so bad. She was close to calling 911 it was scaring her that much. This occurred after she had just eaten a small roll with butter on it. She also had fever of 101 all day, Tuesday (04May2021). She doesn't know when this began, and she finally took temperature mid-day, husband bought a new thermometer and she didn't realize she had a fever. She was taking Tylenol every 8 hours. She wondered if the Tylenol bothered her, she doesn't usually take Tylenol and she was told not to take Ibuprofen by the lady who gave her the second dose vaccination. She did take one Ibuprofen last night because she was feeling terrible and she felt a lot better. The events did not required a visit to the emergency room or physician office. Outcome of event almost passed out at one point, fever of 101 all day, weak after second dose was unknown; nausea, vomiting/almost threw up with severe, almost threw up with severe, frightening, severe, heartburn, felt like esophagus was going to burst it hurt so bad was recovered with sequel; dizzy, arm started hurting all at once and feeling terrible was recovering; and chills/got really bad chills was recovered on an unspecified date.

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| 1350474 | 5/26/2021 | NJ | 35 | M | 5/24/2021 | 5/24/2021 | Systemic: Fainting / Unresponsive-Medium, Additional Details: immediately after administration of the first pfizer dose, patient started hovering over and saying I'm going down. Before I could respond immediately, he fell face first to the floor and got scraped on his nose and forehead |
| 1351004 | 5/26/2021 | | 15 | M | 5/26/2021 | 5/26/2021 | AE: Syncope(at 11am) Treatment: no medication was given. patient was under observation. Water improved symptoms Outcome: symptoms resolved and patient was sent to POV/Home. |
| 1350976 | 5/26/2021 | MN | 40 | M | 5/13/2021 | 5/13/2021 | I got Moderna vaccine #2 at around 11:30 am. That day, I felt tired and my arm was sore and felt really hot then really cold. That night, starting at around 11:30 pm, I woke up every hour and was unable to stay asleep, that continued through the morning. Toward the morning, around 3:30 am, I fainted in the bathroom and came to on the floor, luckily, I didnt get hurt on the way down. I felt crummy that next day and back to normal within 3 days. |
| 1350964 | 5/26/2021 | WA | 43 | F | 5/25/2021 | 5/25/2021 | Instant sharp pain right away, couldnt breath,, had to remove my mask right away put hands in the air, the I got very HOT and lightheaded,, then within 5 minutes or less passed out hit the ground, was passed out over 10 minutes. Having extreme headaches, pain in my shoulder arm, numbness in my hands and feet. I could feel the shot go in it was cold. I am feeling tired and like my right ear is plugged. |
| 1350921 | 5/26/2021 | KY | 19 | M | 5/26/2021 | 5/26/2021 | Syncope |
| 1350935 | 5/26/2021 | | 20 | F | 5/26/2021 | 5/26/2021 | She had a syncopal episode 10 minutes into vaccine administration. Reported history of syncopal episodes with injections. Vital signs checked and stable. She was passed out for approximately 2 minutes, woke up and was not post-ictal. 911 was called and medics came in to check on patient. She was stable. Refused and signed AMA form for hospital transport. We observed her for approximately 30 minutes and made full recovery. Left in stable condition, asymptomatic. |

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| 1350737 | 5/26/2021 | MI | 18 | F | 5/4/2021 | 5/24/2021 | On May 5th and May 24th, my daughter syncope'd randomly and this has never happened before. I took her to her general practitioner and her EKG is now abnormal. It never was in the past. We will be taking her to a cardiologist and neurologist for further testing. |
| 1350883 | 5/26/2021 | ID | 12 | F | 5/18/2021 | 5/18/2021 | Episode of syncope after receiving the covid vaccine. Secondary injury to back of head after falling out of chair. 3:05 PM Vital Signs: BP 118/62 HR 92 Resp 18 O2Sat 98 Skin Signs: Warm and dry Initial Treatment: Initial impression: altered mental status, shallow breathing, pupils Perla. Patient regained consciousness and was able to respond to questions. Patient was placed in a wheel chair and taken to triage area. Vitals taken. 3:20 PM Vitals: BP 116/82 HR 82 Resp 16 O2Sat 98 Skin Signs: Warm and dry Circulation: Cap refill <2sec Respiratory: Breath sound clear bilaterally Follow up Treatment: Denies nausea. AOx1 No longer feeling 'shaky'. Very slight swelling at the site of head injury. Ice pack in place. 3:35 PM Vitals: BP 116/66 HR 78 Resp 16 O2Sat 99 Skin Signs: Warm and dry Circulation: Cap refill <2sec Respiratory: Breath sound clear bilaterally Follow up Treatment: Home with mother with CHI instructions. |
| 1350862 | 5/26/2021 | | 43 | M | 5/25/2021 | 5/25/2021 | Syncope, Dizziness. Pt reported symptoms of dizziness after vaccination that did not improve in observation. Pt taken to private observation room. BP 133/76, HR 77, RR 16 -- > 133/75, 76, RR 16. Pt laying on bed communicating and resting. Pt symptoms resolved and pt was released from the vaccination site. |

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| 1350802 | 5/26/2021 | NM | 18 | M | 5/26/2021 | 5/26/2021 | 18 year old otherwise healthy male, with mild asthma, and history of vasovagal syncope with prior vaccinations, IV's and any type of injection on multiple occasions. He has no history of prior seizures or seizure disorder. He received his vaccine at about 9 AM and walked to our 15 minute observation area. Within 5 minutes of sitting down, he stated he was not feeling well, became unresponsive, and had a series of 3 very brief, witnessed tonic clonic seizure activity, each lasting 5 seconds or less, with only a few seconds between. Following this he was minimally responsive, still sitting up, eyes opened, and only mumbled in response to questions. He was pale, confused, mildly diaphoretic, BP was 119/99 pulse was 61, O2 sat was 96% and resp rate was approximately 20. He was NOT incontinent of stool or urine. He was fully conscious and oriented to person place time and situation within 5 minutes. He soon regained his color and vitals continued to be stable. He does have a history of "low blood pressure" per his report. He was feeling well, but because of the history witnessed seizure activity the decision was made to transport to hospital. He was transported by Ambulance Service to Hospital. Prior to vaccination today was feeling well. He was accompanied by his girlfriend. Diagnosis per supervising MD, was Post vaso-vagal syncope seizure activity. Or seizure activity related to vaso-vagal syncope. |
| 1350777 | 5/26/2021 | TN | 19 | F | 5/25/2021 | 5/25/2021 | Patient had presumed fainting episode post. Blood pressure checked (117/78) pulse 77. once determine glucose was run and ended up 77 after some lemonade. Patient Denied EMS later and signed AMA. Patient stable, with friend at end and was told s/s to re call ems if needed. |
| 1350773 | 5/26/2021 | PA | 12 | F | 5/22/2021 | 5/22/2021 | Patient turned pale after vaccination; fainted without injury. Completely recovered within minutes with hydration and support. |
| 1350757 | 5/26/2021 | | 15 | M | 5/25/2021 | 5/25/2021 | Syncope, Vomiting, flushing/sweating. BP 122/47, HR 51, RR 16 -- > 125/71, 54, 16. Pt fell to the floor but recovered after resting. Pt stable and released from the vaccination site. |

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| 1350955 | 5/26/2021 | | 15 | F | 5/25/2021 | 5/25/2021 | Syncope. Pt fainted and fell on Left side. Had small elbow abrasion. No Bleeding. Pt denies hitting head. No swelling noted. HR stead 80-100, RR 18. BP 128/82 -- > 110/65 -- > 112/74. Pt symptoms resolved. Pt stable and released from the vaccination site. |
| 1349770 | 5/26/2021 | MA | 18 | F | 5/25/2021 | 5/25/2021 | Systemic: Confusion-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Nausea-Medium, Systemic: Shakiness-Medium, Additional Details: patient passed out. did not know were she was. went to her car. came back and was crying, she did not remember getting the shot. |
| 1351059 | 5/26/2021 | NY | 27 | F | 5/24/2021 | 5/24/2021 | Systemic: Fainting / Unresponsive-Medium |

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| 1349440 | 5/26/2021 | GA | 39 | F | 3/26/2021 | 3/26/2021 | could not sleep at all; fainted; felt worse fainted and almost felt passing out; multiple panics attacks during the day; sensitiveness to salty food; palpitations/heart palpitation 138 "bps"; heart raised really quick; felt difficulty breathing; This is a spontaneous report received via COVID-19 Vaccine Adverse Event Reporting System (COVAES). A contable consumer (patient) reported a 39-year-old female patient received dose 1 of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; lot number EN6207) via an unspecified route of administration on 26Mar2021 at 10:00 (at the age of 39-years-old) as a single dose in the left arm for COVID-19 immunization. Medical history included non-alcoholic steatohepatitis (NASH) and pre-diabetic. The patient was not pregnant at the time of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the vaccine. The patient was not diagnosed with COVID-19 prior to the vaccine. Concomitant medications included multivitamins. The patient did not have any allergies. On 26Mar2021, ten minutes after the vaccine (also reported as 10:15) the patient experienced heart raised really quick and felt difficulty breathing but calmed down and left the site. The next day (27Mar2021) she drank coffee like every morning but noticed palpitations, noticed sensitiveness to salty foods after ingestion felt palpitations but was not concerned as she thought it was a side effect. On 31Mar2021 she suddenly woke up at 05:00 with heart palpitations "138 bps." She thought it was going to go away but she felt worse, fainted, and almost "felt" passing out. Paramedics showed up and her heart rate was 115 but nothing serious, suspected panic attack. She never had before so she thought it was going to go away but she had multiple panic attacks during the day and night, could not sleep at all for 3 consecutive days. The patient visited a doctor as a result of the events. She was prescribed trazodone "one at night." The patient also saw a cardiologist for the palpitations and was treated with metoprolol 25 mg twice a day to control palpitations but the meds gave her intrusive thoughts and deep depression with suicidal thoughts. The outcomes of heart raised really quickly/palpitations, difficulty breathing, sensitiveness to salty foods, fainted, almost "felt" passing out, and panic attacks were recovering. No follow-up attempts are possible. No further information is expected. |

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| 1351407 | 5/26/2021 | SC | 52 | F | 5/26/2021 | 5/26/2021 | patient was given vaccine at the pharmacy at 10:14AM, patient fainted 2 hours after receiving the vaccine at about 12:15PM in the deli/bakery, store management called EMS, the patient was sitting up and talking to management and EMS after the fainting episode, she said she felt hot and had not eaten before fainting. |
| 1349552 | 5/26/2021 | WA | 45 | F | 4/30/2021 | | Fainting; Sore arm; Abdominal pain; This is a spontaneous report from a contactable consumer (patient). A 45-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EW0164; Expiration date was not reported) on the left arm on 30Apr2021 (16:30) as a single dose, with route of administration unspecified, for COVID-19 immunization at the workplace clinic. The patient's medical history and concomitant medications were not reported. The patient was not pregnant at the time of vaccination. On an unspecified date in 2021, the patient was fainting; had sore arm; and had abdominal pain. The patient did not receive any treatment for the events. The outcome of the events was recovered on an unspecified date in 2021. The patient was not diagnosed with COVID-19 prior to vaccination, and had not been tested since the vaccination. No follow-up attempts are possible. No further information is expected. |

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| 1349569 | 5/26/2021 | MA | 38 | M | 5/10/2021 | 5/10/2021 | Lightheaded and fainted within 3 minutes of the shot.; Lightheaded and fainted within 3 minutes of the shot.; This is a spontaneous report from a contactable consumer reported for himself. This 38-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 10May2021 16:45 Right arm at 1st dose, single (lot: Ew0182) for covid-19 immunisation. Medical history included COVID-19 from 01Feb2021 to 05Mar2021. Prior to vaccination, the patient diagnosed with COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No other medications the patient received within 2 weeks of vaccination. He experienced Lightheaded and fainted within 3 minutes of the shot on 10May2021. Events resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care. Lab data included Nasal Swab on 01Feb2021: Positive, on 05Mar2021: Negative. Since the vaccination, the patient has been tested for COVID-19: unknown result. Cat scan was received for the events. Outcome of the events were recovered. No follow-up attempts are needed. No further information is expected. |

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| 1349420 | 5/26/2021 | MA | 44 | M | 4/8/2021 | 4/8/2021 | Fainting; Remained unconscious for a few seconds; Sweating; Minor tightness in the chest; Blurred vision; This is a spontaneous report was received from a contactable consumer (patient). A 44-years-old male patient received BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Lot Number: ER8734), via an unspecified route on 08Apr2021 at 13:15 as 1st dose, single in the left arm for covid-19 immunisation. The patient's medical history was not reported. The patient's concomitant medications included Betamethasone Dipropionate Cream USP 0.05%. The patient had known allergies with Keflex (cephalexin). Prior to the vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient did not receive any other vaccines within four weeks prior to the vaccination. On 08Apr2021 (5 minutes after vaccination), the patient experienced sweating, minor tightness in the chest and blurred vision followed by fainting and remained unconscious for a few seconds. After regaining consciousness, continued sweating for maybe 10 minutes. The patient visited emergency room. The patient did not receive any treatment for the events. On an unspecified date in APR-2021, the patient had recovered from the events. |

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| 1349736 | 5/26/2021 | NE | 72 | F | 2/25/2021 | 2/25/2021 | Loss of consciousness; Malaise; Pyrexia; This case was received via FDA VAERS on 11-May-2021 and was forwarded to Moderna on 11-May-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of LOSS OF CONSCIOUSNESS (Loss of consciousness) in a 72-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 023M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Osteoarthritis, Osteoporosis, GERD, Hypercholesterolemia, Irritable bowel syndrome, Hypothyroidism, Hypertension, Diabetes mellitus and Coronary atherosclerosis. Concomitant products included ASPIRIN [ACETYLSALICYLIC ACID], ATORVASTATIN, UBIDECARENONE (COQ10 [UBIDECARENONE]), DOCUSATE SODIUM, BIFIDOBACTERIUM LACTIS, BIFIDOBACTERIUM LONGUM, LACTOBACILLUS ACIDOPHILUS (FLORAJEN3), GLIPIZIDE, LEVOTHYROXINE, OMEPRAZOLE, INSULIN DEGLUDEC (TRESIBA), VALSARTAN, VITAMIN D3 and ZOLEDRONIC acid for an unknown indication. On 25-Feb-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 25-Feb-2021, the patient experienced PYREXIA (Pyrexia). On 26-Feb-2021, the patient experienced LOSS OF CONSCIOUSNESS (Loss of consciousness) (seriousness criterion medically significant) and MALAISE (Malaise). At the time of the report, LOSS OF CONSCIOUSNESS (Loss of consciousness), MALAISE (Malaise) and PYREXIA (Pyrexia) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 26-Feb-2021, Blood glucose: 142 mg/dl (abnormal) 142 mg/dl. On 26-Feb-2021, Blood pressure measurement: 117/60 (normal) normal, Earlier it was noted to be in the 90s systolic. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Treatment information was not provided. On night of 25-Feb-2021. The patient reported running a fever. On 26-Feb-2021, the patient woke up with not feeling well. The patient's blood sugar was checked which was 142 mg/dl and shortly after she passed out. The patient's blood sugar was noted to be in the 90's systolic as taken by her |

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daughter, who was a nurse. On re-checking the patient's blood pressure, it got improved to 117/60. The patient was scheduled to be seen with her primary care provider on 26-Feb-2021 to verify that the patient was stable. Company Comment: Very limited information regarding these events has been provided at this time. No further follow-up information is expected.; Sender's Comments: Very limited information regarding these events has been provided at this time. No further follow-up information is expected.

weakness generalized; . This is a spontaneous report from a non contactable other health care professional, the patient. A 40 year old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EN6205) via an unspecified route of administration, and anatomical site as 2nd dose, single, on 16MAR2021 (at the age of 40-years-old) for COVID-19 immunization. Patient past drug history include BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: not known) via an unspecified route of administration, anatomical site as 1st dose, single, on unspecified date for COVID-19 immunization. On 16MAR2021 after vaccination, during her 15 minute waiting period after the injection, the patient began to experience generalized weakness, need for a quick snack. She denied rash, shortness of breath, difficulty swallowing or syncope treatment included: snacks. It was reported that follow up response to treatment was good. Patient discharge: stable to go home. Clinical outcome of the event generalized weakness was reported as recovered .No follow-up attempts are possible. No further information is expected.

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| 1350294 | 5/26/2021 | ME | 22 | F | 5/25/2021 | 5/25/2021 | Episode of apparent vasovagal syncope a few minutes after receiving the vaccine. This was witnessed by myself. She appeared to have loss of consciousness and collapsed onto the pavement striking her posterior head on the pavement (fortunately, she did not strike it with great force). She regained consciousness within 2-3 seconds. She had a small "knot" on her posterior scalp, but no break in the skin. No other apparent injury. She initially complained of a headache, but this resolved over the course of about 10 minutes. She initially was mildly diaphoretic and had a rapid pulse and mild hypotension, but these also resolved over the course of several minutes. A chemical ice pack was applied to the posterior scalp and neck. She had a completely normal neurologic and musculoskeletal examination. She was provided oral fluids (water and kool aid) and a snack (chewy granola bar) and kept under close observation by medical personal for about 30 minutes. Transport to the emergency room via ambulance was offered, but declined. Her boyfriend was called and came to drive her home after she had made an apparent complete recovery. Both he and she were extensively counseled regarding signs and symptoms to be on the lookout for that would indicate the need for further medical evaluation and they both expressed complete understanding and agreement. Of note, she reported that she has had episodes of syncope in the past when having blood drawn for laboratory tests, but decided not to disclose this to on site personal prior to the vaccination thinking she would probably not have a problem. |
| 1350299 | 5/26/2021 | OH | 26 | M | 5/25/2021 | 5/25/2021 | Systemic: Allergic: Anaphylaxis-Severe, Systemic: Allergic: Difficulty Breathing-Severe, Systemic: Confusion-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Hyperventilation-Severe, Systemic: Seizure-Severe |

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| 1350302 | 5/26/2021 | NY | 23 | M | 5/25/2021 | 5/25/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Exhaustion / Lethargy-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Visual Changes/Disturbances-Medium, Additional Details: Adverse event included loss of color in face (patient turned white) including lips, eye rolled upward staring at ceiling, patient slouching on bench until flat on back on bench (head in mother's arms); patient remained like this for at least a couple minutes while mother was yelling for help; patient eventually regained focus and comforted mother in return; patient reported could not see well and experienced dizziness and still had complete loss of color in face; epinephrine pen was not used |
| 1350306 | 5/26/2021 | IL | 16 | F | 5/25/2021 | 5/25/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Hypotension-Medium |
| 1350314 | 5/26/2021 | OH | 23 | M | 5/25/2021 | 5/25/2021 | Systemic: Fainting / Unresponsive-Medium |
| 1350317 | 5/26/2021 | WA | 24 | M | 5/17/2021 | 5/17/2021 | Site: Pain at Injection Site-Mild, Site: Redness at Injection Site-Mild, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Nausea-Medium, Systemic: Shakiness-Medium, Systemic: Weakness-Medium, Additional Details: Patient was sitting in chair after vaccination and <5 minutes later, he started shaking, then faceplanted on the ground. He regained consciousness within 30 seconds. I elevated his feet and laid him on his back/gave water bottle. Observed for total of 30 minutes before allowing him to leave. he denied emergency services. |

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| 1349620 | 5/26/2021 | MN | 28 | F | 5/6/2021 | 5/7/2021 | lost consciousness/fainted; Feeling feverish; feeling lightheaded/dizzy; drenched in sweat; This is a spontaneous report received from a contactable consumer (the patient). A 28-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number not provided), via an unspecified route of administration in the right arm on 06May2021 16:30 (at the age of 28-years-old) as a single dose for COVID-19 immunization. The patient had no medical history. The patient had no known allergies. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient was not pregnant at the time of vaccination. Concomitant medication included: ethinylestradiol/ norethisterone acetate (LARIN 1.5/30) and multivitamin. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number not provided), via an unspecified route of administration in the right arm on 15Apr2021 16:30 (at the age of 28-years-old) as a single dose for COVID-19 immunization. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient woke up at 03:00 on 07May2021 (also reported as 03:05), the night after receiving her second dose of COVID-19 vaccine, feeling feverish and dizzy. She got up to urinate. While she was on the toilet, she started feeling lightheaded and lost consciousness (07May2021 03:00). The next thing she remembered was coming to on the bathroom floor, drenched in sweat (07May2021 03:00). She had been unconscious for two minutes. This was the first time that she had ever fainted. A doctor or other healthcare professional office/clinic visit was involved. No treatment was received. The outcome of the events was recovering. It was also reported that since the vaccination, the patient had not been tested for COVID-19. Information about lot number has been requested. |
| 1350363 | 5/26/2021 | MA | 23 | F | 5/1/2021 | 5/2/2021 | The day after my 2nd shot, I woke up very nauseous, ended up fainting, then processed to vomit while being unconscious still. |
| 1350462 | 5/26/2021 | WA | 31 | F | 5/24/2021 | 5/24/2021 | Systemic: Fainting / Unresponsive-Medium |

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| 1350457 | 5/26/2021 | NY | 27 | F | 5/24/2021 | 5/24/2021 | Patient stood up within 5 minutes of receiving vaccine and fainted. |
| 1350435 | 5/26/2021 | OH | 22 | M | 5/25/2021 | 5/25/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild |
| 1350414 | 5/26/2021 | PA | 14 | M | 5/25/2021 | 5/25/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Seizure-Severe, Systemic: Vomiting-Severe, Additional Details: AFTER SHOT ADMINISTERED,PATIENT WAS WALKING TO WAITING AREA FOR OBSERVATION, WE FAINTED AND HAD 2 SEIZURES ABOUT 40 SECONDS LONG. NO PULS OR BREATHING. GAVE 10 CHEST COMPRESSIONS AND 2 BREATHS. EMERGENCY WORKER SHOPPING IN STORE HELPED ROLL TO RESCUE POSITION AFER FEEELING PULSE IN THE WRIST. HE SPIT UP A SMALL AMOUNT OF SPIT. HE SHORTLY CAME AORUND IN ABOUT ANOTHER MINUTE. NO EPINEPHRINE WAS ADMINISTERED. |
| 1350386 | 5/26/2021 | WA | 32 | M | 5/24/2021 | 5/24/2021 | Systemic: Fainting / Unresponsive-Medium |
| 1350384 | 5/26/2021 | VA | 27 | M | 5/4/2021 | 5/22/2021 | 27-year-old gentleman with history of mild intermittent asthma, anxiety, presented with complaints of fever of 99.8 °F on 5/22/2021 associated to fatigue and body aches and then chest pain, generalized with radiation to left arm since afternoon of 5/23/2021, which got worse on 5/24/2021 and he was admitted for further evaluation with initial troponin of 472. Had an NSTEMI; chest tightness, pain in left arm, lightheadedness, dizziness, presyncope. Discharge diagnosis - probable myocarditis; clinical picture most consistent with viral myocarditis. |

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| 1349419 | 5/26/2021 | OH | 27 | F | 4/5/2021 | 4/6/2021 | Loss of consciousness; 4 days of chronic stomach pain; diarrhea; This is a spontaneous report from a contactable consumer (patient). A 27-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in Arm Left on 05Apr2021 16:00 (Batch/Lot Number: ER8734) as 1st dose, single for covid-19 immunisation. Medical history included vasovagal syncope which has not occurred in several years, allergies with gluten and covid prior to vaccination. Concomitant medication included ethinylestradiol, ferrous fumarate, norethisterone acetate (JUNEL FE). The patient had no other vaccine in four weeks. The patient previously took amoxicillin and experienced allergies. On 06Apr2021 01:00, the patient experienced loss of consciousness during sleep for about 30 seconds and 4 days of chronic stomach pain with diarrhea which resulted in limited ability to perform daily activities and work. The events were not treated. The patient was not tested for Covid post vaccination. The outcome of the events was recovering. |
| 1350378 | 5/26/2021 | | 13 | F | 5/22/2021 | 5/22/2021 | AE: light headed, dizzy, pale, fainted Tx: n/a, just food and drink Outcome: juice, crackers helped resolve AE. pt was discharged home. |

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| 1349408 | 5/26/2021 | TX | 65 | F | 2/26/2021 | 2/26/2021 | pressure behind ears; Jaw pain; sore throat; fatigue; lightheaded; headache; clammy feeling.; syncopal; This is a spontaneous report from a contactable Nurse. The nurse reported that a 65-year-old non-pregnant female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; formulation: Solution for injection, Lot Number and expiration date were UNKNOWN), first dose via an intramuscular route of administration in the right arm on 26Feb2021 as a single dose for COVID-19 immunisation. The patient's medical history includes artificial heart valve, transcatheter aortic valve replacement and penicillin allergy. Concomitant medications included ramipril, carvedilol and acetylsalicylic acid (ASPIRIN). Patient not received other vaccine in four weeks. Other medications in two weeks: ramipril, carvedilol, aspirin. Immediately following the injection. On 26Feb2021 patient had pressure behind ears, jaw pain, sore throat, fatigue, lightheaded, headache, and clammy feeling. Not received any treatment. Patient not had covid prior vaccination; covid not tested post vaccination. patient had the first vaccine and had syncopal in 2021, dizzy, episodes that lasted for 5 weeks. persistent dizziness, almost immediately, and it has lasted for multiple weeks. she did not have throat tightness, cough or shortness of breath. The outcome of the event syncopal was recovered in 2021. For other events outcome was resolved with sequel. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Based on known drug safety profile, there is reasonable possibility of causal association between the event syncope and the suspect drug. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate. |

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| 1350358 | 5/26/2021 | NY | 14 | F | 5/23/2021 | 5/23/2021 | Systemic: Fainting / Unresponsive-Severe, Systemic: Hypotension-Severe, Systemic: Nausea-Medium, Systemic: Shakiness-Medium, Systemic: Weakness-Severe, Additional Details: within minute of injection patient passed out, parent and witness said patient had seizure like shaking (I did not personally witness this), became extremely pale and non-responsive for few minutes. Before shot given Mom informed me patient normally faints and has extreme anxiety and aversion to needles. |
| 1350342 | 5/26/2021 | TX | 32 | M | 5/25/2021 | 5/25/2021 | Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Medium, Systemic: Hypotension-Mild, Systemic: Nausea-Mild, Systemic: Shakiness-Mild, Systemic: Weakness-Mild |

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| 1348983 | 5/26/2021 | FL | 83 | M | 2/27/2021 | 2/27/2021 | <p> Syncope; Injection site pain; Injection site swelling; Nausea; Vomiting; This case was received (Reference number: 1063219) on 11-May-2021 and was forwarded to Moderna on 11-May-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of SYNCOP (Syncope) in an 83-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 001A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Hyperlipidemia, Diabetes mellitus, GERD and Hypertension. Concomitant products included ATORVASTATIN CALCIUM (LIPITOR), FLUTICASONE PROPIONATE (FLONASE ALLERGY RELIEF), AMOXICILLIN TRIHYDRATE, CLARITHROMYCIN, ESOMEPRAZOLE MAGNESIUM (NEXIUM 1-2-3), METFORMIN, LISINOPRIL and ACETYLSALICYLIC ACID (ASPIRIN 81) for an unknown indication. On 27-Feb-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 27-Feb-2021, the patient experienced SYNCOP (Syncope) (seriousness criterion medically significant), INJECTION SITE PAIN (Injection site pain), INJECTION SITE SWELLING (Injection site swelling), NAUSEA (Nausea) and VOMITING (Vomiting). At the time of the report, SYNCOP (Syncope), INJECTION SITE PAIN (Injection site pain), INJECTION SITE SWELLING (Injection site swelling), NAUSEA (Nausea) and VOMITING (Vomiting) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. </p> |

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| 1349106 | 5/26/2021 | AZ | 50 | M | 3/22/2021 | 4/19/2021 | <p>Passed out; Fell from bed; Low systolic blood pressure at 54mmhg; Arm soreness; Felt sick; Diarrhea; Something was cooking in lung; Productive coughs; Vomiting; Nausea; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out), FALL (Fell from bed) and HYPOTENSION (Low systolic blood pressure at 54mmhg) in a 50-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included COVID-19 in January 2021. Concurrent medical conditions included Diabetes. Concomitant products included SITAGLIPTIN PHOSPHATE (JANUVIA) for Diabetes. On 22-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 19-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 19-Apr-2021, the patient experienced PAIN IN EXTREMITY (Arm soreness), ILLNESS (Felt sick), DIARRHOEA (Diarrhea), LUNG DISORDER (Something was cooking in lung), PRODUCTIVE COUGH (Productive coughs), VOMITING (Vomiting) and NAUSEA (Nausea). On 22-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (Passed out) (seriousness criteria medically significant and life threatening), FALL (Fell from bed) (seriousness criterion life threatening) and HYPOTENSION (Low systolic blood pressure at 54mmhg) (seriousness criterion life threatening). On 21-Apr-2021, PAIN IN EXTREMITY (Arm soreness), DIARRHOEA (Diarrhea), LUNG DISORDER (Something was cooking in lung), PRODUCTIVE COUGH (Productive coughs), VOMITING (Vomiting) and NAUSEA (Nausea) had resolved, ILLNESS (Felt sick) outcome was unknown. On 22-Apr-2021, LOSS OF CONSCIOUSNESS (Passed out), FALL (Fell from bed) and HYPOTENSION (Low systolic blood pressure at 54mmhg) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 22-Apr-2021, Blood pressure systolic: 54 mmHg (Low) Low systolic blood pressure at 54mmhg. Physician treated him with fludrocortisone until he felt better for five days.; Sender's Comments:</p> |

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| | | | | | | | Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |
| 1349156 | 5/26/2021 | NC | 58 | F | 2/19/2021 | 2/20/2021 | Loss of taste; This is a spontaneous report from a contactable other hcp. A 58-years-old no pregnant female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in right arm on 19Feb2021 08:00 (Batch/Lot Number: EN6203) as single dose for covid-19 immunisation. Medical history included asthma, meniere's, hypoactive thyroid, syncope, allergies: Penicillin. There were no concomitant medications. No covid prior vaccination, no covid tested post vaccination. The patient experienced loss of taste (non-serious) on 20Feb2021 07:00 with outcome of not recovered. The case is non serious. Follow-up (14MAY2021): Follow-up attempts completed. No further information expected. |
| 1350469 | 5/26/2021 | NY | 24 | M | 5/26/2021 | 5/26/2021 | patient with immediate syncope with vaccination lasting less than 5 seconds. patient recovered with no recurrence. concomitant nausea without emesis and HA |
| 1350381 | 5/26/2021 | LA | 17 | F | 5/17/2021 | 5/19/2021 | Two days after receiving the vaccine, the patient fainted at the home. Has had intermittent shortness of breath, and dizziness |
| 1351905 | 5/26/2021 | IL | 18 | M | 5/26/2021 | 5/26/2021 | Pt received the vaccine & was advised to sit near the pharmacy for 15 min but pt preferred to walk around the store instead. heard mom yelling to call 911 & went to the aisle. Pt fainted while walking in the cooler aisle. Per mom he hit his head against a shelf. He does not recall hitting his head but said his neck was hurting. Pt was alert. Per pt & per mom pt gets anxious w/shots. 911 was called, pt stayed laying on the floor until EMS came to evaluate pt. EMS did not advise pt to go to hospital. |

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| 1351357 | 5/26/2021 | FL | 29 | F | 5/26/2021 | 5/26/2021 | Documentation completed at the site of the event on 05/26/2021 by MA. 0854: Pt stated that she felt "dizzy" and "clammy". Pt closely monitored and given ice packs. BP 150/70, P 62, O2 sat 100%. 0950: BP 110/60, P 58; O2 sat 100%. No syncope. Pt still feeling dizzy. Pt sts her wife will pick her up, supervisor advised. Pt laid down, feet elevated for 10 minutes. Pt states that after laying down she is feeling better. Color has returned to face, vitals were WNL. 1030: Pt went home, wife picked her up, she did not drive. notified APRN of the event on 05/26/2021 at 1015. APRN-telephone call on 05/26/2021 @ 1211: Called pt at her home. Pt sts she was laying down, still feeling tired/weak but denies syncope or other neurologic signs/symptoms. PLAN: Encouraged pt to push PO fluids with electrolytes and explained rationale. To go to ER if syncope or any other neurologic changes. Pt understood and agrees. APRN- telephone call on 05/26/2021 @ 1526. Pt states she is feeling much better, weakness has subsided. Pt has been drinking a lot of fluids. Reports tenderness to injection site. PLAN: Continue to push PO fluids. May use compresses to arm PRN pain. May take tylenol/advil PRN arm pain. Told pt incident will be reported to VAERS. To call the office if any questions. Pt understood and agrees. |
| 1351590 | 5/26/2021 | CA | 20 | F | 5/21/2021 | 5/21/2021 | Loss of hearing and vision, everything dizzy for about 15 minutes Fainted Lips turned grey |
| 1351593 | 5/26/2021 | | 14 | F | 5/26/2021 | 5/26/2021 | Patient fainted within 10 minutes of receiving vaccine. Patient was woke up within 30 seconds of fainting. Upon awakening patient did experience nausea and vomiting. Medical intervention was not necessary. Patient was able to leave pharmacy on own power. |
| 1351617 | 5/26/2021 | CT | 52 | M | 5/22/2021 | 5/22/2021 | patient fainted right after vaccine administration |
| 1351663 | 5/26/2021 | NJ | 16 | M | 5/26/2021 | 5/26/2021 | Patient had the vaccine and then he fainted after the needled removed. He passed out and then he had seizure after. He brought to the Emergency room and was released. |

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| 1351676 | 5/26/2021 | GA | 13 | M | 5/26/2021 | 5/26/2021 | Patient became nauseous 15 minutes after receiving vaccine, then vomited, then fainted. We lowered him to floor with legs raised. He regained consciousness after a few seconds, but was still not clear-headed. He was very anxious and shaking and pale. 911 was called. He was taken to ER, but was clear headed, with heart rate slightly elevated. |
| 1351711 | 5/26/2021 | MI | 40 | M | 5/26/2021 | 5/26/2021 | Patient experienced syncope after receiving 2nd Pfizer Covid-19 vaccine. He sat in the waiting area for approximately 2 minutes before coming back and knocking on the consult room door. When we opened the door he said he felt like he was going to pass out and then fell to the floor, hitting the left side of his head against the wall. He quickly regained consciousness after only a second or two and was able to scoot into the consultation room where we had him lie on his back and elevate his legs. We also gave him a cold compress for his head. We paged department and when AP arrived he contacted EMS to come check him over. The patient did not lose consciousness again and was able to hold a conversation with us while waiting. EMS arrived and checked his vitals and came to the conclusion that he did not need an ambulance. After EMS left the patient drank water and orange juice and sat in the consultation room with me for 20 more minutes before leaving. Patient has no previous history of vaccine reactions or history of fainting. He had no reactions to his first dose other than a sore arm. |
| 1351722 | 5/26/2021 | MI | 15 | M | 5/26/2021 | 5/26/2021 | FAINTED, AND HIT HIS HEAD ON THE GROUND AND TEETH NOW HURT |
| 1351723 | 5/26/2021 | NH | 18 | F | 5/26/2021 | 5/26/2021 | Immediately after vaccination was administered the patient fainted but stayed in the chair. After she came to in about 10 seconds I offered her a cold compress for her head. After a couple of minutes the patient felt good enough to move to observation area. I started getting a vaccine ready for another patient and this patient saw the needle and fainted again. I rushed over to her chair and kept her from falling. After she came to in about 10 seconds I offered to call 911 but the patient refused. Her brother came over from shopping and after a couple more minutes they decided to leave together. |

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| 1351725 | 5/26/2021 | NY | 20 | F | 5/26/2021 | 5/26/2021 | Patient received Janssen covid19 vaccine, she was sitting in post-vaccination waiting area, when she became little headed. Patient closed her eyes and slumped over in chair and fainted. We brought patient to the floor and she came to. Patient stated this commonly happens after vaccines or giving blood as she has anxiety of both. She also stated she did not eat anything all day. Patient was given ice pack and remained in post vaccination waiting area for 30 minutes. Patient stated she felt fine shortly after laying down on the floor. |
| 1351850 | 5/26/2021 | CT | 46 | M | 5/19/2021 | 5/19/2021 | Within 2 minutes of receiving shot, overwhelming deadening of sound, blackness in eyes, full body sweats, full body discomfort, very close to fainting for first 6-8 minutes. As those symptoms started to diffuse severe muscle cramping started in opposite arm of shot, moved thru body. Within 15 minutes the only symptoms left were the muscle cramps. Those continued for several days. Still lingering today, a week later. |
| 1351869 | 5/26/2021 | MI | 20 | M | 5/26/2021 | 5/26/2021 | Patient begin to feel faint about 5 minutes after receiving vaccine. He became very pale and fainted briefly (less than 2 minutes). Patient sat and waited at the facility for about 30 minutes after regaining consciousness. He regained his color and was able to leave. |
| 1351880 | 5/26/2021 | CO | 14 | M | 5/26/2021 | 5/26/2021 | patient fainted within 1 minute of getting vaccine. Came around very quickly, about 10 seconds. We got him to lay down, rest with legs on chair, felt better in 30 minutes with water and cookies. this is a known issue with patient and vaccinations |
| 1351576 | 5/26/2021 | | 55 | M | 5/22/2021 | 5/23/2021 | first day: fever 100.7, fatigue, extreme thirsty second day: fever 100.8, very disoriented, extreme fatigue, I passed out and was unconscious for atleast 2-3 minutes 911 was called. |

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| 1352136 | 5/26/2021 | WA | 14 | F | 5/26/2021 | 5/26/2021 | Patient with history of syncope following vaccine administration came to the pharmacy for COVID vaccine. She was accompanied by her father. They warned me of the history prior to giving the vaccine. Within a minute after administration, patient fainted in the chair and slide accompanied by myself and dad to the floor. She was out for about a minute. She rested on the floor for 5 minutes and then moved to the chair, where she recovered for 10 minutes. When she felt able to walk, she went the the pharmacy lobby and continued to recover until 4:18pm. |
| 1350336 | 5/26/2021 | NY | 19 | F | 5/25/2021 | 5/25/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: pt has had fainting spells within the last year, pt and parents did not want to seek medical attention or call 911, pt stayed in pharmacy for 45 minutes |
| 1352543 | 5/26/2021 | WA | 26 | F | 5/25/2021 | 5/26/2021 | Syncope (lost consciousness) in the morning after the vaccine. Accompanied by fever, chills, dizziness/presyncope, nausea, headache, body ache, stiff neck on same side as vaccinated arm, sore throat and excessive saliva production |
| 1352536 | 5/26/2021 | WA | 24 | M | 5/26/2021 | 5/26/2021 | Patient with known Syncope reactions to needles answered no on intake form. Patient administered vaccine and immediately passed out. Patient was transitioned to floor. feet elevated and blood pressure returned. rested for 25 min. tried to resume sitting position and passed out again. transitioned again and ok. Hydrated and gave sugar. checked pulse and BP and was normal. took an exaggerated rest period. patient left on own power once fully recovered. Then it was mentioned by the patient that we have a needle phobia and pass out. |

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| 1352528 | 5/26/2021 | CO | 13 | F | 5/1/2021 | 5/22/2021 | Patient fainted immediately after receiving the Pfizer vaccine. She regained consciousness immediately as soon as patient was placed on her back on the floor with feet elevated. Her blood pressure was normal and she was kept under watch for 20-25 mins after receiving the vaccine and she left the clinic after we observed her for 20-25 mins and she was doing absolutely fine. Followed up with the parent on Wednesday 5/26/21 at around 7:45pm. Mother reported patient is doing absolutely fine. I told patient's mom, fainting can be caused due to nervousness and drop in oxygen levels to the brain. However, this adverse effect will be reported to patients doctor and also to the VAERS for Pfizer covid-19 vaccine. |
| 1352150 | 5/26/2021 | WA | 14 | M | 5/26/2021 | 5/26/2021 | 5/25/21 @ Approximately 12:03 pm, 14 year old Patient fainted while waiting in vaccination waiting area after his first COVID-19 vaccination (Pfizer). Patient stated that he started to have ringing in the ears and some blurred vision. Patient's father instructed patient to lay down on the three chairs in vaccination waiting area. At this time store employee came out to assist patient and patient's father. I (employee) came out to assist moments later when I saw what was happening (I had just finished a consultation with another patient). We elevated patient's legs, put and ice pack under his neck, and called 911. Patient was awake but not very talkative. Patient was very alert and talkative in Clinical Service room at the time of immunization, which was a big change from how he was immediately after fainting. Patient appeared sweaty and pale in color. Patient's blood pressure was taken at 12:09 pm and was 88/51 pulse 53 (patient was still laying down at this time). Respiration rate was 20 breaths per minute. At 12:12 pm blood pressure was taken again as patient appeared more responsive and talking more. His BP was 101/63 and pulse 63. Immediately after second blood pressure reading, EMS arrived and they took over. Patient was responsive and drink water and sitting up at this point. EMS checked patient out and was cleared shortly after. EMS stated that this will not defer patient from getting his second COVID vaccination. Before patient left he was continuing to drink water and was eating some crackers. |

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| 1351883 | 5/26/2021 | OH | 45 | M | 5/26/2021 | 5/26/2021 | Patient left the pharmacy area following the vaccination and headed to the employee breakroom to wait the required 15 minutes for observation. He reached the breakroom and sat down. He then became pale and passed out for a few seconds. |
| 1352144 | 5/26/2021 | CA | 22 | M | 5/26/2021 | 5/26/2021 | At 2:15pm patient was seated in the observation area after receiving vaccine. Patient was observed while his head fell back and appeared to have fainted. Patient stated he had not eaten since yesterday. Vital signs were taken blood pressure noted at 117/56, pulse 62, O2 sat 99%. Patient was given a snack and verbalized he felt better. Vital signs were taken again fifteen minutes later and were noted at blood pressure 118/70, pulse :82, O2 99%. Patient was driven home by a friend. |
| 1351884 | 5/26/2021 | FL | 30 | F | 5/24/2021 | 5/25/2021 | I had a fainting spell, confused, fatigue, not oriented x3. Soreness all over my body and needed to be hospitalized for stroke like symptoms. |
| 1352127 | 5/26/2021 | CA | 17 | F | 5/25/2021 | 5/25/2021 | Pt fainted several minutes following vaccination. Pt's mother was vaccinated, then patient, then patient's sister. Pt left vaccination chair following vaccination to allow her younger sister to sit. She stood for several minutes, leaning against wall/counter but immediately after her sister's vaccine she fainted. She slid down the counter but her mother and the vaccination caught her before she landed on the floor. She lost consciousness for approx. 30 seconds, regaining it slowly. While no health conditions were reported on the VAR form the pt appeared to possess traits of a developmental difficult such as Down's syndrome. While she awoke she didn't want to speak and appeared nervous. After approx. 2 min the patient spoke voluntarily. After several more minutes of deep breaths, patient sat up and answer questions regarding the time and place and personal history. She moved to another area to sit, was given water, and after approx. 25 min, left with her family. |
| 1352119 | 5/26/2021 | MI | 17 | M | 5/26/2021 | 5/26/2021 | Patient passed out after receiving vaccine. He hit his head and stated his teeth hurt. |
| 1352113 | 5/26/2021 | PA | 14 | F | 5/26/2021 | 5/26/2021 | patient became dizzy and lightheaded. patient passed out. |

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| 1351926 | 5/26/2021 | NE | 12 | M | 5/26/2021 | 5/26/2021 | PFIZER COVID VACCINE ADMINISTERS APPROX 4PM. 4:03PM (APPROX.) PATIENT FAINTED IN CHAIR IN WAITING AREA. MOM & PHARMACIST GENTLY LAID PATIENT DOWN ON FLOOR, PATIENT REGAINED CONSCIOUSNESS WITHIN 1 MIN & WAS ALERT, KNEW HIS NAME, WHERE HE WAS, WHAT WAS HAPPENING. GAVE PATIENT OJ, WATER, GRANOLA BAR, TRIED TO HAVE HIM SIT IN CHAIR AFTER ABOUT 5-10 MIN, BUT PATIENT STATED FEELING LIKE GOING TO PASS OUT, HAD PATIENT LAY ON FLOOR WITH FEET UP ON CHAIR. APPROX 4:30PM PATIENT VITALS: BP 72/48, HR 81, O2 SAT 99%. PATIENT FEELING DIZZY, LAID ON FLOOR WITH FEET UP ON CHAIR, CONTINUED DRINKING WATER AND OJ. APPROX. 5PM PATIENT SITTING IN CHAIR, VITALS: BP 98/62, HR 95, O2 SAT 98%. PHARMACIST CONSULTED PEDIATRICIAN WHO ADVISED IF PATIENT FEELING OKAY AND NOT DIZZY/FEELING FAINT, OKAY TO LET GO HOME BUT TO REST TONIGHT AND TAKE IT EASY. ADVISED MOM TO TAKE TO ER IF ANY FURTHER FAINTING INTO THE EVENING. APPROX. 5:10PM PATIENT LEFT PHARMACY WITH MOM AND STATED FEELING FINE. MOM ACKNOWLEDGED SHE UNDERSTOOD PLAN FOR EVENING AND TO FOLLOW UP WITH PEDIATRICIAN REGARDING GUIDELINES/HOW TO HANDLD 2ND DOSE OF VACCINE. |
| 1351910 | 5/26/2021 | AL | 33 | M | 5/26/2021 | 5/26/2021 | Patient got light headed and passed out sitting in his chair. His pupils were very dilated and he fell in and out of consciousness for about 2 minutes. EMTs arrived and cleared him to go home. |

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| 1351570 | 5/26/2021 | MN | 13 | F | 5/26/2021 | 5/26/2021 | Patient was vaccinated by Dr. As she was handing her dad, her sticker, she fainted. On the way to the floor, she bumped the top left part of her head. No bump or swelling. She states it is tender but not painful. She recovered from the faint immediately with return to full consciousness. A& O X3. She was moved to a lounge chair and laid back for 10 minutes, then to sit position, then attempted stand. On first attempt she still felt dizzy so she returned to a sit for 5 additional minutes. Then she was able to walk on own accord to observation area. She kept ice pack to head the whole time. She had a juice, water, and a piece of candy. She denied other s/s. Dad was offered a copy of incident report but left prior to completion. PHN will mail to family. RN PHN |
| 1352147 | 5/26/2021 | IL | 37 | M | 5/26/2021 | 5/26/2021 | SHORTLY AFTER RECEIVING VACCINE (APPROXIMATELY 1/2 MINUTE) PATIENT FAINTED. HE SLOWLY SLID OUT OF CHAIR AND I (PHARMACIST) CAUGHT HIM GOING DOWN AND HE LANDED ON HIS LEFT SIDE, ALMOST FACE DOWN. I SHOUTED OUT HIS NAME SEVERAL TIMES, ROLLED HIM ON HIS BACK, AND CHECKED FOR BREATHING. NO BREATH SOUNDS OR CHEST RISING, COULD NOT FIND A PULSE, AND THEN HIS EYES ROLLED UP AND BACK. A STORE CUSTOMER CALLED 911 AND I BEGAN COMPRESSIONS. AT COUNT 20 HE BEGAN TO MOVE AND TRIED TO TALK. STOPPED COMPRESSIONS, AND ROLLED PATIENT ON HIS LEFT SIDE. I WAS ABOUT TO CHECK BLOOD PRESSURE WHEN PARAMEDICS WALKED IN AND TOOK OVER. PARAMEDICS CHECKED VITALS, TEMPERATURE, BLOOD GLUCOSE AND RAN EKG. THEY SAID THEY COULD NOT SHARE RESULTSWITH ME, BUT STATED PATIENT REFUSED TO GO TO THE ER/HOSPITAL. AFTER ABOUT 30 MINUTES PATIENT WALKED OUT OF THE STORE ON HIS OWN. |
| 1351320 | 5/26/2021 | NY | 29 | M | 4/29/2021 | 4/29/2021 | Severe headache, rigors, high fever (subjective), tachycardia, severe nausea. Drenching sweats, "strange thoughts". Rigors and drenching sweats throughout the night. "Crazy shaking fits." Presyncope. Got to point where patient considered calling ambulance. Lasted 12 hours then fully resolved. |

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| 1351069 | 5/26/2021 | CA | 17 | F | 5/25/2021 | 5/25/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild |
| 1351079 | 5/26/2021 | PA | 76 | F | 3/10/1921 | 3/11/2021 | When I woke up I felt my legs wouldn't hold me up. I passed out in the bathroom. Finally managed to get up and walk with the aid of a walker. I have no more memory of that day. Except for meals and bathroom use I remained lying down all day. I was very nauseous and severely weak, light-headed, and had brain fog, Except for the nausea I felt that way for 10 days. On the 10th day I felt able to stand long enough to take a shower. |
| 1351080 | 5/26/2021 | CA | 24 | F | 5/1/2021 | 5/1/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild |
| 1351127 | 5/26/2021 | NY | 23 | M | 5/25/2021 | 5/25/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Exhaustion / Lethargy-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Visual Changes/Disturbances-Medium, Additional Details: Adverse event included loss of color in face (patient turned white) including lips, eye rolled upward staring at ceiling, patient slouching on bench until flat on back on bench (head in mother's arms); patient remained like this for at least a couple minutes while mother was yelling for help; patient eventually regained focus and comforted mother in return; patient reported could not see well and experienced dizziness and still had complete loss of color in face; epinephrine pen was not used. |
| 1351136 | 5/26/2021 | GA | 58 | F | 5/26/2021 | 5/26/2021 | Within 10 minutes of receiving 1st vaccine client exhibited signs of SOB, sweating all over, tingling in both arms from the elbow down to fingers, then syncope for app 1 minute. Received shot at 1:30 PM BP @ 1:50 PM was 81/50 P-68@99%. BP@ 2:08PM 68/43 P-65@99%. Given bottle of water and 2 pieces of bite size chocolate (milky way). Was AVO X3 before leaving with sister to stay the night. If any other symptoms arrive will go to ER. |
| 1351153 | 5/26/2021 | | 19 | F | 5/25/2021 | 5/25/2021 | Patient fainted after approximately 5 minutes after first dose. |

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| 1351179 | 5/26/2021 | WI | 18 | F | 5/26/2021 | 5/26/2021 | Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Hypotension-Medium, Additional Details: Patient became unresponsive (eyes rolled back). Attempted to obtain response and 911 was called. Patient returned to responsiveness in less than 1 min and was confused. Unaware that they had lost consciousness. BP/Pulse was check and was low. EMTs arrived within 5 min and patient BP/Pulse and returned to normal upon recheck. Patient declined further treatment or transport. Mother was present in store and provided food and water. Observed for an additional 20 min. Patient left on own ambulation. |
| 1351190 | 5/26/2021 | OH | 28 | F | 5/25/2021 | 5/25/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: approximately 13 minutes after first covid dose the patient stated she was blacking out. Patient then lost consciousness for approximately 2 minutes. Patient regained consciousness and was breathing normally but remained unresponsive to questions. Patient was moved to bench. Blood pressure was 131/54 with a pulse of 57. Patient remained awake but unresponsive to questions. 911 called after 5 minutes. Squad responded in approximately 5 minutes. Patient regained verbal response and recovered |
| 1351245 | 5/26/2021 | WI | 12 | M | 5/21/2021 | 5/21/2021 | Chief complaint: Fainting post vaccination 1500: Sat up and briefly felt better. Needed to lay back down due to feeling lightheaded and faint again. 1515: Reports feeling "a little better". Able to sit up again. Slight headache 1522: Sitting up in chair, drinking water, reports feeling fine. Went home with his mother |
| 1351258 | 5/26/2021 | MD | 28 | F | 4/22/2021 | 4/23/2021 | Dizziness that lead to almost fainting for 1 week, palpitations if i exert a lot of energy like lifting weights to this day |
| 1351269 | 5/26/2021 | TN | 35 | M | 4/28/2021 | 4/28/2021 | Patient reported vaso-vagal response ~5 minutes post vaccination. He walked out to his car to wait after his vaccination and "felt unwell". He was able to walk to his car but immediately fainted. His wife reports he regained consciousness ~1 minute after. |

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| 1351271 | 5/26/2021 | PA | 66 | M | 5/12/2021 | 5/19/2021 | ED to Hosp-Admission Current 5/20/2021 - present (6 days) Last attending ? Treatment team Syncope and collapse Principal problem History of Present Illness a 66 y.o. yo male presenting to the ED with syncope. Patient is diagnosed with COVID-19. He has passed out twice today. He feels lightheaded and nauseous prior to passing out. He wakes up feeling diaphoretic. Denies chest pain. Admits to shortness of breath and the feeling of difficulty getting a deep breath in. Patient denies history of blood clots, recent unilateral leg swelling or edema, hemoptysis. |
| 1351273 | 5/26/2021 | IN | 63 | F | 5/23/2021 | 5/24/2021 | The morning after I received my second vaccine I began feeling nauseated, then I started sweating profusely, and as I started to get a wash cloth to try to cool myself, I passed out. I came to shortly thereafter, but was weak the rest of that day. The second day after the vaccine I did go to work, but I battled my asthma all day. I had to use my emergency inhaler twice, and at one point thought I was going to have to go to the ER before getting it under control, but I did not have to. |
| 1351588 | 5/26/2021 | HI | 15 | F | 5/15/2021 | 5/15/2021 | Prior to arrival, the patient received her first COVID vaccine at the clinic, after which she suddenly felt dizzy, described as lightheadedness, and felt warm. She was noted to be hypotensive with SBP at 67. She subsequently drank water with some improvement. No syncope, severe headache, numbness, tingling sensations, or focal weakness. Mother was concerned and brought the child to the ED for further evaluation. Currently the patient feels better. No similar symptoms in the past. The patient denies any chest pain or pressure, shortness of breath, or abdominal pain. No recent fever or cough. She is otherwise healthy and has a normal cardiopulmonary exam and reassuring EKG. The description of her symptoms and the environment which happened is very consistent with vasovagal syncope and she does not have any stigmata, and acute neurologic or cardiac emergency. I believe she is safe and stable for discharge home and she was discharged with return precautions and follow-up instructions. |

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| 1351439 | 5/26/2021 | NY | 15 | M | 5/26/2021 | 5/26/2021 | Patient developed a short lived near syncope spell x 30 mins after receiving Pfizer vaccine while getting up from exam bed no injury to report he reported feeling warm and appeared pale and clammy and diaphoretic vitals: B/P 126/90 pulse 77 oxy 99%. He showed no symptoms of allergic reaction no rash no angioedema, lungs were clear with obstruction reporting no tingling or swelling of the tongue he was observed for 30 mins walking around normally before being transitioned back to his guardian he did not lose conscience discharge vitals B/P 123/85 sat 100% pulse 82. |
| 1351526 | 5/26/2021 | IA | 18 | M | 5/26/2021 | 5/26/2021 | 10 minutes following second dose administration, patient began to have blurred vision followed by syncope. After the syncopal episode, patient felt fine. Patient was provided some water to drink and is currently feeling fine. |
| 1351520 | 5/26/2021 | AZ | 28 | F | 5/3/2021 | 5/4/2021 | Pt began feeling bad with chest pain and fatigue, SOB after the vaccine. Per spouse woke up in the middle of the night and tried to get out of bed but fainted and possibly had a seizure, had foam coming out of her mouth. Was transported to the ER and released. |
| 1351516 | 5/26/2021 | CO | 28 | F | 5/26/2021 | 5/26/2021 | The vaccine was administered to the patient. As she was seated in the observation area, she began to feel unwell and stood up to approach one of our clinic assistants to let them know. The assistant states the patient appeared flushed. The assistant then grabbed the patient's arm as she noticed the patient seemed faint. The patient then fainted and the assistant gently lowered the patient to the ground. Upon lying flat on the ground the patient immediately came to. The clinic called for assistance and the first set of vitals were taken. The patient's feet were elevated and a cool compress was placed on her forehead. Pt reported feeling better after a few minutes. First set of vitals: HR 102 RR 16 BP 88/60 O2 99% Second set of vitals: HR 66 RR 14 BP 90/64 O2 99% Third set of vitals: HR 64 RR 14 BP 110/78 O2 99% |

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| 1351513 | 5/26/2021 | MI | 22 | F | 5/26/2021 | 5/26/2021 | After her shot, Patient felt dizzy sitting down on floor, I helped her lift up and had her seat in the chair. She might have passed out for a few seconds because her head was leaning on one side, upon asking her if she was ok, she did respond and complained of feeling dizzy and loss of hearing. After giving water to her, she started feeling better, her hearing came back but she still felt a little light headed and dizzy. We still monitored her and mom was called to pick her up. She was doing lot better after few minutes. Mom came to pick her up and we explained what happened to her to mom. |
| 1351502 | 5/26/2021 | VA | 29 | F | 5/20/2021 | 5/20/2021 | After receiving the shot the patient stiffened in her chair and then passed out for a second. She woke up immediately and the technician and mother stayed next to the patient while the pharmacist contacted 911. She stayed seated and was given something to drink. She seemed to be ok by the time the paramedics arrived. They checked her over and took her vitals and then allowed her to leave the store after observation. Called the store about an hour later and stated the patient was ok. |
| 1351314 | 5/26/2021 | CA | 49 | F | 5/20/2021 | 5/20/2021 | FEVER, PASSED OUT, CARDIAC ARREST |
| 1351456 | 5/26/2021 | VA | 24 | M | 5/26/2021 | 5/26/2021 | patient fainted immediately after for about 1 second, his head dropped but then he woke back up. right after the dose he began breathing quickly, so i instructed him to take his mask off and lay back if he needed. i grabbed him a water and took his blood pressure/hr. EMS was called, patient denied care. HIS BP WAS 104/73 AT 12:53 PM AND HIS hr WAS 72 BPM. I did notice some mild seizure like physical symptoms as he woke up - arms and shoulders jerked a little for a few seconds. he said that the same, but worse, reaction happened after his first dose. |

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| 1351319 | 5/26/2021 | MD | 24 | M | 5/8/2021 | 5/25/2021 | <p>MYOCARDITIS. I experienced extreme chest pain, tightness, shortness of breath, painful heart beats, I could feel each beat. I hunched over in my bed groom grabbing my abdomen and fell onto my bed and almost passed out from whack I?d assume is lack of oxygen. I could barely breathe for about five minutes and felt relatively severe pain particularly in the right side of my chest. I could feel every muscle, tendon, and artery inflamed, enlarged, and hurting. My chest felt like it filled up with a balloon. Heart rate went up too. I have NEVER EVER felt ANYTHING like this in my LIFE. Not even close. It was a brand new sensation to me first time I?ve ever felt anything like this at all, and very intense and frustrating. Keeping in mind I am in perfect health. I am a body builder with a perfect physique. I work at a high end restaurant and have an extremely good diet. I have a normal sleep and sexual routine, I don?t use any medications whatsoever even Tylenol or ibuprofen. I have no pre existing conditions. I have no history of heart or cardio problems. My family has a history of low blood pressure. I have next to no stress or anxiety in my life. I am 24 years old I work out and run miles, five to six days a week. I don?t use nicotine, tobacco, and I haven?t had a drink of alcohol in ten years (14yrs old). I smoke marijuana on a daily basis. After about ten minutes the incident went down and I was able to breathe a little better but still had pain and tightness in my chest. I have had shortness of breath ever since. This is being written the day after the event about 26 hours later. I ran a mile last night and went to the gym it seemed to help both my breathing and the pain and tightness but it has not fully gone away. I feel my heart straining somehow as I am typing this. One thing to note is I did not want to get vaccinated but was pressured to do so, and before getting it I was very nervous and honestly upset. The woman administering it was not helpful at all and actually mocked my unsureness and was very rude and unprofessional. She didn?t answer any technical questions I had. During my interaction with her between my nerves and her behavior I?m absolutely certain my heart rate was elevated at the time of getting the shot. I have only had one shot. The episode of myocarditis occurred two weeks after my first shot. Two days after my scheduled second shot, which I missed because of work and was going to reschedule before this occurred. I am not going to be getting the</p> |

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| 1351425 | 5/26/2021 | MI | 64 | F | 3/3/2021 | 3/31/2021 | <p>second shot. Will be following up with my primary care doctor as soon as possible. Haven?t had time.</p> <p>4/1: Woke up very sick fatigued, dizzy, sweaty, in bed for 24 hours. 4/2: aforementioned symptoms improved and could get out of bed but dizzy and ?off? feeling persisted 4/6: increased dizziness throughout day to point fell when walking out of work (did not follow up with blood pressure or anything at this point). 4/16: Dizziness and ?off? feeling continued to progress over past 10 days and fell when bringing in the groceries. 4/17: woke up feeling heart palpitations when at rest in much. Also much more dizzy to point where could not walk also. Husband recommended taking BP which measure 178. Called PCP who recommended go to hospital. Admitted to hospital and BP erratic. Performed nuclear stress test which was negative and prescribed losartan 25 MG did a nuclear stress test 4/18: discharged from hospital and proceeded to take BP three times a day. Values continued to be erratic also still feeling dizzy (to a lesser extent thought) Approx 5/3: called the doctor to inform of continued erratic BP. He prescribed a new blood pressure medicine- LISINOPRIL 10 MG?s. Despite medication change Bp remained erratic and dizziness persisted 5/18: dizzy woke up on dizzy similar to presentation 4/17 blood pressure 159/98. Proceeded to work and dizziness progressed to point where almost passed out and had to lay head on desk. EMS was called and BP measuring 169. Admitted to hospital took off BP medication and Echocardiogram, CT and MRI of brain all performed- all negative. BP running lower than normal at certain points during hospitalization (as low as 109). Cardiologist prescribed medication for low blood pressure and dizziness (have not filled this medication) 5/20- 5/22: (discharged from hospital) dizziness still more than normal and BP still up and down but better than prior to hospitalization 5/23- current: dizziness but not limiting function and BP remains erratic but still lower than prior</p> |

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| 1351411 | 5/26/2021 | NY | 16 | F | 5/24/2021 | 5/25/2021 | This patient received the Pfizer vaccine on 5/24/21 at 4:30pm and was feeling fine until the next morning at 5:30am when she felt dizzy and passed out. She then was able to get back up and passed out again. Her guardian states that she was gray in color and was very weak. She was able to communicate but was very tired and stayed at home for 2 days. Today she is feeling fine and guardian was asking if she should get the 2nd dose. I said that she should contact her physician. |
| 1351383 | 5/26/2021 | CA | 33 | M | 5/20/2021 | 5/22/2021 | He had black stool on the night of 5/22/21 and on 5/23/21 starting having copious bloody diarrhea, passed out. Went to the ER on 5/23/21 was given blood transfusion and IV because hemoglobin dropped from 9.1 to 7.1 after one bowel movement. He had endoscopy and colonoscopy on 5/25/21 and was diagnosed with a colon ulcer which they cauterized and he was discharged in the afternoon due to hemoglobin being stable at 8. The next morning on 5/26/21 he woke up to use the restroom, defecated brownish-black-red stool and almost fainted and couldn't get up from the floor. I called Dr. (gastroenterologist) who told me to take him to the ER immediately. My husband, is currently back at hospital getting evaluated. |
| 1351346 | 5/26/2021 | OH | 34 | U | 5/26/2021 | 5/26/2021 | Patient received vaccine and was fine then transitioned to another chair, after a couple of minutes he passed out in the chair, his wife was able to shake him and he came back after a minute. The patient stated that he usually passes out after all vaccines due to a severe fear of needles. After he came to it he stated he felt fine. We provided the patient with water and an ice pack to place on the back of his neck. He stayed at pharmacy for additional 15 minutes and when he left he felt fine and his wife was going to be with him for the rest of the day. |
| 1351342 | 5/26/2021 | NC | 15 | M | 5/26/2021 | 5/26/2021 | After receiving patients first Pfizer Covid shot patient passed out twice. EMS was contacted at this time. Patient regained consciousness each time. He then passed out a third time after EMS arrived at the scene. Due to this he was transported to nearest hospital ER for further testing |

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| 1351062 | 5/26/2021 | | 12 | F | 5/26/2021 | 5/26/2021 | AE: Syncope(at 11am) Treatment: no medication was given. patient was under observation. Water improved symptoms Outcome: symptoms resolved and patient was sent to POV/Home. |
| 1351487 | 5/26/2021 | TX | 44 | M | 5/12/2021 | 5/12/2021 | Patient fainted 2 minutes after second vaccination. |
| 1351925 | 5/26/2021 | WI | 23 | F | 4/10/2021 | 4/10/2021 | The day I got the vaccine I had been having health problems. I had been having withdrawal from one of my medications and I had lost weight. Right away after the shot I passed out and when I came to, I threw up a couple of times. I was taken to the ER and I had low potassium levels were low, but all other tests were normal. I had some aches pains and feverishness for a couple of days. Five days after the vaccine I had bad diarrhea several times a day. I was nauseous and feeling bad. I had an appointment with my GI doctor a week later but I had to go to the ER before that. They did not find anything in most tests. The next day I tested positive for CDIFF. I was prescribed antibiotics. I went back to the ER a third time because the Vancomycin prescription had caused severe nausea. I am still feeling bad after six weeks but it has gotten better. |
| 1347348 | 5/25/2021 | CA | 46 | F | 5/24/2021 | 5/24/2021 | The patient experienced an episode of syncope approximately 10 minutes after receiving the first dose of the Moderna vaccine. The patient lost consciousness for less than 45 seconds and was then coherent and responsive. Paramedics were called to the scene due to the brief loss of consciousness. Medics took vitals and performed EKG and cleared the patient to return home without needing to seek further medical treatment or monitoring. |
| 1346976 | 5/25/2021 | ME | 22 | F | 4/15/2021 | 4/15/2021 | Nausea, "fainted~~ |
| 1347284 | 5/25/2021 | FL | 22 | M | 5/25/2021 | 5/25/2021 | Syncope |

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| 1347288 | 5/25/2021 | | 17 | F | 5/25/2021 | 5/25/2021 | Patient passed out after receiving her 2nd dose of the Pfizer COVID19 vaccine. Patient was sitting in waiting area after receiving the dose when she passed out and her mother was holding on to her. Patient came back after a few seconds and was laid to the ground. Her BP read at 107/68 and then later at 101/71. Mom stated that patient has history of passing out before. She stayed with us until she felt better until her mom took her home. |
| 1347294 | 5/25/2021 | CA | 17 | M | 5/24/2021 | 5/24/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Mild, Systemic: Tachycardia-Mild, Systemic: Weakness-Medium, Additional Details: Patient and his father sat down in the observation area post vaccination. Within less than 5 min, the father called for help and pharmacy clerk notified the pharmacist that the patient needed attention. Patient had turned white and started to twitch lost consciousness for less than 30 seconds. Epipen was administered by pharmacist (pt was conscious, alert, and oriented nearly immediately after Epipen) and patient was reclined on his back on the floor. BP/ HR monitored while waiting for 911 |
| 1347302 | 5/25/2021 | CA | 36 | F | 5/21/2021 | 5/21/2021 | After injection 2:01pm - almost passed out. Immediate injection site pain. 4:00pm vaginal bleeding, pain in left and right arm Continuing throughout day- pain in both arms, fatigue, pain in back, feverish and joint pain. 5/22- headache, fever, fatigue, vaginal bleeding, pain under left rib. (Not persistent pain in left rib) feverish and joint pain. 5/23- pain in both arms, shoulder pain, joint pain, fatigue vaginal spotting. Took 1 ibuprofen. 5/24- lessening arm and back pain, fatigue and vaginal spotting, shoulder pain. Pain below left rib (not persistent) and joint pain now localized in left hand/fingers and left ankle area. Took 1 ibuprofen. |
| 1347313 | 5/25/2021 | CO | 16 | F | 5/21/2021 | 5/21/2021 | 16yo female pt had syncope episode approx 15 min after vaccination. Parents said they had just come off of a long international flight and that pt was very tired and had not had anything to eat or drink. After vaccination, the family walked around the store, and pt fainted on other side of store. Emergency services were called. Pt was helped to sitting upright in a chair, and had a scraped knee. |

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| 1347260 | 5/25/2021 | IL | 17 | M | 5/7/2021 | 5/7/2021 | Pfizer-BioNTech COVID-19 vaccine - Immediately after receiving his second dose of the Pfizer covid-19 vaccine, pt expressed dizziness and lightheadedness. Prior to receiving his second dose, he informed the pharmacist administering the vaccine to fainting after receiving his first dose. The pharmacist was prepared and when the pt expressed dizziness after second dose pt was able to lay down on the ground with feet up prior to becoming light headed. Pt also experience sweating and was given an ice pack. He remained on the ground for approximately 10 min until lightheadedness subsided and was then brought to the observation area where he was observed for an additional 20 minutes without incident. |
| 1347318 | 5/25/2021 | CA | 15 | F | 5/24/2021 | 5/24/2021 | Site: Pain at Injection Site-Mild, Systemic: Allergic: Anaphylaxis-Severe, Systemic: Chills-Severe, Systemic: Confusion-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Turning very pale, passed out and unresponsive, sweating-Severe, Systemic: Flushed / Sweating-Severe, Systemic: Nausea-Medium, Systemic: Shakiness-Medium, Systemic: Weakness-Medium, Additional Details: After 5 minutes of vaccination, mom called for help in the waiting area. The patient passed out for a few minutes and responded after we both called her several times. We called 911. She was feeling nauseous. She sipped a little water and was looking very pale and was starting to become unconscious again. Mother thought it was an allergic reaction and asked for Epipen. Epinephrine was administered, and patient became alert and less pale. EMS came and took her away due to low blood pressure |
| 1347361 | 5/25/2021 | CA | 22 | M | 5/25/2021 | 5/25/2021 | 22 year old received Janssen vaccine at 10:50 am, and while in recovery area, reported that he became light headed, dizzy, and passed out. He slumped out of the chair hitting the right side of his head on the floor. Sustained a cut near his right eye. At 10:56 am blood pressure @140/65, pulse @ 53, 97% O2 sats while sitting on the floor. EMS was called 10:57am. When interacting with staff and friend accompanying him, eye was cleaned and ice applied. EMS arrived 11:05am. EMS reported vitals to be 86/49, 59, 100% O2. EMS recommended transport to client. Client accepted. EMS transported to Medical Center at 11:12 am. |

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| 1347367 | 5/25/2021 | NJ | 24 | M | 5/25/2021 | 5/25/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Headache-Mild |
| 1347386 | 5/25/2021 | VA | 68 | F | 5/12/2021 | 5/12/2021 | After 1st shot - day 9 syncope at 5:00 am fell and hit head. Sought ER treatment. General symptoms, dull headache, stomach upset, weak, jittery feeling, heart pounding. After 2nd shot - waves of malaise come and go - generally feel poor in every way. Dull headache, stomach upset, jittery. mild dizziness, weakness, feel faint. |
| 1347392 | 5/25/2021 | NY | 40 | M | 5/25/2021 | 5/25/2021 | Patient looked normal and relaxed before and during vaccination. About 5-10 minutes after vaccination, patient passed out (fainted) while sitting down in a chair. Moved patient on to floor lying down flat and observed him for a few seconds. Patient was un responsive and appeared to struggle to breath. Asked my staff to call 911 for emergency services, and to bring an Epipen just in case, and started to perform CPR on the patient. The patient gained consciousness in about 15 chest compressions and became responsive. He answered the questions like his name, where he lives etc. As the patient became conscious, responsive and appeared to breath normally, I did NOT administer Epipen. Kept patient in observation and kept him engaged in talking until EMS personnel have arrived. They checked his vitals and blood glucose. In the conversation with EMS personnel, they said he is hypertensive and hyperglycemic. Ems took him to the ambulance by walking him (stretcher wasn't necessary) |
| 1347415 | 5/25/2021 | AL | 23 | F | 5/24/2021 | 5/26/2021 | Felt dizzy and had body aches the next day. Went to work and passed out |
| 1347498 | 5/25/2021 | NY | 28 | M | 5/25/2021 | 5/25/2021 | Patient had a vasovagal reaction. Reported sweating, dizzy feeling. Did not experience syncope |
| 1347314 | 5/25/2021 | GA | 16 | F | 5/22/2021 | 5/23/2021 | Felt dizzy and like she would pass out Felt faint and nauseous and very sweaty. MOM noted she was obviously sweating and left wet marks from her arms on the table Did have a syncope episode |
| 1347167 | 5/25/2021 | ME | 23 | M | 4/17/2021 | 4/17/2021 | Almost passed out. Rest, water, ice pack |

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| 1346998 | 5/25/2021 | VA | 17 | M | 4/21/2021 | 4/21/2021 | Patient fainted 10 minutes post-vaccination and reportedly had shaking/seizure-like activity. Patient felt cold and dizzy and requested transport to ER. Transported to medical center by EMS. |
| 1347025 | 5/25/2021 | ME | 46 | M | 4/24/2021 | 4/24/2021 | Syncope 10 seconds |
| 1347026 | 5/25/2021 | MA | 33 | F | 5/25/2021 | 5/25/2021 | Patient sat in front of pharmacy for 15 minute monitoring period. A few minutes after receiving the vaccine the patient informed the pharmacist that she was feeling dizzy and asked for water. The pharmacist went to get water. Upon returning the patient was awake and alert and told the pharmacist that she thinks she passed out. Called 911, firefighters and paramedics responded and evaluated patient who was feeling much better by now. |
| 1347042 | 5/25/2021 | ME | 18 | F | 4/24/2021 | 4/24/2021 | syncope for 10 seconds, dizzy and weakness. patient given water and rest. Symptoms resolved |
| 1347058 | 5/25/2021 | KS | 22 | F | 5/25/2021 | 5/25/2021 | PATIENT GOT LIGHT HEADED WHILE SITTING THEN FAINTED. PHARMACIST WAS ABLE TO HELP PATIENT TO FLOOR SO SHE DID NOT FALL. PATIENT CAME BACK TO IN A FEW SECONDS, WE APPLIED A COOL RAG TO HEAD AND SHE DRANK WATER. PARAMEDICS CAME AND TOOK BLOOD PRESSURE WHICH WAS LOW. SHE STAYED UNTIL BLOOD PRESSURE RETURNED TO NORMAL AND HER BOYFRIEND CAME AND DROVE HER HOME |
| 1347113 | 5/25/2021 | PA | 64 | F | 5/23/2021 | 5/24/2021 | On Sunday May 23, 2021 I received the 2nd dose at 3:50 pm. By 7pm. I was experiencing extreme fatigue. Slept until 6am. Mon. May 24, 2021. Felt fine upon arising with just a mild headache, ate normally and was doing light household activities when suddenly I experienced a very intense headache, with nausea and fainted. I don't know how long I was unconscious. When I came out of it, it was very hard to sit up. My hands and feet felt numb, my body felt very heavy, bad headache and nausea. After a period of time I was able to get up. It took about two hours before the headache and nausea subsided enough that I could function. Tues. May 25, 2021 I am still experiencing a bad headache and mild nausea with all over muscle pain and fatigue. Motrin is dulling it enough that I can function. |

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| 1347268 | 5/25/2021 | CA | 27 | F | 5/24/2021 | 5/24/2021 | Systemic: Allergic: Anaphylaxis-Severe, Systemic: Allergic: Difficulty Breathing-Severe, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Severe, Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Shakiness-Mild, Systemic: Weakness-Mild |
| 1347149 | 5/25/2021 | ID | 15 | F | 5/25/2021 | 5/25/2021 | Pt reported feeling woozy, dizzy, and nauseous after walking out to waiting room after receiving shot. Approximately 3 minutes after shot was given I was called out to the waiting room as the patient had passed out. I helped her mother lower her to the floor and by the time we lowered her down she was regaining consciousness. After about 5 minutes she was feeling better and we moved her into the immunization room to wait for EMS. EMS came and evaluated her and determined she was ok to go home |
| 1347639 | 5/25/2021 | MO | 54 | M | 5/24/2021 | 5/24/2021 | PATIENT FAINTED ABOUT 10 MINUTES POST VACCINE |
| 1347169 | 5/25/2021 | TN | 29 | F | 1/19/2021 | 1/20/2021 | Experienced episode of syncope at work the next day and had to receive IV fluids and be sent home, started having more frequent episodes of syncope, completed several EKGs showing abnormal rhythms, fitted for a 24 hour heart monitor that showed runs of SVT; now being treated by cardiology for POTS and SVT; seeing an Electrophysiologist to consider and Ablation; Also was taken to ER at one point for possible MI |
| 1347195 | 5/25/2021 | ME | 28 | F | 4/20/2021 | 4/20/2021 | Near syncope. |
| 1347197 | 5/25/2021 | ME | 35 | M | 4/20/2021 | 4/20/2021 | Syncope. allowed to rest in supine position and monitored |
| 1347218 | 5/25/2021 | CO | 45 | F | 5/17/2021 | 5/17/2021 | Patient fainted after receiving 2nd dose of covid vaccine while being under 15 minute post vaccine observation. Patient fainted in arms of clinical observer. She did not fall or hit her head. She was aroused after her episode (about 30 seconds in duration). She then drank some juice. She continued to be diaphoretic, pale and felt as though she were going to faint again. Since her symptoms did not seem to be resolving we called an ambulance. EMS arrived within 5 minutes and took patient to the hospital. |

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| 1347223 | 5/25/2021 | MI | 26 | M | 5/22/2021 | 5/22/2021 | The patient fainted shortly after receiving his vaccination. He claimed to have a history of fainting after blood draws. He was fully recovered shortly after. |
| 1347231 | 5/25/2021 | PA | 25 | F | 5/24/2021 | 5/24/2021 | Patient is a 25 year old female. She presented to the clinic for her second dose of Moderna LOT #003C21A. According to patient's husband she has no significant past medical history but has "passed out" with vaccines. No reaction noted with her first COVID vaccine. Approximately 10 minutes after receiving her injection today she told her husband that she wasn't feeling well. She said was light headed and nauseated. Patient then proceeded to become nonresponsive. Her eyes deviated upward and her whole body became stiff. Her skin had notable pallor. She was lowered to the ground by staff, myself, and her husband, and put in a supine position with her legs elevated. 911 was called. This episode lasted approximately 40-60 seconds when she became responsive and cried out for husband. Her muscles relaxed and she became notably upset. She kept saying she wasn't able to see or feel her extremities. Her lack of vision resolved within 10-15 seconds. She had weakness in her arms and legs but was able to squeeze her hands on command. She was alert and oriented X3. BP was 130/90. The patient was stable when the ambulance arrived to transport her to Hospital. |

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| 1347147 | 5/25/2021 | NC | 38 | M | 3/3/2021 | 4/6/2021 | More than 30 days after receiving the Janssen vaccine, I tested positive for COVID-19. Symptoms began as runny nose, sneezing, and sinus pressure/burning on April 6, 2021. Tested for COVID-19 on April 11, 2021 (nasal swab, PCR test) after a family member tested positive. Symptoms worsened on April 12, 2021, including shortness of breath, chest pain, complete loss of taste and smell. Sought treatment for breathing difficulty at ER on April 13, 2021 (Vidant Medical Center and was instructed to rest at home. Sought treatment for breathing difficulty at PCP on April 14, 2021 (Medical Center) and prescribed Prednisone. Symptoms worsened on April 15, 2021, including shortness of breath, chest pain, numbness in face/arms/legs, dizziness, loss of balance, memory and speaking difficulty, near fainting. Sought treatment at ER on April 15, 2021 (Vidant Medical Center, Greenville, NC). Held for three days, treated with Remdesivir (3 doses) and supplemental oxygen. Discharged from hospital on April 18, 2021. Symptoms did not improve following discharge. Sought treatment for ongoing symptoms at ER on April 21, 2021, instructed to rest at home. Symptoms continued to worsen on April 24, 2021, including shortness of breath, chest pain, numbness in face/arms/legs, dizziness, loss of balance, memory and speaking difficulty, near fainting, and slurred/incoherent speech. Sought treatment at ER on April 15, 2021, admitted to hospital on April 25, 2021 diagnosed with probable TIA. Treated with Optiflow high-flow oxygen therapy, nebulizer, and steroids. Received a variety of tests and scans of head, neck, spine, chest, heart; none showed signs of any serious cardiac, vascular, or neurological problems. Transferred to in-patient rehabilitation on May 1, 2021 for physical and occupational therapy. Discharged from in-patient rehabilitation on May 6, 2021. Prescribed out-patient physical and occupational therapy to resolve remaining dizziness, balance, and endurance deficits. |

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| 1348489 | 5/25/2021 | CO | 63 | F | 4/20/2021 | 4/21/2021 | Woke up at 5 AM shivering uncontrollably, weak, unable to move, sweating, feeling feverish, whole body aching. Needed to use heating pad for cold relief (no fever on thermometer). Took Tylenol; symptoms lasted 36 hours; passed out 2x upon standing up to use toilet. Dizzy, nauseous, blurry vision, headache, unable to eat, thirsty, very sleepy; took Tylenol every 6 hours for slight relief. Sick for 2 days but symptoms lessened after 36 hours. Terrible experience. Site of shot was the size of an orange, rash-wise, and very painful for 3 days. |
| 1348077 | 5/25/2021 | WA | 26 | M | 5/25/2021 | 5/25/2021 | 2:01P PT RECEIVED VACCINE. 2:02P PT MOVED TO LOBBY AND SAT AT BP MACHINE. STATED HE FELT DIZZY AND LOST CONSCIOUSNESS AND FELL TO THE FLOOR. REGAINED CONSCIOUSNESS BY 2:04P ASKING WHAT HAPPENED, STATED HIS WRIST HURTS. ACKNOWLEDGED HE ALWAYS FAINTS WITH VACCINES/NEEDLES. BY 2:08PM PT REPORTED FEELING BACK TO BASELINE BESIDES HIS WRIST. EMS ARRIVED BY 2:18PM. WHEN GETTING HIM TO SIT UP HE FELT DIZZY AGAIN AND LIED BACK DOWN. WAS ABLE TO SIT THEN STAND BY 2:25PM. DUE TO THE DIZZINESS AND FAINT FEELING LASTING GREATER THAN 10 MINS, EMS RECOMMENDED AMBULANCE TRANSPORT TO HOSPITAL. PATIENT REFUSED STATING HE FELT EXACTLY AS HE HAD IN THE PAST WHEN HE HAD FAINTED PREVIOUSLY FROM VACCINES. NO REDNESS/ITCHING/SWELLING/PAIN AT SITE OF INJECTION. DECLINED TRANSPORTATION TO HOSPITAL. ONLY COMPLAINT WAS WRIST PAIN WHICH WAS A RESULT OF FALLING. |
| 1348079 | 5/25/2021 | CT | 65 | F | 5/25/2021 | 5/25/2021 | patient had fainted about 5 mins after the vaccine but then she woke up in about 2 mins . Her husband had laid her flat on the ground. She seem to feel better as she was laying on the ground. at that time the ambulance was en route . i had checked on her pulse/bp . the ambulance had arrived but she refuse to go to the hospital . she had felt better . she did walk out of the pharmacy on her own. |
| 1348094 | 5/25/2021 | OH | 19 | M | 5/25/2021 | 5/25/2021 | Pt was sitting in chair after vaccination and passed out |

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| 1348277 | 5/25/2021 | NJ | 49 | F | 5/20/2021 | 5/20/2021 | Extreme body temperature fluctuating; severe dizziness; passed out for 5 seconds (as a result fell to the floor and caused severe bruising - possible concussion sustained) |
| 1348284 | 5/25/2021 | NJ | 18 | M | 5/25/2021 | 5/25/2021 | After vaccination, patient fainted and by the time got over to him he was alert. He was able to sit up and then was able to get into the chair. While in the chair he appeared to faint again (looked like he was asleep in chair) and 911 was called. Patient states he had not eaten today and this was late afternoon. He also said he was nervous. EMS arrived and he agreed to go get checked out. |
| 1348311 | 5/25/2021 | PA | 29 | M | 5/19/2021 | 5/19/2021 | Patient had Moderna vaccine administered at 7:16pm and become unresponsive and began convulsing at 7:27pm. When patient came back around, he was disoriented and didn't know where he was. Patient blood pressure was 131/93 with a pulse of 89. Patient did remember where he was and that he had received his first covid vaccine. He knew the month, day and some other basic questions. The patient stated that before he become unresponsive that he started to feel very lightheaded and woozy. 911 was called and transported the patient to the local hospital for additional testing and evaluation. Upon further discussion with the ER physician, patient was diagnosed with syncope and low potassium. |
| 1347568 | 5/25/2021 | OR | 27 | M | 5/21/2021 | 5/21/2021 | Patient presents with a potential reaction to the COVID19 vaccine. The patient was evaluated in his vehicle as a passenger. He was responsive. He presented with signs and symptoms consistent with vasovagal syncope. He was placed supine with legs elevated and given oral hydration. Vasovagal syncope with rapid return to baseline with repositioning and hydration. Returned home with mother as the driver. |

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| 1348485 | 5/25/2021 | MI | 48 | F | 3/23/2021 | 3/23/2021 | At 1615 (3/23/21), experienced left leg heaviness, intermittent chest pain, body aches, fever 102.5, headache, chills, rigors, and tachycardia - most symptoms lasted only 36 hours. Left leg heaviness persisted and is still present. Intermittent chest pain x 10 days. Near syncope lasting from days 4-11 post vaccine - with one syncopal event occurring on day 5. Tachycardia and palpitations persist. April 14 - chest pain returned. On April 15 - Went to Emergency Department for heart rate of 172, shortness of breath, and palpitations. Persistent left leg heaviness since vaccination. Evaluated for potential pulmonary embolism, myocardial infarction, DVT, and post Covid vaccine infectious pericarditis, Admitted to Hospital overnight. Tested negative for Covid-19. Left leg heaviness persists. Intermittent tachycardia persists. May 10 developed a cold sore 1 day post sun exposure (normal for me). Evening of May 11 - fever, tachycardia, body aches, headache, chills. May 11 - negative Covid test May 20 - message from CDC requesting I fill out a VAERS. |
| 1348023 | 5/25/2021 | RI | 41 | M | 5/20/2021 | 5/20/2021 | Patient passed out after the vaccine....He had mentioned a history of vaso-vagal response when he got a shot as a teenager. He was sitting for about 5 minutes then told us he didn't feel well, then passed out. However, he came to very quickly. He was given a cold compress, some water and was sitting with legs up. We observed him for 45 minutes until he felt well enough to leave. I don't think this was a problem with the vaccine due to a similar history while receiving a different vaccine in the past. |
| 1348498 | 5/25/2021 | FL | 56 | F | 4/10/2021 | 4/17/2021 | Patient stated that she has been suffering from Altered Mental Status, General Malaise, Near Syncope, Weakness |
| 1348625 | 5/25/2021 | CA | 33 | F | 5/25/2021 | 5/25/2021 | Patient fainted after several minutes receiving the 1st dose of Moderna vaccine. |

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| 1348637 | 5/25/2021 | | 15 | F | 5/25/2021 | 5/25/2021 | Female 15-year old client received her first Pfizer shot (Lot# EW0185) at 15:02. She was accompanied by her mother and 12-year-old sister, who was also vaccinated at the same station with her. Client received her shot first and waited while her sister received her shot. After both girls were vaccinated, they were walking with their mother down the hallway to the observation room. RN1 stated that from the opposite end of the hallway she saw client?s knees buckle. RN1 walked toward client to ask if she was OK. Client straightened herself out, slumped onto her mother?s shoulder, and rolled onto her mother, who guided client to the floor. At 15:09 Lead RN heard client fall to the floor, went out to the client, and radioed for EMT assistance. Client was conscious and turned her face up. Client?s mother stated client passed out for 2-3 seconds and that her head did not hit the floor. Client?s mother stated that she cushioned her fall. Client was breathing adequately, appeared pale in face and lips, and stated she was OK. Lead RN and RN1 kept client lying on the floor and elevated her legs on a chair. EMT1 & EMT2 arrived at 15:10 and checked client?s pulse (HR: 74). Client denied head, neck, and back pain. Client was alert & oriented times 3 (person, place, & event). Client stated she was OK to stand up and sit in a wheelchair. Wheeled client to extra vacant breakroom where client vitals were taken by EMT2 at 15:17 (BP: 124/60, HR: 96). EMT1?s assessment found the client exhibited good circulation, sensation, and motor function in all 4 extremities. Client denied chest pain, shortness of breath, and nausea & vomiting. Client was leaning forward in the wheelchair resting her elbows on her lap. She stated she does not remember becoming nonresponsive and that she felt dizzy when lying her head back. Client stated she has a history of anxiety and panic attacks and is currently taking Prozac. Client stated she felt hot. Client?s mother stated client ate a full lunch at 12:35. At 15:20 Lead RN provided client with a bottle of water. Lead RN & EMT also observed client?s color returning to her face at that time. Client sat upright and stated that she felt better and was alert & oriented times 4. Client and mother declined going to the hospital and calling 911 for evaluation. At 15:23 client was wheeled to the observation room with her mother and sister where she remained seated in the wheelchair for 30 minutes for additional observation by EMT1. At 1600 |

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| 1348643 | 5/25/2021 | MA | 41 | F | 4/19/2021 | 4/22/2021 | <p>EMT1 took client vitals while she was seated (BP: 116/82, HR: 68, RR: 16). EMT1 took client vitals again while having client stand (BP: 120/86, HR: 72, RR: 16). Client and mother stated they were OK to go home. Client and mother were instructed by Lead RN to follow up with HCP if client experienced any additional symptoms after going home and to call 911 if client experienced SOB or any difficulties breathing. Lead RN and EMT observed client leave the facility walking with a steady gait with her mother and sister.</p> <p>The left side of my face began to go partially numb on occasion and at times would spread to the right side of my face. The Sunday after the shot which was my 2nd dose, I passed out and paramedics were called. I didn't go to the hospital then but the following Wednesday I felt my face go very numb again so I went to the hospital. They ran a CT scan and blood work & everything looked normal. I followed up with my PCP that week per instruction of the er and as my face was still getting numb and my left leg and hand began periodic jittering. As the day I passed out I had used marijuana, poppy tea and kratom for endometriosis pain, I stayed away from everything to make certain the vaccine was causing the side effects and not the substances. Even without using anything for days and ultimately weeks, the numbness and tingling continued and at times would last for hours. When I first had the initial shots, it jumpstarted my period both times by 2 weeks and I started the same day as the vaccine each time. I was okay with that side effect but these were more worrying. I have more tests scheduled including wearing a heart monitor for 48 hrs, a dental checkup to make 100% sure nothing abnormal there is causing the effects and a neurologist appt lastly if nothing is uncovered otherwise. An appointment for my heart monitor is already scheduled in early June</p> |
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| 1348822 | 5/25/2021 | NV | 27 | F | 5/22/2021 | 5/22/2021 | Around 10pm (almost 12 hours after I got my 2nd dose), it started with nausea and malaise. Within 10-30 minutes, I got very very dizzy and there was pain (but I can't remember where, maybe it was a headache). Soon after, I fainted for a few minutes and when I woke up, I felt VERY nauseous. I ended up vomiting 5-10 minutes after. Twice. Then I think I had a fever and chills so I proceeded to sleep it off. It was hard to sleep because my head just felt off (not sure how to describe it). The following days have been better, but still not feeling 100%. Head feels a little weird, but for the most part, feeling okay. |
| 1348823 | 5/25/2021 | CA | 18 | M | 5/25/2021 | 5/25/2021 | Patient received vaccine and fainted several minutes after receiving dose. When patient retained consciousness he was having difficulty speaking and was having difficulty breathing and kept repeating that he couldn't breath, a dose of epinephrine through an Epi pen was administered 911 was called the patients vitals were checked and he chose not to leave in an ambulance and left |
| 1348339 | 5/25/2021 | NJ | 14 | F | 5/25/2021 | 5/25/2021 | Patient while sitting in the post-vaccination are, fainted in her chair. Upon my immediate arrival, I tapped the patient and she was coming to consciousness. Patient upon awakening, felt nauseous and wanted to vomit, but barely did. I gave the patient water and sports drink and the patient was regaining normalcy. Both the patient and her guardian reported that she did not eat or drink anything prior to coming to the vaccine appointment and that she was very nervous and worried prior. Patient denied history of fainting. I recommended to have the patient sit for at least another 15-20 minutes, but the parent stated his daughter was fine and decided to leave. |
| 1347839 | 5/25/2021 | MA | 64 | M | 5/3/2021 | 5/20/2021 | Syncope on 5/20, found to have acute myocarditis with acute systolic heart failure |
| 1347078 | 5/25/2021 | NY | 20 | F | 5/25/2021 | 5/25/2021 | patient felt lightheaded and then passed out. She also felt a little naseuous. Patient was laid down in supine position with feet elevated and given ice packs. Patient threw up and after 30 minutes felt better and left |

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| 1347643 | 5/25/2021 | PA | 30 | F | 5/25/2021 | 5/25/2021 | The patient received the vaccine in her left deltoid. Immediately following the vaccination, the patient stated that her body felt numb. She became sweaty and said she was having difficulty breathing. She fainted and then was responsive to ammonia inhalant. Due to her difficulty breathing, the paramedics were called and responded. Her blood pressure and oxygen levels were normal. The patient refused additional medical treatment. She remained in the pharmacy for about 45 minutes after her vaccine and said she felt better. |
| 1347689 | 5/25/2021 | NC | 12 | F | 5/25/2021 | 5/25/2021 | Patient was given vaccine and felt fine right after. After awhile a customer came back and alerted the pharmacy that she had fainted and was in one of the aisles with her mom. she did not injure herself in the fall. We had her lay on the floor and took her blood pressure which was slightly low. We had her stay laying down until she felt better and her blood pressure increased. After about 25 more minutes she felt well enough to leave the store with her mom. |
| 1347694 | 5/25/2021 | | 84 | M | 2/15/2021 | 2/17/2021 | 2/17, admitted 2 days after covid vaccine with syncope/rhabdo. Patient admitted for mild rhabdomyolysis after a noncardiac syncopal episode that was thought to be related to recent Covid-19 vaccination. Troponin is elevated 0.25, lactate is elevated at 5.5. BMP shows elevation in glucose and BUN. PT/INR is elevated. VBG is unremarkable. CBC shows a macrocytic hyperchromic anemia. Patient's CK came back significant elevated likely indicating rhabdomyolysis. Admitted for cardiology consult. Patient was treated aggressively with IV fluids. Patient had multiple reevaluations given his history of congestive heart failure. After evaluation- not sure what caused the patient to collapse, but the etiology does not appear to have been cardiac. The patient thinks it may have been due to a reaction to the COVID vaccine. |

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| 1347710 | 5/25/2021 | OR | 17 | M | 5/25/2021 | 5/25/2021 | A 17 Year old boy, received his first dose of COVID - vaccine, Pfizer. He walked out of the health room feeling fine. Stood outside in the waiting room talking to his mom during his 15 min observatory period. within 10 mins, he fainted and fell on his face on the floor. Till the pharmacist came out to him, the pharmacist kept tapping his shoulder and called his name out loud, he recovered and woke up. pharmacist checked his BP and was 121/71 and 68 HR. 911 was called , and paramedics came in, checked his vitals and all were normal . He just hit his chin when he fell, and bled from his gum, no loose teeth reported and a chin wound that might need glue stitches per paramedics. Patient was fine and talking when paramedics transported him to the hospital. |
| 1347765 | 5/25/2021 | OR | 37 | F | 4/14/2021 | 4/15/2021 | I received my second Moderna shot on 4/14/21 at 2pm. When I woke up the next morning on 4/15/21 at 0600 I had a headache. I got out of bed and walked to my kitchen to get some ibuprofen. As I went to get water from the kitchen sink my vision went black and I fainted hitting my head on the kitchen island. When I came to, I was lying on the kitchen floor with excruciating pain on the left back of my head. Since then I have been diagnosed with syncope and concussion. |
| 1348046 | 5/25/2021 | TX | 29 | M | 5/25/2021 | 5/25/2021 | Client fainted post second dose Moderna vaccine. States he has a history of passing out with needles. Alert, Oriented, and answering questions appropriately. |
| 1347798 | 5/25/2021 | ID | 19 | F | 5/25/2021 | 5/25/2021 | Passed out while standing about 8 minutes after receiving vaccination, hit head on the counter and then fell back and hit head on the floor, out for less then 1 minute, was awake by the time a person could get to her side. |
| 1348042 | 5/25/2021 | WI | 62 | F | 3/25/2021 | 3/26/2021 | Early 3/26/21, I experienced low grade fever, chills, and shaking. About 9 hours later, I became light-headed and fainted. I broke my left wrist on a coffee table after losing consciousness on the way down. Wrist was in splint for 4 weeks. 8 weeks later I am still receiving occupational therapy to regain motility/strength. |

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| 1347849 | 5/25/2021 | OH | 18 | M | 5/1/2021 | 5/1/2021 | The patient fainted after receiving the vaccine. It was app. 5 minutes after receiving the vaccine that the patient fell over from his chair in our waiting area. The pharmacist helped him back up and the patient stated he was just nervous/anxious. He was given water and started to feel better. After an additional 15 minute the patient left. No medications were given. |
| 1347876 | 5/25/2021 | NY | 26 | F | 5/25/2021 | 5/25/2021 | patient fainted. Patient said she fainted prior that day during blood work and we were warned that she may do so following vaccination. Pharmacist administered vaccine, patient walked to waiting area and sat down. A minute or so later knew she was going to faint and layed on the ground with knees up. Pharmacist sat with patient while she recovered. Patient refused emergency services on several occasions. After 15 minutes patient felt better and left store. |
| 1347885 | 5/25/2021 | OH | 26 | M | 5/25/2021 | 5/25/2021 | syncope a few minutes after dose-no other injury or reaction |
| 1347889 | 5/25/2021 | AZ | | M | 5/24/2021 | 5/24/2021 | The patient was seated and given a dose of the covid 19 vaccine from jansen. About 10 seconds after administration the patient stated he was feeling light headed then passed out cold. He was supported in the chair for approximately 45 seconds until he regained consciousness . He was very weak and was then placed on the floor and 911 was called. After their evaluation he was determined to be ok. His father picked him up for transport home. |

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| 1347920 | 5/25/2021 | OH | 21 | M | 5/25/2021 | 5/25/2021 | <p>Patient received Janssen COVID19 vaccine (LOT#201A21A) in his left arm at approximately 14:43 on 5/25/21. During the 15 minute observation period, he expressed "I don't feel well" and endorsed dizziness/ lightheadedness, slight tingling feeling in fingers, and nausea. Shortly thereafter at approximately 14:50, he started to slouch and appeared faint while sitting in a chair with eyes closed. He did not fall or hit any part of his body. He was easily aroused with a touch on his arm and responded to verbal questions immediately. He denied trouble breathing, chest pain, palpitations, headache, muscle weakness, vision changes, skin reactions, swelling. He was oriented x3 and not exhibiting verbal or swallowing problems. His vitals were normal- HR 80 bpm and BP 105/80 mmHg. He was offered a receptacle to vomit in if needed; however, he did not vomit. This initial reaction was consistent with potential vasovagal reaction/ near-syncope after vaccination. Patient was encouraged and instructed to sit on the floor to prevent injury in case of fall but he refused. Staff offered him water, a fan, and opened windows while monitoring. Later while waiting for a ride at around 15:10, he endorsed headache (first above his eyes and then toward the back of his head) and clarified this did not feel like a typical migraine that he has had before. Then at around 15:20 he endorsed vision changes in his right eye- he could not see a portion of vision out of that eye except peripheral vision and described not being able to see writing on the right side of a whiteboard in front of him in the room. Later he described a resolution of that gap in vision but then had blurry vision out of that eye. He denied any vision changes in the left eye. Due to alarming symptoms of vision changes and onset of headache, patient was recommended to go to ER for further observation and evaluation. He was not in urgent distress and patient did not wish for EMS to be called but agreed to go to ER when his emergency contact picked him up. Patient's emergency contact came to pick up patient at approximately 15:40 and was recommended to take him to the ER. Patient and emergency contact were amenable to this plan. He was able to stand up and walk to the car without issues.</p> |

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| 1347921 | 5/25/2021 | OR | 53 | F | 5/20/2021 | 5/20/2021 | Patient had syncope within 15 minutes following vaccine. Loss of consciousness <15 seconds, recovered quickly. |
| 1347600 | 5/25/2021 | OR | 34 | M | 5/22/2021 | 5/22/2021 | As a clinical monitor, I was called over to assess a driver slumped over in his seat. He had just received the second dose of the Pfizer vaccine approximately 10 minutes earlier. The passenger (his fiance) said he was acting normal until she heard him grunt and then realized that he was passed out. While attempting to lay flat, I performed a jaw thrust that yielded a stridulous inspiration but was still unresponsive. He did not have a palpable carotid pulse. Paramedics was summoned emergently. Within 30-45 seconds, he awoke but was confused and amnesic to the event. He had no physical complaints and no significant medical or allergy history. I auscultated his larynx (no stridor) and his lungs (CTA). His initial vitals: BP 90/51 HR 61 VR 16 SaO2 100% An electrocardiogram demonstrated a sinus rhythm without ischemic changes or evidence of conduction delay. His glucose was 119. Over the next 30 minutes, he was able to drink two bottles of water and some orange juice. That said, he still said he "felt off." Repeat vital signs: BP 118/62 HR 69 SaO2 100%. The medics advised him to follow up with his doctor, preferably today. His fiance agreed to drive him to an ED near their home for a more thorough evaluation. I provided her my phone number to provide to the ED for any questions. His clinical syndrome was consistent with a syncopal episode associated with orthostatic hypotension. Low suspicion for anaphylaxis. |
| 1347767 | 5/25/2021 | MI | 29 | M | 5/21/2021 | 5/21/2021 | Approximately 5 minutes after receiving his first dose of the pfizer covid vaccine, the patient began feeling faint and ended up fainting while sitting down. He laid his head on his girlfriend's shoulder and fainted. He was alert and conscious within 2 minutes. At that time, the patient said he does suffer from vasovagal syncope and frequently passes out when his anxiety is high. He denied our attempts to call for 911. After 30 minutes, the patient left under his own strength. His girlfriend drove them both home. |

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| 1345841 | 5/25/2021 | GA | | F | 12/30/2020 | 12/31/2020 | Blacked out; Fainted; This spontaneous case was reported by a patient and describes the occurrence of LOSS OF CONSCIOUSNESS (Blacked out) and SYNCOPE (Fainted) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 026L20A and 028L20A) for COVID-19 vaccination. No Medical History information was reported. On 30-Dec-2020, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 27-Jan-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 31-Dec-2020, the patient experienced LOSS OF CONSCIOUSNESS (Blacked out) (seriousness criteria hospitalization and medically significant) and SYNCOPE (Fainted) (seriousness criteria hospitalization and medically significant). On 01-Jan-2021, LOSS OF CONSCIOUSNESS (Blacked out) and SYNCOPE (Fainted) had resolved. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications or treatment information was provided. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Very limited information regarding the events have been provided at this time. No further information is expected at this time.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Very limited information regarding the events have been provided at this time. No further information is expected at this time |
| 1346454 | 5/25/2021 | LA | 25 | M | 5/24/2021 | 5/24/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild |
| 1346443 | 5/25/2021 | NY | 39 | M | 5/24/2021 | 5/24/2021 | Systemic: Allergic: Difficulty Breathing-Medium, Systemic: Chest Tightness / Heaviness / Pain-Medium, Systemic: Chills-Medium, Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Severe, Systemic: Exhaustion / Lethargy-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Weakness-Mild |

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| 1346442 | 5/25/2021 | CA | 12 | F | 5/24/2021 | 5/24/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient briefly fainted for 15 seconds and recovered. Patient was monitored for 30 minutes and was given fluids and granola bar. After 30 minutes passed for observation, patient was confirmed to be completely okay. |
| 1346410 | 5/25/2021 | VA | 23 | F | 5/22/2021 | 5/22/2021 | syncope, nausea, feeling of going to pass out, sweating hot. sat and drank water. was fine but had her mother come and take her home |
| 1346401 | 5/25/2021 | MO | 23 | M | 5/24/2021 | 5/24/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Mild, Systemic: Shakiness-Severe |
| 1346392 | 5/25/2021 | VA | 15 | M | 5/24/2021 | 5/24/2021 | Patient exhibited signs and symptoms of syncope. Felt dizzy, clammy skin, nauseous. Had him lie down for 15 minutes with legs elevated and used an ice pack on the neck to help improve blood flow. Patient recovered. |
| 1346389 | 5/25/2021 | CA | 15 | F | 5/24/2021 | 5/24/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Hyperventilation-Mild, Systemic: Hypotension-Mild, Systemic: Nausea-Mild, Systemic: Visual Changes/Disturbances-Medium, Systemic: Vomiting-Mild, Additional Details: Patient felt dizzy and blackout/ fainted for less than 10 seconds. Vomiting and blood pressure on the low 96/64 |
| 1346384 | 5/25/2021 | IL | 13 | F | 5/24/2021 | 5/24/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: i administered pfizer vaccine to patient and after 5 minutes she experienced syncope and we had to call an ambulance for the patient. The NP within the store helped the patient as well by checking blood sugar, blood pressure and o2. |
| 1346380 | 5/25/2021 | FL | 23 | M | 5/24/2021 | 5/24/2021 | Systemic: Abdominal Pain-Mild, Systemic: Confusion-Medium, Systemic: Fainting / Unresponsive-Medium |
| 1346458 | 5/25/2021 | LA | 25 | M | 5/24/2021 | 5/24/2021 | Systemic: Fainting / Unresponsive-Mild |

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| 1345896 | 5/25/2021 | MS | 65 | F | 1/20/2021 | 1/20/2021 | Hips were sore and achy.; Hips were sore and achy.; She was exhausted; Restless sleep; Diarrhea; Felt a little different; her cheeks were the reddest red she has ever seen; top of her head felt like a plate was on it; This is a spontaneous report from a contactable consumer (reported for himself). A 65-years-old female patient received first dose of bnt162b2 (BNT162B2, solution for injection, Batch/Lot Number: EL8982) administered in left arm via intramuscular route on 20Jan2021 at 09:20am as SINGLE DOSE for covid-19 vaccination. Medical history included family history of Asthma, Thyroidectomy in 2008, Parathyroid disorder. Concomitant medications included Levothyroxine (LEVOTHYROXINE) (100mcg by mouth in the morning) from 2008 as ongoing, Calcitriol (CALCITRIOL) (0.5 mcg daily by mouth) 2008 as ongoing, Calcium Citrate (CALCIUM CITRATE) (1000 mg once a day by mouth) as ongoing. It was reported that parathyroid never returned and patient has to take calcitriol. On an unknown date, the patient experienced hips were sore and achy, she was exhausted and restless sleep. The outcome of the events was unknown. On 20Jan2021, the patient cheeks were the reddest red she has ever seen and top of her head felt like a plate was on it and Felt a little different. The events were recovered on 21Jan2021. On 21Jan2021, the patient had diarrhea. The event diarrhea was recovered in Jan2021. It was reported that the patient received her first dose 20Jan2021 at 9:20am, about 10 hours later at 7:30pm patient reports that the top of her head felt funny, don't know how to describe it. Patient felt like a lid was on head and she would not describe it like a headache. Patient also had flushing of her cheeks stating they were very red, and patient was lit up like a tree. Patient treated this with a cold rag. Patient reports that did not have any of the following event's nausea, fainting, fever, chills, swelling, or welts. Patient took 2 Tylenol to treat the redness, and had a restless night of sleep, upon waking in the middle of the night, the flushing had subsided along with the head symptoms. In the days following vaccination, patient reported 3 days of bad diarrhea. Patient also states she was relatively healthy and active, but her hips were sore and achy after vaccination, but she powered through her 30-minute walk, anyway. Patient wants to know should she receive the second dose of the vaccine as scheduled on 10Feb2021 and |

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should she expect the same AE's. How can she treat them and does she need an Epipen or should she take Benadryl. It was reported that patient received the first dose a week ago as of Wednesday on the 20Jan2021 and in 3 weeks patient was scheduled to revaccinate with the 2nd dose on 10Feb2021. Patient considers a reaction something that happens within 30 minutes of getting a medication and a side effect is something that happens after that. patient reported that she received the first dose on 20Jan2021at 09:20am and exactly 10 hours later that night, patient felt a little different and the very top of her head felt like a plate was on it. It was like a headache, stated that was a little pressure. Patient stated that her cheeks were the reddest red she has ever seen. Patient did not feel like she had a fever or was chilly. She said that her cheeks were flushed. Patient was worried about and has heard about people that have died, gotten bell's palsy, and had strokes. No further details provided. Patient said that she also had diarrhea for about 3-4 days that was pretty bad and drinks lemon water constantly anyway. Patient said that she took 2 Tylenol to treat herself and went to bed and woke up a hour to 1.5 later. The redness in her cheeks were gone. Patient said that she had no shortness of breath, no fever, and no chills. Patient was just scared what would happen next. She was exhausted and thought rest would help her. Patient reported that she still had the feeling in the top of her head at that time she did not sleep well because she was worried. Patient describe it as a restless sleep. Patient stated that the only other thing she noticed was her hip joint were achy. When she got up the next day, patient realized the top of her head and feeling different resolved on 21Jan2021. Diarrhea resolved in the last 2-3 days. Patient ate and drank a lot of liquids and takes vitamins and described them as really good liquid vitamins and she stopped taking it 2 weeks prior to the vaccine and just ate well instead. Follow-up attempts were completed. No further information was expected.

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| 1345753 | 5/25/2021 | MI | 43 | M | | 5/1/2021 | <p>PAIN IN STOMACH; SWEATS; REDNESS ON BODY LOOKS LIKE SKIN IS DISCOLORED; CHILLS; FEVER; NAUSEA; BODY PAIN; MIGRAINE; EVERY BEAT OF HEART HURTS; HYPERVENTILATION; COULD NOT GET A FULL BREATH; PASSED OUT; FINGERS WENT NUMB; GOT A CHARLIE HORSE ON LEG; EVERY SINGLE JOINT AND ANKLES HURTS FOR NO REASON; This spontaneous report received from a patient concerned a 43 year old male. The patient's weight was 135 pounds, and height was 66 inches. No past medical history or concurrent conditions were reported. The patient's concurrent conditions included migraine The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 042A21A, and expiry: UNKNOWN) dose was not reported, administered, 1 total to right deltoid on 19-MAY-2021 around 10 am for prophylactic vaccination. No concomitant medications were reported. On 19-MAY-2021, around 7 pm patient started experiencing side effects. After 1 hour of shot patient had his heart hurt at every beats, hyperventilation. It lasted for 1 -2 hours. The patient also had fever, chills, nausea, sweats and had not taken any medication, as he was afraid of another side effects, had redness on his body which looked like skin was discolored and was like hives. The patient also had body pain appeared suddenly. The patient also had pain in stomach which felt like nastiest gas cramp patient had ever and it was continuous like a rock blocking in stomach, he did not know if it is pain or gas but was hurting. Patient had migraine which lasted long time and was continuous than he ever had. The patient was fine as he was speaking at the time of reporting. On MAY-2021 (dates unspecified) the patient experienced Charlie on his leg (muscle spasm) for which he stood up and didn't do anything on leg, he was passed out and fingers went numb, felt every single joint and ankle hurt with sharp pain like a stuffed knife (intermittent pain for 3-5 minutes).He could not get a full breath of air, and was breathing really fast. Then patient tried to slow down breathing as he didn't want to be hyperventilated but it happened. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from body pain, hyperventilation, migraine, pain in stomach, chills, fever, nausea, and sweats, and the outcome of passed out,</p> |

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| | | | | | could not get a full breath, redness on body looks like skin is discolored, got a charlie horse on leg, every single joint and ankles hurts for no reason, fingers went numb and every beat of heart hurts was not reported. This report was serious (Other Medically Important Condition); Sender's Comments: V0: 20210540430-COVID-19 VACCINE AD26.COV2.S --Every beat of heart hurts, Passed out. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s). | |
| 1345840 | 5/25/2021 | CO | | F | 2/17/2021 | Faint for 15 minutes; This spontaneous case was reported by a consumer and describes the occurrence of SYNCOPE (Faint for 15 minutes) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 007M20A and 040A21A) for COVID-19 vaccination. No medical history information was provided by the reporter. Concomitant products included PROPRANOLOL from 26-Mar-2021 to an unknown date for Blood pressure, ATORVASTATIN from 17-Apr-2021 to an unknown date for Cholesterol, AMITRIPTYLINE from 03-Aug-2020 to an unknown date for Depression. On 17-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 21-Mar-2021, received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 2 dosage form. On an unknown date, the patient experienced SYNCOPE (Faint for 15 minutes) (seriousness criterion medically significant). At the time of the report, SYNCOPE (Faint for 15 minutes) outcome was recovered. Action taken in response to the events was not applicable as she has taken 2 doses. This case was linked to MOD-2021-056362 (Patient Link).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. |

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| 1345835 | 5/25/2021 | PA | 33 | M | 3/1/2021 | | <p>Worse coughing; Neck hurts from artery pumping hard; Back pain; Arm pain; has been in bed all month; Flu like symptoms; Nausea; Headache; Joint ache; Cold chills; Jaw pain; Hot flushing; Severe bilateral foot pain; Shortness of breath; Felt like having heart attack with bad chest pain; sick to his stomach; Feeling worse since getting second covid shot; Fainted a couple times/collapsed/becomes faint if he exerts himself; Pulmonary hypertension was high at 124; Suspected immune response to the vaccine; This spontaneous case was reported by a health care professional (subsequently medically confirmed) and describes the occurrence of SYNCOPE (Fainted a couple times/collapsed/becomes faint if he exerts himself) and PULMONARY HYPERTENSION (Pulmonary hypertension was high at 124) in a 33-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product MACITENTAN tablet for Pulmonary hypertension. Concomitant products included SILDENAFIL CITRATE and TREPROSTINIL SODIUM for an unknown indication. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form and MACITENTAN (Oral) 10 mg once a day. In March 2021, the patient experienced SYNCOPE (Fainted a couple times/collapsed/becomes faint if he exerts himself) (seriousness criterion medically significant), PULMONARY HYPERTENSION (Pulmonary hypertension was high at 124) (seriousness criterion medically significant), VACCINATION COMPLICATION (Suspected immune response to the vaccine) and CONDITION AGGRAVATED (Feeling worse since getting second covid shot). On an unknown date, the patient experienced PAIN IN JAW (Jaw pain), HOT FLUSH (Hot flushing), PAIN IN EXTREMITY (Severe bilateral foot pain), DYSPNOEA (Shortness of breath), CHEST PAIN (Felt like having heart attack with bad chest pain), ABDOMINAL DISCOMFORT (sick to his stomach), COUGH (Worse coughing), NECK PAIN (Neck hurts from artery pumping hard), BACK PAIN (Back pain), PAIN IN EXTREMITY (Arm pain), BEDRIDDEN (has been in bed all month), INFLUENZA LIKE ILLNESS (Flu like symptoms), NAUSEA (Nausea), HEADACHE</p> |

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(Headache), ARTHRALGIA (Joint ache) and CHILLS (Cold chills). At the time of the report, SYNCOPE (Fainted a couple times/collapsed/becomes faint if he exerts himself), PULMONARY HYPERTENSION (Pulmonary hypertension was high at 124), VACCINATION COMPLICATION (Suspected immune response to the vaccine), PAIN IN JAW (Jaw pain), HOT FLUSH (Hot flushing), PAIN IN EXTREMITY (Severe bilateral foot pain), DYSPNOEA (Shortness of breath), CHEST PAIN (Felt like having heart attack with bad chest pain), ABDOMINAL DISCOMFORT (sick to his stomach), CONDITION AGGRAVATED (Feeling worse since getting second covid shot), COUGH (Worse coughing), NECK PAIN (Neck hurts from artery pumping hard), BACK PAIN (Back pain), PAIN IN EXTREMITY (Arm pain), BEDRIDDEN (has been in bed all month), INFLUENZA LIKE ILLNESS (Flu like symptoms), NAUSEA (Nausea), HEADACHE (Headache), ARTHRALGIA (Joint ache) and CHILLS (Cold chills) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2021, Brain natriuretic peptide: 570 (High) elevated up to 570. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Treatment information included paracetamol. Company Comment: Based on current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded.; Sender's Comments: Based on current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded.

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| 1345831 | 5/25/2021 | MI | 40 | M | 1/13/2021 | 2/1/2021 | missed beats; become sensitive to light and cannot go outside without sunglasses; sweating more especially acidic and disgusting; splitting headaches; pain in the left arm at the vaccination site; arrhythmias; altered smell; heart rhythm, palpitations; tachycardia; joint pains; chills; mild fever; dizzy.; "feels like my body has been split into 1000 different microclimates; This spontaneous case was reported by a consumer and describes the occurrence of ARRHYTHMIA (arrhythmias) in a 40-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 004M20A and 025J20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Chronic fatigue syndrome, Fibromyalgia and Neurocardiogenic syncope. On 13-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 10-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 01-Feb-2021, the patient experienced DIZZINESS (dizzy.). On 10-Feb-2021, the patient experienced ARTHRALGIA (joint pains), CHILLS (chills) and PYREXIA (mild fever). In February 2021, the patient experienced FEELING ABNORMAL ("feels like my body has been split into 1000 different microclimates). On 18-Feb-2021, the patient experienced ARRHYTHMIA (arrhythmias) (seriousness criterion medically significant), PAROSMIA (altered smell), PALPITATIONS (heart rhythm, palpitations), TACHYCARDIA (tachycardia), PHOTSENSITIVITY REACTION (become sensitive to light and cannot go outside without sunglasses), HYPERHIDROSIS (sweating more especially acidic and disgusting), HEADACHE (splitting headaches) and VACCINATION SITE PAIN (pain in the left arm at the vaccination site). On an unknown date, the patient experienced EXTRASYSTOLES (missed beats). On 14-Feb-2021, ARTHRALGIA (joint pains) and CHILLS (chills) had resolved. On 24-Feb-2021, HEADACHE (splitting headaches) had resolved. At the time of the report, ARRHYTHMIA (arrhythmias), PAROSMIA (altered smell), FEELING ABNORMAL ("feels like my body has been split into 1000 different microclimates), DIZZINESS (dizzy.), PALPITATIONS (heart rhythm, palpitations), TACHYCARDIA (tachycardia), EXTRASYSTOLES |

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(missed beats), PHOTSENSITIVITY REACTION (become sensitive to light and cannot go outside without sunglasses), HYPERHIDROSIS (sweating more especially acidic and disgusting), VACCINATION SITE PAIN (pain in the left arm at the vaccination site) and PYREXIA (mild fever) outcome was unknown. No concomitant medications were provided. Treatment taken were Diphenhydramine (Benadryl) , Ibuprofen (Advil), Prednisone and acupuncture to alleviate the symptoms experienced. Company comment: Limited information regarding the events has been provided at this time and a causal relationship cannot be excluded; Sender's Comments: Limited information regarding the events has been provided at this time and a causal relationship cannot be excluded

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| 1345804 | 5/25/2021 | CA | 52 | F | 2/26/2021 | 2/26/2021 | <p>Double vision; Confusion; Dry mouth; All over body itchininess; My body was filled with sores on my breasts, armpits and back; my blood pressure was high; Neck rigidity; Retinal Hemorrhage; Blood shot eye in right eye; Headache; I thought I was going to pass out; I started shaking; Palpitations; Half of my head (the right) felt a little cold; The vein in my head was swollen; the half part of my body on the right became very stiff; it started to hurt; my mouth started tingling; tachycardia; Right eye started to water; On the left side, in the groin, I had a numbing sensation; My tongue also got dry; runny nose; Half of my head (the right) felt a little cold; Chills; nausea; Extreme fatigue; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of RETINAL HAEMORRHAGE (Retinal Hemorrhage) in a 52-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 014M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Drug allergy (Allergy to Tramadol). Concomitant products included TRAMADOL. On 26-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 26-Feb-2021, the patient experienced LACRIMATION INCREASED (Right eye started to water), PALPITATIONS (Palpitations), HYPOAESTHESIA (On the left side, in the groin, I had a numbing sensation), TONGUE DRY (My tongue also got dry), RHINORRHOEA (runny nose), NASOPHARYNGITIS (Half of my head (the right) felt a little cold), HEAD DISCOMFORT (Half of my head (the right) felt a little cold), VEIN DISORDER (The vein in my head was swollen), MUSCULOSKELETAL STIFFNESS (the half part of my body on the right became very stiff), PAIN (it started to hurt), PARAESTHESIA ORAL (my mouth started tingling), TACHYCARDIA (tachycardia), CHILLS (Chills), NAUSEA (nausea) and FATIGUE (Extreme fatigue). On 27-Feb-2021, the patient experienced PRESYNCOPE (I thought I was going to pass out) and TREMOR (I started shaking). On 11-Mar-2021, the patient experienced RETINAL HAEMORRHAGE (Retinal Hemorrhage) (seriousness criterion medically significant), OCULAR HYPERAEMIA (Blood shot eye in right eye), NUCHAL RIGIDITY (Neck rigidity) and</p> |

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HEADACHE (Headache). On 12-Mar-2021, the patient experienced HYPERTENSION (my blood pressure was high). On an unknown date, the patient experienced DIPLOPIA (Double vision), CONFUSIONAL STATE (Confusion), DRY MOUTH (Dry mouth), PRURITUS (All over body itchiness) and MYALGIA (My body was filled with sores on my breasts, armpits and back). At the time of the report, RETINAL HAEMORRHAGE (Retinal Hemorrhage), OCULAR HYPERAEMIA (Blood shot eye in right eye), LACRIMATION INCREASED (Right eye started to water), DIPLOPIA (Double vision), NUCHAL RIGIDITY (Neck rigidity), HYPERTENSION (my blood pressure was high), PALPITATIONS (Palpitations), PRESYNCOPE (I thought I was going to pass out), CONFUSIONAL STATE (Confusion), HYPOAESTHESIA (On the left side, in the groin, I had a numbing sensation), TONGUE DRY (My tongue also got dry), RHINORRHOEA (runny nose), NASOPHARYNGITIS (Half of my head (the right) felt a little cold), DRY MOUTH (Dry mouth), HEAD DISCOMFORT (Half of my head (the right) felt a little cold), VEIN DISORDER (The vein in my head was swollen), MUSCULOSKELETAL STIFFNESS (the half part of my body on the right became very stiff), PAIN (it started to hurt), PARAESTHESIA ORAL (my mouth started tingling), TACHYCARDIA (tachycardia), PRURITUS (All over body itchiness), TREMOR (I started shaking), HEADACHE (Headache), MYALGIA (My body was filled with sores on my breasts, armpits and back), CHILLS (Chills), NAUSEA (nausea) and FATIGUE (Extreme fatigue) outcome was unknown.

DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 27-Feb-2021, Blood glucose: low (Low) Dropped to 60. On 27-Feb-2021, Blood pressure measurement: high (High) 174/90 mm Hg.. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown.

Treatment information was not provided. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 10-May-2021: Events retinal hemorrhage, diplopia, nuchal rigidity, palpitations, headache, etc were added.; Sender's Comments: Based on the current available information and temporal association between

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| 1346968 | 5/25/2021 | NY | 19 | M | 5/25/2021 | 5/25/2021 | <p>the use of the product and the start date of the event, a causal relationship cannot be excluded.</p> <p>The patient is a 19 yo male with pmh of anxiety d/o on clonazepam, who is also afraid of needles. He presented with his father to the site of vaccination and was very worried about the phobia to needles. He was nervous, about 4 minutes after vaccination he experienced lightheadness and near syncope, he was lie down flat on the floor and had legs elevated about 90 degrees, at this time the father was looking for water and when he came back he noticed that we were assising his son. He stayed for 15 mins there, VS: were stable 120/75 HR: 80 taken by the nurse. Denied any headaches, no palpitations and felt better, he just landed from California. Pt and dad refused EMS and wanted to leave home. Patient was stable a</p> |

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| 1345735 | 5/25/2021 | FL | 27 | F | | 5/19/2021 | <p>SYNCOPE; CUT ON LIP FROM THE FALL; FELL; This spontaneous report received from a pharmacist concerned a 27-year-old female. The patient's height, and weight were not reported. The patient's past medical history included syncope (when she had blood draw), and concurrent conditions included fear of syringes. Patient was not pregnant at the time of reporting. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 205A21A, and expiry: 23-JUN-2021) dose was not reported, 1 total administered on 19-MAY-2021 for prophylactic vaccination into Right Deltoid. No concomitant medications were reported. On 19-MAY-2021 HCP (Health Care Practitioner) reported that the patient experienced syncope after receiving the vaccine. Patient fell face down for about 5 seconds from a sitting position seconds after receiving the shot. HCP called 911. The patient experienced cut on lip from the fall. Emergency medical services mentioned it was syncope and patient did not need to go to the hospital as patient seemed to have fully recovered. HCP reported the patient mentioned this had happened to her before when she had a blood draw. She had a fear of syringes. Emergency medical services advised patient to lie down for blood draws and shots in the future. HCP did not administer any other medications to the patient. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from syncope on 19-MAY-2021, and the outcome of fell and cut on lip from the fall was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0. 20210540040-COVID-19 VACCINE AD26.CO2.S-Syncpoe. This event(s) is considered not related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: MEDICAL HISTORY</p> |
| 1347127 | 5/25/2021 | ME | 22 | M | 4/17/2021 | 4/17/2021 | fainted and fell. given rest, water and monitored.. |

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| 1345435 | 5/25/2021 | CA | 34 | F | 5/14/2021 | 5/14/2021 | 5/14/21 Sore and tender arm, overnight fever and chills, nauseous, body aches and pain especially neck, back, and hips. 5/15/21 Continued fever symptoms, throbbing headache, nearly passed out, light headed upon transitions from supine to sit or sit to stand. Fatigue and lethargy. Excedrine after nausea resolved decreased other symptoms somewhat. 5/16/21 Poor temperature regulation i.e. hot then cold all day, continued light headedness upon standing, less body aches, no longer nauseous but gassy with loose stools. 5/16-5/18/21 Warmth and swelling, mild redness and skin texture change right arm 1-2 inches distal to injection site, intermittent itching. Gradually decreased until resolved. 5/19/21 Mildly sore throat right side. All symptoms seem resolved by reporting date of 5/24/21. |
| 1345419 | 5/25/2021 | HI | 24 | F | 5/24/2021 | 5/24/2021 | Patient fainted in the aisle a few minutes after receiving 1st dose of Moderna |
| 1346359 | 5/25/2021 | RI | 30 | M | 5/24/2021 | 5/24/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Mild |
| 1346955 | 5/25/2021 | VA | 16 | F | 4/19/2021 | 4/19/2021 | Patient fainted and vomited within 15 minutes of vaccination. No treatment needed. Patient released to home with parent. |

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|-----------------|-----------------|--------------|----------------|------------|-----------------|-------------------|--|
| 1345678 | 5/25/2021 | KY | | F | | | <p>PASSED OUT; SUNBURN FEELING IN VACCINE INJECTION ARM; SEVERE STOMACH ISSUES FOR A WEEK; UNSPECIFIED DISORDER OF JOINT OF SHOULDER REGION; FEELS LIKE NERVE DAMAGE; FEELING IRRITATED; FEELS LIKE THE HAIR ON ARMS HURT; ARM FROM SHOULDER TO PINKY FINGER HURTS IF SOMETHING TOUCHES IT; This spontaneous report received from a consumer concerned a female of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: UNKNOWN) dose was not reported, administered on 08-APR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date in 2021, patient passed out. The patient had severe stomach issues. The patient's arm that she received the vaccine in, felt like a sunburn- no redness, rash or swelling. The patient's arm didn't hurt unless something was touching it. It was not hot to the touch but felt very strange and very sensitive from her shoulder all the way to the tip of her pinky finger on the outer portion of arm. It was very sensitive even when washing the hands. The patient felt like nerves have been damaged. It felt like hair on arm hurt. It fell irritated. These events didn't last as long-maybe a couple of days and it was gone. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from passed out, sunburn feeling in vaccine injection arm, severe stomach issues for a week, unspecified disorder of joint of shoulder region, feels like nerve damage, feeling irritated, feels like the hair on arms hurt, and arm from shoulder to pinky finger hurts if something touches it on 2021. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to 20210525585.; Sender's Comments: V0;20210531194 -covid-19 vaccine ad26.cov2. s passed out. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.</p> |

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| 1346520 | 5/25/2021 | NV | 65 | F | 5/24/2021 | 5/24/2021 | Systemic: syncope-Medium, Systemic: Nausea-Mild, Systemic: Shakiness-Mild, Additional Details: Patient sat down for more than 15mins after receiving vaccine then walk out side to wait for pick up. While waiting, she got syncope and fell down on the side walk, got a bump on the leftside of her forehead. Pt complained of nausea. She felt better after given some water. She refused to call 911. Patient came back inside and continue waiting for 45 mins when her pick up arrived, she stated feeling better and wanting to leave to go back to her hotel |
| 1346961 | 5/25/2021 | AL | 38 | M | 5/24/2021 | 5/24/2021 | Patient experienced excessive sweating and light headedness approximately 2 minutes following his vaccination. Management was called. Patient was instructed to lean towards knees incase of fainting. Patient was given water and EMT responded. When offered to be assessed by EMT, patient responded that he was feeling better. Patient was observed for 30 minutes following vaccine and stated he felt fine before leaving. |
| 1346924 | 5/25/2021 | WA | 13 | F | 5/25/2021 | 5/25/2021 | Approximately 3 minutes after her injection, the patient experienced stomach pain, hot flashes, and pallor so was taken to our roof for fresh air. While being escorted by parent and staff, the patient fainted and was supported to the ground. Epinephrine was administered and 911 was called. Paramedics arrived shortly thereafter and examined patient. Patient was cleared by paramedics and walked out of the clinic unassisted. |
| 1346909 | 5/25/2021 | PA | 31 | F | 5/25/2021 | 5/25/2021 | Patient fainted after being seated for several minutes and standing up |
| 1346873 | 5/25/2021 | ME | 27 | F | 4/10/2021 | 4/10/2021 | Fainted. Past history of fainting episodes. Drank water and felt better. |
| 1346807 | 5/25/2021 | FL | 62 | M | 5/4/2021 | 5/13/2021 | Heart Racing near fainting/ possible A-Fib |
| 1346746 | 5/25/2021 | NY | 53 | M | 5/24/2021 | 5/25/2021 | PT Fainted approximately 17 hours post Covid-19 vaccination. No other health conditions. |

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| 1346677 | 5/25/2021 | MN | 26 | M | 5/24/2021 | 5/24/2021 | Received shot and waited for the 15 minutes as required, feeling no good with no symptoms. While driving home after leaving the pharmacy, I started experiencing light headed ness and dizziness. This eventually turned into tunnel vision which I thought was going to result in me fainting. This led me to start pulling over, but then the tunnel vision went away. During my short 10 minute drive home, this happened to me twice. After getting home, I had about 3 similar episodes during which similar light headedness happened. These all felt like they were getting close to fainting, and at one point while walking up the stairs in my house I could not stand. All of these symptoms started approximately 20 minutes after leaving the store, and then took place in a 20-30 minute timespan. Roughly 4-5 episodes in total, including the drive home and short time spent at home. No issues after lightheadedness stopped, besides feeling tired. I do not have a history of anxiety attacks due to needles. Donated blood and plasma in college, and have recieved many vaccines and never had this happen. |
| 1346557 | 5/25/2021 | VA | 37 | M | 5/20/2021 | 5/21/2021 | Lethargy, fever, chills, body aches, headache...beginning at hour 6 and lasting until hour 24. One episode of fainting, while standing up and using the restroom. Blood pressure dropped severely and blacked out, woken up on the floor in the bathroom by wife who explained my eyes were open, dilated, and darting and body was twitching. Loss of consciousness lasted approximately 20-30 seconds. Occurred at hour 12 after receiving vaccination. Gastrointestinal distress, diarrhea, cramping, nausea from hours 40-76 |
| 1346649 | 5/25/2021 | NJ | 15 | F | 5/24/2021 | 5/24/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Seizure-Mild |
| 1346646 | 5/25/2021 | OH | 23 | M | 5/20/2021 | 5/20/2021 | Pt. stated he felt a little dizzy and that is the last thing he remembers. Patient passed out and was found on the floor. Denies hitting head. Patient was diaphoretic blood sugar was taken and was 71 . Patient drank juice and ate crackers. Sugar was rechecked and was 101. BP 145/83 HR- 67. Patient was feeling much better and left. |
| 1346636 | 5/25/2021 | NH | 17 | F | 5/24/2021 | 5/24/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Shakiness-Mild |

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| 1346623 | 5/25/2021 | MN | 12 | F | 5/24/2021 | 5/24/2021 | Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium |
| 1346521 | 5/25/2021 | NY | 58 | F | 5/21/2021 | 5/21/2021 | felt lightheadedness/fainted and loss of appetite a few hours after getting 2nd shot. called 911, checked vitals, everything normal limits. ems insisted she went to ER. |
| 1346614 | 5/25/2021 | | 67 | F | 5/24/2021 | 5/24/2021 | fainting for about 5 minutes |
| 1346613 | 5/25/2021 | AL | 17 | F | 5/25/2021 | 5/25/2021 | PATEINT RECEIVED INJECTION AND ABOUT 6 MIN LATER SHE FAINTED AND HAD A 5 SEC SEIZURE. WOKE UP ON HER OWN |
| 1346965 | 5/25/2021 | VA | 17 | F | 4/19/2021 | 4/19/2021 | Patient fainted within 15 minutes of vaccination. She had not eaten that day. Given some food; no treatment needed and she was released to home with a parent. |
| 1346535 | 5/25/2021 | MA | 24 | M | 5/23/2021 | 5/23/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Severe, Additional Details: patient felt normal immediately after vaccine, remained sitting for about 3 minutes and then stood up and told me he felt like he was going to faint. i told him to sit back down and as soon as he sat, he fainted and head went back. patient was unresponsive for about 60 seconds and then came to and felt ok. i did call 911 and EMS assessed patient and gave him the OK to leave. patient told me after the incident that this occurs regularly when he sees needles. |

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| 1346660 | 5/25/2021 | UT | 35 | F | 5/21/2021 | 5/21/2021 | This is a 35-year-old female, G2, P1 Ab0, 23 weeks pregnant, who presents to the emergency department for chest pain. Patient reports receiving her second Madura COVID-19 vaccine yesterday at around noon. She states that later that evening, she reports onset of fatigue, and pleuritic chest discomfort. She reports increasing in discomfort into this afternoon, with shortness of breath. She also reports body aches, and bilateral lower extremity calf pain. No fevers, or chills. No nausea, or vomiting. Patient is currently being followed by doctor of OB/GYN, with whom she had a conversation with this morning. Doctor already recommended she come in for evaluation. Otherwise patient denies any vaginal bleeding, discharge. No urinary symptoms. No prior history of a cardiac or pulmonary disease. No lightheadedness, dizziness, or syncope. No prior history of DVTs, pulmonary embolisms. |
| 1344002 | 5/24/2021 | WI | 61 | M | 5/20/2021 | 5/20/2021 | Patient began sweating and feeling lightheaded shortly after vaccination at approximately 1125. Patient then fainted in his chair and was initially non-responsive to the nurse. At this time I called 911. The nurse administered a single epi pen in patient's quad and he woke up. The nurse then took patient's vitals at 1138: BP - 109/73; P-84; SPO2-99%; T-97.4; R-16. Patient stating he was still feeling dizzy and fatigued. The paramedics arrived and took patient to hospital for continued evaluation. I called patient later in the afternoon and he had already been discharged and was at home resting and feeling better. |
| 1344014 | 5/24/2021 | PA | 22 | F | 5/21/2021 | 5/22/2021 | Moderna COVID-19 Vaccine EUA Around 4am on 5/22 I developed a mild fever. Got up around 7am 5/22 and took my temperature (99.8). I walked down my stairs to make toast and around 7:20 am I fainted in my kitchen. I had eaten and drank plenty of water the night before, so I don't think I was dehydrated or hypoglycemic. No other fainting events the rest of the day but I was extremely dizzy and nauseous. |
| 1344019 | 5/24/2021 | TX | 35 | M | 5/24/2021 | 5/24/2021 | after receiving the vaccine patient was feeling nausea and light-headed and he fainted on the floor 5 minutes after the vaccine administration |
| 1344054 | 5/24/2021 | ME | 25 | M | 4/29/2021 | 4/29/2021 | syncope episode while getting the vaccination, diaphoretic, pale, weak. Given rest and water |

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| 1344170 | 5/24/2021 | CO | 14 | F | 5/22/2021 | 5/22/2021 | Pt was vaccinated and had a syncopal episode in response. Pt was supported in her chair so that she did not experience a fall. Estimated syncope time of 8 seconds. Pt was taken to private observation area via wheelchair after she regained consciousness. Her vital signs and mentation were monitored continuously. Upon leaving clinic, pt was AOx4 with stable vitals. |
| 1343931 | 5/24/2021 | IL | 30 | F | 5/24/2021 | 5/24/2021 | pt became dizzy shortly after administration (3-5 minutes est.) said she felt like she was going to pass out and then lost consciousness for est. 15-20 seconds. She regained consciousness and answered general questions correctly then felt faint again a few minutes later and passed out for a shorter time 2-3 seconds est. Paramedics called and arrived about 1:20pm checked her blood pressure/HR 3 times over a course of 10 minutes 88/62,93/62, 108/70 respectively. HR was 60bpm (one reading recorded). EKG -normal (paramedic ambulance). pt refuse ride to hospital and left facility following paramedic examination- signed waiver a left facility at 1:35pm |
| 1344193 | 5/24/2021 | WI | 15 | F | 5/24/2021 | 5/24/2021 | patient fainted about 3 minutes after getting her vaccine injection. SHe was out for about 3 to 5 seconds and then came to. she was sweaty but her temperature was ok and pulse seemed normal. The pharmacy called 911 as a precaution. paramedics verified her vitals and gave mom the option to take her to the ER or just let her stay and be monitored. mom decided to have her stay. Mom and patient stayed by phramcy for 30 minutes as the child drank 2 bottles of water and ate a granola bar. when she felt 100% they left the store. |
| 1344196 | 5/24/2021 | IL | 35 | M | 5/24/2021 | 5/24/2021 | Patient walked over to the post vaccine waiting area and fainted falling face forward hitting his head onto the concrete. Rph went to patient, he started to shake and open his eyes. Paramedic was near and came over to aid patient. Patient's head was bleeding. Medic radioed out to the ambulance and they came in with a stretcher. Patient was alert |
| 1344114 | 5/24/2021 | NC | 73 | F | 5/13/2021 | 5/13/2021 | shaking, fever, passed out, muscle weakness, lost muscle control |

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| 1343961 | 5/24/2021 | WI | 17 | M | 5/21/2021 | 5/21/2021 | Patient fainted (loss consciousness) a couple of minutes after receiving injection. Mom caught him and called for help and reported his eyeballs rolled up and he started down when she caught him. by time Pharmacist and store staff got there (less than a minute) he had regained consciousness but very lightheaded. No breathing difficulty. So got a chair and had him sit with head down and store staff observing. After another 10min he still reported lightheaded and nausea, so ambulance was called. When they arrived and checked him out everything checked out normal and he was feeling better so they released him to his parents care. Called on 5/24/21 at 10:10am and spoke to mom who reported he was doing fine and no apparent after effects. |
| 1343946 | 5/24/2021 | MO | 28 | F | 5/24/2021 | 5/24/2021 | Patient upon registration for vaccine informed us that she typically faints when getting shots, I asked patient if she was sure this was the best setting to receive the vaccination and she said yes. I asked her boyfriend to remain with her during the vaccination and to stay with her after. I administered the vaccine to the patient whom did not pass out immediately I talked with her and she said she felt fine actually. I advised her to stay in the same chair in vaccination booth and I walked back into the pharmacy and a few minutes later noticed she was sitting on her friends lap in a chair. I went to check on the patient and she had fainted but was doing ok friend with her said. I offered water, wet towel and ice pack which patient did take. I stayed with patient for a couple minutes and then followed up 5 minutes after patient was still feeling faint. I told patient to sit as long as needed. After about 20 minutes I checked on patient again and she was feeling well. I offered to sit with her while her friend pulled up his car to the front of the store so she did not have to walk far. I told patient I will follow up with her later tonight. |

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| 1343932 | 5/24/2021 | CA | 60 | F | 4/30/2021 | 5/1/2021 | approx 18 - 19 hours after shot, having had arm soreness, tiredness and low grade fever, woke up in morning with sweats and headache. Got up to get drink in kitchen to wash down Advil with, got dizzy, fainted and fell to floor. Time down unknown but very short duration. Stood up with dripping sweat and felt like was going to vomit. Had dry heaves but did not vomit. Rest of day tired and sore, woke up next morning perfectly fine and feeling good. |
| 1343911 | 5/24/2021 | MD | 19 | M | 5/24/2021 | 5/24/2021 | After receiving the Janssen Covid 19, patient fainted while sitting on a chair approximately 10 minutes after receiving the vaccine. Paramedics were called. BP and EKG were normal. Patient returned to work. Patient informed Pharmacist and Paramedics that he fainted before when donating blood. |
| 1343887 | 5/24/2021 | NC | 39 | F | 5/20/2021 | 5/20/2021 | vasovagal syncope bleeding at injection site nausea excessive thirst lightheadedness sweating feeling faint sense of doom tunnel hearing |
| 1344206 | 5/24/2021 | OH | 69 | F | 4/10/2021 | 4/16/2021 | The weekend after the shot, I noticed deep purple coloring at the top of my thighs, pubic area, arm pits. There are also welts on the top of my thighs, where coloration is more blotchy. After a couple days I realized I was having small episodes of near-fainting. I would have the sensation that I was was going to faint, and it went away without any fainting or dizziness. It was a warning sensation. This occurred 10-15 times a day. It would grab my attention & be gone just as quickly. The same weekend I started with the rash, my anxiety level rose very high. I felt a motor in my chest all the time. Sleeping was very difficult. This anxiety & motor are indicative of a thyroid rage, which I have experienced p |
| 1344594 | 5/24/2021 | CA | 22 | M | 5/24/2021 | 5/24/2021 | HX SYNCOPE, UNPRESCRIBED MARIJUANA INTAKE. AFTER PFIZER VACCINE, PT IS SWEATING/DIZZINESS, HEADACHE BUT EASILY AROUSABLE. PROVIDED WATER, SX RESOLVED. REFUSED TRANSPORT. |

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| 1343871 | 5/24/2021 | TX | 15 | F | 5/22/2021 | 5/22/2021 | Pt received vaccine and was standing outside of immunization room with her parents waiting for her brother to receive vaccine. She felt dizzy and fainted. She hit her head and collapsed. She was seizing/shaking on the floor. She was conscious with no visible bleeding. She was able to say her name and DOB correctly. Mother reported no history of epilepsy or seizure. Called emergency services and pt was taken to Clinic for further evaluation. A 1.5cm laceration was noted behind her left ear. Pt received 2 staples in the lacerated area. |
| 1343864 | 5/24/2021 | NJ | 20 | F | 5/24/2021 | 5/24/2021 | PATIENT GOT THE SHOT & COMPLAINED OF FEELING DIZZY. HER MOM WAS WITH HER. SHE WAS PROVIDED WITH WATER & FELT OK. SHE SAID SHE GAVE HER EXAM AND CAME TO GET SHOT, DID NOT EAT OR DRINK. THEN SHE FAINTED FOR SECONDS. WE CALLED 911 & AMBULANCE. SHE WAS CONSCIOUS AGAIN, SAID SHE IS FEELING BETTER. THEN AFTER 2 MIN FAINTED AGAIN. WAS BREATHING OK. AMBULANCE ARRIVED AND SHE WAS CONSCIOUS AGAIN. SHE FELT BETTER AS SHE DRANK WATER. SHE WAS OFFERED TO GO TO HOSPITAL IN AMBULANCE BUT PREFERRED TO GO TO HOSPITAL WITH HER MOM IN CAR. SHE SAID SHE WAS FEELING MUCH BETTER WHEN SHE LEFT. RECOMMENDED TO KEEP HER HYDRATED AND GIVE ELECTROLYTES AND WATER |
| 1343934 | 5/24/2021 | IL | 27 | M | 5/24/2021 | 5/24/2021 | Patient fainted during the post 15 minute wait period |
| 1344585 | 5/24/2021 | CA | 76 | M | 4/8/2021 | 4/10/2021 | 03/18/2021 FIRST COVID19 VACCINE 04/08/2021 SECOND COVID19 VACCINE 04/09/2021 FELT DIZZY AND FAINTED BREIFLY IN THE MORNING 05/03/2021 AT NIGHT, SLUGISH SPEACH, DIZZY, HIGH BLOOD PRESSURE 05/04/2021 WENT TO EMERGENCY ROOM AND HOSPITAIZED (STROKE) |

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| 1344064 | 5/24/2021 | AR | 63 | M | 5/24/2021 | 5/24/2021 | Patient has severe phobia of needles. About 10 minutes following administration of Janssen vaccine, patient began turning pale and said that he felt dizzy. Moments after, patient fainted and was out for about 30 seconds. During this time, 911 was called and then patient came to but was still very pale and lips were blue. EMTs came minutes later and took patient to ambulance to be checked out. Patient was feeling better by then and did not leave in ambulance. |
| 1343842 | 5/24/2021 | CA | 17 | M | 3/19/2021 | 3/19/2021 | Syncope/fall s/p vaccine #1, abrasion under chin>ED>dc'd declined txt |
| 1345273 | 5/24/2021 | WA | 16 | M | 5/24/2021 | 5/24/2021 | patient received first dose. Left the consultation room and fainted within a few minutes. Emergency personell were called and patient taken to the ER. Patient given fluids and sent home follow up with family stated patient fine. |
| 1345247 | 5/24/2021 | IN | 30 | F | 3/13/2021 | 4/3/2021 | Started feeling faint and dizzy more often about 2 weeks after the vaccine. After almost fainting at work, the paramedics came to find out it was due to a dangerously high blood pressure of 180/110. |
| 1344914 | 5/24/2021 | TX | 68 | M | 1/15/2020 | 1/21/2020 | My husband had the shot at a center. A few days pass I noticed his strength deteriorated. By that morning he passed out with chest pains. We went to the er. Then off to the hospital. He had inflammation around his heart. 24 ounces of fluid! After being released with in a few days again chest pain back to the hospital. This time fluid around the sac of one lung. So questions were asked. Our cardiologist said she had another younger patient who got the Moderno shot as well and had the same issues. So weeks of steroids, meds to clear up the liquids as well as the inflammation. This had already caused scarring. They did a cath on him and unrelated to the reaction and inflammation and scarring. He needed a several bypasses. Because of the scarring they couldn't find arteries to get my husband back into shape. I believe this has set my husband back, on returning to the hospital and talking to several cardiologist there?s a 10% rise with patients in the hospital right now with the same issues! Why arnt you sharing this! I now feel that my husband is living on borrowed time. I wish we never got the shot! Now younger adults are having issues. |

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| 1344876 | 5/24/2021 | SC | 18 | F | 5/24/2021 | 5/24/2021 | Patient frequently faints following vaccinations. About 2-3 minutes after receiving vaccination, patient fainted while sitting in a chair. Once patient began to come to, she convulsed. Pharmacist and nearby customers helped lay her on the ground. Patient came to and was given water and a glucose tablet. EMS was called at the start of the incident. Patient remained lying down until she felt ok to sit up. EMS checked her blood pressure, which was normal and she was ok to go home. |
| 1344868 | 5/24/2021 | PA | 16 | F | 5/24/2021 | 5/24/2021 | Patient was visibly nervous/anxious about the vaccination. Patient had reported syncope from a previous vaccination on their consent/screening form. Vaccine was administered as prescribed and patient initially appeared fine but lost consciousness approximately 15 to 20 seconds after. The patient's mother, who was present as her legal guardian, helped me cushion the the patient to ensure she did not fall and injure herself. Patient regained consciousness in 10 to 15 seconds but then passed out again. I was then able to elevate the patient's legs and she regained consciousness. Provided patient with chilled bottled water and allowed her to rest in the vaccination booth for 15 minutes. I stayed with the patient during that time and observed her. Afterwards she said she was feeling better and the color in her face was returning. She felt comfortable standing up and moved to a different seat in front of the pharmacy where she waited another 15 minutes. I observed her from the bench during that time. When the patient and her mother felt comfortable they left the pharmacy together. |
| 1344576 | 5/24/2021 | NJ | 19 | M | 5/24/2021 | 5/24/2021 | patient fainted and regained consciousness |
| 1344654 | 5/24/2021 | MA | 19 | M | 5/23/2021 | 5/23/2021 | Patient received vaccine. Patient fainted into mother's arms about 3-5 minutes later. Patient reported feeling light headed after getting up too fast. EMS responded. Patient vomited 5-10 minutes later while speaking with paramedics. |

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| 1344212 | 5/24/2021 | IA | 17 | F | 5/24/2021 | 5/24/2021 | Patient became light headed and fainted from a seated position about 10 minutes after her first Pfizer COVID-19 vaccination. She doesn't think she lost consciousness. Her skin was quite warm and sweaty after this event. I had her remain laying down on the ground while she recovered and I assessed her symptoms. She felt better almost immediately so I had her move to the pharmacy office for observation for an additional 15-20 minutes. She then reported that she has fainted with shots before and she hadn't eaten anything today. Her mother said this has happened before and drove her home once she felt well again. |
| 1344420 | 5/24/2021 | NY | 37 | M | 5/24/2021 | 5/24/2021 | Within two minutes from getting his second shot, Pt passed out from a standing position striking the back of his head. Pt was unresponsive for 2 minutes before he was able to talk to EMS, Pt was picked up by staff and with his head supported placed on the stretcher to be take to the medical for treatment. While in treatment room, vitals and demographics were obtained. Treatment included ongoing vitals, ice pack for his head (large contusion to the right back of his head approx. 50 mm in dia. After 20 minutes of treatment and assessment, Pt tried to sit up and upon doing so became very dizzy and light headed. At this time the decision to call for a transport ambulance was made by calling 911. ambulance arrived within 10 minutes verbal report make to the medic and care was turned over at that time. |
| 1344416 | 5/24/2021 | AZ | 27 | M | 5/24/2021 | 5/24/2021 | Patient fainted following vaccine administration |
| 1344334 | 5/24/2021 | FL | 19 | M | 5/22/2021 | 5/22/2021 | Patient received the vaccine and fainted within 5 minutes after receiving the vaccine. He fell and hit his head and had a nose bleed. He was put in the Trendelenburg position and recovered immediately. The EMT was called and provided care to the patient. Checked on patient and patient said he was able to walk home on his own. |
| 1344316 | 5/24/2021 | CA | 13 | F | 5/18/2021 | 5/18/2021 | About 3 min after getting vaccinated, patient fainted Reason for visit in ER: Near Syncope Diagnosis: Syncope and collapse |

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| 1344313 | 5/24/2021 | MD | 28 | M | 5/24/2021 | 5/24/2021 | Patient fainted due to carry over fear of the needle. He stated before the shot that he did not like needles. After the shot I took him to the waiting area to wait for 15 minutes. After about 3 minutes, he lost consciousness and fell off of his chair. After about a minute he came to and slowly got to his knees and came to and was able to sit back down in the chair. |
| 1344304 | 5/24/2021 | CA | 16 | M | 5/16/2021 | 5/16/2021 | ONE MINUTE AFTER ADMINISTERING PAITENT HIS FIRST DOSE OF PFIZER COVID-19 VACCINE, THE PATIENT FELL TO THE FLOOR. PATIENT REPORTS , " HE FELL ASLEEP", BUT CLAIMED HE WAS OKAY. THE PATIENT WAS ESCORTED TO THE WAITING AREA AND INSTRUCTED TO WAIT FOR 15-30 MINUTES FOR OBSERVATION. SOON AFTER SITTING IN THE WAITING AREA,THE PHARMACIST WHO ADMINISTERED THE VACCINE REPORTS THE PATIENT PASSED OUT FOR THE SECOND TIME. PER PHARMACIST REPORT, THE PATIENT WAS UNRESPONSIVE AND SEEMED NOT TO BE BREATHING. EPINEPHRINE 0.3MG DOSE WAS GIVEN INTRAMUSCULARLY AND EMERGENCY WAS CALLED AT 11:56AM. THE PATIENT REVIVED AND REPORTED HE "FELT FINE". EMERGENCY HEALTHCARE AND AMBULANCE ARRIVED AT 12:06PM AND TOOK OVER CARE OF THE PATIENT. |
| 1344301 | 5/24/2021 | UT | 15 | M | 5/22/2021 | 5/22/2021 | Pt dad thinks pt has vasovagal syncope. Pt passed out immediately after getting vaccinated and vomited when regained consciousness. Pt turned white in the face and fell forward in chair when he fainted and after vomiting pt continued to go in and out of consciousness. Took about 10-15 minutes of placing feet on another chair and raising hands over head but pt color returned and he felt much better. |
| 1344268 | 5/24/2021 | MI | 17 | F | 5/24/2021 | 5/24/2021 | Patient was extremely nervous prior to vaccine. Got shot, walked out of room to waiting area. about 2-3 minutes post vaccine, realized did not feel well. Passed out. Mom said patient felt a touch rigid and twitched a couple times, then came too. Did hit head when patient fell to floor, although was not a major hit. Patient was worked up after coming to. |

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| 1344844 | 5/24/2021 | PA | 17 | F | 5/17/2021 | 5/18/2021 | The day after the vaccine, she had an episode of syncope while in the bathroom. She does not remember the event, but was at a friend's house and was found in the bathroom after they heard a bang and was noted to be shaking. She then passed out again and continued shaking. She texted her mom and was given a cold rag on her forehead but has no recollection of any of that. Afterwards, she returned to normal. |
| 1342959 | 5/24/2021 | CT | 32 | M | 5/23/2021 | 5/23/2021 | Systemic: Confusion-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Exhaustion / Lethargy-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Severe, Systemic: Headache-Severe, Systemic: Shakiness-Medium |
| 1343333 | 5/24/2021 | WA | 18 | F | 5/13/2021 | 5/13/2021 | Patient passed out about 5 minutes after getting the covid vaccine. Pharmacist was called right away and the patient was found lain on the floor, coherent and talking to the mother. She rested there for a few minutes, drank some water. She looked ok and refused further EMS help when EMS arrived. |
| 1343326 | 5/24/2021 | NJ | 15 | F | 5/22/2021 | 5/22/2021 | One of the physician observers wrote: From what I understand she had her shot and switched places with her sister and was standing and then just went down. I don?t believe she hit her head we didn?t see a lump. She came too right away and got nauseated and light-headed again sitting up so we took her to lay down on the stretcher. She was doing ok but laying down when I left. The nurse that administered the immunization wrote: She got vaccinated, tolerated it well. Told her sister she barely felt it and expressed relief. Sat for a minute while in handed her mom paperwork (vaccination card). Then got up, stood with mom and brother. Was standing one minute and went down without warning, standing next to brother and mom. I had just finished vaccinating the sister, I was putting a bandaid on her when it happened so couldn't have been more than a couple of minutes. Dr. observed this patient after they passed out at the vaccination clinic and subsequently released her home with the family. |

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| 1343258 | 5/24/2021 | NC | 54 | F | 5/6/2021 | 5/6/2021 | 10 mins post, severe syncope, and headache, severe ringing in ears * Severe headaches every morning * continued moderate ringing ears * Severe dehydration every morning * Frequent heartburn * lungs tight, a bit shallower breathing * Vertigo all day and night * Chills and hot flashes but no fever * Nausea every morning until I eat; have to eat every few hours to avoid nausea * random dry raspy cough * 100+oz. H2O daily+powerade(S/F)p * urine near clear by afternoon * using RR 3x/night, but avg 5a wake-up with severe headache & PARCHED with very dry mouth |
| 1343253 | 5/24/2021 | CA | 27 | M | 5/17/2021 | 5/17/2021 | 5 min after shot. Warming sensation spread from arm across my entire body. Felt nauseous and blacked out. Passed out face first on the floor. No fear of needles. I have records of getting previous flu vaccines without passing out. I have been experiencing hot flashes, nausea and fatigue for 6 days now. |
| 1343203 | 5/24/2021 | TX | 15 | M | 5/21/2021 | 5/21/2021 | Patient reported feeling "nauseous" about 5 minutes after having received vaccine. Patient had an episode of syncope in the restroom. Assisted patient to sitting position was A&O x4, no signs of active bleeding or cuts. O2 saturation was 99% with HR of 83. Patient was able to swallow and answer basic commands. |
| 1343140 | 5/24/2021 | NY | 51 | F | 2/27/2021 | 2/28/2021 | Since receiving the vaccine I have extreme lightheadedness requiring me to grab things to avoid falling over until it passes. I passed out once. I have chest pain and fullness as well. My doctor told me to drink juice, wear compression socks, eat salty foods and drink more water. I began tracking my BP and my diastolic is in the 40s and 50s when these incidents occur which is often. The chest pain is consistent. I saw a cardiologist who told me to drink more water and eat more salt. EKGs are fine. I'm going to the Clinic on June 2nd since we all know women's heart issues are dismissed. The pain and fullness in my chest are becoming annoying and distressing. Since taking the vaccine my exercise fell off almost completely except for pickel ball and when I did play I couldn't play as I had before at all. I've now stopped playing and I'm walking as I used to so that I keep moving. I can't run. :(|

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| 1343105 | 5/24/2021 | | 24 | F | 4/28/2021 | 4/28/2021 | Patient presents for Pfizer COVID-19 vaccination # 2 and disclosed that with the first dose of the Pfizer vaccination, which she received at Pharmacy, she had immediate (within 2 minutes of rec'ing injection) difficulty "getting air and taking good breaths" that lasted about 10 minutes and resolved without intervention. This was associated with nausea that persisted throughout the evening. She denies significant anxiety, tachypnea, tachycardia, near-syncope or syncope, rash, swelling of the lips, tongue, throat, or face. She denies allergic reactions to any other medications or foods and has denies significant past medical hx. Per updated CDC guidelines, the Pfizer booster is contraindicated and should be listed as an allergy. Additionally, she is eligible for the J & J COVID-19 Vaccination at least 28 days from the time of her first vaccination if okay with her primary care physician |
| 1343095 | 5/24/2021 | PA | 13 | M | 5/22/2021 | 5/22/2021 | syncope, pt started experiencing fainting symptoms such as sweating, paleness, hearing disturbances, weakness, dizziness, coldness of extremities after about 3 minutes of the vaccine, symptoms resolves in about 20 minutes. |
| 1343013 | 5/24/2021 | CA | 15 | F | 5/23/2021 | 5/23/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Shakiness-Mild, Additional Details: pt immediately said she felt dizzy& eyes began to roll. Mom stated she has a fainting condition. Her Mom & I eased her to the ground. she briefly passed out, but immediately came to and asked what was happening. Her right leg was bent back but we lifted her to straighten leg. I elevated her feet & got her some water. I also got her some gatorade & a cool wet paper towel for forehead. She leaned against her Mom for a little while, then she sat. Mom said not to call 911 |
| 1343005 | 5/24/2021 | MD | 17 | F | 5/23/2021 | 5/23/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Headache-Mild |

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| 1342993 | 5/24/2021 | MA | 14 | F | 5/22/2021 | 5/22/2021 | Systemic: Chills-Mild, Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Weakness-Medium, Additional Details: pt passed out after about 10 minutes while in observation area. dad was next to her and she did not fall. emt were called to check her out and after 1/2 hr pt seemed to be ok |
| 1342984 | 5/24/2021 | NJ | 23 | M | 5/23/2021 | 5/23/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: pt was in chair in waiting area and fell out of chair when passed out 8 minutes after vaccine, pt had rug burn on left side of forehead, pt said felt ok and soemtimes passes out after blood work-Mild, Systemic: Flushed / Sweating-Mild, Additional Details: i stayed with patient and asked the manager on site to get patients father from car. pt was responsive within seconds of going to him, pt was pale and said he was ok. patient remained in lying position on floor, I cleaned his forehead with alcohol swab that had "rug burn and helped him int ositting positon then standing slowly. patient was given gatorade and washelped to sit in chair and father came in and stayed with him. patient refused ambulanceand further care and was in good mood |
| 1343354 | 5/24/2021 | NY | 14 | M | 5/24/2021 | 5/24/2021 | Patient felt dizzy and passed out, did not hit head, was lowered to the ground. All vital signs were normal throughout experience. Patient was transported with a wheelchair, ate some crackers and drank some juice. No concerns noted, patient left clinic site, self ambulated. |
| 1342960 | 5/24/2021 | NY | 32 | M | 5/20/2021 | 5/25/2021 | Severe fever and chills. Dehydration. Loss on conscience/fainting. |
| 1343248 | 5/24/2021 | TX | 43 | M | 5/23/2021 | 5/23/2021 | Patient fainted after receiving first dose of moderna, patient came to immediately with no confusion, he was able to answer all questions |
| 1342956 | 5/24/2021 | CO | 30 | M | 5/23/2021 | 5/23/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient fainted for about 1 minute. Patient presented symptoms 10 min after injection while being observed. Called 911 but patient recovered fairly quickly with no need for hospitalization. Was told after event that patient has fainted in past due to being cut but never while being vaccinated. |

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| 1342953 | 5/24/2021 | CA | 14 | M | 5/21/2021 | 5/21/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: Nausea-Medium, Systemic: Weakness-Medium |
| 1342948 | 5/24/2021 | GA | 14 | F | 5/23/2021 | 5/23/2021 | Site: Pain at Injection Site-Mild, Systemic: Chills-Medium, Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Hypotension-Mild, Systemic: Shakiness-Medium, Systemic: Weakness-Medium, Additional Details: Pt received vaccine, spoke to her shortly after and decided to shop around the store. Shortly after walk pt started feeling light headed, and dizzy and fainted. Mom stated that this had happen to her before. Monitored patient for 30 min, gave water and a snack. Mom decided against calling 911. |
| 1342936 | 5/24/2021 | NC | 22 | F | 5/23/2021 | 5/23/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Shakiness-Mild, Systemic: Tachycardia-Mild, Additional Details: about 10 minutes after patient got the vaccine. she fainted in the chair. her head swung back and she was shaking. she woke soon afterwards. she became increasingly pale and reported feeling palpitations with some blurred vision. nurse checked EKG with normal results. normal blood glucose readings. EMS was called for evaluation then medic transport to nearby hospital |
| 1342935 | 5/24/2021 | MD | 14 | F | 5/23/2021 | 5/23/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Additional Details: PT fainted after receiving the vaccine, she hit her head against a shelf and got bruises. 911 was called to inspect the patient, intial BP was 90/60 and it became 105/60 after about 10 minutes. |
| 1342933 | 5/24/2021 | MI | 15 | F | 5/21/2021 | 5/21/2021 | Systemic: Confusion-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Numbness (specify: facial area, extremities)-Medium, Systemic: Tingling (specify: facial area, extremities)-Medium, Systemic: Visual Changes/Disturbances-Medium, Additional Details: TINGLING IN FEET |
| 1342927 | 5/24/2021 | NY | 13 | M | 5/22/2021 | 5/22/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Shakiness-Medium |

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| 1342918 | 5/24/2021 | NY | 26 | M | 5/21/2021 | 5/21/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Mild |
| 1342915 | 5/24/2021 | NH | 23 | F | 5/23/2021 | 5/23/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Mild, Additional Details: patient reported dizziness, and fainted 13 minutes after vaccine administered, paramedics called, helped patient sit on ground to lie down with feet elevated until help arrived, patient refused transport to hospital but had a friend pick her up to avoid driving. |
| 1342420 | 5/24/2021 | AZ | 40 | M | 5/13/2021 | 5/14/2021 | Very ill feeling started on the following morning from the vaccination. Joint and muscle ache, chills, headache, stomach ache and fever. The symptoms were severe on the first day, and they were gradually fainting during the next two days. Was unable to work on the next day following the vaccination. |
| 1343844 | 5/24/2021 | CA | 58 | F | 3/20/2021 | 3/20/2021 | Syncope s/p vaccine #1, full body spasm, tingling>ED w/ pain meds/ IVF>dc'd home |
| 1343843 | 5/24/2021 | NJ | 21 | F | 5/24/2021 | 5/24/2021 | patient felt lightheaded and dizzy 10 minutes after vaccine, passed out, came through and had emesis for about 20 minutes |
| 1342978 | 5/24/2021 | TX | 45 | F | 5/23/2021 | 5/23/2021 | Systemic: Chills-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Nausea-Mild, Systemic: Shakiness-Mild, Systemic: Weakness-Mild, Additional Details: pt started feeling weak, shaky, clammy, nauseated, flushg and sweating after pzizer vaccine administration. pt had a fainting spell. gave pt epi-pen and called 911. i had pt lie down with her feet elevated. paramedics got her vitals and it was normal. BP (120/80), normal HR. After a few minutes of rest, pt felt better. she did not go to the hospital. advised pt to seek her pcp for further advise to get the 2nd dose. |
| 1343760 | 5/24/2021 | TX | 20 | F | 5/14/2021 | 5/14/2021 | Patient fainted in the observation area after receiving vaccine. Patient was assessed by RN and refused EMS. Patient appeared flushed and diaphoretic. Patient was unaccompanied but waited for her mother to pick her up. Patient left in stable condition. |

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| 1343830 | 5/24/2021 | TX | 13 | M | 5/22/2021 | 5/22/2021 | Patient (13 years old) fainted at the vaccination table after receiving his first dose of the Pfizer vaccine, while waiting for his mother as she was getting vaccinated. Patient saw his mother bleed after the vaccine and fainted in the chair, as he began to fall, the vaccinator was able to catch him and assist him to the floor. Patient was turned on his side. EMS was called at 0912 and arrived at 0919. Patient was assessed by paramedics and found to be stable. Patient's mother reported no PMH and the he doesn't usually faint after injections. Patient left accompanied by his mother. |
| 1343827 | 5/24/2021 | CO | 39 | F | 5/24/2021 | 5/24/2021 | At 10:58, patient reported feeling of "foggy ness" which she stated was "like air in my head" after receiving Janssen vaccination at 10:53. Patient was found sitting outside of vaccination bus, alert and oriented to person, time, place and event and did not appear to be in distress. Patient denied shortness of breath, dizziness, blurry vision, weakness to one side of body, feeling of syncope, and was negative to all signs of the Cincinnati stroke scale test. Patient's vital signs were monitored for the duration of event. After 15 minutes of monitoring, patient stated that her feeling of "foggy ness" had improved but that it still mildly lingered. Patient was offered a call for emergency services but patient denied them and stated that she would seek further medical help if her condition worsened, or continued. Patient stated that she was going to visit a medical facility after leaving vaccination clinic. |
| 1343823 | 5/24/2021 | NV | 17 | F | 5/22/2021 | 5/22/2021 | Systemic: Allergic: Anaphylaxis-Severe, Systemic: Fainting / Unresponsive-Severe |
| 1343820 | 5/24/2021 | NH | 55 | M | 5/1/2021 | 5/23/2021 | I received the vaccine in the right arm and within about 20 seconds I felt like I was going to faint and had rapid heart rate (pulse of 155) measured by EMT. I needed to remove the mask as I was having difficulty with the rapid heart rate and feeling of fainting. I also felt pins and needles type feeling in my legs and my face felt slightly swelled. I felt tired and that tired feeling lasted for the entire day. I stayed at the vaccination site for approximately 30 minutes at the advice of the EMT and went home. Later I had a slight headache but heart rate became more normal. |

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| 1343810 | 5/24/2021 | CA | 20 | F | 5/24/2021 | 5/24/2021 | Patient did not disclose she is prone to fainting after getting shots/blood drawn. 3-5 minutes after getting Janssen vaccine patient fainted in one of our aisles. We had her sit down. We gave her some water, kiwi strawberry, and a tootsie lollipop. We monitored her for 15-20 minutes, then her mother took her out to parking lot. We asked if they needed anything else while at our store, and just re-iterated that she is okay and is prone to fainting after any kind of shots/blood drawn. |
| 1343792 | 5/24/2021 | TX | 14 | M | 5/17/2021 | 5/17/2021 | Patient (14 years old) fainted in the observation area receiving the first dose of the Pfizer vaccine. Patient fell from chair and had some scratches to right temporal region. Patient was accompanied by his mother. Patient was assisted to chair and appeared very pale and disoriented to time and place. EMS was called at 1138. Patient also stated his vision was blurred, reported nausea (emesis x1), and reported feeling very weak and ?really weird?. Patient also reported he was very sleepy and wanted to go to sleep. Patient was kept awake. Mother stated patient had history of ADHD and anxiety but no other past medical history. Paramedics arrived at 1145 and assessed patient. Blood glucose and VS were normal. Patient continued to report feeling unwell and wanted to go to the hospital but also wanted to ?stop for food?. Patient?s mother reported that patient was starting to sound like his normal self and that his color was returning. Patient?s mother agreed for the paramedics to transfer patient to ED for further evaluation. Patient left in ambulance at 1157. |
| 1343184 | 5/24/2021 | IN | 23 | M | 5/22/2021 | 5/22/2021 | Passed out in observation room approx. 5 minutes after the dose, had a mild seizure and tore up my left ear on the carpet. History of passing out in hospital settings, possible vasovagal syncope, no history of seizures. recovered on hallway bed with granola bars and sprite. Approx. 9:30 pm temperature jumped within a couple of hours to around 101, after going to bed was half-awake-half-asleep until 7 am with vivid dreams/internal dialog. |
| 1343780 | 5/24/2021 | FL | 19 | F | 5/19/2021 | 5/19/2021 | Site: Pain at Injection Site-Mild, Systemic: Allergic: Anaphylaxis-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Severe |

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| 1343373 | 5/24/2021 | WI | 26 | F | 5/24/2021 | 5/24/2021 | Patient worked the rest of her shift, but just informed me today when I passed her in the store that she had actually fainted 3 times when she got home. |
| 1343744 | 5/24/2021 | ME | 17 | F | 5/22/2021 | 5/22/2021 | Fainted for 5 sec, HR 75 bpm, oxygen saturation 99%, recovered w water and oreos |
| 1343742 | 5/24/2021 | MA | 21 | F | 5/24/2021 | 5/24/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Exhaustion / Lethargy-Mild, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Mild, Systemic: Nausea-Mild, Systemic: Numbness (specify: facial area, extremities)-Mild, Systemic: Shakiness-Mild, Systemic: Tingling (specify: facial area, extremities)-Mild, Systemic: Weakness-Mild |
| 1343730 | 5/24/2021 | OH | 16 | F | 5/24/2021 | 5/24/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Exhaustion / Lethargy-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Nausea-Medium, Systemic: Seizure-Medium, Systemic: Shakiness-Medium, Additional Details: Patient had seizure with 1st vaccine, pediatrician informed mother to have patient lay down if it happens again. Patient said she felt out of it (at 11am) after administration of this vaccine so we helped her lay down on the floor with her head propped up. Gave her water and turned on the fan to try and make her more comfortable. Patient decided to try sitting up slowly after 10-15 minutes, then after another 10 minutes she was able to stand and felt back to normal and left the store 11:30am. |
| 1343726 | 5/24/2021 | NY | 38 | M | 1/14/2021 | 1/18/2021 | started a severe headache with blurry vision, feeling of fainting, chills |
| 1343714 | 5/24/2021 | PA | 20 | M | 5/23/2021 | 5/23/2021 | Systemic: Fainting / Unresponsive-Medium, Additional Details: Patient fainted approximately 5 minutes after administration. Did not hit floor, was caught by father. Paramedics came and took him to hospital. Report given by mom later in the night said he was stable, vitals were fine and he was discharged to home. |

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| 1343538 | 5/24/2021 | | 13 | M | 5/21/2021 | 5/21/2021 | Pt c/o lightheadedness, dizziness, flushing/sweating, nausea. Pt vomited 200mL digested food. Pt given PO fluids. BP 93/42, HR 66, RR 20 -- > 105/57, 59, 18 -- > 108/60, 65, 16 -- > 109/68, 68, 16. Pt was COVID positive Jan 2021 (s/sx body ach). No h/o fainting with vaccines or blood draws. Pt's symptoms resolved after drinking water and laying down with knees bent. Advised taking 2nd dose supine. |
| 1343402 | 5/24/2021 | FL | 43 | M | 5/21/2021 | 5/21/2021 | patients fainted, low blood pressure, transported for follow up |
| 1343787 | 5/24/2021 | RI | 23 | F | 5/24/2021 | 5/24/2021 | patient received vaccine and got dizzy and fainted |
| 1343679 | 5/24/2021 | NC | 24 | M | 5/24/2021 | 5/24/2021 | patient was hot and sweaty, passed out, came around and felt better over next 15-20 minutes, patient's parent contacted ems but when they arrived patient was much improved |
| 1343460 | 5/24/2021 | MN | 15 | F | 5/21/2021 | 5/21/2021 | Patient is here today for his covid vaccination. It was noted that he was unconscious. At 11:00, monitored by EMS for 15 minutes. History of:NA Nursing Assessment: Airway: Open Breathing: Spontaneous Circulation: Pulse present Mentation: Alert Skin: Normal Patient fainted after receiving Pfizer vaccine and was lowered to the floor, feet were raised, cold towels were applied to the patient's face, and patient was monitored on site by EMS with no further incidence and released to home care with his parent at 11:20. |
| 1343464 | 5/24/2021 | ME | 40 | F | 5/1/2021 | 5/8/2021 | Headache reported following administration. However, on 5/8 patient reported she had shaking chills, dizzy, fatigue- passed out twice in husbands presence. No fever. |
| 1343444 | 5/24/2021 | MA | 20 | F | 5/24/2021 | 5/24/2021 | Patient received the Janssen vaccine at approximately 11:30 AM and was asked to stay sitting for a 15 minute observation period. After five minutes, the patient reported signs of blurred vision and upset stomach. The patient was also noticeably sweating. The pharmacy called 911 and medics came to assess the patient. Medics decided to take the patient by ambulance to the hospital because of "a risk of fainting". |

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| 1343550 | 5/24/2021 | AR | 39 | F | 5/24/2021 | 5/24/2021 | Patient's husband said patient passed out and had a seizure around 30 minutes after vaccine. When I arrived at patient she was sitting up conscious. Ambulance arrived and she was turned over to their care. |
| 1343558 | 5/24/2021 | PR | 46 | F | 4/14/2021 | 5/7/2021 | Syncopal, R25.9 Unspecified abnormal involuntary movements. R55 Syncopal and Collapse. I don't remember how it happen just collapse, ambulance took me to the hospital. |
| 1343559 | 5/24/2021 | KY | 14 | F | 5/20/2021 | 5/20/2021 | Approximately 2 hours after receiving her first covid vaccine, my 14 year old fainted. She was standing in our kitchen at home and became dizzy and started falling backwards. She said her vision was black, she was hot, her head hurt, I could see sweat on her face and chest, and she said she was having tightness in her chest/not able to get full breaths. She didn't totally lose consciousness, but she was disoriented. These symptoms lasted a few minutes, then she felt fine. |
| 1343575 | 5/24/2021 | IA | 17 | M | 5/18/2021 | 5/18/2021 | Patient reported they couldnt stand the sight of blood and had fainted during draws before. Father was present in the vaccine office as well. Immediately following the administration of the vaccine patients eyes glazed over and he fainted. A few seconds later he began to have a spastic seizure that was short in nature, followed by a voiding of his bladder before he regained consciousness. Patient was given water, glucose tablets, and instructed to lay on the floor of the room with his feet elevated while a member of the staff stayed with him to treat and watch him. Followed up with patient and doctor soon after to learn this was the only time it has happened, patient fully recovered. |
| 1343597 | 5/24/2021 | PA | 20 | M | 5/17/2021 | 5/18/2021 | In the middle of the night he stood up to go to the bathroom, turned the light on, felt dizzy and light headed. Passed out and woke up confused unable to speak correctly and unstable when trying to stand up. Eyes were dilated. After he layed down for a few minutes he was ok, could walk and talk fine. Migraine Chills Slightly warm |

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| 1343598 | 5/24/2021 | MI | 28 | F | 5/22/2021 | 5/22/2021 | Patient fainted and stated troubled breathing multiple times once regained consciousness. Epi Pen administered and symptoms resolved within 10 minutes. Patient did not need further medical attention. |
| 1343678 | 5/24/2021 | AZ | 14 | F | 5/23/2021 | 5/23/2021 | Patient had episode of vasovagal syncope approximately 3 minutes after the vaccine. Pharmacist assisted dad in comforting patient. Patient was placed flat on the floor. 911 was called by technician. Patient aroused before EMS arrived on scene approximately 2 minutes after syncopal episode. Patient recovered. EMS did not take patient. |
| 1341983 | 5/23/2021 | CO | 27 | M | 5/23/2021 | 5/23/2021 | While the patient was being observed after his vaccine, he informed me after close to 10 minutes that he was starting to feel dizzy and couldn't see clearly because of the dizziness. He was moved to the floor, lying on his back, and his legs were elevated on the chair. I informed the patient to take slow, deep breaths. The patient said he immediately started to feel better once moving to the floor. He remained in this position for about 10 minutes, feeling better the entire time. He slowly sat up to a seated position for about a minute, and upon feeling fine, he stood up and felt normal. The patient informed me that he has a history of dizziness and fainting with different vaccines in the past and this is not an unusual reaction for him. |
| 1341832 | 5/23/2021 | IL | 12 | F | 5/23/2021 | 5/23/2021 | Patient fainted after receiving 1st dose of the Pfizer vaccine. Once vaccine was administered in the pharmacy area, patient moved to the waiting area near one of the aisles. She was in the aisle with her father when she fainted, and father brought her to one of the nearby chairs where she sat down. Patient was conscious and stated she was feeling dizzy, no other symptoms, and did not want us to call 911. She drank some water and remained seated for 30 minutes. Pharmacist checked on her every 10 minutes to make sure she was still feeling okay. Patient stated that she was "really nervous" to get the vaccine. She denied feeling any other symptoms, and after sitting down said she was feeling better. |

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| 1341935 | 5/23/2021 | IL | 14 | F | 5/23/2021 | 5/23/2021 | pt fainted/had seizure 50 to 10 minutes after covid vaccine. pt did not fall, dad held her.head and eyes rolled back, shaking and stiff for 2 seconds per dad. pt alert, breathing, and movement looked normal when I saw pt . pt mom called 911 and pt was taken to hospital . no history of fainting or seizures per dad |
| 1341863 | 5/23/2021 | OH | 13 | M | 5/21/2021 | 5/23/2021 | My son woke up the day following his vaccine and had mild complaints of headache and ?feels like I have a touch of the flu?. He hydrated with water that day very well and I gave him 500 mg of Tylenol. On Sunday (2 days after vaccine) we were at church celebrating outdoor Mass. about 20 minutes into church my son said he didn?t feel well and needed water. He was standing at the time he said this. He had been standing under and umbrella the entire time to shade him from the sun. About 1 minute later he fainted. He visually looked very pale at the time. We treated him with by having sit down, moved him to air conditioning. It took about an hour before he felt back to baseline. |
| 1341844 | 5/23/2021 | | 18 | M | 5/22/2021 | 5/22/2021 | Dizziness, lightheadedness, nearly fainted Given crackers, water and juice |
| 1341497 | 5/23/2021 | NV | 48 | F | 2/6/2021 | 2/6/2021 | Around 2:00pm, I was feeling tired. I went home to take a nap. Upon arriving at home,, I started to feel light headed and the room began to spine,. I realized I was about to pass out. I made my last call to my daughter for help. When she came home I was unresponsive. She called 911 and started doing what the 911 operator was instructing her to do. I came to for a few seconds and pasted out again. I woke up with my sister pounding my chest area. I passed out again and work to EMTs asking me questions. I lost my bodily function when I passed out. On the way to the ambulance, I began to throw up. I passed out again and woke up on February 14. I say up work because I have no recollection of what happened to me after I got in the ambulance. I was taken to Hospital. They ran all types of tests. I know my heart was elevated. I ended up leaving the hospital on dialysis and a implanted defibrillator. I have 1342 pages of medical records that I can share. |
| 1341817 | 5/23/2021 | NY | 13 | F | 5/22/2021 | 5/23/2021 | Pt woke up day after vaccine with dizziness, nausea/vomiting, fatigue and had syncope x 3 |

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| 1341808 | 5/23/2021 | NY | 32 | F | 3/31/2021 | 4/19/2021 | Severe menstrual cramping. I have never experienced physical pain like this in my life. My first cycle after the Jansen vaccine, I had an acute cramp attack that lasted about 15 minutes. This was in April. I almost asked my partner to take me to the hospital. During the second cycle I had since being vaccinated, on the first day I started menstruating, I nearly fainted and was seeing stars while trying to get home. I had taken two Advil and this was not enough to help at all. I took two more shortly afterwards. The blinding pain lasted for 20-30 minutes. I can't express the severity of this pain. It was unprecedented and terrifying. The rest of my menstrual cycle is different as well. The first day was extremely heavy aside from being alarmingly painful, and then from the second day on, it was very light. I also believe that I may have developed seasonal allergies post-vaccine as I have never had them in my life. I am currently struggling with this common discomfort. |
| 1341769 | 5/23/2021 | DC | 26 | M | 4/30/2021 | 5/6/2021 | 10 days after the second dose, experienced minor chest pains, eventually almost fainted. Went to the ER and found troponin levels that peaked at 5.78, eventually trended down to 3.55 by the next morning. MRI revealed myocarditis in the left ventricle. |
| 1341680 | 5/23/2021 | CA | 49 | F | 5/20/2021 | 5/21/2021 | Patient developed fever and 3 episodes of syncope on the day following the vaccine. The third episode of syncope occurred while being driven to the hospital. She arrived at the hospital in cardiac arrest with asystole. She was resuscitated and is currently in the ICU intubated. |
| 1341606 | 5/23/2021 | TX | 18 | M | 5/22/2021 | 5/22/2021 | Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Severe, Systemic: Hypotension-Mild, Additional Details: Patient went to observation area after receiving Pfizer Covid-19 Vaccine. Patient became lightheaded and faint and fell to floor. Patient was unconscious for approximately 30 sec. After being repositioned, patient did regain consciousness; however was a little confused as to what had happened. Patient did injure his lip during fall. Vitals were all within normal limits with a slightly low blood pressure reading. 911 was called immediately. Stated had not eaten today/slept night before either. |

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| 1341585 | 5/23/2021 | CT | 12 | F | 5/22/2021 | 5/22/2021 | Systemic: Fainting / Unresponsive-Severe, Additional Details: upon exiting vaccination room pt fell forward. it is unknown if she fainted or tripped, mom was standing behind her and was unsure as well. pt bumped head and had a welt on her upper right eyebrow, also her nose began to bleed. ice pack was given/applied to head/eye, paper towel given to stop nose bleed. also water/starburst given. 911 was called. dispatchers came and questioned if she felt dizzy when she left room to which pt responded no, ambulance took pt. |
| 1341937 | 5/23/2021 | IL | 15 | F | 5/22/2021 | 5/22/2021 | Passed out about 5 minutes after receiving the shot. Was sitting in a chair and collapsed to the ground. She regained consciousness within 30 seconds and was sitting in a chair again 5 minutes later |
| 1341984 | 5/23/2021 | PA | 63 | F | 5/18/2021 | 5/18/2021 | The injection did hurt quite a bit more than other injections I have had in the past but it began to feel better and I sat in a chair and was on my phone to send a message, spoke to a stranger who was looking for where to go, and was ok until the feeling of fainting began 10 minutes after the shot. I put my head between my knees but it did not help so I called for help and eventually was helped onto the floor to lie down which began to help. I had vision trouble and hearing trouble and could not speak. I was told my neck became bright red as my face grew white and my hands twitched and my eyes rolled around. I found out later that I had also peed my pants. I have fainted only once before in 1989, and found this reaction pretty frightening although I do not believe it happened as a result of anxiety or fear, the adverse effect itself was frightening and unexpected- not listed on any paperwork I received and was not aware it could occur. |

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| 1341586 | 5/23/2021 | CT | 14 | F | 5/19/2021 | 5/19/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Severe, Systemic: Headache-Severe, Systemic: Nausea-Medium, Additional Details: after getting vaccine, pt felt dizzy/lightheaded. pt has had hx of fainting after getting vaccines due to anxiety, pt was very sweaty/hot. laid pt on the ground and instructed her to put legs up on the chair. provided water stated that was helping. nurse, lpn came and checked pts vitals. while we called 911. ambulance came and took her away. mom came back and said daughter was feeling better and did not go to ER |
| 1342224 | 5/23/2021 | FL | 25 | M | 5/19/2021 | 5/22/2021 | Passed out randomly while out with my wife. Felt nauseous, became sweaty, heart rate dropped |
| 1341917 | 5/23/2021 | ME | 18 | F | 5/23/2021 | 5/23/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Mild, Systemic: Shakiness-Mild, Additional Details: Patient has vasovagal and experiences syncope somewhat regularly. 911 was called when she did not immediately regain consciousness, however she came to within 1-2 minutes. After 45 minutes of rest, reporting she felt normal again and being evaluated by EMTs she was cleared to leave on her own. |
| 1342331 | 5/23/2021 | OH | 18 | F | 5/23/2021 | 5/23/2021 | Brother told doctor at clinic patient was feeling dizzy & lightheaded. Doctor assisted patient from chair to ground and layed her on floor. Cool compress was applied to forehead. No loss of consciousness and pulse maintained throughout conversation. No history of syncope in the past but brother passed out in eye doctor in the past. After few minutes patient felt better was able to sit up on the floor and take some fluids. after feeling better doctor assisted to walk to car. |

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| 1341993 | 5/23/2021 | NY | 31 | M | 5/23/2021 | 5/23/2021 | 5/23/2021-Pt received J&J vaccine at pharmacy today approx one hour prior to arriving to the ER, passed out after receiving the vaccine in the room at the pharmacy. Pharmacist was in the room with pt and he had no injuries/did not fall. After leaving pharmacy he passed out again in the car and was shaking per pts wife, then started vomiting. He arrived to the ER c/o feeling "like crap." vitals with normal bp, temp, RR , hr 69. given 1 Liter normal saline. he was observed in the ER and discharged home to recover. |
| 1342304 | 5/23/2021 | OH | 15 | F | 5/22/2021 | 5/22/2021 | Patient has history of passing out. 2-3 min after Pfizer shot patient started to feel hot and was pale. A volunteer doctor assisted to sit down on floor. Has syncope episode after seated on ground. Use ammonia capsule . Pulse was intact throughout. Airway as cleared of gum in mouth. Loss of consciousness for 15 sec. Then alert able to call mother who was in the parking lot. 911 EMS called and arrived. Cool compress applied. Ems arrived. Patient felt better. Vital by Ems Glu 80 BP 120/80. Patient was able to drink water. MD instructed mother to clear with PCP or Cardiologist to clear before getting 2nd shot. Mother declined EMS transport. MD walked patient to car. |
| 1342346 | 5/23/2021 | IN | 36 | M | 5/18/2021 | 5/19/2021 | The reaction started on Wednesday morning May 19 around 7:00a.m. Vomiting, diarrreaha Fainted 3 times vomited again fever 103.2. Slept until the next morning couldn?t keep anything down fainted again. Gave Gatorade Propell and water. Very fatigued couldn?t walk at all. Very dizzy no color on his face very pale lol |
| 1342212 | 5/23/2021 | SC | 24 | M | 5/22/2021 | 5/22/2021 | he fainted |

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| 1342184 | 5/23/2021 | NY | 97 | F | 5/14/2021 | 5/15/2021 | Patient was well 5/13/21 vaccinated 05/14/2021 with second Moderna COVID Vaccine and according to son pt rapidly declined with recurrent falls 5/15-seen in er 5/16 and sent home and cont to have worsening profound weakness presenting to the ER again 5/18 and admitted with Sepsis secondary to right lower lobe pneumonia, right 8th, 9th and 10th rib fractures, syncope/ rhabdomyolysis and NSTEMI, profound weakness and new anemia with GIB needing 2 units prbcs. Pt was living independently alone pta with help from his son and was at his baseline up until getting his second vaccine. he was ultimately discharged to nursing home on 5/21/21. he was still too weak to walk or get out of bed at the time of discharge. |
| 1342134 | 5/23/2021 | CA | 15 | M | 5/22/2021 | 5/22/2021 | Patient fainted 5 minutes after the vaccination. He regained his conscious but complained severe headache. Patient also had some jerky motion after fainting. Paramedics was called. Patient's vital signs were normal. He was taken to facility for further follow-up. |
| 1342113 | 5/23/2021 | FL | 35 | M | 5/23/2021 | 5/23/2021 | Patient fainted after vaccine, pharmacist elevated patients legs while another employee was holding patients head. EMS personnel were in the store shopping and came to the pharmacy and responded. Patient blood pressure dropped very low and therefore fainted per EMS. Patient was later taken to the hospital for observation. Later patient returned to pick up his shoes and felt thankful and expressed gratitude for helping him. Per patient felt normal and was fine. |

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| 1342095 | 5/23/2021 | CA | 78 | M | 3/30/2021 | 5/1/2021 | My uncle had a stroke almost exactly one month after second moderna shot. He is/was one of the most healthy older men I have ever known. Avid bike rider and exercise buff usually runs circles around guys half his age. I?m talking biking in the hills fit. He does have a pacemaker now and has to tame things done, but I think he got the pacemaker because he pumped so much blood through that thing doing all those hills for all those years. Not on any other meds expect whatever might be expected for the pacemaker. He was at the gym on May 1 working out and sitting down doing some arm curls when all of a sudden he passed out, he regained consciousness as a couple of guys were helping him to his feet, that?s all he could remember. He managed to drive himself home and then couldn?t shake the headaches and on coming symptoms, so one of his sons took him to the emergency room. Within 30 minutes it was already determined the doctors needed to operate fast. The stroke nightmare and recovery has process has been ongoing ever since. He was transferred to a rehab on May 19th where it looks like he will stay for at least a couple weeks, hopefully. He looks like he aged fifteen years, speech is ok, but he?s slow almost as if he is not hearing me? I think his hearing is fine but it seems like he works to formulate the thought of what he wants to say as I write this summary on May 23rd. He?s got two staples in his head, one pretty much top center and the other just a little off to his right. Drain blood I assume as I?ve never seen a post stroke victim up close like that. Our family do not get strokes! Maybe too much tequila and stuff like that, but my huge family usually all live into their 90?s and a few into their 100?s like my grandparents and my 104 year old great grandma. But of course they did not grow up with flu shots and vaccines. My grandparent grew a substance and stored in jars of olive oil or canola oil and rubbed that stuff on their our bodies if ailments go really bad. Other than that it?s highly concentrate oil of oregano. Couple drops on your tongue will set your mouth on fire. That?s the concentration we are talking about! Anyhow, my uncle hasn?t done vaccines or flu shots in the past, but all this gloom and doom from the mainstream media convinced him to get the shot. This now make the second person to stroke out after these unicorn shots. Yeah thanks big pharma and you scandalous mainstream media for just |

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| 1342090 | 5/23/2021 | NY | 30 | M | 5/23/2021 | 5/23/2021 | reading your script and following along. No thanks to all you physicians and nurses out there that also know better, but are keeping your fat traps shut and your hand out receiving your paycheck. We wonder why there is vaccine hesitancy? It?s not hesitancy, it actually watching family and friend bite the bullet right before our very eyes. You healthcare providers are going to have to pay pounds of flesh to our creator for propagating this mess we are in. Your stronger delusion excuse will only carry you so far, before it becomes unforgiveable. God Bless and let?s see how long this report really take to get published on vaers. The world see this one! You better WelcomeTheEagle! |
| 1342083 | 5/23/2021 | NJ | 21 | M | 5/23/2021 | 5/23/2021 | Pt received the Janseen vaccine and two-three minutes later the patient fainted and regained consciousness intermittently as they were waiting for the 30 min post vaccine observation. Code white as called and was by the patient to make sure they did not fall out of the chair. EMS responded and took over as they called 911 to have the patient checked out. The ems confirmed the patient was stable and the patient did not need to be put in the ambulance. Pt was given orange juice and an ice pack. Pt was checked on before they left and they were ok. |
| 1342076 | 5/23/2021 | CA | 15 | F | 5/23/2021 | 5/23/2021 | Patient is fainting right after getting the vaccine and lasts for 1 minute and then recovered back after tapping on the patient and then fainting second time and then recover from fainting. Then he said he felt nauseous and after giving some water he recovered gradually. EMS was dispatched to the scene and they checked on his blood pressure and pulse oxygen and was confirmed to be going back to normal. He refused to go to the hospital then EMS and police left the scene |
| | | | | | | | single episode of syncope 15 minutes after vaccine after standing up, likely vasovagal vs. orthostatic. completely resolved |

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| 1342025 | 5/23/2021 | VA | 15 | M | 5/23/2021 | 5/23/2021 | one minute after injection, pt started to fall forward in the chair. father caught him and I was immediately called into the immunization room. pt was laid onto the floor and his legs were elevated onto a chair. father stated pt had never had a reaction to a vaccine before. no health conditions. 911 was called..... but then parent decided he didn't want them. pt states his vision started to go black before he briefly passed out... probable vasovagal syncope. we waited for 911 to come since they were already alerted. pt sat in chair but then started to get lightheaded again, so he returned to a position where his feet were elevated in the chair. EMS arrived and monitored him. father and EMS made decision to return pt to home. |
| 1342328 | 5/23/2021 | CA | 15 | F | 5/23/2021 | 5/23/2021 | Syncope that self resolved after 5 minutes |
| 1340473 | 5/22/2021 | NV | 57 | F | 4/13/2021 | 4/13/2021 | Passed out without warning; This is a spontaneous report from a contactable consumer (patient). A 57-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: ER8729; Expiration date was not reported) on the left arm on 13Apr2021 (09:00) as a single dose, with route of administration unspecified, for COVID-19 immunization at the public health department. Medical history included lower back pain; allergy to latex; and allergies with bananas and avocados. The patient was not pregnant at the time of vaccination. The patient's concomitant medication included an unspecified pain medication. The patient previously took ketorolac (TORADOL), and had allergies with this medication. On 13Apr2021 (10:00), the patient had passed out without warning; assessed as serious (medically significant). The patient did not receive any treatment for the event. The outcome of the event was unknown. The patient was not diagnosed with COVID-19 prior to vaccination, and had not been tested post-vaccination. |

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| 1340490 | 5/22/2021 | | | F | 5/5/2021 | 5/6/2021 | she had hypotension for 9 hours and was unable to sit up because her blood pressure was so low; she had hypotension for 9 hours and was unable to sit up because her blood pressure was so low; passed out and was in the hospital ED for 12 hours but was not admitted; This is a spontaneous report received from a contactable consumer (patient's mother). A 16-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, formulation: solution for injection, Batch/Lot number was not reported), via an unspecified route of administration on 05May2021 as single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient historical vaccine includes BNT162B2 on unspecified date for as single dose COVID-19 immunisation. On 06May2021, patient passed out and was in the hospital ED for 12 hours but was not admitted. She states she had hypotension for 9 hours and was unable to sit up because her blood pressure was so low (on an unspecified date). She wants to know if there have been reports of syncope or vasovagal reactions associated with the vaccine. The outcome of the event was reported as unknown. Follow-up needed. Information about batch/lot number has been requested. |

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| 1340513 | 5/22/2021 | CA | | M | 4/1/2021 | 4/1/2021 | lose his life after the vaccine; Passed out; swelling and pain in his side of his arm; swelling and pain in his side of his arm; asthma trigger; allergies; This is a spontaneous report from a contactable consumer (patient's wife). A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) dose 1 via an unspecified route of administration on Apr2021 (Batch/Lot number was not reported) as 1st dose, single for covid-19 immunisation. The patient medical history included bad allergies and has asthma. Concomitant medications were not reported. He lose his life after the vaccine in Apr2021. He took the vaccine in Apr2021. After 3 days he took the vaccine on Tuesday, then Friday he was gone, that first dose. That day he died, he had like the asthma trigger like 10 minute after then he passed out but Thursday he was saying that he had like swelling and pain in his side of his arm. He had night shift and then morning came, Friday came home and then he ate and then he slept and then he woke up at 10 am just to go to kitchen and thought he was saying like having had allergies and 10 minutes then he passed out and then that was it. The reporter was just wondering how come, he still passed. Seriousness for lose his life after the vaccine was reported as death. The outcome of event lose his life after the vaccine was fatal and other events was unknown. The patient died in Apr2021. The cause of death was unknown. It was unknown if an autopsy was performed. Information on the Lot/Batch number has been requested.; Reported Cause(s) of Death: lose his life after the vaccine |

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| 1340514 | 5/22/2021 | | | M | | | suddenly passed out; This is a spontaneous report received from a contactable consumer reporting on behalf of the patient. A 30-year-old male (nephew) patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as 1st dose, single for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The reporter wanted to know if there were reports on patients passing out after not being able to eat after the first shot of the COVID-19 vaccine. The reporter's nephew suddenly passed out after the first shot and was rushed to the hospital on unspecified date. The reporter confirmed that the patient was healthy. The reporter wanted to find out if it is safe for the patient to receive the 2nd shot of the vaccine. Outcome of the event was unknown. The event was assessed as serious (hospitalization). Information on the lot/batch number has been requested. |
| 1340516 | 5/22/2021 | | | M | 4/7/2021 | 4/7/2021 | fainted; headache; shortness of breath; chest tightness; pain/burning the left neck; pain/burning the left neck; mild nausea; 70% side from waist to head is warm; This is a spontaneous report received from a contactable consumer. A 37-year-old male patient received bnt162b2 (BNT162B2, Formulation: Solution for injection, Batch/Lot number:UNKNOWN), via unspecified route of administration on 07Apr2021 as a single dose for COVID-19 immunisation. The patient's medical history was not reported. The patient concomitant medications were not reported. On 07Apr2021, the patient reported that he fainted right after the vaccine received. The patient was also stated after the vaccine he had headache, shortness of the breath, chest tightness lasted 3-4 days, pain/burning the left neck, 70% side from waist to head is warm and mild nausea. The outcome of the events fainted, headache, shortness of the breath, pain/burning the left neck, 70% side from waist to head is warm and mild nausea was unknown. The outcome of the event chest tightness was recovered. Information on the Batch/Lot number has been requested. |
| 1340594 | 5/22/2021 | NY | 12 | F | 5/21/2021 | 5/21/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Medium |

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| 1340614 | 5/22/2021 | NC | 23 | F | 5/21/2021 | 5/21/2021 | Systemic: Fainting / Unresponsive-Medium, Additional Details: Patient informed us prior to vaccination that she is prone to fainting and this happens when she receives vaccine or gets blood draw. |
| 1340617 | 5/22/2021 | MN | 23 | M | 5/21/2021 | 5/21/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild |
| 1340620 | 5/22/2021 | NE | 18 | F | 5/21/2021 | 5/21/2021 | Systemic: Fainting / Unresponsive-Severe, Additional Details: Patient had trouble walking 5 minutes after vaccine injection. Sat patient down. She fainted and was unresponsive for over 1 minute. 911 called and emergency team came to check vitals. NP on duty also assisted checking vitals. Patient became conscious 1 minute after fainting. Her and her mom stayed in the store for an extra 30 minutes and decided to leave. Patient feeling normal. |
| 1340643 | 5/22/2021 | CA | 16 | F | 5/21/2021 | 5/21/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: See statement below-Medium, Additional Details: Minor patient with parents in attendance. After receiving immunization, patient stood up, took a few steps and fainted, falling backward and hitting head on the floor. Pharmacy staff immediately called 911 and provided supportive first aid. Patient quickly regained consciousness, RPh had her continue to lay in the floor, provided pillow for head, elevated feet and ice pack was applied to back of head. Paramedics arrived to evaluate patient's condition, patient was released home with parents. |
| 1340464 | 5/22/2021 | PA | | F | 4/15/2021 | | reaction of fainting and was taken to the hospital; This is a spontaneous report from a Pfizer-sponsored program. A contactable consumer (parent) reported that a female patient (daughter) of unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 15Apr2021 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The caller calling about her daughter who received her first covax in a mall on 15Apr2021 and had reaction of fainting and was taken to the hospital. She was asking what they should do about the second covax. The outcome of the event was unknown. Information on the lot/batch number has been requested. |

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| 1340712 | 5/22/2021 | KS | 30 | M | 5/21/2021 | 5/21/2021 | Patient passed out after having the Johnson and Johnson vaccine. It occurred about 20 minute after the vaccine. Causing him to crash into another car. The patient loss consciousness and the EMT came to the site. |

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| 1340354 | 5/22/2021 | CA | 59 | M | 4/9/2021 | 4/1/2021 | <p>Passed out; Vertigo; Nausea; felt like he was going to pass out; Lost 12 pounds since getting the second shot; 103 fever; Severe chills/Shivering uncontrollably; Every inch of body ached; Headache; Low back pain; could barely walk; Blood in stool; This is a spontaneous report from a contactable consumer (patient). A 59-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: ER8729), via an unspecified route of administration, administered in left arm on 09Apr2021 at 17:00 (at 59-year-old) at single dose for COVID-19 immunization. Patient medical history was reported as none. He had a family history of ulcers but he has never had any ulcers but that could maybe be related to the blood in stool. The patient's concomitant medications were not reported. No additional administered vaccines. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN6208), via an unspecified route of administration, administered in right arm on 20Mar2021 at 18:00 (at 59-year-old) at single dose for COVID-19 Immunization, and experienced soreness in the arms. On 10Apr2021 03:00 (reported as 10 hours after receiving the second dose of the vaccine), the patient had a 103 fever, severe chills, every inch of his body ached, headache, shivering uncontrollably and most of this was just for 2 or 3 days. Patient stated then in Apr2021 (reported as a week ago) he had severe low back pain where he could barely walk. Patient stated then last weekend in Apr2021 he had noticed blood in his stool, this started either on last Thursday (29Apr2021) or Friday (30Apr2021). Patient stated and on Tuesday (04May2021) he started getting vertigo, nausea, and passed out. Caller asked was that common side effects or was this an unrelated virus. For event headache, patient stated for 1 day it was a severe headache and then it was a bad headache for 2 or 3 days but he was still experiencing a headache currently. Patient stated the worst part of the headache he has recovered from but he still had a headache and it has gotten much better. For event low back pain, patient stated the back pain got really severe for a week then it got better then came back and right now it was minor but the severe pain was only for about a week. Patient stated that nausea comes and goes. That was another symptom he has lost 12 pounds since getting the second shot. He</p> |

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1340707 5/22/2021

18 F

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still felt like he was going to pass out but only passed out that one time. He still had symptoms that he could pass out at any minute. Patient clarified that he went to the emergency room the day after the second dose of the vaccine when his first set of symptoms started. He had also taken ondansetron hydrochloride (ZOFTRAN), dimenhydrinate (DRAMAMINE), and paracetamol (TYLENOL). Patient did not visit physician office but he let the physician know. No relevant tests. The outcome of the event severe chills/shivering uncontrollably was recovered on 11Apr2021, events 103 fever and every inch of body ached were recovered on 12Apr2021, event passed out was recovered on 04May2021; outcome of events headache, low back pain, could barely walk, nausea was recovering; outcome of events blood in stool, vertigo, lost 12 pounds since getting the second shot, felt like he was going to pass out was not recovered.

DIZZINESS, SYNCOPE FOR A FEW SECONDS, THEN REGAINED CONSCIOUSNESS. PARAMEDICS CAME, SX RESOLVED, NO TRANSPORT.

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| 1340358 | 5/22/2021 | MI | 51 | F | 4/19/2021 | 4/19/2021 | nearly passed out; the shoulder where she got her injection started hurting really bad; getting hot; sweating; thirsty; Her blood pressure dropped; couldn't breathe; arm hurting really bad; got very weak; turned gray, like an elephant; felt floaty; This is a spontaneous report from a contactable consumer (patient). A 51-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration at left shoulder (Arm Left) on 19Apr2021 10:00 AM at age of 51 years old (Batch/Lot number was not reported) as 1ST, SINGLE for covid-19 immunisation. The patient's medical history was reported as just told her blood pressure dropped on an unknown date, hooked patient up to a bunch of wires and stomach, monitoring her on a machine. The last couple of time patient had blood drawn, the one last time, she went into shock and passed out. This wasn't quite the same thing with this time. This was maybe 2 years before unspecified date. One time it was pretty bad and patient fell down, get the doctor and hook patient up to all that stuff. Didn't quite feel the same way as this time. She didn't get hot and sweaty. Patient was not taking any pills. The concomitant medications were not reported. After first dose of the Pfizer covid vaccine. After the injection on 19Apr2021, patient sat for 15 minutes (wait for 15 minutes) and the shoulder where she got her injection started hurting really bad. Arm hurting really bad, walked across the hall and sat in the chair, maybe 2 minutes later. Then started tearing her mask off because she couldn't breathe. Patient started getting hot, sweaty and thirsty. Patient was sweating, started getting hot and thirsty and then got really sweaty and super hot. Got really thirsty and was given water. She was trying to grab a bottle of water and she didn't have the strength. She got very weak, turned gray, like an elephant and her blood pressure dropped, and nearly passed out. It lasted maybe 10 or 15 minutes. They called the ambulance. By the time they got there, she was feeling more back within herself and it was pretty much done and was totally better, maybe 90 percent. She just wanted to go home and did not go in the ambulance. She felt floaty but did not pass out. With the first one, she had a reaction and is wondering if she should even take the second one. Therapeutic measures were taken as a result of thirsty included water. Treatment for other event was reported |

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as none, and she was not taking any medication. The event outcome of recovered on 19Apr2021. Information about lot and batch number was requested.

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| 1340164 | 5/22/2021 | TN | 30 | F | 1/19/2021 | 1/19/2021 | Seizure; Syncope; Diarrhoea; Chills; Vomiting; This case VAERS (Reference number: 0989940) on 11-May-2021 and was forwarded to Moderna on 11-May-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of SEIZURE (Seizure) and SYNCOP (Syncope) in a 30-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Epilepsy. Concurrent medical conditions included Drug allergy (sulfa). Concomitant products included LAMOTRIGINE, PHENYTOIN SODIUM (DILANTIN D.A.) and LEVONORGESTREL (MIRENA) for an unknown indication. On 19-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 19-Jan-2021, the patient experienced SEIZURE (Seizure) (seriousness criterion medically significant), SYNCOP (Syncope) (seriousness criterion medically significant), DIARRHOEA (Diarrhoea), CHILLS (Chills) and VOMITING (Vomiting). At the time of the report, SEIZURE (Seizure), SYNCOP (Syncope), DIARRHOEA (Diarrhoea), CHILLS (Chills) and VOMITING (Vomiting) had resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Patient experienced profuse vomiting and diarrhea, syncope, chills, seizures. Emergency room visit received 3 bags of lactated ringers, 12 mg of IV zofran, 12.5 mg of IV Phenergan. Full blood work and 2 computerized tomogram (CT) scans but results were not provided. Based on the current available information and temporal association between the use of the product and the start date of the events of chills, vomiting, and diarrhea, a causal relationship cannot be excluded. Causality for the events of seizure and syncope are probably related to the patient's medical history.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events of chills, vomiting, and diarrhea, a causal relationship cannot be excluded. Causality for the events of seizure and syncope are probably related to the |

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patient's medical history.

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| 1340210 | 5/22/2021 | VA | 22 | M | 5/14/2021 | | FEVER; ANAPHYLACTIC REACTION (PASSING OUT/ COULD NOT BREATHE/ SWOLLEN LIPS AND FACE); LIPS WERE DROOPING TO THE RIGHT SIDE OF FACE; This spontaneous report received from a parent concerned a 22 year old male. The patient's height, and weight were not reported. The patient's concurrent conditions included asthma (as a child), non-alcoholic, and cigarettes smoker. The patient experienced drug allergy when treated with Tamiflu (oseltamivir phosphate). The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown, expiry: unknown, NDC number: 59676-0580-15) dose was not reported, 1 total administered on 14-MAY-2021 at 10:00 for prophylactic vaccination on left arm. The batch number was not reported and has been requested. No concomitant medications were reported. On 14-MAY-2021, as soon as the patient got the shot (within the 15 minutes of wait at the pharmacy), he had an anaphylactic reaction. It was further reported that he could not breathe, his lips and face started to swell and then he passed out. The patient was taken to ER (emergency room) and his doctor gave him EpiPen (epinephrine) shot, Medrol (methylprednisolone), Benadryl (diphenhydramine hydrochloride) and IV (intravenous) fluids. The patient's lips were drooping to the right side of his face even after taking the medications. The patient stayed at the ER for 6 or 7 hours then was sent back to home on the same day. On 15-APR-2021 (reported as Saturday), the patient had fever. On 16-MAY-2021 (reported as yesterday from the date of reporting), the patient was much better, and his drooping lips was there a little bit but not as bad. The reporter did not have patient's vaccination card (for lot number or expiration date). The action taken with Covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from anaphylactic reaction (passing out/ could not breathe/ swollen lips and face) on MAY-2021, and was recovering from fever, and lips were drooping to the right side of face. This report was serious (Other Medically Important Condition, and Life Threatening).; Sender's Comments: V0: 20210532244-COVID-19 VACCINE AD26.CO2.S-ANAPHYLACTIC REACTION. This event(s) is considered related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and is scientifically plausible. There is no |

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information on any other factors potentially associated with the event(s). 20210532244-COVID-19 VACCINE AD26.COV2.S-LIPS WERE DROOPING TO THE RIGHT SIDE OF FACE. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).

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| 1340272 | 5/22/2021 | NY | 61 | F | 3/23/2021 | 3/26/2021 | Fell again, breaking left leg; Breaking ankle; Breaking foot; Passed out; Stroke; Fell again; Swollen arm; Did not get second Covid shot; Joint pain; This case was initially received via an unknown source (no reference has been entered for a health authority or license partner) on 28-Mar-2021. The most recent information was received on 12-May-2021 and was forwarded to Moderna on 13-May-2021. This spontaneous case was reported by a consumer and describes the occurrence of CEREBROVASCULAR ACCIDENT (Stroke), LOSS OF CONSCIOUSNESS (Passed out), LOWER LIMB FRACTURE (Fell again, breaking left leg), ANKLE FRACTURE (Breaking ankle) and FOOT FRACTURE (Breaking foot) in a 61-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 013M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No medical history was provided by the reporter. On 23-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 26-Mar-2021, the patient experienced ARTHRALGIA (Joint pain). On 30-Mar-2021, the patient experienced LOSS OF CONSCIOUSNESS (Passed out) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced CEREBROVASCULAR ACCIDENT (Stroke) (seriousness criteria hospitalization prolonged and medically significant), LOWER LIMB FRACTURE (Fell again, breaking left leg) (seriousness criterion hospitalization), ANKLE FRACTURE (Breaking ankle) (seriousness criterion hospitalization), FOOT FRACTURE (Breaking foot) (seriousness criterion hospitalization), FALL (Fell again), PERIPHERAL SWELLING (Swollen arm) and INCOMPLETE COURSE OF VACCINATION (Did not get second Covid shot). The patient was hospitalized for 13 days until 12-Apr-2021 due to CEREBROVASCULAR ACCIDENT, then until 12-Apr-2021 due to ANKLE FRACTURE, FOOT FRACTURE, LOSS OF CONSCIOUSNESS and LOWER LIMB FRACTURE. The patient was treated with Physical therapy for Cerebrovascular accident; Physical therapy for Lower limb fracture; Physical therapy for Ankle fracture and Physical therapy for Foot fracture. At the time of the report, CEREBROVASCULAR ACCIDENT (Stroke), PERIPHERAL SWELLING (Swollen arm) and |

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ARTHRALGIA (Joint pain) outcome was unknown, LOSS OF CONSCIOUSNESS (Passed out), FALL (Fell again) and INCOMPLETE COURSE OF VACCINATION (Did not get second Covid shot) had resolved and LOWER LIMB FRACTURE (Fell again, breaking left leg), ANKLE FRACTURE (Breaking ankle) and FOOT FRACTURE (Breaking foot) was resolving. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No Concomitant product use was reported. Treatment medication included Benadryl. Very limited information regarding these events has been provided at this time. This case also refers to an incomplete schedule of vaccination. Further information has been requested. Most recent FOLLOW-UP information incorporated above includes: On 12-May-2021: Case upgraded to serious (Hospitalization), Added Additional events experienced, Events description, and updated Treatment information.

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| 1340320 | 5/22/2021 | KS | 17 | F | 4/19/2021 | 4/26/2021 | White papule; Scab; This is a spontaneous report from a contactable other hcp (patient's mother). A 17-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EW0162), dose 2 intramuscular, administered in right arm on 19Apr2021 09:15 as 2nd dose, single for covid-19 immunisation. Medical history included vaso vagal syncope. The patient's concomitant medications were not reported. The patient previously received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: ER8733,) intramuscular administered in right arm on 29Mar2021 16:00 for COVID-19 Immunization. On 26Apr2021, the patient developed white papule which turned into a scab approximately 1 week following second injection, roughly three inches below injection site. Seriousness criteria-Congenital anomaly/birth defect: Yes. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. There is no list of any other medications the patient received within 2 weeks of vaccination, no known Allergies. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The outcome of the vents was resolved with sequel. Information on Lot/Batch number was available. Additional information has been requested.; Sender's Comments: Based on temporal association, the contribution of the suspect drug to the onset of events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate. |

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| 1340335 | 5/22/2021 | | 57 | F | 3/24/2021 | 3/24/2021 | Passed out for 1 minute; Near syncope; Felt dizzy; Epigastric pain x3 days w/N/V; This is a spontaneous report from a non-contactable Pharmacist. A 57 years old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: ER8727) intramuscular at single dose for COVID-19 immunisation on 24Mar2021. Relevant history included Pancreatitis, Abdominal cancer and Colostomy. Prior to vaccination, the patient was diagnosed with COVID-19. Relevant concomitant drug was unknown. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient had near syncope in parking lot after COVID vaccine on 24Mar2021. When walked out of hospital entrance, she felt dizzy, sat down, and passed out for 1 minute, she was met by code team and brought to ED. The patient reported epigastric pain for 3 days w/ N/V. Relevant lab tests included POC BG: 111; A&Ox1 VS @1409: Temp 98.2F, BP 134/96, HR 67, SpO2 99%, RR 18. The adverse events resulted in emergency room/department or urgent care. Treatment therapy included ondansetron and morphine injections. The outcome of events was resolved . No follow-up attempts are possible. No further information is expected.; Sender's Comments: Based on the available information and known product profile, the causal relationship between the reported loss of consciousness and the use of BNT162B2 cannot be fully excluded. As there is limited information available to further assess the case, the case will be assessed further upon receipt of new information. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate. |

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| 1340346 | 5/22/2021 | CA | 34 | F | 5/5/2021 | 5/6/2021 | <p>passed out; loss of vision for a few minutes; Dizziness; blurred vision; Severe weakness; couldn't walk; chills; fever; Fatigue; soreness in right arm; muscle aches; This is a spontaneous report from a contactable other health professional (patient). A 34-year-old female patient (not pregnant) received bnt162b2 (BNT162B2), dose 2 via an unspecified route of administration, administered in Arm Right on 05May2021 15:00 (Lot Number: ew0161) as single dose for covid-19 immunisation. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient did not have COVID tested post vaccination and did not have COVID prior vaccination. The patient had no known allergies. The patient had no other medical history. Concomitant medications included ethinylestradiol, norgestimate (TRI LO MARZIA); ascorbic acid, betacarotene, biotin, calcium lactate, choline bitartrate, chromium nicotinate, colecalciferol, cyanocobalamin, dexpantenol, dl-selenomethionine, folic acid, inositol, magnesium lactate, manganese gluconate, nicotinamide, potassium citrate, potassium iodide, pyridoxine hydrochloride, retinol palmitate, riboflavin phosphate, thiamine hydrochloride, tocopheryl acetate, zinc gluconate (MULTI VITAMIN & MINERAL); probiotics (PROBIOTICS) all taken for an unspecified indication, start and stop date were not reported. The patient received first dose of Covid-19 vaccine (manufacture Pfizer, lot number ew0151) on 14Apr2021 01:00 PM in Left arm for covid-19 immunisation. The patient experienced dizziness with blurred vision / loss of vision for a few minutes, possibly passed out. Severe weakness, couldn't walk for a few minutes. Dizziness with chills/fever lasted a few hours. Fatigue for 12 hours. Soreness in right arm and muscle aches all over. Headache for 12-16 hours, all on 06May2021 06:30 with outcome of recovered. No treatment was received for the events. Information on the lot/batch number has been requested.; Sender's Comments: The causal association between the reported events passed out and loss of vision for a few minutes and the suspect drug BNT162B2 cannot be totally excluded based on a temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated a part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern</p> |

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| 1340379 | 5/22/2021 | MD | 36 | F | 4/16/2021 | 4/1/2021 | identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory authorities, Ethics committees, and Investigators, as appropriate. Passed out 15 min into taking first vaccine jab; Have been dizzy ever since with palpitations; Have been dizzy ever since with palpitations; Could hardly walk few steps; Vertigo; This is a spontaneous report from a contactable consumer (patient). A 36-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Batch/Lot Number: EW0164), via an unspecified route of administration, administered in left arm on 16Apr2021 15:00 as 1st dose, single for COVID-19 immunisation. Medical history was not reported. The patient's concomitant medications were not reported. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient passed out 15 min into taking first vaccine jab on 16Apr2021. She has been dizzy ever since with palpitations. Initial 2 weeks after vaccine, her dizziness was very severe, and could hardly walk few steps. Her physician mentioned she has developed vertigo and prescribed Meclizine which made it even worse for her, so she stopped taking it. Though the dizziness was not severe right at 3 weeks, it didn't stop, and she experiences it throughout the day. The adverse events resulted a doctor or other healthcare professional office/clinic visit. The outcome of the events was not recovered. |
| 1340967 | 5/22/2021 | IL | 13 | F | 5/22/2021 | 5/22/2021 | Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild |

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| 1340456 | 5/22/2021 | | | F | 4/21/2021 | 4/21/2021 | difficulty processing information/ attention deficit; Episodic HAs; earaches worst on the left and fullness/left ear pain (ear pain); earaches worst on the left and fullness/left ear pain (ear pain); Mild sore throat; Upper back muscle pain; redness around the bite; redness around the bite; low platelet volume; severe weakness; pain; nearly passed out 2 times/near syncope; Vomited; Some loose bowel movements; Myalgias/ muscle pains; sweating; feeling cold or hot sometimes; 100/60 and then blood pressure would drop and settle at 85-95/60 or low 90s/60s, hypotension; fatigue/very tired in the mornings/Extreme fatigue limiting activities; Dizziness; pain and numbness of left arm/ pain and numbness on my arms and hands; headache; upper back pain; Numbness in left arm where vaccine was injected radiating down to hand/pain and numbness of left arm/numbness on the arms and hands; Chills/body shivering; Low fever; period of rapid heart rate/episode of tachycardia; This is a spontaneous report from a contactable health care professional (patient's husband). A female patient of an unspecified age received the second dose of BNT162B2 (Pfizer-BioNTech COVID-19 vaccine, lot number and expiry date unknown), via an unspecified route of administration, administered in the left arm on 21Apr2021 at 16:00 as a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient previously received the first dose of BNT162b2 on 31Mar2021 for COVID-19 immunization. It was reported that immediately after being vaccinated, the patient had numbness in the left arm where vaccine was injected radiating down to hand lasting about 24 hours. Also on 21Apr2021, during the first night after vaccination, chills, body shivering for a half hour. The patient also had low fever (extremely rare for the patient) for a while and a period of rapid heart rate/episode of tachycardia while in bed lasting for 30 (as reported). The patient had hypotension, 80/58. On 22Apr2021, the patient had fatigue, dizziness, pain and numbness on arms and hands sometimes, headache, upper back pain and myalgias. On 23Apr2021, the patient was very ill most of the day. The patient nearly passed out 2 times/near syncope, vomited, some loose bowel movements (unusual for the patient), extreme fatigue limiting activities, muscle pains/myalgias, headaches, numbness, |

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sweating, feeling cold or hot sometimes. The patient's blood pressure dropped to 80/58 (usually 110/ 70). The patient lay flat on kitchen counter to avoid fainting. On 24Apr2021, the patient had fatigue limiting activities, pain, numbness, dizziness and feeling cold or hot sometimes. The patient felt a bump around her right collar bone in the evening which later turned out to be a tick. The patient's BP was measured every day which generally were initially 100/60 and then blood pressure would drop and settle at 85-95/60 or low 90s/60s, hypotension accompanied with severe weakness. On 25Apr2021, the patient had fatigue limiting activities, pain, numbness, dizziness, constant headache and feeling cold or hot sometimes. On 26Apr2021, the patient was nearly feeling normal in the first half of the day. Then severe body fatigue limiting activities, pain, numbness on the arms and hands. The patient was feeling cold or hot, sweaty at times and had persistent headache in the afternoon. The patient also had upper back muscle pain. In evening of 26Apr2021, the tick was noticed and pulled out dry with fingers and tweezers. The tick was not engorged with blood and appeared dry and dead. The patient had some redness around the bite but no target lesion. The patient was administered 200mg of Doxycycline orally. On 27Apr2021, the patient had fatigue, pain, numbness, cold or hot obviously in the first half of the day. Then feeling better (close to normalcy). On 28Apr2021, the patient was feeling much better in the first half of the day. Then, pain, numbness, feeling little cold or hot sometimes and persistent headache. That day and episodically thereafter, the patient noted left ear pain, earaches worst on the left and fullness and mild sore throat. The patient has also complained of difficulty processing information (attention deficit described in the papers) on an unspecified date. On 29Apr2021, there was severe fatigue all day. Pain, numbness, cold or hot sometimes, upper back muscle pain and sweating sometimes. On 30Apr2021 to 02May2021, the patient was very fatigued and was feeling dizzy frequently, activity was limited, a muscle pain, numbness and was cold or hot. The patient went to Urgent Care and was examined. Limited physical exam was normal. They drew blood tests which showed normal CBC on 23 machine differential both on 23Apr2021 and platelets except Low Platelet Volume on an unknown date in 2021, normal

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electrolytes and anaplasma test, negative blood smear for Babesia and Anaplasma and neg IgM and IgG for Lyme all on an unknown date in 2021. The patient's creatinine, BUN and renal function (fx) was unknown on an unspecified date in 2021. On 03May2021 and 06May the patient had similar symptoms, lasting about half of each day. On 06May2021, the patient had a nasal swab for COVID. On 07May2021 to 09May2021 the patient was very tired in the mornings, dizziness, episodic HAS, limiting activity. The events were partly improved by rest but the patient had constant ear pain mainly on the left side. The reporter stated that he deeper dive into the literature this weekend and came up with lots of papers of which the following publications are of special interest which includes: 1. One case report of Postural Orthostatic Tachycardia Syndrome (POTS) after Pfizer mRNA vaccine showing that POTS is frequently associated with auto-antibodies to G protein-coupled receptors, particularly norepinephrine receptors, epinephrine receptors and ACE2 receptors. In addition patients have elevations in a number inflammatory cytokines (IL-1beta, IL21, TNFalpha, IFNgamma, CD30) and platelet pool efficiencies (associated with low platelet volumes, dense granules, easy bruising). By the way, one can see dysautonomic disorder like POTS but without the tachycardia. One report described 31 patients with long COVID who had autoantibodies to the G protein coupled receptors with a variety of symptoms which can act as agonists or antagonists and are associated with a variety of syndromes (see their Table 1) with prominent fatigue, dysautonomic syndromes like POTS, neurologic and pain syndromes and cardiovascular syndromes. A potential synthesis is that these auto-antibodies are fairly common after COVID- 19 and perhaps also after other severe viral infections such as mono. Influenza etc which may lead to what we have called ME/CFS. There are a number hypothesis papers that predict that the spike protein-ACE2 receptor complex would elicit auto-Ab to ACE2. Its plausible that COVID-19 vaccines, particularly mRNAs which express spike intracellularly and cause a lot of inflammation also occasionally induce the syndrome. The reporter's question was whether abnormalities should be documented thoroughly including a full COVID-19 work-up for virus and antibody, auto-antibody panel, inflammatory markers, platelet work-

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up and a dysautonomia work-up. He added that pending the findings, the case should probably be reported. His most important goal is understanding the pathogenesis since that may lead to a logical therapeutic intervention in the event that these symptoms continue for a long time. The outcome of the events episodic HAs, period of rapid heart rate/episode of tachycardia, pain and numbness of left arm/numbness on the arms and hands, Some loose bowel movements, sweating, Mild sore throat, difficulty processing information/ attention deficit, severe weakness, redness around the bite and low platelet volume was unknown. The outcome of the events numbness in left arm where vaccine was injected radiating down to hand was recovered on Apr2021 and the events Chills/body shivering and low fever recovered on 21Apr2021. The outcome of the events fatigue/very tired in the mornings/Extreme fatigue limiting activities, Dizziness, upper back pain, headache, nearly passed out 2 times/near syncope, Vomited, Myalgias/ muscle pains, feeling cold or hot sometimes, 100/60 and then blood pressure would drop and settle at 85-95/60 or low 90s/60s, hypotension, pain, Upper back muscle pain and earaches worst on the left and fullness/left ear pain (ear pain) was not recovered. Information on the lot/batch number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of event Heart attack cannot be excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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| 1340725 | 5/22/2021 | WI | 17 | M | 5/13/2021 | 5/13/2021 | Client Fainted ~5min after the vaccine. BP 86/42, repeat 97/40, HR 71, 99% pulse ox. Patient lowered to the ground, vitals obtained, wheeled to Health office. |
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| 1340386 | 5/22/2021 | CA | 28 | F | 5/6/2021 | 5/6/2021 | ear ringing; stomach and kidney pain; stomach and kidney pain; nausea; achiness; inflammation; light headed; vasovagal response; some chest pain; collapsed/fainted; low grade fever; congestion; chills; This is a spontaneous report from a contactable consumer (patient). This consumer reported similar events for two patients. This is the first of two reports. A 28-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration on 06May2021 11:00 (Batch/Lot number: EW0170) as 2nd dose, single, at the age of 28-years-old for COVID-19 immunization. The patient is not pregnant. The patient had no known allergies. Medical history included a few kidney stones and one surgery to remove stones. She reported she was very healthy and active otherwise and hadn't had any sort of cold or illness in 2 years. The patient's concomitant medications were not reported. Historical vaccine included first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), on 15Apr2021 09:45 AM in the left arm as 1st dose, single for COVID-19 immunization. The patient did not have any other vaccine in four weeks and no other medications in two weeks. At 06May2021 9:00pm (10 hours after her 2nd shot), she started having a low grade fever, congestion, and chills. She went to sleep at 12:00am, chills and fever were more intense at this point. At 2:00am on 07May2021, she woke up with a fever of 103, no chills, but intense ear ringing (a volume of 9/10) in her left ear, extreme stomach and kidney pain, nausea, and achiness. The ringing in her ears was the worst symptom. She sat up and drank water for the next 5 hours, to try to get the inflammation down. She went to the bathroom every hour and her ear ringing started to lessen. At 7:00am she went to the bathroom for the 5th time and began to feel extremely light headed. She had a vasovagal response and collapsed/fainted (luckily, she had a family member who was monitoring her). She went back to rest and have had on and off low-grade fever, some chest pain, and aches since then. She has a twin sister, who got her shot on the same day and time, and she also had a vasovagal response, but not nearly as many of the other symptoms. The patient had no prior vaccination and was not tested for COVID post-vaccination. No treatment was received for the events. The outcome of the events was unknown. Information on |

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| 1340401 | 5/22/2021 | MD | 58 | F | 5/4/2021 | 5/5/2021 | <p>the lot/batch number has been requested.; Sender's Comments: Linked Report(s) : PFIZER INC-2021521315 same reporter/drug, similar event, different patient</p> <p>fainted; feeling horrible; dizzy; ringing in ears; nausea; chills; fever; This is a spontaneous report from a contactable consumer (patient). A 58-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; Batch/Lot Number: EW0175), via an unspecified route of administration, administered in Arm Left on 04May2021 09:45 (58-years-old) as 2nd dose, single for COVID-19 immunization. The patient medical history was not reported. Patient was not pregnant. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. No known allergies. Facility where the most recent COVID-19 vaccine was administered was Clinic (Public Health Clinic/Veterans Administration facility). Concomitant medication included levothyroxine sodium (SYNTHYROID) and multivitamin. The patient previously took first dose of bnt162b2 (lot number: EW0164) , on 13Apr2021 01:30 PM at 58-years-old, on Left arm for COVID-19 immunization. The patient was fine until 17 hours after the second dose. She woke up around 3 am feeling horrible, got up to go to bathroom. She was very dizzy, had ringing in ears, nausea, then fainted. She had chills and fever for the next ~ 12 hours. Events started on 05May2021 03:15. No treatment was given. The outcome of the events was recovered.</p> |

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| 1340415 | 5/22/2021 | | | F | 3/6/2021 | 3/6/2021 | all burnt inside: redness and dryness; all burnt inside: redness and dryness; burning sensation from top of her head and through her chest, arms and into her vagina and down her legs/her insides were burning.; burning sensation from top of her head and through her chest, arms and into her vagina and down her legs;; arm where she got injection was pretty dead; moment of pre syncope/pre syncope. She felt like she didn't know where she was and felt like she was going to pass out.; This is a spontaneous report from a non-contactable consumer (patient). A 65-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), dose 1 via an unspecified route of administration on 06Mar2021 (Batch/Lot Number: EN6199) as 1ST DOSE, SINGLE for covid-19 immunization. Medical history included hysterectomy (At Age: 32 and does not have a cervix), anaphylactic reaction (Anaphylactic shock to Formaldehyde), hypersensitivity (A lot of allergies: allergic to a lot of animals, cats, dogs, horses and lots of trees, grass, eggs, not shellfish), blood cholesterol increased ('little high cholesterol'), asthma, hypertension, food allergy (egg protein), Covid-19 for 5Mar 'She had covid when it first came out' and was sick 3 months (Being asthmatic, she was put on Prednisone/never hospitalized/Covid test was a false negative. They found out later it was positive) dyspnea, She took Prednisone and the second night she couldn't breathe (had Zpack in her system), rash all of the symptoms with Covid, the rash, neurological, severe headaches and cough. Being asthmatic, she was put on Prednisone. Consumer also stated Has no health issues other than being asthmatic and has a lot of allergies. The patient's concomitant medications were not reported. Past drug history includes Miralax. (allergic to polysorbate or polyethylene glycol, which is Miralax) The patient experienced burning sensation from top of her head and through her chest, arms and into her vagina and down her legs/her insides were burning, arm where she got injection was pretty dead, moment of pre syncope/pre syncope. She felt like she didnt know where she was and felt like she was going to pass out, all burnt inside: redness and dryness, all burnt inside: redness and dryness. The patient underwent lab tests and procedures which included blood test: normal on an unspecified date, body temperature: 97.2 on an |

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unspecified date, chest x-ray: normal on an unspecified date, Normal. Therapeutic measures were taken as a result of burning sensation from top of her head and through her chest, arms and into her vagina and down her legs/her insides were burning, all burnt inside: redness and dryness. Clinical course was reported by the patient as follows: Within 5 minutes of getting the vaccine, the arm where she got the injection went pretty dead, she even dropped her cell phone. That passed. Had a moment of pre syncope. She felt like she did not know where she was and felt like she was going to pass out. She drank some water and did some deep breathing. The next reaction almost killed her. She had a burning sensation from the top of her head and through her chest, arms and into her vagina and down her legs. Had to call for help. They were going to give her an Epi Pen, but she did not want to do that, as she knew she would have to go to the hospital. They opted for an injection of Benadryl and she also had oral Benadryl with her. She was able to stop the reaction with Benadryl before it got any worse because if not, she was going to have the get the Epi Pen Patient mentioned she is post hysterectomy since age 32 and does not have a cervix. When she contacted the doctor she said it was all burnt inside. She asked her what happened to her. She said the Pfizer vaccine. She was given medicine to avoid bacterial and fungal infections, because of the amount of dryness and redness. She had to take Sitz baths with baking soda once or twice a day to relieve the burning. It took about 2 weeks to go back to normal. Stated It was against her better judgment to get the first one. She has a history of anaphylaxis. Has many allergies but no allergies to polyethylene glycol or polysorbate. She is not getting the second one, she was told by her primary doctor not to, as she may not live to report it. The clinical outcome of the events was unknown. No follow-up attempts are possible. Were reporter is non-contactable.

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| 1340426 | 5/22/2021 | | 27 | F | 5/7/2021 | | This is a spontaneous report from a non-contactable consumer (patient). A 27-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 2 via an unspecified route of administration, administered in right arm on 07May2021 10:00 (lot number and expiration date not reported) at the age of 27 years old, as 2ND DOSE, SINGLE for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was not pregnant at the time of vaccination. Historical vaccination included first dose of BNT162B2 for COVID-19 immunization on an unspecified date (anatomical location: right arm). The patient fainted approximately 29 hrs after receiving dose on an unspecified date with outcome of recovered. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. No treatment was given for the event. No follow-up attempts are possible; information on the lot/batch number cannot be obtained. |

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| 1340428 | 5/22/2021 | PA | 50 | F | 5/4/2021 | 5/4/2021 | sharp passing pain near my heart; Almost fainted; wooziness; disorientation; weakness in arm; Pain going across shoulders and across upper back; Pain going across shoulders and across upper back, lasted through part of the night; Fever started after I came home. I usually get fevers when I have an allergic response.; This is a spontaneous report from a contactable consumer (patient). This 50-years-old female (not pregnant) patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration, administered in left arm on 04May2021 15:00 (Lot Number: EW0172) as single dose for covid-19 immunisation. Medical history included penicillin and latex (allergy). Prior to vaccination, the patient was not diagnosed with COVID-19. Concomitant medication(s) included echinacea purpurea root, olea europaea leaf, sambucus nigra fruit (ELDERBERRY ECHINACEA & OLIVE LEAF). The patient previously received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: ER8729) administered in left arm on 13Apr2021 02:45 pm (at 50-year-old) as single dose for covid-19 immunisation. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 04May2021 at 15:15, patient experienced almost fainted, wooziness, disorientation and weakness in arm, could feel the loss of control of arm, pain going across shoulders and across upper back, lasted through part of the night. Fever started after patient came home, she usually get fevers when had an allergic response. Patient experienced discomfort as drug initially moved through the body, she had a sharp passing pain near heart, this subsided after a few minutes on 04May2021. Since the vaccination, the patient had not been tested for COVID-19. No treatment received for the events. Outcome of the event sharp passing pain near heart was recovered on 04May2021, other events was recovered in May2021. No follow-up attempts are needed. No further information is expected. |

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| 1340348 | 5/22/2021 | CA | 46 | M | 4/15/2021 | 4/15/2021 | <p>Almost fainting 3 minutes/Almost fainted/Really close to blacking out; Almost passed out; Nauseated/Swirling strong nausea through the body up to the chest; Rapid heart rate; Hyperventilation; Labored breathing; 5-10 minutes before able to uncramp his hands; Waves of the feelings came throughout the day; This is spontaneous report received from a contactable consumer (patient). A 46-year-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot number: ER8733), via an unspecified route of administration, administered in Arm Left on 15Apr2021 11:00 as single dose for covid-19 immunization. Medical history included sensitivities to ephedrine from an unknown date and unknown if ongoing. The patient had no concomitant medications. The patient experienced almost fainting 3 minutes/almost fainted/really close to blacking out, nauseated/swirling strong nausea through the body up to the chest, rapid heart rate, hyperventilation, labored breathing, 5-10 minutes before able to uncramp his hands, waves of the feelings came throughout the day, almost passed out/ really close to blacking out; all on 15Apr2021. The events were not required a visit to emergency room, nor physician office. Caller is a 47 years old patient who received the 1st dose of the Pfizer Covid vaccine on 15Apr2021. He complained of feeling nauseated, and rapid heart rate, with hyperventilation, and almost fainting 3 minutes after the 1st dose of the Pfizer Covid vaccine. This lasted approximately 15 minutes. 3 minutes after receiving a vaccine. He started to complaint about feeling nauseated. He started rapid heart rate which caused him to have hyperventilation and almost fainted. The episode last for 15 minutes and he just want to go and report it. Consumer confirmed it was the Pfizer Covid19 vaccine. The consumer wasn't still experiencing the side effects. They lasted to 5pm. I got my shot at 11am. The event was no longer persisting but he was wanting to understand the effect of the second shot, the consumer wasn't took any treatment for adverse event. Caller states that he is calling about the Covid Vaccine. Says with the first round of the vaccine he had an adverse event. He is looking to Pfizer and his doctor for some feedback to understand whether or not he should get the second dose. Says that about three minutes after the vaccine he felt a swirling, strong nausea throughout his body up to</p> |

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| | | | | | | | his chest. He had labored breathing and a really fast uncontrolled heart rate for about 5 minutes. States he was hyperventilating and almost passed out. He had to sit on the ground of the parking garage where he had gotten his vaccine. About 5-10 minutes later he was finally able to uncramp his hands. States that before the vaccine he was calm and not at all in an elevated state. States he is wondering about the second dose being stronger. He almost blacked out after the first dose. States it was close to the limit of what he could tolerate. States he needs further details. He was reading about clinical trials and some doctors. States that he did not have all the symptoms of anaphylaxis that they described. Says his symptoms lasted about 5 minutes or so. About 10-15 minutes later he was recovered. Says waves of these feelings came over him throughout the day. Says they decreased each time and ended that evening around 1700. Caller says he did not go to the Emergency Room when it happened. The nurses at the vaccination site attended him. At the end of the call the caller mentions that he has a sensitivities to ephedrine. States he does not take any Sudafed or Dayquil or anything like that. States he didn't know if that was relevant to mention or if anything like that is in the vaccine to make him have the response that he did. History of all previous immunizations with the Pfizer vaccine considered as suspect (or patient age at first and subsequent immunizations if dates of birth or immunizations are not available) was none. No prior Vaccinations (within 4 weeks). No family medical history relevant to events. No Relevant Tests. The outcome of events was resolved on 15Apr2021. |
| 1341267 | 5/22/2021 | IL | 13 | F | 5/22/2021 | 5/22/2021 | patient was given shot and fainted and started rash at site lips turned blue also shot was given at 10:23am and at 10:26am adverse event started epipen was given at 10:26am paramedics called and patient was taken to hospital for followup |
| 1340952 | 5/22/2021 | KS | 17 | M | 5/21/2021 | 5/21/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Hypotension-Medium |

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| 1341111 | 5/22/2021 | TX | 14 | F | 5/22/2021 | 5/22/2021 | Patient fainted and felt dizzy roughly after 10 minutes upon receiving the vaccine. She immediately gain consciousness but could not recall that she fainted and just said she "blacked out". The pharmacy staff took her blood pressure, and said it was low but after monitoring for 10 minutes, it went back to normal. She felt no more dizziness, was able to stand up, walk normally and went home shortly after. |
| 1341157 | 5/22/2021 | CO | 31 | M | 5/22/2021 | 5/22/2021 | Patient fainted about 10 minutes after vaccine administered. Came to within a couple of minutes and vitals were stable upon examination by EMT's within about 15 minutes. |
| 1341170 | 5/22/2021 | TX | 17 | M | 5/22/2021 | 5/22/2021 | Patient fainted 3 minutes after receiving the first covid vaccine. |
| 1341197 | 5/22/2021 | NC | 13 | F | 5/22/2021 | 5/22/2021 | PATIENT FAINTED WHILE SITTING DOWN, MOM CAUGHT HER AND HELPED HER STAY IN THE SEAT. PATIENT LOOKED PAIL AND WAS FEELING NAUSEATED. MEDIC ARRIVED AND TOOK VITALS AND OBSEEREVED. PATIENT WENT HOME WITH MOTHER |
| 1341106 | 5/22/2021 | WI | 53 | M | 5/17/2021 | 5/17/2021 | He fainted 5 minutes after vaccine administration. After he came to on his own, he starting vomiting. Paramedics were called and took him to the emergency room for further evaluation. |
| 1341243 | 5/22/2021 | FL | 17 | M | 5/22/2021 | 5/22/2021 | Less than a minute after administration patient started to feel not well. Patient displayed symptoms of possible syncope. Eyes were unfocused and unable to sit up straight. Epipen was administered immediately. EMS was called. Patient's blood pressure was taken multiple times and was low at each reading . Patient's blood pressure would also drop upon standing up. After about half an hour of not resolving EMS took patient to hospital for further evaluation. |

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| 1341102 | 5/22/2021 | SC | 17 | F | 5/22/2021 | 5/22/2021 | Immediately after the receiving dose #1 of Pfizer COVID-19 immunization the patient fainted. Patient remained seated until she came back to after 2 mins. Patient's mother was in the room, and stated this happens every-time she gets a shot. VAR stated no history of fainting or reaction after any vaccinations. Patient remained seated for 15 minutes while being monitored. After she stated she felt normal and left in her mothers care. No medication was administered. |
| 1341270 | 5/22/2021 | NY | 13 | M | 5/22/2021 | 5/22/2021 | Pt fainted shortly after the vaccine, regained consciousness immediately. Patient was given an ice pack and water. There was no harm to patient. |
| 1341293 | 5/22/2021 | CA | 18 | F | 5/22/2021 | 5/22/2021 | Patient's friend reported to pharmacy patient passed out as they walked out the store about 15 minutes after the shot, and someone already called 911. Pharmacist walked out to check on patient, paramedics were already there checking on her. Paramedics said patient is ok, and they will release her. Patient came back to the pharmacy about 10-15min later to tell us she is ok. |
| 1341375 | 5/22/2021 | CA | 25 | M | 5/22/2021 | 5/22/2021 | SYNCOPE, PALE, COLD, UNRESPONSIVE X 30 SECS, ASSISTED TO FLOOR, WOKE UP, PARAMEDICS ON SITE, BP 141/72, HR 91, PROVIDED WATER, SX RESOLVED, NO TRANSPORT. |
| 1341384 | 5/22/2021 | PA | 15 | F | 5/22/2021 | 5/22/2021 | Patient fainted within a minute of receiving vaccine. Pale, diaphoretic, nauseated. No treatment. Recovered without incident. |
| 1341420 | 5/22/2021 | CA | 14 | M | 5/22/2021 | 5/22/2021 | The client was accompanied by his mother. Staff vaccinated the client. When filling out the consent form, the client started looking pale and was about to pass out. Staff caught the client before falling off the chair. They laid him down and put a cool pack on his neck. Called 911 to scene at 1731. EMT arrived at the scene at 1740. The client passed out for a minute but was still breathing. Vitals BP, 124/66, HR 56, Pulse Ox, 98%. Vaccinated lot num Pfizer EW0179 exp. 08/2021. EMT Transported client at 06:05pm |

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| 1341165 | 5/22/2021 | | 15 | U | 5/22/2021 | 5/22/2021 | Minutes after the vaccination patient felt dizzy and fainted and came back to consciousness shortly after. Patient felt much better just had a slight headache after regaining consciousness. Patient was given water and feet were lifted to help with circulation. Patient after additional 30 minutes of observation felt a lot better and was alert with no symptoms reported. |
| 1341242 | 5/22/2021 | FL | 20 | M | 5/21/2021 | 5/21/2021 | Patient fainted after vaccine. Previous history of fainting with shots |
| 1340993 | 5/22/2021 | NY | 37 | M | 5/22/2021 | 5/22/2021 | Systemic: Fainting / Unresponsive-Mild |
| 1340754 | 5/22/2021 | NY | 14 | F | 5/21/2021 | 5/21/2021 | moderna clinic - Patient sat for a bit after vaccine - fainted when got up to leave. I heard the commotion from the pharmacy while i was giving a vaccine. Patient had signed up online for the vaccine with the date of birth 6-20-2001 (showing 19 years of age). Patient came to quickly after fainting - felt dizzy, nauseated, warm and blurred vision (seeing spots). Patient did not hit her head during fall. EMS came to check her out. Took blood pressure and pulse - within normal limits for patients age. Being that she's 14 and received Moderna instead of Pfizer that could have been the reason. Patient faulted age during online sign up stating she was 19. I checked with the mom the day after the incident - patient feels fine - no flu like symptoms or feeling dizzy, nauseated or blurred vision. |
| 1340778 | 5/22/2021 | MA | 50 | F | 5/22/2021 | 5/22/2021 | Patient fainted after leaving booth . It appears she may have whacked her head on the concrete floor. No blood. She was back to consciousness but didn't remember what happened. Ambulance came, took her away in stretcher. |
| 1340836 | 5/22/2021 | MA | 14 | F | 5/22/2021 | 5/22/2021 | Patient had vaccine and entered waiting area for monitoring period. Started feeling dizzy and started to sit on ground but passed out while transferring to ground. Patient came to confused, pale, sweating and then proceeded to pass out 2-3 additional times. EMS was called as a precaution since patient reported feeling confused, weak, heart palpitations. Patient was advised to remain on the ground while waiting for EMS and was given an ice pack, water, juice and crackers. |

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| 1340853 | 5/22/2021 | DC | 14 | M | 5/22/2021 | 5/22/2021 | After 3 minutes of observation in a chair, he got up to move to the observation area in clinic and then fainted. He fell backward against a closed door and slid down. He quickly regained consciousness and his vitals were stable. within 10 minutes he was no longer dizzy or hot. He was able to sit up right without issues. Per dad, this is the same reaction he had to the flu vaccine in fall of 2020. |
| 1340880 | 5/22/2021 | GA | 28 | F | 5/22/2021 | 5/22/2021 | Patient had vasovagal reaction and dry heaving. Fainting resolved within 30 to 60 seconds |
| 1341108 | 5/22/2021 | WA | 16 | M | 5/22/2021 | 5/22/2021 | AFTER RECIEVING FIRST COVID VACCINE PATIENT FAINTED. PT HAS A HISTORY OF FAINTING AFTER VACCIATIONS |
| 1340956 | 5/22/2021 | CA | 14 | F | 5/22/2021 | 5/22/2021 | Patient got her 1st dose of Pfizer vaccine, was told by provider and mother to sit down for 15 minutes. After awhile patient 's mom came back to pharmacy and alert us patient is fainting. I came to patient and she could barely stood up. patient looked pale. We assisted patient to come to pharmacy sitting area. I measured patient 's bp. BP reading was 60/43 and 70HR. Patient 's mom informed us she has not been drinking or eating breakfast, so they went to grab some snacks while waiting and that was when patient fainted. A by stander called 911 when patient first fainted. EMS came and brought patient to ER for further check up. |
| 1340750 | 5/22/2021 | | 22 | F | 5/22/2021 | 5/22/2021 | The patient fainted a minute after receiving the vaccine, woke up a minute later, and felt very nauasiated 5 minutes after waking up. The patient expressed a lot of fear prior to the vaccine, due to a fear of syringes. Her guardian was around to help make sure that she did not suffer any injuries during syncope. |

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| 1341001 | 5/22/2021 | WA | 37 | F | 4/21/2021 | 5/17/2021 | Patient without significant past medical history presented 5/18/21 to the ED with sudden shortness of breath, chest pain and syncope. Found to have narrow complex tachycardia with 1st degree heart block with elevated troponin. Patient was admitted 5/18/21 with diagnosis of myopericarditis. Also found to have junctional tachycardia. Workup included CTA of chest negative for PE, echo showed preserved ejection fraction and cardiac cath was negative for CAD. Patient was treated with colchicine with improvement in chest pain and was discharged on 5/21/22. She was readmitted 5/22/21 with near syncopal event with sinus arrest and junctional bradycardia. |
| 1341009 | 5/22/2021 | KY | 15 | F | 5/22/2021 | 5/22/2021 | Vaccine was administered. The mom made a comment that her daughter has a tendency to pass out after vaccines after administering the vaccine to the patient. We kept the patient in the counseling room seated for observation to be on the safe side. Within 5 minutes, the patient got light headed and stated she didn't feel well. She passed out. We laid her down for about 10-15 minutes and gave her some candy since she stated she hadn't eaten all day. Pt regained consciousness and was fine after. |
| 1341045 | 5/22/2021 | MI | 16 | F | 5/22/2021 | 5/22/2021 | Patient was fine after vaccine administration, but while sitting down patient passed out while sitting next to her mother. Patient was laid on the floor and regained consciousness while on the floor. Eventually with other help, got patient into wheel chair. Mom didn't want EMS called and just let patient sit for awhile until our store director in charge left with patient in wheel chair and Mom to make sure patient was alright. |
| 1341060 | 5/22/2021 | IL | 12 | F | 5/22/2021 | 5/22/2021 | Patient told her mom she was not feeling well right after the vaccine. Mom told her she would go buy her an icepack to bring home to help her. The patient got up to follow her mom and fainted in the aisle. Her sister came and got the pharmacist and by the time I got to her she was already coming to. We did call an ambulance but by the time they paramedics arrived the patient was ok to leave on her own with her mom. |

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| 1341085 | 5/22/2021 | MN | 14 | F | 5/21/2021 | 5/21/2021 | Patient received 1st dose of Pfizer covid vaccine and was told to stay 15 minutes after vaccine was administered to monitor for symptoms. We were then informed she fainted at the front of the store. It was reported she was unconscious for roughly 30 seconds. When I came up to her, she was conscious on sitting on the floor. She was given cold water and an ice pack while EMTs were on their way. |
| 1341093 | 5/22/2021 | MO | 18 | F | 5/22/2021 | 5/22/2021 | Approximately 10 minutes post-vaccine, patient fainted (while sitting in chair for observation) and fell to the floor. Bystanders stop to help, and I grabbed my IMZ cart to go on scene; one bystander called 911 for EMS. Patient was breathing, conscious, and had a pulse; she was coherent and able to talk. She denied hitting her head or losing consciousness. Her mother, who was with her at the time, said the patient "shook" a little after she fell. Patient stated she had not eaten all day and thought that may have contributed to her fainting. We provided patient with water, and she was able to sit up on floor and lean against the wall. EMS arrived on scene to take over. The reported her blood sugar and blood pressure were within normal limits. This may have been a vasovagal reaction. Patient was standing after EMS evaluated her, and they approved for her to leave. The patient and her mother left the pharmacy. I told them to call the pharmacy if they have any questions or concerns and to report the event to patient's MD. |

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| 1340912 | 5/22/2021 | NC | 14 | M | 5/14/2021 | 5/17/2021 | Pt received first shot of Pfizer vaccine on 5/14 - 12:30 PM EST. On 05/17 around 7:45 AM, Pt passed out/fainted. He woke up few minutes prior to the event and this event started after he passed urine. As soon as he finished Urination, he felt nauseated, dizzy and then lost consciousness thereafter. He fell backwards as a result and hurt his back as well as back side of the head. During his unconsciousness his body was completely stiff and his eyes were rolled back. For few seconds then he became completely still (it felt he was not breathing). I gave him physical stimulus (slight slaps on the face) post which he started reviving. During this time we called 911. I gave him few sips of water forcibly and he started reviving thereafter. on 5/15 and 5/16 (post vaccination on 5/14) he was feeling tired and seemed bit dull. This was unusual as Pt is a competitive soccer player and highly active. |
| 1341122 | 5/22/2021 | OK | 17 | M | 5/22/2021 | 5/22/2021 | Syncope- pale, nauseous, initially disoriented when regained consciousness, sweating. Patient was taken to ED. Escorted out by EMS. |
| 1336679 | 5/21/2021 | GA | 41 | M | 5/20/2021 | 5/21/2021 | REPORTED FAINTING BY WITNESSES, NURSE VISUALIZED DIAPHORESIS, DRY HEAVING, PT REPORTED WEAKNESS. |
| 1337368 | 5/21/2021 | CA | 13 | F | 5/21/2021 | 5/21/2021 | AFTER GETTING SHOT, PATIENT PASSED OUT. I CHECKED BLOOD PRESSURE AND 73/42 AND PULSE WAS 51. CALLED 911. PUT PATIENTS LEG UP AND PUT SOME ICE ON BACK OF HER NECK AND UNDER ARM. PATIENT GAINED CONSCIOUS. FELLING OK. PARAMEDICS ARRIVED AND TOOK HER TO HOSPITAL. PATIENT WAS ABLE TO TALK AND ANSWER CORRECTLY. |
| 1337325 | 5/21/2021 | CA | 15 | M | 5/21/2021 | 5/21/2021 | Client reported feeling, "lightheaded" approximately 10 minutes following the vaccine administration. Patient was immediately placed in the anti-gravity chair, and given food and water. The patient denied history of fainting but reported similar experiences with previous vaccines. The lightheadedness was relieved following the consumption of food, water, and placing in the patient in a semi-Fowler's position. |

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| 1337288 | 5/21/2021 | NY | 15 | M | 5/21/2021 | 5/21/2021 | Patient experienced as 15- 20 second syncope spell when he sat up from a sitting position after receiving the covid vaccine initial vitals 102/60 pulse 40 after regaining consciousness BP was 111/60 pulse at 60 patient prior to fainting appeared diaphoretic, pale and cool to the touch there were no signs of allergic reaction including flushing of the face lack of hives or angioedema no wheezing, no stridor or labored breathing patient complained of dizziness upon standing equal to 30 mins.. EMS was notified when arrived patient was up and alert without difficulties EMS recommended patient be released to his guardian BP at release 112/57 pulse 62 father advised to call physician if any concerns arise or go to nearest hospital in an emergent situation |
| 1337265 | 5/21/2021 | NC | 13 | F | 5/18/2021 | 5/18/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Additional Details: Pt had dentist appointment the morning of vaccine. After pt got vaccine and was seated in observation area pt got dizzy and passed out and hit head. BP was taken and was 84/54. 911 was called and pt went to ER due to continuous low blood pressure. |
| 1337247 | 5/21/2021 | VA | 17 | F | 5/20/2021 | 5/20/2021 | Systemic: Fainting / Unresponsive-Medium, Additional Details: Pt fainted after vaccine, hit head on nearby object. sustained approx 2 cm laceration to scalp with moderate bleeding. applied saline wound wash and gauze. bleeding stopped. VS normal BP110/72, P90,RR14,O297%RA. Pt revived after 1-2 min. She sat up and was able to walk. Mom at work. Mom called neighbor to pick up pt. Mom agreed to have FM take pt to ER/urgent care. |
| 1337232 | 5/21/2021 | OR | 32 | M | 5/20/2021 | 5/20/2021 | Site: Pain at Injection Site-Medium, Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Shakiness-Mild, Systemic: Tingling (specify: facial area, extremities)-Mild, Systemic: Weakness-Medium |
| 1337208 | 5/21/2021 | TX | 16 | M | 5/20/2021 | 5/20/2021 | Patient fainted, lost consciousness and was treated by paramedics. Patient was administered oxygen. Patient did not need further treatment. |

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| 1338833 | 5/21/2021 | PA | 19 | F | 5/15/2021 | 5/15/2021 | Immediately after receiving her vaccination client developed blurry vision and R arm pain. Denied cp/syncope/dizziness. She reported that she had not had breakfast in the AM. She was offered water and her symptoms resolved within 15 minutes of being observed. |
| 1337129 | 5/21/2021 | AL | 13 | F | 5/18/2021 | 5/19/2021 | Vasovagal syncope with full passing out the following day after the vaccine |
| 1337086 | 5/21/2021 | | 18 | M | 5/20/2021 | 5/20/2021 | Pt fainted after administration of Pfizer vaccine. RN caught pt and sat him in a chair. Pt never fell out of chair. Pt regained consciousness and was transported via w/c to the observation bay. Father was present. BP 121/83 HR 68, RR 16. Pt recovered, was stable and released from the vaccination site. |
| 1337009 | 5/21/2021 | MO | 13 | M | 5/19/2021 | 5/19/2021 | Systemic: Fainting / Unresponsive-Mild |
| 1337003 | 5/21/2021 | NY | 16 | F | 5/20/2021 | 5/20/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Severe, Systemic: Hypotension-Severe, Systemic: Nausea-Severe |
| 1337440 | 5/21/2021 | VA | 17 | M | 5/21/2021 | 5/21/2021 | Patient fainted approximately 5 minutes after receiving his second Pfizer vaccine. He was observed to have tonic-clonic jerking but this was not seizure nor does the patient have a history of seizures. His mother reported fainting previously during stressful situations. Ice pack was given and BP was taken at 11:20 and was 100/65 and pulse was 101. When EMS arrived, patient's BP was 134/80 and pulse was 83. Patient reported stomach pains post-fainting. EMS cleared patient to leave and he signed off that he did not want to go to the hospital. |
| 1336806 | 5/21/2021 | IA | 19 | M | 5/21/2021 | 5/21/2021 | patient fainted, fell off chair and hit head on wall we had him lie down on floor, took his blood pressure and put ice pack on bump on his head he eventually sat up and felt better |

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| 1337219 | 5/21/2021 | IL | 13 | M | 5/20/2021 | 5/20/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Exhaustion / Lethargy-Medium, Systemic: Fainting / Unresponsive-Mild, Systemic: Hypotension-Mild, Systemic: Shakiness-Mild, Systemic: Weakness-Mild, Additional Details: The pt felt lightheaded and passed out for a few seconds. His father was with him and caught him and laid him on the ground. I contacted my nurses who stayed with the pt and monitored him for more than 30 mins. The pt was awake but felt light headed, had low blood pressure and blood sugar. The pt was given water and crackers. My DM was also here and called the paramedics who took him to the hospital. |
| 1336675 | 5/21/2021 | PA | 18 | F | 5/20/2021 | 5/20/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: Headache-Mild, Additional Details: got emotionally excited after shot fainted for 25 seconds, patient was tired bur responsive |
| 1336653 | 5/21/2021 | NY | 35 | M | 5/20/2021 | 5/20/2021 | Approximately 2-5 minutes after receiving vaccine patient fainted. Patient was pale, sweaty and unresponsive. Patient regained consciousness shortly after but was still pale and sweaty for some time. Patient was given water, ice pack and closely monitored for 30 minutes. Patient and family with him stated that he does not do well with shots and this is a common occurrence. After approximately 15 minutes color came back to patient and he stated he was fine although monitoring continued until 30 minutes. |
| 1336612 | 5/21/2021 | TX | 18 | M | 5/20/2021 | 5/20/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Shakiness-Mild, Additional Details: mother informed rph prior to shot that patient exhibits these reactions after receiving shots. mother and rph held pt. he fell on his buttocks but was unhurt while changing location. rph had advised mother to keep him sitted. we fanned him to cool his sweating. he drank 2boxes of juice. he left after 15minutes. |
| 1336524 | 5/21/2021 | OH | 20 | M | 5/21/2021 | 5/21/2021 | 5 minutes after vaccination patient had sign and symptoms of Vasovagal reaction. Patient felt dizziness, passed out. Patient was given apple juice, salty snack, bottle of water. |

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| 1336522 | 5/21/2021 | WA | 20 | F | 5/21/2021 | 5/21/2021 | Patient was in the waiting area for about 10 minutes then turned pale and passed out. They fell out of the chair they were in and hit their head on the floor. They regained consciousness within about 10 seconds. EMT was called and responded to help treat and advise the patient on the next steps. |
| 1336287 | 5/21/2021 | | 19 | M | | 5/6/2021 | FAINTED; This spontaneous report received from a patient via a company representative concerned a 19 year old male of an unknown ethnicity and race. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1808982, and expiry: Unknown) dose was not reported, 1 total administered on 06-MAY-2021 for prophylactic vaccination. No concomitant medications were reported. On the same day, the patient fainted (syncope) after vaccination. The patient woke up later and did not had to go to the hospital, however someone had to drive patient home. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from fainted on 06-MAY-2021. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210535593-COVID-19 VACCINE AD26.CO2.S-fainted. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s). |
| 1336258 | 5/21/2021 | KY | 37 | M | 5/20/2021 | 5/20/2021 | pt received second dose of pfizer vaccine and within ten minutes started feeling dizzy and nauseated, sweating and feeling as though having a panic attack. Pt had syncope episode and ammonia inhalant used and pt non responsive. 911 called and pt monitored. Once pt placed on stretcher pt became more responsive and was able to state name and todays date, bp 109/62 p73 @ 15:48 / bp 109/74 p 88 @ 15:52. Pt verbal and states he is feeling better, states he has not had much to drink today and has been mowing today. EMS on scene and pt leaves clinic with EMS. |

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| 1336140 | 5/21/2021 | | 15 | M | 5/15/2021 | 5/15/2021 | (Vasovagal Response) Fainted when standing up after getting vaccine. Hit shoulder on table. C/o of mild pain to shoulder, but no additional complaints. Laid down and no additional treatment needed. |
| 1336139 | 5/21/2021 | | 17 | F | 5/15/2021 | 5/15/2021 | (Vasovagal Response) Felt tired and ?felt like fainting? immediately after shot. Pt laid down and elevated feet. No additional treatment needed. (Initial BP 87/58) |
| 1336137 | 5/21/2021 | | 13 | F | 5/15/2021 | 5/15/2021 | (Vasovagal Response) Fainted as walking to court yard. Parent was able to assist w/o fall. Pt laid down and elevated feet. No additional treatment needed. (Initial BP 80/62 ? BP 96/68) |
| 1336112 | 5/21/2021 | WA | 15 | F | 5/20/2021 | 5/20/2021 | Light headed and dizzy without fainting. Patient laid flat with legs elevated approximately 30 minutes, was then able to travel home in personal vehicle with driver. |
| 1336110 | 5/21/2021 | WA | 21 | M | 5/12/2021 | 5/12/2021 | Patient experienced syncope about 5 minutes after receiving vaccine. he fainted fell to the floor bumped his head then got up immediately later and reported to pharmacist around 7:40. Patient was asked to sit down, given water and powerade for fluids and electrolytes. after 20-30 minutes patient vomited. 911 was called immediately after. first responders came in 10 minutes around 8pm and took vital signs and questioned patient. patient refused to go with them stating he felt better. patient left pharmacy around 8:30 pm 5/12 |
| 1336880 | 5/21/2021 | TX | 13 | F | 5/20/2021 | 5/20/2021 | patient fainted after vaccine administration. Patient was given the vaccine and slumped in the chair ten seconds later. We were able to revive her after 20 seconds. We had her lay on her back and lift her feet. after 15 minutes she said she was feeling fine and left with her father. |
| 1338384 | 5/21/2021 | TX | 24 | F | 5/21/2021 | 5/21/2021 | Patient temporarily fainted, and immediately came back, she was sweating, was given gatorade. Checked her blood pressure it was initially 87/58 at 4:21 pm. Sat with her and checked pressure again at 4:30 pm, and bp had returned to 113/75. she was fully recovered by 04:45pm and she left the pharmacy. |

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| 1338101 | 5/21/2021 | CA | 17 | F | 5/21/2021 | 5/21/2021 | Pt. Is a 17 y/o female with NKA, no past medical history. Second dose of Pfizer was given in L deltoid at 1536. Approx. 1543 pt. Began to c/o of nausea and dizziness. Pt. Was moved for privacy, she verbalized wanting to lay on the floor for comfort due to her history of fainting after injections. Pt. Was A&O x4 during event. VS were performed before patient departed. 1546: 100/70 HR:71 o2:91% RR 19 (Laying) 1550: 110/80 HR: 93 o2: 99% RR: 19(sitting) 1552: 120/90 HR:93 o2:99% RR:20 (standing) |
| 1338135 | 5/21/2021 | WI | 19 | M | 5/21/2021 | 5/21/2021 | Patient fainted roughly 5 minutes after vaccine. He was nervous and stated he had fainted in the past from vaccines. He asked to have his partner with him during the shot and after to help prevent fainting. She was there when he asked to put his head down, then fainted. We moved him to floor. By the time we were able to get him to floor, he was waking. |
| 1338138 | 5/21/2021 | CA | 14 | F | 5/21/2021 | 5/21/2021 | Client received the 1st or 2nd COVID vaccine (Pfizer Lot # EW0185 expiration 05/22/2021) at 1312. RN vaccinated the client at 1312, the client then told her that she was feeling lightheaded and dizzy. RN alerted and they responded. EMTs alerted PHN at 1315 and vital signs were taken (blood pressure 102/60, oxygen 98, pulse 62). Skin color was appropriate to skin tone, client was alert and oriented. Client?s mother was with her and sated that the client as anxiety to needles and has passed out before from receiving a vaccine. Client stated that she did eat today. She has no medical conditions, no allergies, and is not taking any medications. Client refused Benadryl. At 1320 client stated that she was feeling a ?little better? and was escorted to zero gravity chair when dizziness and lightheadedness subsided. Client given juice which she accepted and drank. Vital signs taken at 1325 (blood pressure 118/74, respirations 18, heart rate 72, oxygen 97). Vital signs taken at 1335 (heart rate 76, oxygen 96, respiration 18, blood pressure 122/76). Client and mother provided education to seek emergency services if life threatening symptoms appear, and to follow up with primary care provider. Vital signs taken at 1345 (oxygen 97, heart rate 82, blood pressure 118/78). At 1347 client stated that she was doing fine and did not have any more symptoms. Client left with her mother at 1347 unassisted with a steady gait. |

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| 1338145 | 5/21/2021 | | 51 | M | 5/21/2021 | 5/21/2021 | Fainted. Evaluated by EMS-Cleared |
| 1338365 | 5/21/2021 | NJ | 13 | F | 5/16/2021 | 5/17/2021 | Patient had a syncopal episode passed out hit her head and suffered bilateral nose fractures and concussion |
| 1337959 | 5/21/2021 | NM | 34 | F | 5/21/2021 | 5/21/2021 | Patient received vaccine. Patient then sat down for the required 15 minutes. Patient got nauseous and went to the bathroom. After several minutes in the bathroom, patient passed out or fainted and fell on the floor. Patient was able to get up with help from our associates. Patient then was able to leave on her own. |
| 1337580 | 5/21/2021 | MO | 15 | F | 5/21/2021 | 5/21/2021 | Pt had an episode of syncope, pt's mother supported the pt's head, ammonia tablet was used to rouse pt and pt was assisted to the floor. Vitals were monitored, legs elevated, cold compress provided to the pt and placed on her neck. Pt rested and awoke 2-3 minutes later. |
| 1338378 | 5/21/2021 | | 14 | F | 5/21/2021 | 5/21/2021 | This reporter received paperwork for report of Pt. experienced fainting event seven minutes after first dose of pfizer. Feet were elevated by EMS. Pt. cleared by EMS to leave with parent. |
| 1337160 | 5/21/2021 | NV | 31 | M | 5/20/2021 | 5/20/2021 | DIZZY, PASSED OUT IN HIS SEAT, MOVED TO COT, REMAINED UNRESPONSIVE FOR 30-45 SECS, INCONTINENT OF URINE. EMS CAME, BP 137/72, HR 56, PROVIDED GATORADE AND SNACKS, SYMPTOMS RESOLVED, REFUSED TRANSPORT. |
| 1338391 | 5/21/2021 | PA | 22 | M | 5/20/2021 | 5/20/2021 | patient's friend's alerted me that he was feeling dizzy about 2:10pm. I went over to patient just as he was passing out. small muscle jerk was noted. I obtained assistance to place patient on the floor. He regained consciousness before we could put him on the floor. He was out only 5-10 seconds. he was given some water and proceeded to sit for 20 more minutes. Patient was feeling fine. He did state he had fainted receiving flu shot previously. Patient walked home and called to inform us he made it home safely and was feeling fine. He was instructed to hydrate and take it easy for the day. He refused offer to call the squad |

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| 1338588 | 5/21/2021 | CA | 14 | M | 5/21/2021 | 5/21/2021 | Patient appeared to be fainting, shook back and forth in a repeated manner after sitting down for observation following the COVID vaccination. Did not have any blurred vision, was responsive. To be safe, an ambulance was called. This occurred minutes after being vaccinated, the ambulance arrived about 30 minutes afterwards and picked the patient up. |
| 1338622 | 5/21/2021 | PA | 28 | F | 5/15/2021 | 5/15/2021 | Client became dizzy and lightheaded immediately after receiving her vaccination. No episode of syncope, shortness of breath or rash noted. She reported not having breakfast prior to coming for vaccine. She was offered water and her dizziness resolved within her 15 minute wait time from receiving her vaccine. |
| 1338822 | 5/21/2021 | PA | 19 | M | 5/15/2021 | 5/15/2021 | Client had an episode of dizziness , presyncope immediately after receiving his vaccine. Denied shortness of breath or chest pain . He reported tingling in his hands. He had not had breakfast prior to arrival . He was offered water . His symptoms resolved within 15 minutes and he was able to leave after his symptoms were resolved. |
| 1338830 | 5/21/2021 | PA | 75 | F | 5/15/2021 | 5/15/2021 | Client received her vaccine and immediately after injection she reported ?feeling weird and anxious?. VS: 1130 BP 192/82, 1134 138/79. She denied CP, SOB, dizziness or syncope. Her symptoms resolved within 15 minutes . |
| 1338366 | 5/21/2021 | TX | 15 | F | 5/21/2021 | 5/21/2021 | Patient collapsed on shelf after fainting in diabetes care/oointment isle at around 6:10 PM after receiving shot |
| 1337792 | 5/21/2021 | | 78 | M | 5/6/2021 | 5/8/2021 | Patient was admitted from ED due to feeling week for approximately 1 week prior. Has passed out 2-3 times a day over past week. Patient tested on admission for Covid with a positive diagnosis via POC Rapid SARS-COV-2 Antigen. Patient was treated with remdesivir, albuterol, ceftriaxone, dexamethasone. Patient discharged after 5 days with dexmethasone as new med. |

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| 1338386 | 5/21/2021 | WA | 31 | F | 5/21/2021 | 5/21/2021 | Adverse event: PT abruptly felt lightheaded approximately 14 minutes after receiving Moderna COVID vaccine at 1235. PT lowered herself to the floor to lay on her left side. PT presented with pallor and diaphoresis. RN responding called for aid at 1249, aid arrived at 1251. SPO2 was 97% on RA. PT reported a history of syncope, especially after injections, denies significant medical history and was unsure of baseline BP. EMTs prompted PT to sit in chair, PT was able to rise without difficulty, but continued to c/o 'lightheadedness'. EMTs provided education on vaso-vagal response, provided juice and water to PT. PT reported feeling "stable, but a little warm" and then reported increasing nausea. PT provided emesis bag and chose to lay down once again, reporting that she felt better laying down. At 1304, PT reported that her nausea was resolved, and that she felt 'normal'. Denied vision changes, vertigo when moving head side to side. Color improved. EMTs medically cleared PT at 1313 to be driven home by husband. Treatment: Juice and water were provided, EMTs assessed/treated (Vitals at 1250: Bp 100/P laying, HR 106, SPO2 97% RA. 1255: BP 100/P sitting, HR 92, SPO2 99% RA. 1303: BP 96/52 laying. 1308: BP 102/60 sitting). Pupil check at 1300 WNL, PT declined CBG check. Education provided on s/s to watch for, when to seek medical care provided by RN. Outcome: PT was medically cleared by EMTs at 1313, driven home in private vehicle by husband. HCP Responding: RN, EMT, EMT, RN |
| 1337934 | 5/21/2021 | NY | 32 | M | 7/8/1988 | 5/21/2021 | patient passed out, he was pale and sweaty |
| 1337606 | 5/21/2021 | NC | 20 | M | 5/21/2021 | 5/21/2021 | Syncope - patient experienced lightheadedness, sweating, paleness, blurred vision and cold extremities. I reassure patient that he will be okay and this is the body's response to pain/anxiety. I also provided patient with water and make sure he was seated so he does not fall. His vision return to normal after 5 minutes or so and he started recovering within 15 minutes. |
| 1337693 | 5/21/2021 | MO | 15 | M | 5/21/2021 | 5/21/2021 | vasovagal syncope |

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| 1337783 | 5/21/2021 | WI | 23 | F | 3/16/2021 | 3/17/2021 | I woke up around 12:30 in the morning and felt achy. I fainted twice after getting out of bed. I experienced severe aches and body chills. I felt fine the day after better. |
| 1337815 | 5/21/2021 | MO | 25 | M | 5/21/2021 | 5/21/2021 | Patient received vaccine. He has a history of fainting/becoming light headed after vaccination. He began to feel light headed and decided to lay down. Patient was given water and an ice pack. Patient was nauseous, and sweating profusely. After ~5 minutes, patient began to feel better. He waited another 15 min in the pharmacy before leaving with a driver. |
| 1337820 | 5/21/2021 | TN | 15 | F | 5/18/2021 | 5/18/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: Seizure-Medium |
| 1337860 | 5/21/2021 | | 15 | F | 5/21/2021 | 5/21/2021 | 15 Y/O F syncopal event following vaccine. PT had LOC. Woke within 30-40 seconds, vomited x1. Was oriented x3. Treated w/ rest (supine, then sitting) and PO fluids. PT released to home w/in 45 mins. Dx: Vaso Vagal Syncope |
| 1337875 | 5/21/2021 | NM | 18 | M | 5/21/2021 | 5/21/2021 | Systemic: Fainting / Unresponsive-Severe, Systemic: Nausea-Medium, Systemic: Shakiness-Medium, Systemic: Vomiting-Medium, Additional Details: Patient was administered first dose of Pfizer vaccine approximately 9:40am (MSD). Upon reviewing intake sheet there were no discrepancies to continue with the vaccination. Upon successful administration, patient was instructed to sit near Pharmacy in waiting area. Patient was standing next to wellness room where patient had fainted. Dr. and N.P. rushed to the scene to take control of the situation. Patient was assessed and asked a series of questions. He hadn't eaten in the morning. |
| 1337886 | 5/21/2021 | MA | 12 | M | 5/21/2021 | 5/21/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Additional Details: Pt has history of passing out after shots. passed out briefly after administration. did not fall or hit head. was given water and ice pack while mom attended to him. EMTs were called and took blood pressure did not bring to hospital |
| 1337894 | 5/21/2021 | CA | 32 | M | 5/18/2021 | 5/18/2021 | Systemic: Fainting / Unresponsive-Mild |

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| 1337905 | 5/21/2021 | FL | 32 | M | 5/21/2021 | 5/21/2021 | Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Severe |
| 1337923 | 5/21/2021 | MN | 18 | F | 5/20/2021 | 5/20/2021 | Patient fainted three minutes after receiving the Moderna vaccine. Patient's mom was at clinic with her and reported after the patient had fainted that the patient had played an outdoor La Crosse game in the heat & humidity the evening before receiving the MODERNA vaccine & had not eaten breakfast or had much to drink the day of the MODERNA vaccine. Provider who responded to take care of the patient indicated the patient was most likely dehydrated & needed IV fluids. Blood pressure was 97/58; pulse 64; Oxygen saturation 96%. Patient became responsive within 30-45 seconds from fainting but then fainted a second time when being transferred from a wheelchair to an exam room table. Patient was very tired and would be awakened & responsive when patient mom speaking to her, but faded in & out. 911 called & patient transported to hospital for hydration with IV fluids. |
| 1337765 | 5/21/2021 | MI | 14 | F | 5/20/2021 | 5/20/2021 | Patient fainted two minutes after receiving vaccine. Loss of consciousness was not total. Patient was pale, clammy, and lethargic. Patient's mother and myself held patient in place while she recovered in chair. Resolution was within 15 minutes from start of episode. Followed up with mother two and one-half hours post incident and mother said patient was completely recovered. |
| 1334739 | 5/20/2021 | MD | 14 | M | 5/13/2021 | 5/13/2021 | Patient has a history of fainting at needles, and he lost consciousness briefly immediately after injection. When he awoke, the patient said he felt "weird." EMT evaluated patient and administered a cold compress, water, and juice. Patient's uncle drove him home. completed the following: 5/14/21: 12:43pm - TC to mom who reports her son is doing fine. No problems or concerns. |

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| 1336009 | 5/20/2021 | CA | 42 | M | 5/20/2021 | 5/20/2021 | Within 10 minutes i felt clammy and light headed. I passed out in my chair. I awoke moments later to fellow patients and staff tending to me. They attempted to move me to a place to lay down. I immediately passed out again trying to stand. I woke up covered in sweat lying flat on the concrete. Staff and customers did not let me fall so no trauma. They called an ambulance. My bp dropped fo 88/50 in the ambulance with a pulse as low as 36bpm. Chills and uncontrollable shivers started about 30 minutes in and lasted for 2 hours. By 3pm I felt better. 2 bags of IV, chest x-ray, and blood work showed everything normal. Home now and will update my report if anything changes. Feeling much better as of 7pm. I belive they called it normal Sinus rhythm with sinus arrythmia |
| 1334872 | 5/20/2021 | LA | 15 | F | 5/20/2021 | 5/20/2021 | Fainted, blurred vision, ringing in the ear, 911 was contacted, EMT came and shortly ambulance, patient was taken away shortly |

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| 1334819 | 5/20/2021 | | | F | 4/30/2021 | 4/30/2021 | swollen right arm; rash in the right arm; she fainted; flu like symptoms; fever; tiredness; itchiness in the right arm; This spontaneous case was reported by a consumer and describes the occurrence of SYNCOPÉ (she fainted) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 039B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 30-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 30-Apr-2021, the patient experienced INFLUENZA LIKE ILLNESS (flu like symptoms), PYREXIA (fever) and FATIGUE (tiredness). On 03-May-2021, the patient experienced SYNCOPÉ (she fainted) (seriousness criterion medically significant). On 07-May-2021, the patient experienced VACCINATION SITE SWELLING (swollen right arm) and VACCINATION SITE RASH (rash in the right arm). On an unknown date, the patient experienced VACCINATION SITE PRURITUS (itchiness in the right arm). At the time of the report, SYNCOPÉ (she fainted), INFLUENZA LIKE ILLNESS (flu like symptoms), VACCINATION SITE PRURITUS (itchiness in the right arm), VACCINATION SITE SWELLING (swollen right arm), VACCINATION SITE RASH (rash in the right arm), PYREXIA (fever) and FATIGUE (tiredness) outcome was unknown. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No concomitant medication information was provided. No treatment medication information was provided. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |

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| 1334821 | 5/20/2021 | NJ | 25 | F | 4/7/2021 | 5/5/2021 | fainted; Can't do a lot,has been staying in bed; Dizzy; Aches and pains; Fever of 102.5 degrees; right arm soreness; Vomiting a little; very nauseous/nausea; Headache; Dry heaving; She can't drink a lot of liquids; Can't keep food down; This spontaneous case was reported by a consumer and describes the occurrence of SYNCOPE (fainted) in a 25-year-old patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 023b21 and 016b21a) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No medical history was provided by the reporter. Concomitant products included ETHINYLESTRADIOL, NORETHISTERONE ACETATE (JUNEL) and ISOTRETINOIN for an unknown indication. On 07-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 05-May-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 05-May-2021, the patient experienced FOOD INTOLERANCE (Can't keep food down), RETCHING (Dry heaving), DYSPHAGIA (She can't drink a lot of liquids), PAIN IN EXTREMITY (right arm soreness), VOMITING (Vomiting a little), NAUSEA (very nauseous/nausea) and HEADACHE (Headache). On 06-May-2021, the patient experienced SYNCOPE (fainted) (seriousness criterion medically significant), BEDRIDDEN (Can't do a lot,has been staying in bed), PAIN (Aches and pains), DIZZINESS (Dizzy) and PYREXIA (Fever of 102.5 degrees). On 05-May-2021, PAIN IN EXTREMITY (right arm soreness) had resolved. On 06-May-2021, SYNCOPE (fainted) and DIZZINESS (Dizzy) had resolved. On 07-May-2021, PYREXIA (Fever of 102.5 degrees) had resolved. At the time of the report, FOOD INTOLERANCE (Can't keep food down), BEDRIDDEN (Can't do a lot,has been staying in bed), RETCHING (Dry heaving), DYSPHAGIA (She can't drink a lot of liquids), PAIN (Aches and pains), VOMITING (Vomiting a little), NAUSEA (very nauseous/nausea) and HEADACHE (Headache) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 06-May-2021, Body temperature: 102.5 (High) 102.5 degree F. No treatment medication were received. Company Comment : Based on current available information and |

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the temporal association between product use and the start date of the events a causal relationship cannot be excluded.; Sender's Comments: Based on current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded.

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| 1334823 | 5/20/2021 | GA | 38 | F | 3/15/2021 | 4/16/2021 | fainted; Patient was dizzy; migraine; Patient had a panic attack before heading to the emergency room; fatigue; uncontrollable vomiting; temperature was 103; injection site pain; joint pain; Headache; neck pain; back pain; general body pain; This spontaneous case was reported by a non-health professional (subsequently medically confirmed) and describes the occurrence of SYNCOPE (fainted) in a 38-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 039A21AE and 031L20AE) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concomitant products included THYROID (ARMOUR THYROID) and ESCITALOPRAM OXALATE (LEXAPRO) for an unknown indication. On 15-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 16-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 16-Apr-2021, the patient experienced NECK PAIN (neck pain), BACK PAIN (back pain), PAIN (general body pain), VACCINATION SITE PAIN (injection site pain), ARTHRALGIA (joint pain) and HEADACHE (Headache). On 17-Apr-2021, the patient experienced SYNCOPE (fainted) (seriousness criterion medically significant), DIZZINESS (Patient was dizzy), MIGRAINE (migraine), PANIC ATTACK (Patient had a panic attack before heading to the emergency room), FATIGUE (fatigue), VOMITING (uncontrollable vomiting) and PYREXIA (temperature was 103, high temperature). On 17-Apr-2021, SYNCOPE (fainted) had resolved. At the time of the report, DIZZINESS (Patient was dizzy), MIGRAINE (migraine), PANIC ATTACK (Patient had a panic attack before heading to the emergency room), NECK PAIN (neck pain), BACK PAIN (back pain), PAIN (general body pain), FATIGUE (fatigue), VOMITING (uncontrollable vomiting), PYREXIA (temperature was 103, high temperature), VACCINATION SITE PAIN (injection site pain), ARTHRALGIA (joint pain) and HEADACHE (Headache) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 17-Apr-2021, Body temperature: 103 (High) 103. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Treatment included Imitrex, |

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Tylenol, Steroids, Benadryl, Zofran, and Morphine.
Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

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| 1334834 | 5/20/2021 | WV | 67 | F | 4/3/2021 | 4/3/2021 | <p>Caller stated his wife passed out and hit her head on the floor; hit her head on the floor and split it open; transferred to hospital due to cardiac complications; fall; His wife passed away; This spontaneous case was reported by a patient family member or friend (subsequently medically confirmed) and describes the occurrence of DEATH (His wife passed away), LOSS OF CONSCIOUSNESS (Caller stated his wife passed out and hit her head on the floor), SKULL FRACTURE (hit her head on the floor and split it open), CARDIAC DISORDER (transferred to hospital due to cardiac complications) and FALL (fall) in a 67-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 03-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 03-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (Caller stated his wife passed out and hit her head on the floor) (seriousness criteria hospitalization and medically significant), SKULL FRACTURE (hit her head on the floor and split it open) (seriousness criteria hospitalization and medically significant), CARDIAC DISORDER (transferred to hospital due to cardiac complications) (seriousness criterion hospitalization) and FALL (fall) (seriousness criterion hospitalization). On 04-Apr-2021, LOSS OF CONSCIOUSNESS (Caller stated his wife passed out and hit her head on the floor), SKULL FRACTURE (hit her head on the floor and split it open), CARDIAC DISORDER (transferred to hospital due to cardiac complications) and FALL (fall) outcome was unknown. The patient died on 04-Apr-2021. The cause of death was not reported. It is unknown if an autopsy was performed. Concomitant product use was not provided by the reporter. Treatment information was not provided. On 03 Apr 2021, the reporter stated approximately 45 minutes after receiving the COVID-19 vaccine, the patient passed out in the parking lot and hit her head on the floor which caused it to split open. The patient was taken to a hospital but had to be transferred to another hospital after experiencing cardiac complications. On 04 Apr 2021 at 4:00 am, the patient passed away. Very limited information regarding this events has been provided at this time. Further</p> |

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| 1334861 | 5/20/2021 | MI | 30 | M | 5/18/2021 | 5/18/2021 | information has been requested.; Sender's Comments: Very limited information regarding this events has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Unknown cause of death |
| 1334878 | 5/20/2021 | NC | 17 | M | 5/20/2021 | 5/1/2021 | The patient received their vaccination and before my immunizing technician could apply his bandaid he fell straight back while seated in his chair. She was able to catch his fall and lie him on the ground. I went into the immunization room to assist immediately and he was apologizing for scaring. I asked him to lie there for a few minutes and take some deep breaths. He was talking and aware of his surroundings. I asked him about his medication history which was null. I asked him if he had been nervous and he said he didn't think so. She said that he did mention he did not like needles. He had not eaten since the morning (a bage!) and it was late in the afternoon. After a few minutes I asked him if he would like to sit up so I could see how he was doing. Management arrived and observed while I went to get a cold cloth for his neck/face. Management asked him if he would like to sit in a chair. He sat in a chair and before I came back after just a few minutes, he had slumped over to the side with his eyes rolling back. Management was concerned so they immediately called 911. fire department and EMS arrived. They tested his blood pressure, etc and said they believed he had just passed out. They asked him if he wanted to go to the hospital. He declined. He called a family member to pick him up who arrived about 45 minutes after his vaccination. He was walking around and coherent when he left. |

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| 1334890 | 5/20/2021 | WI | 13 | F | 5/20/2021 | 5/20/2021 | Patient fainted while doing IM COVID injection. RN called another staff to assist lowering patient to ground and elevating feet. Patient felt better after laying down. Nursing staff took vitals (supine), which were BP - 118/84, SPO2 - 97%, pulse - 48. Patient rested for a while, taking some deep breaths and putting an ice pack on the back of her neck. After approx. five minutes staff helped patient to a seated position and re-took vitals which were 122/80, SPO2 - 99%, pulse - 57. Patient drank some water and was observed for approx. 30 minutes following injection, stating she "felt better". |
| 1334912 | 5/20/2021 | MI | 22 | M | 5/20/2021 | 5/20/2021 | Patient received the vaccine and proceeded to walk to the front of the store. He describes the experience as his ears stopped hearing and he fell to his knees (passed out). Patient did not report that he had been hurt in any way. He came back to the pharmacy where we had him sit with his legs up. He already had a bottle of water and was drinking. Patient's blood pressure was a bit elevated 139/104. He declined a second blood pressure check. He stayed waiting for approximately 15 minutes then felt well enough to leave. |
| 1334928 | 5/20/2021 | CA | 16 | F | 5/20/2021 | 5/20/2021 | Patient experienced fainting symptoms immediately after administration of vaccine. Further investigation showed patient had low blood pressure 73/57 mm Hg. |

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| 1334945 | 5/20/2021 | CA | 16 | F | 4/30/2021 | 4/30/2021 | Fainted; Didn't know if it was a convulsion or a seizure; Shaking; was very anxious; This is a spontaneous report from two contactable pharmacists. A 16-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EW0167, expiry date: Aug2021), via an unspecified route of administration, administered in the left deltoid, on 30Apr2021 15:30, as 1st dose, single, for COVID-19 immunisation, at a pharmacy/drug store. There were no medical history and concomitant medications. On 30Apr2021 15:30, the patient received the first dose of the COVID-19 vaccine and was very anxious. She wanted her mom to be present. On the same day, 30Apr2021 15:35, five minutes later, the patient was shaking, and she fainted. The reporter did not know if she was having a convulsion or a seizure. A few minutes later, the patient was sitting and becoming more alert. The patient was given water and one dose of Benadryl. The patient's vital signs were checked (unknown result). The reporter talked to the patient's mother and contacted the patient's pediatrician. The events resulted to emergency room and physician's office visits. Later in the evening, the reporter followed up with the mother and she confirmed that the patient was doing well and better. The mother asked the reporter if the patient should get the second dose of the COVID-19 vaccine. The outcome of the events fainted, shaking, "didn't know if it was a convulsion or a seizure" and "was very anxious" was recovering. The reporter assessed the events fainted, shaking, "didn't know if it was a convulsion or a seizure" as serious (medically significant). The reporter considered that BNT162B2 has a causal effect to the adverse events. Follow-up (18May2021: New information received from a contactable pharmacist includes: reporter information, lab data, suspect drug details (vaccination site and vaccination time), event details (onset time provided, outcome updated to recovering, causality and seriousness assessment provided). Follow up attempts are completed. No further information is expected.; Sender's Comments: Based on the available information, and on a reportedly closed temporal association, the company assessed that a reasonable possibility could not be excluded that the reported events (fainted; didn't know if it was a convulsion or a seizure) were related to the suspect product BNT162b2 (PFIZER-BIONTECH |

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COVID-19 VACCINE). The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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| 1335954 | 5/20/2021 | IL | 46 | F | 2/4/2021 | 2/4/2021 | Loss of consciousness; Hyperhidrosis; Panic attack; Nausea; Vomiting; This case was received via FDA VAERS (Reference number: 1005525) on 11-May-2021 and was forwarded to Moderna on 11-May-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of LOSS OF CONSCIOUSNESS (Loss of consciousness) in a 46-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 029L20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 04-Feb-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 04-Feb-2021, the patient experienced LOSS OF CONSCIOUSNESS (Loss of consciousness) (seriousness criterion medically significant), HYPERHIDROSIS (Hyperhidrosis), PANIC ATTACK (Panic attack), NAUSEA (Nausea) and VOMITING (Vomiting). At the time of the report, LOSS OF CONSCIOUSNESS (Loss of consciousness), HYPERHIDROSIS (Hyperhidrosis), PANIC ATTACK (Panic attack), NAUSEA (Nausea) and VOMITING (Vomiting) outcome was unknown. Concomitant product use was not provided by the reporter. Treatment information was not provided. It was reported that the patient became nauseous and started vomiting approximately 20 minutes after the vaccine. She initially refused to go to the emergency room by ambulance. The vomiting continued and she then passed out and became diaphoretic. 911 was called and she was transported to the emergency room and tests were being ran. She said they did not feel it was vaccine related. Based on the current available information and temporal association between the use of the product and the events, a causal relationship cannot be excluded, although the events are likely related to the act of being injected rather than the vaccine itself |

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| 1335983 | 5/20/2021 | VA | 29 | M | 5/20/2021 | 5/20/2021 | PATIENT FAINTED IN THE OBSERVATION CHAIR ABOUT 10 MINUTES AFTER RECEIVING THE J & J COVID -19 VACCINE. HE FELL OUT OF THE CHAIR BUT WAS NOT SERIOUSLY INJURED, HE MAY HAVE BUMPED HIS MOUTH. THE PHARMACY TECHNICIAN IMMEDIATELY HELPED HIM UP BACK TO HIS CHAIR AND GAVE HIM A BOTTLE OF WATER. SHE ALSO CHECKED HIS BLOOD PRESSURE (NOW AT 136/94). I CALLED 911 BUT HE DECLINED ANY ADDITIONAL ASSISTANCE SO I TOLD THEM TO CANCEL. WE ASKED HIM TO WAIT AN ADDITIONAL 5-10 MINUTES AND HE WAS FINE. HE LEFT ON HIM OWN ACCORD. I TOLD HIM THAT HE MAY RECEIVE A CALL FROM US AS A FOLLOW UP TO THE EVENT. |
| 1334628 | 5/20/2021 | ID | 20 | F | 5/19/2021 | 5/19/2021 | Patient had a vasovagal response and fainted a few minutes after her injection. She was unconscious, not breathing for a few seconds as her head fell to her chest, but resumed breathing when we opened her airways. Her body seized upon taking in air and 911 was called. She regained consciousness before the paramedics arrived and her vitals were within normal limits when they checked her. Pt went home on her own with mom. |
| 1335982 | 5/20/2021 | MT | 14 | M | 5/20/2021 | 5/20/2021 | PATIENT PASSED OUT WHILE STANDING AND HIT HEAD. ELEVATED FEET AND PARAMEDICS CAME AND CHECKED ON HIM, BUT HE FELT FINE AND WENT HOME |
| 1333383 | 5/20/2021 | CA | 24 | F | 5/20/2021 | 5/20/2021 | client stated feeling dizzy few seconds after injection and had vasovagal response and passed out for approx 3 seconds, v/s remained stable, client required no further treatment, observed for a total of 35 mins, client states feeling better after 5 mins. left facility in stable condition, ambulating w/o assist, accompanied by mother (who also received injection w/o incident) |
| 1334703 | 5/20/2021 | OR | 14 | F | 5/17/2021 | 5/17/2021 | Vaccine Administered: Pfizer COVID-19 Patient reaction: Flushing Pale Skin Nausea/Vomiting Fainting Dizziness Action taken: Antihistamine given. Outcome: Patient recovered. Late charting for 5/17/2021 - 5ml Diphenhydramine given PO 10 minute after c19 vaccine - patient dizzy, diaphoretic, and nauseous. Emergency medication entered and signed. |

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| 1333213 | 5/20/2021 | CA | 14 | M | 5/19/2021 | 5/19/2021 | Pfizer vaccine given 5/20/2021 Per mom/ pt the shot was given at 11:02 around 11:07 he leaned forward and became unresponsive. He was slightly drooling from the mouth. Mom says that his body was tight and that he was shaking a little. His eyes were closed and did not appear to be rolling back in his head. This episode lasted for less than 1 minute. He did not remember what happened and thought he wet himself after; which he did not. About 1-2 min after that episode mom states that he appeared to "passed out" for less than a minute. The ambulance was called and he was taken to hospital. He was evaluated and appeared well at that time. No fever. EKG was done and per pt it was normal. No EEG was done. He was discharged without admit That evening he has multiple episodes of vomiting > 10 times. No diarrhea or fever. Seen today at medical office for follow up. Vaccine not given at our clinic |

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| 1333218 | 5/20/2021 | PA | 71 | M | 2/24/2021 | 3/19/2021 | ED, Discharged , 3/13/2021 (4 hours), Hospital ED, MD Last attending o Treatment team Shortness of breath +1 more Clinical impression Chest Pain o Shortness of Breath o Dizziness Chief complaint, Patient presents with o Chest Pain, o Shortness of Breath o Dizziness. History of Present Illness , Patient is a 71 yr.. male with Hx of stage IIICM Metastatic Adenocarcinoma of the sigmoid Colon, Coronary disease, Hypertension, Dyslipidemia, Chronic Renal insufficiency, presenting to the ED with chest pain. Patient notes that he woke up this morning with pain in the right side of the chest with some associated shortness of breath. Notes symptoms. Additional information for Item 18: Notes symptoms are worse when he is up trying to exert himself and gets incredibly short of breath and fatigued. States he tried to do some workout in the garage but was unable. Denies chest pain worsening with exertion, but has been fairly constant since it began. Reports it is a dull ache. Pain is dissimilar from his previous heart attack. States he has had a mild cough, but no significant production. Denies any fevers, chills. No abnormal nausea or vomiting other than typical chemo induced side effects. Given continued issues, decided to come in for further evaluation. Review of Systems; Constitutional: Positive for fatigue. Negative for appetite change, chills, diaphoresis and fever. HENT: Negative for sore throat. Eyes: Negative for visual disturbance. Respiratory: Positive for cough and shortness of breath. Negative for choking and chest tightness. Cardiovascular: Positive for chest pain. Negative for palpitations and leg swelling. Gastrointestinal: Positive for nausea and vomiting. Negative for abdominal pain and diarrhea. Genitourinary: Negative for dysuria. Musculoskeletal: Negative for back pain and neck pain. Skin: Negative for rash. Neurological: Positive for light-headedness. Negative for seizures, syncope, numbness and headaches. ED to Hosp-Admission, Discharged, 4/5/2021 - 4/25/2021 (20 days) Hospital, MD, Last attending Treatment team Sepsis, due to unspecified organism, unspecified whether acute organ dysfunction present. Principal problem Discharge Summary, DO (Physician), Inpatient Discharge Summary; BRIEF OVERVIEW; MD, Discharge Provider: DO, Primary Care Physician at Discharge: MD, Admission Date: 4/5/2021, Discharge Date: 4/25/2021. Discharge Diagnosis; Medical Problems ;Hospital |

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Problems; POA, (Principal) Sepsis, due to unspecified organism, unspecified whether acute organ dysfunction present, Yes, Essential hypertension Yes, Chemotherapy-induced peripheral neuropathy, Yes. Overview Signed 5/10/2019 2:03 PM by MD, Pins and needles and numbness in tips of finger and toes, Lung metastasis Yes. Hypoxia Yes. COVID-19 Unknown, Acute respiratory failure with hypoxia Yes, Palliative care encounter Not Applicable, Declining functional status No. DETAILS OF HOSPITAL STAY; Presenting Problem/History of Present Illness/Reason for Admission, Sepsis, due to unspecified organism, unspecified whether acute organ dysfunction present. Acute hypoxemic respiratory failure due to COVID-19, Respiratory failure. Sigmoid perforation with abscess. Hospital Course; 71-year-old male prolonged admission for acute hypoxic respiratory failure secondary to COVID-19. No history of colorectal adenocarcinoma with lung mets. Prior resection of bowel, prior chemotherapy. Required management in the ICU due to worsening respiratory failure over the time that he has been admitted to Hospital (20 days). He had remained on BiPAP therapy throughout that time, received appropriate corticosteroids, and antiviral therapies. Approximately 1-1/2 weeks ago he began to develop mild left lower quadrant abdominal pain. In the last 48 hours this is significantly worsened. CT abdomen and pelvis was obtained on Friday, which displayed pneumoperitoneum, sigmoid abscess with sigmoid perforation. There is a prior anastomotic site distal to this. Given his overall complexity he was to be medically managed to avoid the need for OR and intubation. He did well through the initial 24 hours of IV antibiotics, fluids and bowel rest. This afternoon he became increasingly dyspneic, required implementing nonrebreather mask, and subsequently developed severe rigors, tachycardia. I obtained a stat follow-up CT scan which shows similar findings of free air within the abdomen. Given signs of impending sepsis, BiPAP therapy was initiated, bolus IV fluids were given. Blood gas, blood counts, lactic acid are pending. He is receiving empiric Zosyn. I discussed this with general surgery, whom is well-known to the patient. In agreement the patient likely needs surgical intervention. However given his overall complexity and in light of the fact that this area surrounds the ureter, and

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we do not have urology coverage. It was felt he was most appropriate to be managed in Hospital. Case was discussed with Dr. at Hospital, patient will be transferred there via air transit. At this time his blood pressure appears stable, he is tachycardia, is currently on BIPAP which will be transitioned to CPAP for transport. He has received several doses of Dilaudid, for improved pain control. No further advancement of airway was performed prior to discharge. Case was discussed with family at length, all risks and benefits of transfer were discussed with wife and patient. It is recommended to involve pulmonary critical care services including surgical ICU care as if requiring surgery he is high likelihood for prolonged vent needs. Operative Procedures Performed: Treatments: See above; Procedures: Na Consults: pulmonary/intensive care and general surgery. Pertinent Test Results: CT abdomen pelvis with contrast [3279871876] (Abnormal) Resulted: 04/25/21 1811. Order Status: Completed Updated: 04/25/21 1812. Narrative: PROCEDURE INFORMATION: Exam: CT Abdomen And Pelvis With Contrast, Exam date and time: 4/25/2021 17:36, Age: 71 years old, Clinical indication: Abdominal pain; Additional info: Sepsis, bowel perf. HX of Covid19 +, malignant colon with lung metastasis. Bowel perf. TECHNIQUE: Imaging protocol: Computed tomography of the abdomen and pelvis with contrast. Radiation optimization: All CT scans at this facility use at least one of these dose optimization techniques: automated exposure control; mA and/or kV adjustment per patient size (includes targeted exams where dose is matched to clinical indication); or iterative reconstruction. Contrast material: 350 OMNI; Contrast volume: 80 ml; Contrast route: INTRAVENOUS (IV); COMPARISON: CT ABDOMEN PELVIS W CONTRAST 4/23/2021 16:46, FINDINGS: Tubes, catheters and devices: Catheter terminates in the right atrium in satisfactory position. Lungs: Moderate airspace opacities throughout the lung bases are similar to prior and consistent with Multilobar pneumonia consistent with the history. Liver: No hepatic masses. Gallbladder and bile ducts: Cholelithiasis. Pancreas: No ductal dilation. No masses. Spleen: No splenomegaly or focal lesions. Adrenal glands: No mass. Kidneys and ureters: 10 mm benign left renal cyst, no follow-up necessary. No renal masses or Hydronephrosis bilaterally. Stomach and bowel: Redemonstration of

perforated proximal sigmoid diverticulitis. Small pneumoperitoneum is stable. Predominantly gas containing, 25 x 28 mm collection adjacent to the inflamed sigmoid colon similar to prior; a fistulous tract extends toward the midline containing gas and fluid, with suspected fistula to adjacent loops of small bowel. Moderate to severe descending and sigmoid diverticular burden. Minor right diverticular burden. No small bowel obstruction. A somewhat clumped appearance of small bowel in the right lower quadrant near the colon enteric fistula. Appendix: No evidence of appendicitis. Intraabdominal space: Mesenteric edema around the small bowel, slightly increased, however no new mesenteric collection. There is no extravasation of enteric contrast into the collection adjacent to the sigmoid colon. Vasculature: Mild aortoiliac atherosclerosis. Lymph nodes: No significantly enlarged lymph nodes. Urinary bladder: Unremarkable as visualized. Reproductive: Unremarkable as visualized. Bones/joints: Degenerative changes in the spine. Multilevel disc space narrowing. Multilevel central canal and neuroforaminal stenosis in the lumbar spine. No acute fracture or subluxation. Soft tissues: Small fat-containing right inguinal hernia. Small fat-containing left inguinal hernia. Large ventral abdominal hernia containing gas, which has replaced the previous contents of fat and bowel loops. Volume increased compared to prior. IMPRESSION: 1. Redemonstration of perforated proximal sigmoid diverticulitis. Small pneumoperitoneum is stable. 2. Similar perisigmoid collection; colon enteric fistula, probably at least subacute in duration. The perisigmoid collection is prominently gaseous and there is no frank abscess. 3. Suspected mild enteritis the small bowel loops or loops associated with the fistula. No obstruction. 4. Additional findings as described are similar to recent prior imaging. COMMENTS: Any incidental renal lesion less than 1 cm or classified as too small to characterize, or any incidental cystic renal lesion characterized as simple-appearing, is likely benign. No follow-up imaging is recommended for these lesions per consensus recommendations based on imaging criteria. THIS DOCUMENT HAS BEEN ELECTRONICALLY SIGNED BY MD, CT abdomen pelvis with contrast (Abnormal) Resulted: 04/23/21 1804, Order Status: Completed Updated: 04/23/21 1804, Addenda: THIS

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REPORT CONTAINS FINDINGS THAT MAY BE CRITICAL TO PATIENT CARE. The findings were verbally communicated via telephone conference with RN at 6:03 PM EDT on 4/23/2021. The findings were acknowledged and understood. THIS DOCUMENT HAS BEEN ELECTRONICALLY SIGNED BY MD Signed: 04/23/21 1804 by, MD. Narrative: PROCEDURE INFORMATION: Exam: CT Abdomen And Pelvis With Contrast, Exam date and time: 4/23/2021 4:42 PM, Age: 71 years old Clinical indication: Abdominal pain; Localized; Left; Additional info: HX of colon cancer. Worsening left sided abdominal pain. HX of colon cancer. Worsening left sided abdominal pain. TECHNIQUE: Imaging protocol: Computed tomography of the abdomen and pelvis with contrast. Radiation optimization: All CT scans at this facility use at least one of these dose optimization techniques: automated exposure control; mA and/or kV adjustment per patient size (includes targeted exams where dose is matched to clinical indication); or iterative reconstruction. Contrast material: OMNIPAQUE 350; Contrast volume: 80 ml; Contrast route: INTRAVENOUS (IV); Other contrast: Oral, omnipaque 12mg premixed solution, 500mL pt unable to drink 1000mL; COMPARISON: 1. CT ABDOMEN PELVIS W CONTRAST 2/12/2021 11:06 AM, 2. CT ABDOMEN PELVIS W CONTRAST 11/13/2020 11:42:26 AM, 3. CT ABDOMEN PELVIS W CONTRAST 8/24/2020 10:14:40 AM, FINDINGS: Lungs: Bilateral lower lung consolidation. Liver: No mass. Gallbladder and bile ducts: Cholelithiasis, no biliary ductal dilatation. Pancreas: Normal. No ductal dilation. Spleen: Normal. No splenomegaly. Adrenal glands: Normal. No mass. Kidneys and ureters: Normal. No hydronephrosis. Stomach and bowel: Collection of fluid and gas adjacent to the proximal sigmoid colon where there are multiple diverticuli, extraluminal gas arises from a proximal sigmoid perforation which is proximal to the sigmoid anastomosis. No bowel obstruction, no wall thickening at the anastomosis. Appendix: No evidence of appendicitis. Intrapertitoneal space: Pneumoperitoneum. Small collection of fluid and gas in the left pelvis and left lower abdomen, maximum short axis diameter approximately 2 cm, arising from the proximal sigmoid colon. Vasculature: No abdominal aortic aneurysm. Lymph nodes: No significant adenopathy. Urinary bladder: Unremarkable

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as visualized. Reproductive: Unremarkable as visualized.
Bones/joints: No acute findings. Soft tissues: Ventral hernia containing bowel without entrapment.
IMPRESSION: Perforated diverticulitis, small pericolic abscess; the sigmoid perforation is proximal to the sigmoid anastomosis. Physical Exam at Discharge; Heart Rate: (!) 131, Resp: (!) 42, BP: (!) 168/92 Temperature: 37.1 °C (98.7 °F) Weight: 107 kg (236 lb. 12.4 oz.), General appearance: alert, appears stated age, cooperative, severe distress and morbidly obese, Head: Normocephalic, without obvious abnormality, atraumatic, Neck: supple, symmetrical, trachea midline and thyroid not enlarged, symmetric, no tenderness/mass/nodules. Lungs: retractions and diminished breath sounds Heart: tachycardia, RR. Abdomen: Distended significantly tender in the left lower quadrant with guarding throughout. Extremities: Trace pretibial, Skin: Skin color, texture, turgor normal. No rashes or lesions or Ecchymosis areas throughout upper extremities. Neurologic: Alert and oriented X 3, no focal deficit. Discharge Instructions; Condition at Discharge, Discharge Condition: critical. Admission, Discharged 4/25/2021 - 5/1/2021 (6 days) Hospital, MD, Last attending Treatment team Respiratory failure, acute. Principal problem, Discharge Summary MD (Resident) Cosigned by: MD at 5/18/2021 1:24 PM; Final Summary for Deceased Patient, BRIEF OVERVIEW; Admitting Provider: MD; Discharge Provider: MD Primary Care Physician at Discharge: MD Admission Date: 4/25/2021, Discharge Date: 5/1/2021, Final Diagnosis, Principal Problem: Respiratory failure, acute. Active Problems: Malignant neoplasm of sigmoid colon. Sepsis, due to unspecified organism, unspecified whether acute organ dysfunction present COVID-19. Perforated viscus. DETAILS OF HOSPITAL STAY Presenting Problem/History of Present Illness/Reason for Admission Respiratory failure, acute, Hospital Course; Patient is a 71 yr.. male with history of metastatic colorectal adenocarcinoma with lung metastases, prior bowel resection and chemotherapy. The patient initially tested positive for Covid in early March. His symptoms at that time are mild and resolved. He was later vaccinated and that month. He started having severe symptoms again on 4/3 for which he presented to Hospital. Since that time, he has received full course of Remdesivir and steroids.

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He had a CT scan performed on 4/23 which revealed pneumoperitoneum secondary to presumed perforated sigmoid diverticulitis with focal sigmoid abscess. Patient was weaned down to minimal nasal cannula settings but somewhat suddenly earlier on 4/25 patient had increased work of breathing, became tachycardia, and had rigors. Hospital ordered repeat CT scan which showed similar findings in the abdomen. Patient had been maintained on Zosyn. Repeat labs were sent which were largely unremarkable. Given concerns for worsening sepsis and potential need for surgery, he was subsequently transferred Hospital. On admission to hospital, he had a normal lactic acid and no leukocytosis. He did not have evidence of peritonitis. The decision was made to treat his diverticulitis conservatively. However, early on 4/26 the patient started to develop a lactic acidosis. An extensive discussion was had with the patient and his wife regarding surgery and the possibility the patient may never be able to separate from the vent given his worsening Covid pneumonia. The patient elected to undergo an exploratory laparotomy with with segmental resection of distal descending and loop transverse colostomy. However, as the days progressed the patient had worsening respiratory status that required deep sedation, paralytics and proning all of which were unsuccessful in maintaining his oxygen saturation greater than 88%. His wife, knowing that he would not want to have a prolonged course on the ventilator, elected for transition to palliative extubating with comfort care on 4/30 and the patient expired roughly 10 minutes after extubation.

1333281 5/20/2021 NY

33 F

4/6/2021

4/6/2021 When vaccine was administered, 4/6/21 - I passed out. Within 24 hours - i was vomiting and had severe nausea. I had extremely bad headaches that went away for 2 days then started up again extremely bad the Monday (4/12/21) after my vaccine. Visited my primary care doctor on Wednesday (4/14) as they wouldnt go away. advised to take motrin. On friday (4/17) they still had not gone away and went to Urgent care due to fear since the vaccine had been pulled for preventative measures. they did blood work and advised to take some decongestants as the weather had been strange (Snow and 80degrees in the same week) that helped.

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| 1333283 | 5/20/2021 | | 17 | F | 5/19/2021 | 5/19/2021 | While waiting for 15 mins monitoring after getting Pfizer covid vaccine, she fainted and fell off the chair. She fell on the ground and hit her head. Nurse and pharmacy staff rushed to her aid. She appeared to have convulsions for about a couple seconds but regained consciousness right away. We checked vital signs : low blood pressure but high heart rate, oxygen level was good. We placed ice pack on her head where said was hurting. She and her mother refused to call 911. She felt better, however we recommended her mom to take her to urgent care for further evaluations |
| 1333319 | 5/20/2021 | MA | 15 | F | 5/19/2021 | 5/19/2021 | Patient received vaccine and while walking around the store began to feel lightheaded/dizzy and fainted. Her parent caught her and brought her to the ground where she began to have a seizure. Paramedics were called and took over care of the patient. She was conscious and breathing after her seizure |
| 1333323 | 5/20/2021 | IA | 23 | M | 5/14/2021 | 5/14/2021 | Patient received the Janssen vaccine. Less than 1 minute after receiving the vaccine, passed out and had seizure like activity for 10 sec. When he fell, his hit the right side of his head. When he came to, he knew where he was. Ambulance was called, he refused to go to the hospital. BP was 138/78 and pulse was in the 60's. Leading up to passing out, reported that he felt warm, then passed out. After waking up and coming to, he was feeling better. |
| 1333196 | 5/20/2021 | MI | 21 | M | 5/14/2021 | 5/14/2021 | Patient had a bout of syncope without warning. He awoke less than 3 minutes later disoriented. He felt light-headed and nauseous for several minutes and vomited but produced nothing substantial. Patient was monitored for 30 minutes and felt tired and light-headed for most of that time. He recovered fully and left of his own accord. |
| 1333375 | 5/20/2021 | PA | 16 | F | 5/20/2021 | 5/20/2021 | pt began to fill light headed about 5 minutes after vaccination. She then had some vomiting. The room was very warm. She was a little diaphoretic. The vomiting happened about 3 times then subsided. Patients color came back. She sat for a few additional minutes. Drank some water and left clinic completely stable. She has had a history of fainting with heat and with injections. |

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| 1333176 | 5/20/2021 | CA | 49 | M | 5/20/2021 | 5/20/2021 | Pt was sitting in post-vaccinating area after a covid shot. Suddenly he felt his heart racing, started hearing noises, feeling dizziness, and he passed out briefly. |
| 1333440 | 5/20/2021 | NY | 13 | F | 5/20/2021 | 5/20/2021 | 5 minutes after vaccine patient started feeling dizzy and fainted, while body was shaking for 20 seconds. Body then regained consciousness |
| 1333471 | 5/20/2021 | SC | 18 | F | 5/19/2021 | 5/19/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Exhaustion / Lethargy-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium |
| 1333487 | 5/20/2021 | FL | 13 | M | 5/19/2021 | 5/19/2021 | BP 102/60, P 70, O2Sat 98%. As client walking to the observation room he passed out for a few seconds. Complained of dizziness. Assisted with ENT to observation. Stabilized after few minutes. |
| 1333504 | 5/20/2021 | FL | 18 | M | 5/19/2021 | 5/19/2021 | Systemic: Fainting / Unresponsive-Mild |
| 1333516 | 5/20/2021 | MO | 18 | M | 5/19/2021 | 5/19/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: "passed out" but was never unresponsive - said he felt very faint while sitting in the observation chair-Mild, Systemic: Flushed / Sweating-Mild, Additional Details: BP and HR were normal for pt. - he laid on the floor for ~10-15 minutes and then stayed seated for additional time and had someone come pick him up as he didn't feel comfortable driving. He stated he hadn't eaten anything this mornign before coming to recieve the immunization - he felt fine by the time he left and we checked in with him later in the day and he was still feeling fine |
| 1333547 | 5/20/2021 | PA | 20 | M | 5/16/2021 | 5/16/2021 | Systemic: Fainting / Unresponsive-Severe |

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| 1333554 | 5/20/2021 | IA | 25 | M | 5/19/2021 | 5/19/2021 | Systemic: Fainting / Unresponsive-Medium, Additional Details: lost consciousness during his 15 min wait (while he was sitting). Bumped his head. I immediately got his legs elevated and put something under his head. He regained consciousness within a minute, but I had him remain on the ground. The pharmacy tech called 911 right away. EMT services arrived within 10 minutes, although patient was persistent about wanting to leave on his own as he stated he regularly passes out with needles and has in the past as well. Emt evaluated him and let him leave. |
| 1333355 | 5/20/2021 | MA | 32 | M | 5/20/2021 | 5/20/2021 | Patient fainted after vaccination while he was seated during the 15 minute observation window. Patient quickly recovered (less than 1 minute) but was feeling cold and clammy. Patient was given water to rehydrate and stay seated for observation; Pt did not require EMS to be called as he recovered quickly on his own. Patient left with his friends when he recovered. A follow-up phone call to the patient was made a few hours after vaccination and patient was doing well. Patient instructed to rest up and contact MD if needed. |

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| 1332743 | 5/20/2021 | NC | 17 | M | 4/15/2021 | 4/1/2021 | Fainted; Dizziness; Sweaty palms; Heart rate dropped; Weird burning sensation in the back of his neck with tension; Weird burning sensation in the back of his neck with tension; Disorientated; Lost his color; Weird sensation in throat; Headache; Had pressure in his ears; Gassy; This is a spontaneous report from a contactable consumer (mother of the patient). A 17-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: ER8731; Expiration date was not reported) on 15Apr2021 (15:00) as a single dose, with route of administration unspecified, for COVID-19 immunization at the clinic (not a military facility). The patient had no relevant medical history and concomitant medications. On 15Apr2021, after the first dose of vaccination, the patient had fainted; dizziness; sweaty palms; heart rate has dropped; had weird burning sensation at the back of the neck with tension; was disorientated; and had lost his color. In Apr2021, the patient had weird sensation in the throat; headache; had pressure in his ears; and was gassy. The outcome of the events was unknown for 'lost his color'; was not recovered for 'headache'; and was recovered on an unspecified date in 2021 for all the other events. Information on lot/batch number was available. Additional information has been requested. |

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| 1332356 | 5/20/2021 | CA | 47 | M | 5/1/2021 | | <p>GUILLAIN-BARRE SYNDROME; PASSED OUT; This spontaneous report received from a patient via a Regulatory Authority Vaccine Adverse Event Reporting System (VAERS) concerned a 35 year old female of unknown ethnicity. The patient's height, and weight were not reported. The patient's past medical history included thrombocytopenia, and concurrent conditions included congestive heart failure, hypertension, diabetes type 2, atrial fibrillation, and sustained ventricular tachycardia, and patient had no known allergies. Patient had no current illnesses at the time of vaccination. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: Unknown) dose was not reported, 1 total administered on the left arm 02-APR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 02-APR-2021, the patient started to get lethargic. Two weeks into the shot, it was getting hard to walk and he started falling at work. The patient was out of work for a week, and couldn't get up by himself anymore, and he had to get a cane. On 28-APR-2021, he went to the doctor again with no results. On 01-MAY-2021, the patient passed out and was not able to get up. On 02-MAY-2021, the patient went to the emergency room and had a spinal tap and was diagnosed with Guillain-Barre Syndrome (also conflictingly reported as developing Guillain-Barre Syndrome on 07-MAY-2021). The patient was hospitalized from 02-MAY-2021 to 07-MAY-2021 (also conflictingly reported as hospitalized for 6 days). The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from passed out and had not recovered from Guillain-Barre Syndrome (unable to get up, unable to walk, stumbling, pain, could not get up, started falling, falling at work, lethargic). This report was serious (Hospitalization Caused / Prolonged and Other Medically Important Condition).; Sender's Comments: V0 : 20210520943- COVID-19 VACCINE AD26.CO2.S - Guillain-Barre Syndrome, Passed out. This events are considered unassessable. The events has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the events.</p> |

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| 1332366 | 5/20/2021 | KY | | F | | 5/12/2021 | ARM FROM SHOULDER TO PINKY FINGER HURTS IF SOMETHING TOUCHES IT; FEELS IRRITATED; FEELS LIKE NERVE DAMAGE; FEELS LIKE THE HAIR ON ARMS HURT; PASSED OUT TWICE; SUNBURN LIKE FEELING IN VACCINE INJECTION ARM WITH NO REDNESS OR RASH; SEVERE STOMACH ISSUES FOR A WEEK; This spontaneous report received from a patient concerned a female of unspecified age. The patient's height, and weight were not reported. The patient's pre-existing medical conditions included patient donated blood and passed out twice. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, administered on 08-APR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. 4 days later, the patient donated blood and for the first time ever, passed out twice. The patient had severe stomach issues for about a week but that have resolved. The patient's arm that she received the vaccine in, felt like a sunburn- no redness, rash or swelling. The patient's arm didn't hurt unless something is touching it. It was not hot to the touch but felt very strange and very sensitive from her shoulder all the way to the tip of her pinky finger on the outer portion of arm. It was very sensitive even when washing the hands. The patient mentioned that it felt like nerves have been damaged. It felt like hair on arm hurt. It felt irritated. The caller mentioned that her daughter got the vaccine the same day and experienced the same thing but didn't last as long-maybe a couple of days and it was gone. On an unspecified date, the patient felt like passed out twice, sunburn but no redness, no rash and it started from the shoulder to pinky finger (coded as sunburn like feeling in vaccine injection arm with no redness or rash), arm from shoulder to pinky finger hurts if something touches it, feels irritated, feels like nerve damage and feels like the hair on arms hurt. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from severe stomach issues for a week on MAY-2021, and the outcome of passed out twice, sunburn like feeling in vaccine injection arm with no redness or rash, arm from shoulder to pinky finger hurts if something touches it, feels irritated, feels like nerve damage and feels like the hair on arms hurt |

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| 1332430 | 5/20/2021 | CA | 14 | M | 5/19/2021 | 5/19/2021 | was not reported. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to 20210531194.; Sender's Comments: V0:20210525585-covid-19 vaccine ad26.cov2.s-Passed out twice. This event(s) is considered not related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: MEDICAL HISTORY |
| 1332440 | 5/20/2021 | HI | 16 | M | 5/19/2021 | 5/19/2021 | PATIENT FAINTED WITHIN 20 SECONDS OF RECEIVING PFIZER COVID-19 VACCINATION. PATIENT'S FATHER AND STORE MANAGEMENT CALLED 911. FATHER AND ADMINISTERING PHARMACIST MONITORED PATIENT; PATIENT REGAINED CONSCIOUSNESS SHORTLY AFTER FAINTING. PARAMEDICS ARRIVED APPROXIMATELY 10 MINUTES LATER AND FURTHER ATTENDED TO PATIENT. PARAMEDIC DIAGNOSED VASOVAGAL SYNCOPE. PATIENT AND FATHER WENT WITH AMBULANCE TO HOSPITAL FOR FURTHER EVALUATION. |
| 1332602 | 5/20/2021 | NJ | | F | | | fainted; This is a spontaneous report from a non-contactable consumer. A female patient of unspecified age received BNT162B2 (BNT162B2, lot number and expiration date were not reported), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. On an unspecified date, approximately 8:40 AM, the patient fainted while waiting after receiving the Pfizer/biotech Covid vaccine. The patient was observed and was evaluated by EMT. She was released around 9:20 AM. Outcome of the event was unknown. Amendment : This follow-up report is being submitted to allow appropriate reporting to health authorities. No follow-up attempts are possible; Information on the lot/batch number could not be obtained. No further information is expected. |

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| 1332687 | 5/20/2021 | CA | 34 | F | 4/7/2021 | 4/7/2021 | fainted; weakness in my legs/Arms fairly weak too; extreme fatigue/Exhausted; brain fog/felt as though someone was throwing cold water at me; I don't feel safe to drive/ missed significant work; shake with a lactic acid type feeling; had a racing heart; diarrhea; fevers of 100 degrees (101 the first night) lasting off and on for the first 11 days; parasthesia a pins and needles feelings in my hands and feet; Most side effects have been neurological; Sunlight hurts my eyes; hard to walk; impossible to exercise.; This is a spontaneous report from a contactable consumer. A 34-year-old female patient (Age at time of vaccination, 34-year-old) received first dose of BNT162B2 (BNT162B2) via an unspecified route of administration, administered in Arm Right on 07Apr2021 at 10:30 (Batch/Lot Number: ER8737) as SINGLE DOSE for covid-19 immunization. Medical history was reported as none. The patient's concomitant medications were not reported. The patient Fainted and experienced weakness in my legs/arms fairly weak too, extreme fatigue/exhausted, brain fog/felt as though someone was throwing cold water at me, i don't feel safe to drive/ missed significant work, shake with a lactic acid type feeling, had a racing heart, diarrhea, fevers of 100 degrees, parasthesia a pins and needles feelings in my hands and feet, most side effects have been neurological, sunlight hurts my eyes, hard to walk and impossible to exercise all on 07Apr2021 at 10:30. The patient reported; It is now day 27 post vaccine and I have weakness in my legs, extreme fatigue, brain fog. I don't feel safe to drive. I have missed significant work. Can't walk down my block without my legs getting so weak they shake with a lactic acid type feeling. Arms fairly weak too. Initially, when I got the vaccine my right leg went weak. The night of the vaccine, I fainted, legs so weak I could barely get off the bathroom floor. Had a racing heart and felt as though someone was throwing cold water at me. Had diarrhea. I had fevers of 100 degrees (101 the first night) lasting off and on for the first 11 days. For the past several days I've been experiencing paresthesia a pins and needles feelings in my hands and feet. Most side effects have been neurological. Sunlight hurts my eyes. Was in ER for the weakness in my legs. Neg for covid. CBC normal. It was deemed that since my reflexes work GBS is unlikely. Exhausted and still extremely weak and it is hard to walk, and impossible to exercise. The patient |

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1332700 5/20/2021 FL

77 F

3/15/2021

3/15/2021

had no covid prior to vaccination and was not tested post vaccination. No other medications were taken in two week and no allergies was reported. Seriousness assessment was reported as disability. Therapeutic measures were taken as a result of all the events. The outcome of all the events was unknown. No follow-up attempts are needed. No further information is expected.

became extremely dizzy; when I came home and passed out.; Hit my head on floor; received a concussion; cut on scalp; This is a spontaneous report from a contactable consumer (patient). A 77-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration administered in left arm on 15Mar2021 13:45 (at the age of 77-year-old) (Batch/Lot Number: en6205) as 2ND DOSE, SINGLE for COVID-19 immunisation. The patient was not pregnant at the time of vaccination. The patient had no other vaccine in four weeks. The patient had no COVID prior to vaccination. The patient had no relevant medical history. The patient had no known allergies. Concomitant medications included atorvastatin; furosemide; and calcium. Historical vaccine includes first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number: e19265), administered in left arm on 22Feb2021 at 02:30 PM (at the age of 77-year-old) for COVID-19 immunisation. On 15Mar2021, the patient became extremely dizzy when she came home and passed out. She hit her head on floor and received a concussion and cut on scalp. The events caused hospitalization for 2 days. The patient was tested for COVID post vaccination via nasal swab on 22Apr2021 which was negative. Therapeutic measures were taken as a result of all events which includes computed tomography (CAT) scan and electrocardiogram (EKG) with unknown results. The patient recovered from the events on an unspecified date.

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| 1333212 | 5/20/2021 | CA | 34 | M | 5/16/2021 | 5/16/2021 | While waiting for 15-mins monitoring after getting Johnson&Johnson covid vaccine, he fainted and fell off the chair. Pharmacy staff rushed to his aid and he regained consciousness within a minute. He said he was feeling flushed and dizzy. He said he was having too much anxiety and has had fainting issue with vaccinations/MRI in the past. His blood pressure was low with high heart rate. We called 911 and paramedics came immediately. He was still unstable so the paramedics took him for further evaluation |

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| 1332702 | 5/20/2021 | PA | 43 | F | 5/4/2021 | 5/5/2021 | fainted; hit my head; I woke up disoriented moments later; ears are ringing from my head hitting; Headache; Feel dizzy; noticed muscle aches; This is a spontaneous report from a contactable consumer (patient). A 43-year-old female patient (not pregnant) received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), dose 2 via an unspecified route of administration, administered in Arm Left on 04May2021 11:15 (at 43 years old, not pregnant) as 2nd dose, single for covid-19 immunisation. The patient's medical history was not reported. Concomitant medications included cetirizine hydrochloride (ZYRTEC); mometasone furoate (NASONEX). The patient took Fioricet before and had allergies. The patient had her first dose of bnt162b2 vaccine on 13Apr2021 for Covid-19 Immunisation on left arm at 43 years old. All events reportedly started on 05may2021 03:00. Patient woke up in the middle of the night to use the bathroom. She thought she was feeling fine, but then noticed muscle aches as she walked. She decided to take Motrin. She walked to the sink and felt dizzy. She got so lightheaded, She sat on the edge of the tub with my head between her legs. That was the last thing She remembered. Based on the evidence the next morning, she must have stood up put Motrin in my mouth and poured a glass of water. Then she fainted and hit her head on the bathroom floor. She had never fainted before in her life. She woke up disoriented moments later with two Motrin still on her tongue and having no idea where she was. She had to crawl back to bed. The next morning, she found the spilled a glass of water and Motrin pills all over the floor. She now had a persistent headache and her ears are ringing from her head hitting the bathroom floor. She did not know that dizziness was a potential side effect or she may have taken precautions. The outcome of the events was recovering. No other vaccine in four weeks.No Covid prior vaccination.Not Covid tested post vaccination. Information about the Lot/batch number has been requested. |

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| 1333577 | 5/20/2021 | IL | 12 | F | 5/18/2021 | 5/18/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Medium, Systemic: Seizure-Mild, Systemic: Vomiting-Mild, Additional Details: Patient passed out within 30 seconds of receiving the Pfizer COVID vaccine. She was out for about 15-20 seconds, during which time she had a couple spasms. After that, she woke up, was aware that she had passed out, then threw up once. She waited with her mom for 30 minutes after that, but felt fine during that period. |
| 1332755 | 5/20/2021 | PA | 17 | F | 5/6/2021 | 5/6/2021 | Passed out; Vasovagal reaction; Dizzy; Skin was sweaty; Pale; This is a spontaneous report from contactable Pharmacist. A 17-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 intramuscular, administered in Arm Left on 06May2021 10:15 am (Lot Number: EW0171) at the age of 17-year-old as single dose for covid-19 immunisation. Medical history reported as none. No known allergies. The patient was not pregnant. The patient's concomitant medications were not reported. Vaccine was given, patient was sitting with her mother. Approximately 10 minutes after vaccine, she slumped to the side and passed out. When the reporter got to her she was just waking up. She still felt dizzy, skin was sweaty and pale. Paramedics arrived within 5-10 minutes to evaluate. They said they had seen this vasovagal reaction with the covid vaccine. Patient left on gurney with the paramedics. Adverse events start date was 06May2021. Events resulted in Emergency room/department or urgent care. The outcome of the events was unknown. The patient had no covid prior vaccination, no Covid tested post vaccination.; Sender's Comments: Based on a positive temporal association, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported event of Loss of consciousness. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate. |

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1332797 5/20/2021

F

A week after the bruises appeared patient had syncope episode and a heart rate of 160s; A week after the bruises appeared patient had syncope episode and a heart rate of 160s; Patient was tested for COVID and came back positive; Patient was tested for COVID and came back positive coded as COVID-19; After patient received COVID vaccine bruises appeared all over patient's body; This is a spontaneous report from a contactable other health professional (HCP). A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot number was not reported), via an unspecified route of administration on an unspecified date as 1st dose, single for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. After the patient received COVID vaccine, bruises appeared all over patient's body on an unspecified date. A week after, the bruises appeared. Patient also had syncope episode and a heart rate of 160s. Patient was tested for COVID and came back positive. A week after showing positive for COVID, patient started to show Covid symptoms. The outcome of the events was unknown. No follow-up attempts are possible, information about batch number cannot be obtained. No further information is expected.; Sender's Comments: Based on the available information, the company assessed there was not a reasonable possibility that the reported events Syncope, Heart rate increased, Covid -19 were related to the suspect product BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE). The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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| 1332840 | 5/20/2021 | NC | 18 | M | 4/22/2021 | 4/22/2021 | Fainted within 30 seconds/Passed out completely after shot; Passed out completely after shot; Some intermittent light headedness and dizziness; Some intermittent light headedness and dizziness; Irritating; scary/ fearful; scary/ fearful; This is a spontaneous report from a contactable consumer (patient's mother). An 18-year-old male patient received the first dose of BNT162B2 (Pfizer-Biontech Covid-19 Vaccine, Lot. EW0169) at single dose, on 22Apr2021 at 17:30, for COVID-19 immunization. The patient had not received any other vaccines within 4 weeks prior to the BNT162B2 vaccine. Relevant medical history and concomitant medications were unknown. Patient's mother reported that her son fainted within 30 seconds of receiving the Pfizer vaccine 1st dose and since then he had experienced some intermittent light headedness and dizziness. He passed out completely after shot. Adverse events were described as following: "patient is due to get his second dose of the shot later this evening but is having periods of lightheadedness and dizziness. Patient's mother states that her son also feels like he is going to pass out. She states that this started 30 seconds after the first shot. Her son only passed out once, completely right after the shot, it was a bad experience. She's glad he actually wants the other one today, but he is concerned because he is still lightheaded and dizzy after 3 weeks. Patient's mother states that he has been trying to function, work, and live his life but its irritating to him and scary. The doctor suggested that he should get his second dose but her son is a little fearful". Physician Office Visit required. The patient did not recover from intermittent light headedness and dizziness, while clinical outcome of the other events was unknown.; Sender's Comments: Based on known drug safety profile and strong temporal relationship there is reasonable possibility of causal association between the reported events and the suspect drug. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate. |

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| 1332860 | 5/20/2021 | CT | | F | 4/12/2021 | 5/12/2021 | <p>has had 4 very brief episodes of syncope in the past 4 days/ dizzy and passed out; Test: On monitor for 24hr w/ no, Result: Arrhythmia; After each episode, she consistently describes dark and blurred vision for 15 min; arm twitching; then dizzy and passed out; she felt scorching hot for a few minutes; This is a spontaneous report from a contactable physician. A female patient of an unspecified age received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, lot number: EP6955 and expiration date were unknown), via an unspecified route of administration in arm right on 12Apr2021 as single dose for COVID-19 immunisation. Medical history included anxiety , depression from an unknown date and unknown if ongoing. Concomitant medication included escitalopram oxalate (LEXAPRO) taken for anxiety, depression from an unspecified date. Previously the patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, lot number: EP6955 and expiration date: 30Jun2021), via an unspecified route of administration in arm right on 22Mar2021 as single dose for COVID-19 immunisation. It was reported that the patient who will be 20 years has had 4 very brief episodes of syncope in the past 4 days and spent 8 hours in ER Friday. Blood work, ECG, Echo, and MRI without contrast were normal. Doctors are baffled. Reporter enquired about the vaccine-related seizures 1 month after the second dose and asked for email address for a medical monitor supporting the vaccine trial. It was reported that the patient is perfectly healthy She does not drink or use any illicit drugs. She takes BCP to regulate her period and one month ago she started 5 mg/day Lexapro for test anxiety and COVID-induced depression. On Wed 12May2021 10 am while at work, she felt scorching hot for a few minutes, then dizzy and passed out; witnessed by 2 work colleagues. She will ask her colleagues tomorrow how long she was unconscious. On Thurs 13May2021 while at work she felt dizzy briefly but did not pass out. On Fri 14May2021 shortly after lunch while working in her cubicle, she woke up with computer keyboard imprint on her face. Unwitnessed, no warning whatsoever. Sat pm after dinner while in backseat of car, she felt dizzy and within a minute or so she had brief LOC lasting less than 1</p> |

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minute. Sun 16May2021 after breakfast while bathing, she passed out. Unwitnessed. Her phone was nearby so she was able to call me. After each episode, she consistently describes dark and blurred vision for 15 min. Then she feels fine. No obvious seizure activity although last night her boyfriend said her right arm was twitching. No incontinence. Seen by her PMD on Thurs 13May2021 and we spent 8 hours at the ER Friday 14May2021: PE, orthostatics, CBC, Chem 18, pregnancy test, U/A, ECG, ECHO and MRI of brain without contrast was normal. No Neuro or cardiology consult (yet). Today her doctor is recommending she be admitted for observation, consults and further testing. The patient has not received any other vaccinations prior 4 weeks and has no history of allergies. All tests done at the hospital came back normal. Daughter is currently in the hospital being discharged today 17May2021. She will wear a Holter monitor for 2 weeks to record any further events. Cardiology and neurology both conclude the adverse events were not cardio or neurological origin. Physician does not think it was seizures. She did not intend to report seizures-it was syncope. She does not have any further adverse events or history to report at this time beyond what she already reported. The patient underwent lab tests and procedures which included blood test: normal, blood thyroid stimulating hormone: normal, electrocardiogram: normal, electroencephalogram: normal, investigation: normal, investigation: arrhythmia, investigation: normal, physical examination: normal, pregnancy test: normal, urine analysis: normal on 13May2021, echocardiogram: normal, electrocardiogram: normal, full blood count: normal, investigation: normal, magnetic resonance imaging normal: normal on 14May2021. The outcome of the events was unknown.; Sender's Comments: As there is limited information in the case provided, the causal association between the events syncope, arrhythmia, dizziness, feeling hot, vision blurred, muscle twitching and the suspect drug BNT162B2 cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified

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| 1332861 | 5/20/2021 | ME | 52 | M | 5/4/2021 | 5/5/2021 | <p>to regulatory authorities, Ethics Committees, and Investigators, as appropriate.</p> <p>I passed out or fainted; I passed out or fainted; Hand and feet were extremely cold; This is a spontaneous report from a contactable consumer. A 52-years-old male patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 2 via an unspecified route of administration, administered in Right arm on 04May2021 (Batch/Lot Number: EW0164; Expiration Date: Aug2021) as single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. On 05May2021, 1 day after the administration of vaccine the patient experienced I passed out or fainted and Hand and feet were extremely cold. Clinical course reported as I passed out or fainted and my hand and feet were extremely cold before fainting. Patient stated, that he had been trying to report an adverse reaction to the Pfizer COVID 19 Vaccine, the second shot through the 'portfolio' on the website and he tried 3 times and for whatever reasons it just won't transmit the information. So he was wondering, it is possible to report that with a live agent today. The outcome was not recovered for Hand and feet were extremely cold and unknown for rest of the events.</p> |

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| 1332965 | 5/20/2021 | CA | 26 | F | 5/7/2021 | | <p>FAINTED POST IMMUNIZATION; CONFIRMED COVID-19 INFECTION; This spontaneous report received from a patient concerned a 26 year-old white and Hispanic or Latino female. The patient's height, and weight were not reported. The patient's concurrent conditions included needle phobia, alcohol use (Social - 1-2 drinks per week; very light drinker) and non-smoker. The product was stored in appropriate temperature conditions (it was stored properly from receipt to administration). The patient was not pregnant. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: unknown, expiry: unknown) administered on 07-MAY-2021 to left arm as prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On 07-MAY-2021, the patient fainted post immunization. On the same day, she was feeling exhausted and had headache. On 08-MAY-2021, she experienced low grade fever and lethargy. Till 10-MAY-2021, she was feeling exhausted and had headaches. On 13-MAY-2021, she identified lack of smell while cleaning house (cleaning products). On the same day, she had positive rapid home test for COVID 19 and she tested negative at health care professional (HCP). On 14-MAY-2021, she was tested positive polymerase chain reaction (PCR) for Covid 19 (headache, exhausted, low grade fever, lack of smell and lethargy). The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from fainted post immunization on 07-MAY-2021, and was recovering from confirmed covid-19 infection. This report was associated with product quality complaint: 90000179636 This report was serious (Other Medically Important Condition). The narrative states the patient received the vaccine on 07-May-2021 and had a positive Covid-19 test on 14-May-2021 with 7 days elapsed between vaccine and test. There was not sufficient time elapsed for the patient to achieve immunity therefore this report was not considered a lack of effect. The suspected product quality complaint has been confirmed to be voided there was no PQC identified within the reported complaint. Voided based on the PQC evaluation/investigation performed"; Sender's Comments: V0:20210530216-covid-19 vaccine ad26.cov2.s-Fainted post immunisation. This event is</p> |

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| 1332972 | 5/20/2021 | MN | 51 | F | 5/18/2021 | 5/18/2021 | <p>considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.</p> <p>FAINTING; DIZZINESS; BLURRED VISION; PAIN AT THE INJECTION SITE; HEADACHE; This spontaneous report received from a patient concerned a 51-year old White Hispanic or Latino female. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1808986 expiries: UNKNOWN) frequency one total, dose was not reported, administered on left arm on 16-MAY-2021 for prophylactic vaccination. No concomitant medications were reported. After the vaccination Symptoms started on 18-MAY-2021 dizziness, pain at the injection site, and blurred vision.it was also reported she fainted while walking back home. All the symptoms resolved.The Patient was complaining of a headache at the moment of reporting. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from fainting, dizziness, blurred vision, and pain at the injection site on 18-MAY-2021, and had not recovered from headache. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210534713-COVID-19 VACCINE AD26.COV2.S-Fainting. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p> |

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| 1332701 | 5/20/2021 | MI | 43 | F | 4/25/2021 | 4/25/2021 | fainting; Very intense dizziness; vomiting; headache; This is a spontaneous report from a contactable consumer (patient). A 43-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; Batch/Lot number was not reported), via an unspecified route of administration, administered in Arm Left on 25Apr2021 11:45 (43-years-old) as 2nd dose, single for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient previously took first dose of bnt162b2 for COVID-19 immunization. Patient was not pregnant. No known allergies. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. Vaccination Facility Type was Pharmacy. The patient experienced very intense dizziness, with a few seconds of fainting on the first day, vomiting, headache 10 hours following the administration of the second dose and continuously since then, for 10 days now. All events started from 25Apr2021 22:00 with outcome of not recovered. Events resulted in Emergency room/department or urgent care. No treatment was given. Information on the lot/batch number has been requested. |
| 1334302 | 5/20/2021 | CA | 52 | M | 4/23/2021 | 4/24/2021 | Within one day of receiving the 2nd shot started having heart palpitations in the middle of the night, Went to Urgent care, not help. Went back to hospital and a got a heartmonitor and wore that for a week. Thenon Friday, May 7th went to the emergency with sweats and almost passed out. They kept him there for over a day, ran tests, etc. Blood work came out fine. He was released the following day. No answers. One doctor there admitted that he believed it's related to the vaccine. Now here we are, May 20th, no answers and feeling the same, but now chest pain, shortness and breath. Never had ANY HEART PROBLEMS BEFORE THIS! |
| 1334052 | 5/20/2021 | WA | 15 | F | 5/20/2021 | 5/20/2021 | severe syncope and fainting, vomiting, lowered BP and lowered heart rate. First signs about 10 min post injection. Paramedics attending within 25-30 min of injection |

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| 1334070 | 5/20/2021 | NY | 50 | M | 5/20/2021 | 5/20/2021 | Patient had syncopal episode after vaccination. Had been recently traveling (flew from Spain with minimal food and sleep in last 24 hours). Patient has history of syncope in the past with Botox injection. Patient regained consciousness spontaneously. No seizure activity or head injury. Symptoms resolved and patient discharged |
| 1334139 | 5/20/2021 | VA | 13 | F | 5/20/2021 | 5/20/2021 | Syncope immediately following vaccine administration. No loss of consciousness, oriented, alert, responding appropriately to questions. Described "seeing spots in front of eyes, cold feeling". Pt denied nausea. |
| 1334145 | 5/20/2021 | NC | 22 | M | 5/18/2021 | 5/18/2021 | Within 60-90 seconds after receiving J&J vaccine, patient became lightheaded, sat down, then subsequently passed out. Then had 2-3 jerking motions similar to seizure activity. Was lowered to the floor and called a CODE ASSIST. patient was not registered at the time, but was in a hospital. No previous reaction to injections. Patient taken to ED for workup. Patient diaphoretic and bradycardic at 36. given IV fluids and performed EKG. was later discharged from ED |
| 1334149 | 5/20/2021 | OH | 16 | F | 5/1/2021 | 5/2/2021 | Patient started experiencing numbness and tingling on her right side and then all over on Sunday evening 5/2/21. It affected her gait and the numbness and tingling in her legs caused her to have to catch herself and hold on to something to keep from falling. She described that her legs felt weak for a few seconds when walking. This sensation gradually decreased in intensity and duration. When I saw her at 5 pm on 5/3, she had normal gait and only felt the numbness and tingling very briefly. Her exam including her neuro exam was normal on 5/3 when I saw her. The sensation of numbness and tingling completely resolved by 5/4. She also experienced HA, nausea and fatigue, but did not have syncope, dizziness or fevers. |
| 1334173 | 5/20/2021 | NC | 16 | F | 5/19/2021 | 5/19/2021 | Patient fainted approx. 1 minute after getting the vaccine. Layed down on the floor with feet elevated and head supported for 15 min after, given water and cold compress for forehead. No additional care needed |

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| 1334208 | 5/20/2021 | IL | 18 | M | 5/20/2021 | 5/20/2021 | Patient is 18 year old male who received his first dose of Pfizer COVID 19 vaccine. graduate intern, administered the dose and within the first minute, patient tensed up and passed out. He appeared to look like he had a seizure. Patient was passed out for less than a minute. When he came to, he said he fell asleep. He said he felt warm. We checked his Blood pressure and it 94/62 and pulse was 54. We called 911 and laid patient on a mat. He was given gatorade and a warm wash cloth. Paramedics arrived and rechecked BP. It was 110/66 and pulse was 66. They evaluated him and told him to have someone drive him home. Patient has not history of seizures and no history of adverse reaction to vaccine. He did receive a tetanus booster on 5/17/21. Only other medical history is asthma. He uses albuterol prn but has not had to use it for > 4 years. |
| 1333558 | 5/20/2021 | CA | 34 | F | 5/19/2021 | 5/19/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Additional Details: Patient was unresponsive for 10 seconds then after she became responsive should couldn't remember today's date or where she was for about 30 seconds. Then she was ok. Talkative and could answer all of my questions perfectly. She was very sweaty and thirsty. Patient drank 2 bottles of water and was monitored for 30minutes before she was allowed to leave the store. |
| 1334255 | 5/20/2021 | WA | 12 | F | 5/18/2021 | 5/18/2021 | The patient was vaccinated and then got up to walk to observation area. While waiting for her COVID vaccination card, she started leaning on mom and fainted. Mom caught her and placed her flat on the floor. A medical professional volunteering at the clinic responded to the incident and checked her O2 levels and blood pressure. Patient cam to shortly after fainting. Vitals were good and the doctor recommended she stay in observation for an additional 10 minutes. Patient left clinic with mom after waiting and without further incident. |

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| 1333981 | 5/20/2021 | TN | 27 | F | 5/19/2021 | 5/19/2021 | This is my first pregnancy. My estimated date of delivery is August 2021. I was to preface this by saying I have a history of passing out due to shots, examinations, blood tests, etc. So this might not have been because of the vaccine, but my own medical history of passing out. However, I do want to say I am 28 weeks pregnant, and ten minutes after receiving the vaccine, I fainted and then vomited. The EMT team was called, and the nurse practitioner on site examined me. They said that I was ok after monitoring me for about half an hour and checking my blood pressures four times. They also monitored my heart rate. I recovered fully after about an hour. |
| 1334326 | 5/20/2021 | OR | 22 | F | 4/8/2021 | 4/9/2021 | Fever (unknown temperature), headache, and fainted/passed out twice. |
| 1334335 | 5/20/2021 | MI | 35 | F | 5/20/2021 | 5/20/2021 | THE PATIENT FAINTED AFTER VACCINE WAS ADMINISTERED. PATIENT REGAINED CONSCIOUS BACK WITHIN FEW SECONDS. SAT DOWN AND OBSERVED FOR 30 MINS. PATIENT WAS NORMAL BY THE TIME SHE LEFT THE PHARMACY. |
| 1334385 | 5/20/2021 | IL | 70 | F | 5/6/2021 | 5/6/2021 | Passed out on a walk and broke my arm falling on the concrete. Have had stomach pains and diarrhea off and on since getting the shot.. very tired |
| 1334442 | 5/20/2021 | CO | 14 | M | 5/20/2021 | 5/20/2021 | 10 minutes after his vaccination, the patient was sitting with his mother and sister in our waiting room per protocol after a vaccine. I heard a mom scream while I was giving another patient a vaccine. I ran out with an epipen but he was awake, alert, and breathing normally. I asked what happened and she said he fainted for a second and seized or twitched a little. I did not give him any epinephrine because he was not having any issues breathing and was able to tell me he felt fine. We did call 911 per moms request and they came and checked him out. |

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| 1334548 | 5/20/2021 | IL | 28 | M | 5/20/2021 | 5/20/2021 | Pt received janssen vaccine, within 5 minutes pt was seated in waiting area and fainted very briefly and fell to the ground. Fell slowly and did not hit head. 911 was called. With the help of pt's mother, pt placed on his side, appeared pale, slow to response, generalized weakness. Within 1 to 2 minutes pt become more responsive, was placed on his back and raised his feet up on a chair. An ice pack was applied to pt's forehead and was monitored until EMTs arrived and care was transitioned to paramedics. Pt was assessed and taken with paramedics to be evaluated. |
| 1334610 | 5/20/2021 | IN | 32 | F | 4/1/2021 | 4/1/2021 | 15 minutes after the vaccination I passed out and a week later I lost feeling in my leg and had to go to the ER and now I'm currently wheel chair bound with no diagnosis but all the doctors can say is it from the COVID 19 vaccine. |
| 1333922 | 5/20/2021 | NY | 30 | F | 5/20/2021 | 5/20/2021 | patient fainted within 11min during the 15min observation window. patient woke up within seconds after I approached her to see if it was an allergic reaction. EMS was called immediately. |
| 1334213 | 5/20/2021 | OH | 12 | M | 5/20/2021 | 5/20/2021 | After vaccine was administered, patient was asked to wait for 15 minutes, at which time Parent notices that child had passed out, looked pale and unresponsive to name calling. I (pharmacist) was alerted to the event and I and couple technicians went out to assist patient. I elevated child's feet, supported head, took blood pressure and pulse. Child regained consciousness and was able to respond to name in less than two minutes. Child stated that he was hot and agreed to drinking cold water. I also applied cold compress to child's forehead and wrists. Child took sips of water and BP was continuously monitored. Parents stated that child looked much better and had regained color to his face. Child was monitored to 30 mins by the pharmacy team with no event before parents took child home. |
| 1333740 | 5/20/2021 | KY | 15 | F | 5/20/2021 | 5/20/2021 | Patient passed out about 15 minutes after receiving the vaccine. She stated that she had not eaten since breakfast and is the reason she felt lightheaded. Staff provided water and a snack for the patient and sat with her until she felt ready to stand up. |

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| 1334680 | 5/20/2021 | CA | 15 | M | 5/20/2021 | 5/20/2021 | near syncope, got dizzy and pale BP: 107/58 @ 9:23am HR 66 provided water. within a few minutes patient felt fine. BP rechecked @9:36am was 117/68 HR: 90 patient recovered and ready to go home. |
| 1333584 | 5/20/2021 | NY | 15 | M | 5/19/2021 | 5/19/2021 | Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Additional Details: possibly seizure related. patient fainted and hit head on wall upon fall. came to and went in and out a couple times. stable until EMS arrival |
| 1333597 | 5/20/2021 | TX | 17 | M | 5/18/2021 | 5/18/2021 | Vasovagal reaction with near miss syncope. 10-15 mmHg drop in BP |
| 1333605 | 5/20/2021 | AL | 13 | F | 5/18/2021 | 5/18/2021 | Systemic: Fainting / Unresponsive-Severe, Systemic: Hypotension-Medium, Systemic: Nausea-Medium, Additional Details: Immunizing pharmacist checked patient's blood pressure after syncopal episode, and again before sending patient home. He then called later to follow up and was informed of a second episode, after which he accompanied patient and mother to hospital. He remained with them until she was cleared to go home. |
| 1333619 | 5/20/2021 | FL | 18 | F | 5/19/2021 | 5/19/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild |
| 1333631 | 5/20/2021 | CA | 12 | M | 5/19/2021 | 5/19/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Exhaustion / Lethargy-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Mild, Systemic: Nausea-Medium, Systemic: Weakness-Medium |
| 1333657 | 5/20/2021 | MI | 12 | F | 5/19/2021 | 5/19/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Nausea-Mild, Additional Details: Patient fainted and immediately regained consciousness. Father broke her fall but she may have hit her head on a shelf so we called paramedics to check her out. She declined to go to the hospital and paramedics cleared her to go home. She was instructed to go to hospital if any signs of severe reaction or concussion. |

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| 1334035 | 5/20/2021 | CA | 16 | F | 5/20/2021 | 5/20/2021 | PATEINT WAS ANXIOUS BEFORE GETTING VACCINE, ABOUT 10 MINUTES AFTER GETTING VACCINE PATIENT FAINTED FOR A FEW SECONDS. PARAMEDICS WERE CALLED PATIENT WAS EVALUATED AND NOT SYMPTOMS WERE FOUND. PATIENT WAS NOT EXPERIENCING ANY OTHER SYMPTOMS AND WENT HOME WITH MOM. |
| 1333672 | 5/20/2021 | MD | 14 | F | 5/19/2021 | 5/19/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Mild |
| 1333995 | 5/20/2021 | TX | 15 | M | 5/20/2021 | 5/20/2021 | Patient fainted |
| 1333757 | 5/20/2021 | WA | 15 | M | 5/20/2021 | 5/20/2021 | Patient got shot on 05/20/21, waited in the pharmacy for 15 mins and felt fine. Patients mom called after about an hour and said patient fainted but recovered soon. He was not hurt, mom was advised to keep an eye on patient and call 911/ or urgent care visit. Per mom will wait. Called patient after some hrs per patient he is fine and has no adverse symptoms anymore. |
| 1333777 | 5/20/2021 | IL | 18 | M | 5/17/2021 | 5/17/2021 | PATIENT FAINTED IMMEDIATELY FOLLOWING THE VACCINE ADMINISTRATION. LAID PATIENT FLAT ON THE FLOOR, PUT HIS FEET UP AND PATIENT WAS OK WITHIN 30 SECONDS. |
| 1333822 | 5/20/2021 | CA | 18 | F | 5/18/2021 | 5/18/2021 | PATIENT GOT THE VACCINE COVID 19 FIRST DOSE, SHE WAS TOLD TO SIT FOR 15 MINUTES BEFORE LEAVING! ABOUT FEW MINUTES LATER, SHE PASSED OUT AND DROP HER BODY ON THE FLOOR! WE PUT HER BACK IN THE CHAIR , GAVE HER SOME WATER. SHE FELT OK AFTER THAT, DENIED TO CALL AMBULANCE! HER VITAL SIGNS WERE OK, WE CALLED THE MOM TO PICK HER UP! FOLLOW UP CALL PATIENT IS DOING OK! |

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| 1333842 | 5/20/2021 | PA | 19 | M | 5/20/2021 | 5/20/2021 | Patient seated in waiting area for 15 minute observation. Notified per staff that patient was not feeling well. Patient reported that he "passed out" while seated. Pt diaphretic and pale. VS obtained and blood pressure 98/60. No baseline blood pressure to compare. Pt given Orange Juice x 2 with improvement. Blood pressure retaken and 110/72. Pt with complaint of tingling in fingers , but stated that that was not new. RN sat with patient until patient felt better. Offered to call Paramedic to evaluate patient, but patient declined. Patient reported that he felt better and was going to sit for a few minutes longer and drive home. Patient did admit to fear of shots prior to receiving vaccine. |
| 1333845 | 5/20/2021 | VA | 37 | M | 5/18/2021 | 5/20/2021 | red bump from injection itchy at injection almost passed out at the gym this morning was dizzy and need to sit for a moment on the floor |

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| 1333863 | 5/20/2021 | PA | 52 | M | 4/9/2021 | 4/30/2021 | <p>Clinical Support 3/31/2021. Exposure to SARS-associated coronavirus +1 more. Dx Labs Only. Reason for Visit ED Discharged 4/30/2021 (2 hours) Treatment team. Providers COVID-19 Clinical impression, Fever, Generalized Body Aches, Chills. Chief Complaint Patient presents with Fever, Generalized Body Aches, Chills. HPI: 52-year-old male with history of diabetes, hypertension, obesity presents the emergency department with gradual onset of moderately severe generalized nasal congestion with associated cough unproductive of sputum and fever, T-max 103.8 at home the patient states began approximately 1 week prior to arrival. The fever worsened today and he decided to be seen at that time. He states he had his first dose of Pfizer COVID-19 vaccine 3 weeks ago. Denies sick contacts, chest pain, shortness of breath, syncope, dizziness, lightheadedness, numbness, focal weakness, abdominal pain, nausea, vomiting or diarrhea, changes in bowel or bladder habits or other complaint. No other signs or symptoms and no treatment prior to arrival. ED Discharged 5/1/2021 - 5/2/2021 (5 hours). Last attending Treatment team COVID-19 +1 more. Clinical impression, Chest Discomfort, Chief complaint. ED Provider Notes. Expand AllCollapse All. HPI. Chief Complaint Patient presents with. Chest Discomfort. Patient History. 52-year-old male with history of asthma, diabetes, heart murmur, hypertension, obesity, sleep apnea and was seen in the emergency department yesterday complaining of generalized nasal congestion, fever and cough and was discharge with a diagnoses of COVID-19 4/30/2021 presents to the emergency department with complaint of chest tightness. The patient states that tonight he developed chest pain which woke him from sleep. He describes the pain as burning. He states the pain is similar to the pain he had when he had a gallbladder attack. He also states the pain is well localized and does not radiate. Initially the pain was 10/10 initially and is currently a 4/10. He took his temperature and states he had a fever of 101.6 and took 1,000 mg of tylenol just prior to arrival. His O2 saturation today has not gone under 90%. Medical History. Past Medical History: Diagnosis Date Asthma 5/29/2017, Diabetes mellitus, Heart murmur, Hypertension, Obesity, Sleep apnea, obstructive. APAP 8-20CM WME AIRVIEW. Surgical History. Past Surgical History: Procedure Laterality Date</p> |

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CARDIAC CATHETERIZATION 03/2004. OTHER SURGICAL HISTORY ear surgery as a baby. STRABISMUS SURGERY repair of congenital strabismus-childhood. Family History. Problem Relation Age of Onset. Hypertension Mother. Diabetes Father. Hypertension Father. Hearing loss Other. Kidney disease Other. Social History. Tobacco Use. Smoking status: Never Smoker. Smokeless tobacco: Never Used Vaping Use. Vaping Use: Never used. Substance Use Topics. Alcohol use: No. Drug use: No. Review of Systems. Constitutional: Positive for fever. Respiratory: Positive for chest tightness. Cardiovascular: Positive for chest pain. All other systems reviewed and are negative. ED to Hosp- Admission. Discharged 5/4/2021 - 5/6/2021 (2 days) Hospital. Last attending Treatment team Acute hypoxemic respiratory failure due to COVID-19. Principal problem. Presenting Problem/History of Present Illness/Reason for Admission. Acute hypoxemic respiratory failure due to COVID-19. Hospital Course. Patient is 52 yo BMI around 40, presents to the hospital with severe sepsis secondary to COVID-19 pneumonia. He was first positive on 04/30, had progressive shortness of breath with weakness and worsening cough. He presented to the hospital originally on 05/04, and desaturated to 85% on room air. He admitted to the medicine service, pulmonology was consulted. Severe sepsis (tachycardia, tachypnea, and fevers with acute hypoxemic respiratory failure) secondary to COVID-19 pneumonia. He was started on dexamethasone IV, and transition to oral dexamethasone. He will continue 7 more days at home to complete 10-day therapy. He was started on remdesivir therapy and received 3-day treatment. Pulmonary consulted, as he was a possible candidate for Actemra, however his inflammatory markers including D-dimer, ferritin, CRP improved, and his oxygen requirements also improved. On discharge, he will continue with oxygen supplementation 2 L with rest, 4 L with activity, 2 L with sleep to be infused into his CPAP therapy. Hyperlipidemia. Continue rosuvastatin 10 mg Monday, Wednesday Friday. Benign essential hypertension. Holding hydrochlorothiazide Continue lisinopril and metoprolol.

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| 1333904 | 5/20/2021 | | 17 | F | 5/20/2021 | 5/20/2021 | Blurry vision, near syncope after receiving vaccine. Onset of symptoms was 3-4mins after vaccine administration. Did not eat breakfast this morning Given juice and crackers Exam was normal Discharged to home |
| 1333564 | 5/20/2021 | CA | 43 | F | 5/19/2021 | 5/19/2021 | Site: Pain at Injection Site-Mild, Systemic: Fainting / Unresponsive-Severe, Systemic: FAINTING LEAD TO SCRAPE ON FOREHEAD-Severe |
| 1333666 | 5/20/2021 | MD | 12 | M | 5/19/2021 | 5/19/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Medium |
| 1333897 | 5/20/2021 | | 15 | F | 5/19/2021 | 5/19/2021 | Stood up after vaccine and then passed out. Evaluate by EMS BP 100/72 P 60. Felt better. Went home with mom. |
| 1330774 | 5/19/2021 | NH | 13 | M | 5/19/2021 | 5/19/2021 | Patient received dose of vaccine. While standing patient experienced syncope and fell to floor. Bumped head against wall while falling but was caught by father before hitting floor. He quickly regained consciousness and had a strong pulse. He remained on the floor with feet elevated for 10 minutes. He then sat in chair IN front of pharmacy for an additional 15 minutes. At that point he felt fine and left the pharmacy with his father. |
| 1331029 | 5/19/2021 | | 16 | M | 5/19/2021 | 5/19/2021 | ANXIOUS, LIGHTHEADED, DIAPHORETIC WITH SYNCOPE S/P VACCINATION. PARAMEDICS CAME, VSS, SX RESOLVED, REFUSED TRANSPORT, AMA SIGNED. |
| 1331022 | 5/19/2021 | TX | 31 | M | 5/19/2021 | 5/19/2021 | patient became light-headed after immunization and fainted, falling off of the chair. Emergency services were called and he was determined to be okay. |
| 1331013 | 5/19/2021 | PA | 17 | F | 5/18/2021 | 5/18/2021 | patient experience dizziness after receiving immunization and later fainted . Patient sat on ground before completely fainting to floor with help of mother and regained consciousness about 1 minute later. patient complained of muffled voices and trouble hearing for about 4 minutes, sweating , dizziness and shakiness. patient received water and Gatorade and cool cloth behind neck area. patient able to leave after approximately 20minutes in care of mother feeling better. |

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| 1330974 | 5/19/2021 | | 14 | M | 5/19/2021 | 5/19/2021 | Dizziness, sweaty, blurred vision approx 2 mins after getting vaccine. Brought over to medical. Patient was alert, pale and diaphoretic. Patient was given water, crackers, alert and talkative, feeling much better. Patient sent home Past Medical Hx Had presyncope episodes with vaccine/blood draws in the past No recent illness and ate today |
| 1330925 | 5/19/2021 | PA | 21 | F | 5/19/2021 | 5/19/2021 | Pt passed out after receiving vaccine. Patient had gone to the restroom post vaccine and passed out. Patient was given two glucose tablets and water. Rested at pharmacy for 30 minutes and was fine. |

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| 1330900 | 5/19/2021 | NY | 19 | M | 5/15/2021 | 5/17/2021 | <p>Patient is a 19 y.o. male with a variety of minor past medical problems but without any significant PMH who presents with 24h of acute onset chest pains. He reports yesterday morning he was woken from sleep at 3-4 am with severe substernal chest pains that radiated to his arm and neck. This was worsened by laying flat and better if he waked around/pacing. He took ibuprofen and it got better so he went back to sleep. The pain returned about 6 hours later and was getting more severe so he went to see his doctor. There an EKG was abnormal so he was referred to the ED where a work up showed ST elevations c/w pericarditis and an elevated trop I of 24. The night prior, he reported a low grade temperature. He has not had any more fevers for the past 12-18 hours. He denies any other symptoms such as palpitations, shortness of breath, cough syncope. He denies sick contacts but did have a sore throat 4-5 days ago without any other associated symptoms. He has had recent negative COVID tests while at college. Of note he did receive the 2nd dose of Pfizer on 5/15 about 24-36 hours before onset of symptoms. Of note, he does boxing at school and has been participating in work outs until about a week ago. ED course: EKG w/ diffuse ST segment elevation in V3-V6, I, II, AVF. Troponin I 24. Creatnine 1.2 with baseline of 0.5 but BUN WNL (11). CBC WNL, CRP mildly elevated to 3.1, Transferred to another ED. Second ED Course: BP 120/64 Pulse 83 Temp 36.7 °C (98.1 °F) (Temporal) Resp 18 Wt 76.3 kg SpO2 97% exam non-focal, COVID ab notable for +spike neg nuclear capsid consistent with vax but no infection, D-Dimer, procal, ESR, ferritin, Coags all WNL, Trop T elevated to 1.46., ECG with consistent diffuse ST seg elevations, seen by ped cards who did echo in ED and notable for EF ~50%, admitted to PCICU for further management and treatment Admitted to the PCICU in stable condition. Placed on telemetry monitoring for the duration of the admission. Started on IV steroids and given IVIG on hospital day 1. Continued on toradol which was switched to motrin on hospital day 2. Cardiac MRI did not show signs of fibrosis. Troponin downtrended throughout his stay. At the time of DC echo showed normal function, ekg showed T wave inverions, and troponin was down trending to 0.57. Pt to be restricted from physical activity until cleared by cardiology. Infectious workup also sent, most of which was pending</p> |

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| 1330866 | 5/19/2021 | IL | 16 | F | 4/26/2021 | 5/10/2021 | <p>at time of discharge.</p> <p>is a 16-year-old female patient admitted with tachycardia. Starting 1-1/2 weeks ago, mom notes that she has had episodes where she feels her heart racing. It began 1-1/2 weeks ago with her crying and her watch that her heart rate was 208. They went to the ED, where she was given some fluids and her heart rate improved so she was sent home. She had had prior episodes of mild tachycardia up to the 140s in the past but which has always improved with fluids. Mom states that she used to have a lot of trouble maintaining her hydration and would not drink a lot of water. Since the last 1-1/2 weeks, she has been having these episodes 1-2 times a day that last about 1 to 2 minutes with a max of 5 minutes. When it comes on, she feels dizzy and lightheaded, and after the episode she feels a big rush of blood to her head. She also has some associated shortness of breath. She denies having any episodes of chest pain at all. She has never passed out, she has never felt like she was going to pass out, she has never felt like she was out of balance. She denies any nausea or vomiting during episodes. She denies any headaches during the episodes. She does have history of migraines, but has not had one in the last couple weeks. Her prior resting heart rate was in the 80s per her watch, and lately it has been in the 110s to 120s while awake in 80s while asleep. Along with the episodes, she also feels some pulsating sensation in her abdomen. She does not have any abdominal pain. Today, her heart rate was again in the 200s, but it was worse than before because it lasted about 30 minutes total. Lately they have been using an app that continuously monitors her heart rate. Since these episodes started, she has cut down on her caffeine intake and she has increased her water intake. Does not feel that this helped. She has never had syncope in the past and has never had seizures in the past. Patient was started on carvedilol which has helped control heart rate and was encouraged to drink fluids. Per primary care team, her current episode of tachycardia was not due to the vaccine.</p> |

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| 1330858 | 5/19/2021 | TX | 25 | M | 5/19/2021 | 5/19/2021 | The patient passed out and fell on the floor. He woke up. He laid down. He drank some water. The nurse took his vitals BP 128/80, P:82, SPOZ: 99%. He stated that he was ok. EMS checked him out. He stated that he was ok and refused transport. |
| 1332388 | 5/19/2021 | CA | 15 | M | 5/19/2021 | 5/19/2021 | PATIENT FAINTED AFTER VACCINATION. PATIENT REGAINED CONSCIOUSNESS WITHIN 30 TO 60 SECONDS. |
| 1330800 | 5/19/2021 | | 59 | M | 5/19/2021 | 5/19/2021 | Patient experienced syncope less than 5 minutes after receiving the Janssen COVID-19 shot. We alerted store management and called 911. He regained consciousness after about 15 seconds or so. We laid him on the floor and got cold, wet paper towels to hold on his head. He felts weak but was alert. EMS arrived and checked his vitals. His vitals were ok. He refused to go with EMS when he was asked. We called his wife and she came and picked him up. |

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| 1331159 | 5/19/2021 | CA | 17 | F | 5/19/2021 | 5/19/2021 | Client received 1st COVID vaccine of Pfizer (Lot# EW0185 expiration 05/23/2021). At 1347, RN assisted Client to stand up from vaccination chair. Client began to have unsteady gait. Both RN and RN assisted Client back to the gravity chair. At 1348, RN and PHN responded to the event. At 1348, vital signs are blood pressure 116/72, heart rate 64, oxygen saturation 100%. Client reported no blurry vision no headache, appearance is pale. Client is accompanied by mother. Per client's mother, Client has no medical history, allergies to dogs, and a history of syncope and lightheaded with needles/vaccines. At 1352, vital signs are blood pressure 118/82, heart rate 62, oxygen saturation 100%. Client reports lightheaded, feels tired, no shortness of breath, no headache. Supplemental nutrition and fluids provided to Client . Client accepted. At 1357, vital signs are blood pressure 116/76, heart rate 63, oxygen saturation 100%. Client reports no headache, no blurred vision, lightheaded improving, feels "sleepy", and skin tone returning to appropriate ethnicity. PHN educated client and mother ED precautions, common adverse effects of COVID vaccine, and emphasize a follow up with primary care provider. At 1400, vital signs are blood pressure 118/72, heart rate 63, oxygen saturation 100%. At 1402 Client stood up with no complains. At 1403 Client walked out of vaccination facility with a steady gait accompanied by mother. |
| 1330762 | 5/19/2021 | NY | 17 | F | 5/19/2021 | 5/19/2021 | Patient experienced syncope shortly after receiving vaccine while standing. Patient fell and remained on ground per advice of EMTs who arrived and escorted via ambulance for evaluation due to the patient experiencing nausea and vomiting upon rising back up. |
| 1330722 | 5/19/2021 | TN | 30 | M | 5/19/2021 | 5/19/2021 | The patient experienced vasovagal syncope a few minutes following vaccine administration. Patient became alert seconds after fainting and made a full recovery. |

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| 1330717 | 5/19/2021 | OK | 23 | M | 5/18/2021 | 5/18/2021 | Pateint was given vaccine on 5/18/2021, soon after her injection, she passed out in the lobby. Code Blue was called. After medical team arrived, her HR= 48; BP= 89/56; O2= 100% on 3L and she responded to verbal commands. Hx of needle phobia. Not sure whether her Syncope was secondary to Vasovagal vs. J&J Vaccine vs. Seizures, therefore, we called EMS to take her for further evaluation. |
| 1330702 | 5/19/2021 | VA | 17 | M | 5/19/2021 | 5/19/2021 | After patient received the vaccine, went to sit on a chair for observation, he fainted and fall on the floor. He reported to fill dizzy and sweaty. Applied cold pack in the neck area on the back. The ambulance was called and patient was taken to the hospital for further treatment. |
| 1330667 | 5/19/2021 | OH | 52 | F | 3/6/2021 | 3/7/2021 | 14 hrs after injection I was freezing, three hrs later I was burning up this was at 3am, 4am still burning up and not able to sleep, 5am sat up and had a headache that was at least a ten on the pain scale, I went down our flight of stairs to get water and ibuprofen, I had to sit down before I could get the water, when I finally got up I went to the counter and was getting this stuff out and I started to sway and white spread across my field of vision and I grabbed for the counter to lower my self down and passed out before I could grab the counter, I laid there burning up and with a headache that was killing me. I finally got the water and 800mg of ibuprofen went back to bed and slept until 11am, got up no headache but since then I have been experiencing hot flashes daily the rest of March and into April a few in May. I realize that I am of the age to experience hot flashes heading into menopause but this was to coincidental and I had never had hot flashes before. |
| 1330624 | 5/19/2021 | FL | 25 | M | 5/19/2021 | 5/19/2021 | Within 5 min of administration, pt states ge felt lightheaded and passed out. Pt was seated and under care of RN. RN secured pt's airway and applied sternal rub to which the pt quickly revived. VS were normal. EMS was called and pt refused to go. Pt felt much improved within 45 min of the event and left the clinic w/o further incident. |
| 1330618 | 5/19/2021 | | 15 | F | 5/19/2021 | 5/19/2021 | Almost passed out BP 102/70 pulsestrong and regular. Pick up by mom. |

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| 1330585 | 5/19/2021 | | 12 | F | 5/19/2021 | 5/19/2021 | An incomplete Vaers report was previously submitted for this patient. Please reference Report. Please disregard previous report. Adverse Event At 10:10am, patient was sitting with her mother when she started to convulse while sitting upright in a chair and vomited as well. This episode lasted for about 15seconds. Past medical Hx Patient reported one syncope episode after receiving a shot in the past, blood was drawn. No Hx of seizure disorder Treatment Patient was given crackers, juice, water EMS called at 10:31am for patient to have further evaluation. Patient was in stable condition prior to transport to ER A translator used, parent consent was provided. |
| 1330573 | 5/19/2021 | OK | 33 | F | 5/18/2021 | 5/18/2021 | Syncope 5 minutes post vaccine. Increased headache and fever up to 102.4 degrees for 15 hours |
| 1330839 | 5/19/2021 | FL | 16 | F | 5/19/2021 | 5/19/2021 | A few moments after receiving the vaccination, patient fainted and had some tremors afterwards. We picked her up off of the floor and placed her in a chair. She was pale and had some discoloration around her nose area. She was able to speak to us. She felt cold and was sweating at the same time. Her body temp was 97 degrees F. According to her mom, she's had a previous reaction similar to this but not to this extreme with the HPV shot. We called 911 to have her assessed by the paramedics |
| 1331743 | 5/19/2021 | MD | 17 | M | 5/19/2021 | 5/19/2021 | Syncope shortly after the shot |
| 1332239 | 5/19/2021 | AZ | 16 | M | 3/27/2021 | 3/27/2021 | Within minutes of receiving the vaccine, he, vomited and then fainted twice. His blood pressure plummeted (60/40) and required the on site EMT medics to intervene with a 800 cc saline IV and Zophran medication. He responded well to the treatment and was able to be release 45 minutes after the IV started. |
| 1332231 | 5/19/2021 | CO | 29 | F | 5/19/2021 | 5/19/2021 | PATIENT PASSED OUT WITH EYES OPEN. SHE COULDN'T SEE ANYTHING FOR A FEW SECONDS. SHE CAME TO AND THEN ABOUT A MINUTE LATER, IT HAPPENED AGAIN. SHE WAS COMPLETELY PALE BUT CAME TO WITHIN A COUPLE OF SECONDS AND THEN FELT BETTER. WE DID CALL PARAMEDICS, WHO CHECKED HER HEART RATE AND BLOOD SUGAR. THEY DID NOT TRANSPORT HER. |

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| 1332228 | 5/19/2021 | CA | 15 | F | 5/19/2021 | 5/19/2021 | patient fainted after receiving pfizer vaccine. became alert after 1 minute. school nurse attended to patient and checked vitals and mother took patient home after recovery within 15 minutes |
| 1332220 | 5/19/2021 | CA | 12 | F | 5/19/2021 | 5/19/2021 | patient fainted 5 minutes after receiving pfizer vaccine. became alert after 30 seconds. school nurse attended to patient and checked vitals - bp was low and final bp returned to levels within range after 30 minutes. mother took patient home |
| 1332034 | 5/19/2021 | DE | 25 | M | 5/19/2021 | 5/19/2021 | during 15 minute observation period after the vaccine, patient passed out briefly. |

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| 1332029 | 5/19/2021 | PA | 80 | M | 3/16/2021 | 3/25/2021 | Office Visit 3/23/2021 Urgent Care PA-C Family Medicine 2019 novel coronavirus disease (COVID-19) Dx Covid-19 Screening Reason for Visit Progress Notes PA-C (Physician Assistant) ? ? Family Medicine ? ? Encounter Date: 3/23/2021 ? ? Signed Cosigned by: MD at 3/24/2021 4:39 PM Expand AllCollapse All MDM Number of Diagnoses or Management Options 2019 novel coronavirus disease (COVID-19); Diagnosis management comments: Patient is an 80-year-old male with history of atrial fibrillation and positive POCT COVID-19. 6 days of symptoms. Excellent candidate for antibody therapy. The health system treatment navigator was notified of this and will schedule him for antibody infusion treatment. Patient is stable at present with no severe or concerning symptoms at this time. Tylenol/continued Eliquis recommended. Clinical Support 3/24/2021 Health system RN COVID-19 virus infection Dx Progress Notes RN (Registered Nurse) ? ? Encounter Date: 3/24/2021 ? ? Signed Patient is here for MAB Infusion Consent for infusion prior to this visit reviewed and verified. O2 sats > or = 90% Signs of potential reaction reviewed with patient. Tolerated IV start and MAB infusion without complication. Pt has access to pulse oximeter and thermometer for home monitoring Provided fact sheet for patients, parents and caregivers-Emergency Use Authorization of BAM for Coronavirus Disease 2019 for pt to review. Discharge instructions reviewed. Patient denies any questions ED to Hosp-Admission Discharged 3/25/2021 - 3/26/2021 (39 hours) Hospital MD Last attending ? Treatment team COVID-19 Principal problem Chronic anticoagulation Persistent atrial fibrillation (CMS/HCC) COVID-19 Confusion Hypoxemia Hospital Course: In his hospital stay we managed his medical issues as follows; Confusion/Syncope in the setting of COVID-19 infection Chronic atrial fibrillation/sinus node dysfunction Hypertension Prediabetes Patient received first dose of vaccination on 3/16 and afterwards started having muscle aches and body pains, later on found out to be having Covid 19+ test, he might be having Covid infection before vaccination as well and symptoms showed with vaccination. On 3/24 he was found out to be having confusion, family called EMS. They tried to debride patient on his feet and he collapsed for about 10 seconds. He did mention that he usually get |

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| | | | | | | | dizziness/lightheadedness upon standing from bed. Although patient has a history of A. fib but remained rate controlled during hospital stay, we held his antihypertensives including HCTZ and ARB while continued his Eliquis. I believe his syncope was likely due to dehydration with decreased oral intake in the setting of acute illness with COVID-19 symptoms. Before discharge blood pressure was rising so his ARB were restarted while decision regarding HCTZ will be made by primary care physician. In regard to his COVID-19 infection, initially was started on 2 L of supplemental oxygen but his oxygen demand decreased rapidly and most of the time he remained room air, he was not showing any dyspnea, cough, fever or any other generalized symptoms of Covid 19 infection. He did get plasma and remdesivir while inpatient, decision was made to discharge him on 3/26 as patient was symptom-free. He also had received first dose of vaccination. I believe that he would need further remdesivir. We will continue him on steroids for now after completion of dexamethasone for next 8 days he can recent resume his home medication of prednisone. |
| 1332011 | 5/19/2021 | RI | 61 | M | 4/6/2021 | 5/4/2021 | Wasn't able to stand up at all... nausea fainting dizziness etc... had to take rescue twice within 5 days... was in the ICCU unit at one point.. diagnosed with orthostatic hypotension |
| 1331781 | 5/19/2021 | NM | 18 | F | 5/19/2021 | 5/19/2021 | Patient fainted after receiving vaccine. Patient said she had history of fainting with other vaccines and blood draws in the past. Patient fainted about 5 minutes after receiving vaccine. Patient fell off the post vaccine chair. Patient was coherent |
| 1331772 | 5/19/2021 | WA | 16 | M | 5/19/2021 | 5/19/2021 | Patient fainted after standing up. Immediately came to, Bp was 146/76. Gave water, pt sat with feet up. After 35 minutes felt better, bp now 121/85. Pt left with father. |
| 1331144 | 5/19/2021 | OR | 12 | F | 5/16/2021 | 5/16/2021 | Patient with vasovagal syncope. Rapidly improved with position change, hydration, and monitoring. Returned home with mother as the driver. |
| 1331744 | 5/19/2021 | VA | 14 | F | 5/19/2021 | 5/19/2021 | Patient had syncope-type reaction, chills, sweating, and passing out. Started around 12:35-12:40pm, lasted until 12:50pm after pharmacist intervention. |

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| 1331147 | 5/19/2021 | IL | 31 | M | 5/19/2021 | 5/19/2021 | Patient started feeling lightheaded about 2- 3 mins of vaccine administration. Patient moved from the chair to the floor because he felt like he was going to pass out. Patient passed out for about 30 seconds, slight twitching during episode and then came through. He was a bit disoriented but alert, we had him stick around until his wife came and picked him up. |
| 1331533 | 5/19/2021 | CA | 15 | M | 5/14/2021 | 5/14/2021 | patient had the vaccination and waited for 15 minutes, then when he was walking out the store then he felt dizzy and fainted for seconds, Dad was there to catch him when he was falling. he came back to conscious as I was there, we called 911 and paramedics came and checked on pt. then he went home with parents after he was done with the checkup with the paramedics. |
| 1331525 | 5/19/2021 | CA | 16 | F | 5/19/2021 | 5/19/2021 | PT HAD A SEIZURE APPROX. 30 MINS AFTER RECEIVING THE COVID VACCINE, PT FAINTED, STIFFENED UP, AND BEGAIN TO CONVULSE. PT WAS PLACED ON COTT IN THE RECOVERY POSITION, 911 WAS CALLED AND VS OBTAINED. P74, R22, BP118/80, O2SAT 98% ON RA. SEIZURE LASTED APPROX 10 SECONDS, AMBULANCE ARRIVED WITHIN 10 MINS, AND TOOK OVER PT'S CARE. PT'S COLOR REMAINED PINK THROUGHOUT, AND SHE WAS SLEEPY BUT ABLE TO ANSWER QUESTIONS APPROPRIATELY. VS: P83, R24,BP116/80, POX99% ON RA. PT TAKEN IN AMBULANCE TO HOSPITAL FOR FURTHER EVALUATION |
| 1331482 | 5/19/2021 | FL | 46 | M | 5/19/2021 | 5/19/2021 | PATIENT BECAME DIZZY AND FAINTED FOR A FEW MINUTES. WHEN PATIENT WOKE UP HE WAS PALE AND I CHECKED TO MAKE SURE HE WAS BREATHING. HE SAID HE WAS BREATING FINE BUT WAS VERY DIZZY. HE GOT NAUSEAS WITH SENSATION OF VOMITING. |
| 1331476 | 5/19/2021 | TN | 27 | F | 5/19/2021 | 5/19/2021 | 28 WEEKS PREGNANT- PT EXPERIENCED SYNCOPE AND VOMITING |

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| 1331304 | 5/19/2021 | NY | 16 | F | 5/14/2021 | 5/14/2021 | At approximately 1825 a patient fainted over in her seat at the observation area. The EMS transported her to the other side of the gymnasium where a privacy screen is set up. She was fine to leave around 1835 per the EMT but stayed till 1848 and left on her own will. Patient was 16 years of age, female. Girl has a history of passing out, i.e. when she received novocaine and when she got her ears pierced. Her guardian declined to give a name for the report. |
| 1331268 | 5/19/2021 | MD | 15 | F | 5/19/2021 | 5/19/2021 | Was standing passed out and fell to ground. Vital signs: @13:15 B.P.=100/50 118/80 HR: 70 Pso2:100% @13:45 B.P. 97/50 Trending hypotension Recorded by staff |
| 1331267 | 5/19/2021 | WI | 19 | M | 5/19/2021 | 5/19/2021 | Immediately after sitting down in the waiting area after receiving the shot, the pt reported feeling a strange pressure in their arm. Following this, the patient described the sensation of "blacking out". The pt fell off their chair and lacked alert consciousness for roughly five seconds. When the pt came to, they appeared confused and twitchy, with wide eyes and an overall appearance of shock. Pt remained in their state for roughly a minute, before stating that they felt completely better. The pt had developed a sweaty back but didn't state that they felt overally hot. They didn't mention being in any pain. The local injection site appeared a bit red but nothing of significant note. Pt did bump their head on the side wall behind the chair, receiving a minor bruise. Pt was given some water to drink and was monitored for 30 minutes. They pt stated they felt fine. They had no past history of fainting with vaccines, thought pt claimed to have passed out like this before but only after suffering a head injury. After their wait, the pt was allowed to leave and assured us that they felt completely fine. |
| 1331230 | 5/19/2021 | MD | 12 | F | 5/19/2021 | 5/19/2021 | Pale diaphoretic, syncope witnessed loc Possible seizure Transported by ambulance with mother at 11:45am BP 67/30 P 46 14 99% at 12:00am BP 84/62 P 58 12 100% |
| 1330504 | 5/19/2021 | CO | 15 | M | 5/19/2021 | 5/19/2021 | Was sitting in observation room, felt dizzy and put his hands on his head, then passed out. Hit head on carpeted surface. LOC less than 10 seconds. |

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| 1331747 | 5/19/2021 | TX | 14 | M | 5/19/2021 | 5/19/2021 | The patient briefly fainted about 7 minutes after getting the vaccine. EMS were called into the scene and the patient was fine. |
| 1329491 | 5/19/2021 | | 26 | M | 5/4/2021 | 5/4/2021 | Woke up feeling weak and tired; Woke up feeling weak and tired; Lost consciousness/passed out for several minutes; This is a spontaneous report from a non-contactable consumer (patient). A 26 years-old male patient received the first dose of BNT162B2 (Pfizer-Biontech Covid-19 Vaccine, Lot. EW0173) in the left arm, at single dose, on 04May2021, at 08:45 AM, for COVID-19 immunisation. COVID-19 vaccine was administered at Pharmacy or Drug Store. The patient had not received any other vaccines within 4 weeks prior to the BNT162B2 vaccine. The patient had not received any other medications within 2 weeks of vaccination. Prior to vaccination, was not the patient diagnosed with COVID-19. Relevant medical history and concomitant medications were unknown. It was reported that the patient received the first dose of vaccine in left arm, then 5 minutes later, on 04May2021, lost consciousness/passed out for several minutes. Woke up feeling weak and tired on an unspecified date. Emergency Room Visit /department or urgent care required. Post the vaccination, the patient has not been tested for COVID-19. Clinical outcome of the events was unknown at time of this report. No follow-up attempts possible. No further information expected. |
| 1329881 | 5/19/2021 | CA | 25 | M | 5/18/2021 | 5/19/2021 | Waking up at 4:30 AM I went to urinate. Feeling weak I started to slouch and have trouble standing while urinating. Upon returning to my room I fainted. I suddenly lost consciousness and fell on my clothes/bed. I drank about 1.5 liters of water and felt better after about 15 minutes. |

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| 1329875 | 5/19/2021 | OK | 18 | M | 5/17/2021 | 5/17/2021 | Site: Pain at Injection Site-Medium, Systemic: Allergic: Anaphylaxis-Medium, Systemic: Allergic: Difficulty Breathing-Medium, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Weakness-Severe, Additional Details: Patient lost consciousness a few minutes after dose was given. Patient was unresponsive for approximately 2 minutes. Neck felt tight, difficulty breathing, was not alert/oriented when finally awoken. Patient was given 1 shot of epi 0.3 due to a temporary interruption in breathing that lasted seconds. By the time paramedics arrived, he was becoming more alert. Was taken to the ER and discharged. |
| 1329867 | 5/19/2021 | PA | 13 | F | 5/18/2021 | 5/18/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Visual Changes/Disturbances-Mild |
| 1329861 | 5/19/2021 | CA | 25 | F | 5/18/2021 | 5/18/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Headache-Medium, Systemic: Hypotension-Medium, Systemic: Nausea-Medium, Additional Details: 911 was called immediately. Paramedics monitored patients BP and over all alertness at the store. Patient was advised by the paramedics to go to ER. Pt declined and had to sign AMA (against medical advice) form. |
| 1329857 | 5/19/2021 | NY | 25 | F | 5/18/2021 | 5/18/2021 | Systemic: Allergic: Difficulty Breathing-Mild, Systemic: Fainting / Unresponsive-Severe, Additional Details: Patient stated was nervous around needles, but never fainted from a vaccine. Patient fainted twice in administration room, but recovered well afterwards. Patient stated difficulty breathing, but did not need an epipen as airway was not blocked. Water was given, she recovered well, and patient rested outside pharmacy for almost 1 hour. Patient left with no issues. |
| 1329685 | 5/19/2021 | MO | 30 | M | 5/18/2021 | 5/18/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Mild, Systemic: Nausea-Mild |

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| 1329677 | 5/19/2021 | TN | 57 | F | 3/8/2021 | 4/6/2021 | <p>had severe Vitamin D deficiency; Chills; Fainted; Total and complete exhaustion/soo tired; confusion; cried; could barely function, weak; flashes in eyes; i think i am going to die/ horrid / never felt so horrible in my life; headache immediately; This spontaneous case was reported by a consumer and describes the occurrence of SYNCOPE (Fainted) in a 57-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 030V21A and 029A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 08-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 06-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 06-Apr-2021, the patient experienced HEADACHE (headache immediately). On 08-Apr-2021, the patient experienced SYNCOPE (Fainted) (seriousness criterion medically significant), CONFUSIONAL STATE (confusion), CRYING (cried), ASTHENIA (could barely function, weak), VITREOUS FLOATERS (flashes in eyes), FEELING ABNORMAL (i think i am going to die/ horrid / never felt so horrible in my life) and FATIGUE (Total and complete exhaustion/soo tired). On an unknown date, the patient experienced VITAMIN D DEFICIENCY (had severe Vitamin D deficiency) and CHILLS (Chills). At the time of the report, SYNCOPE (Fainted), VITAMIN D DEFICIENCY (had severe Vitamin D deficiency), CONFUSIONAL STATE (confusion), CRYING (cried), ASTHENIA (could barely function, weak), VITREOUS FLOATERS (flashes in eyes), FEELING ABNORMAL (i think i am going to die/ horrid / never felt so horrible in my life) and CHILLS (Chills) outcome was unknown and HEADACHE (headache immediately) and FATIGUE (Total and complete exhaustion/soo tired) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2020, Blood test: vitamin d normal (normal) Vitamin D normal. In 2021, Blood test: severe vitamin d deficiency (abnormal) severe Vitamin D deficiency. The treatment reported was patient was prescribed Vitamin D 50,000 units once weekly and Tylenol. Action taken with mRNA-1273 in response to the drug was not applicable. This case was linked to MOD-</p> |

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2021-109872 (Patient Link).; Sender's Comments: Based on current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded.

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| 1329542 | 5/19/2021 | AR | 71 | F | 4/8/2021 | 4/8/2021 | Swelling and pain on right side of body; Swelling and pain on right side of body; Sore arm; Arm swollen; Everything in vision went white; Felt weak and sick; Felt weak and sick; This is a spontaneous report from a contactable consumer (patient). A 71-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in Arm Right on 08Apr2021 (Lot Number: BRZU13) as 1st dose, single for covid-19 immunisation. Medical history included ongoing glaucoma (she was diagnosed with glaucoma when she was 37, the glaucoma only started to really get worse over the last few years, her pressure was up pretty high and she has to go on 11May2021 to the eye doctor), ongoing rheumatoid arthritis (she has had rheumatoid arthritis for more than a couple of years, she had rheumatoid arthritis when she was diagnosed as disabled and no one bothered to tell her), ongoing hypertension (it has been 5, 6, or 7 years since she was diagnosed with high blood pressure), ongoing small cataracts (she was diagnosed with small cataracts about a year ago), ongoing severe osteoporosis (it has been a few years since she was diagnosed with severe osteoporosis, reported that some physicians didn't even bother to check to see if she had osteoporosis), ongoing Can't take statins (she can't take statins and her doctor is giving her Omega 3's instead of statins, she tried to take statins and couldn't do it), ongoing allergies (if she eats a grapefruit, her whole face and lips and eyes swell up, she had to go to the emergency room following consumption of a grapefruit, she can't eat oranges or she will have to be taken to the emergency room, she cannot wash her clothes or sleep on sheets that have been washed in certain things), reaction to polyethylene glycol (25-30 years ago, she went into the hospital to have a colonoscopy, she drank the Polyethylene Glycol, went to the bathroom, and passed out, the hospital staff had to come in and get her from the bathroom, the medical staff figured out it was the Polyethylene Glycol that caused her to pass out and made her sick, she has not had a colonoscopy since the incident 25-30 years ago), problems with her hair and scalp started about a year ago (her hair was just thinning at first, and then it went to going bald and got worse and worse. Even with Rogaine and steroids, the balding was moving to the front of her |

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head. She stopped taking the steroids because she couldn't stop eating). Concomitant medications included amlodipine taken for blood pressure abnormal from an unspecified start date and ongoing (has been taking amlodipine for a year or a year and a half); hydrochlorothiazide taken for swelling from an unspecified start date and ongoing (she retired in 2005 and may have started taking hydrochlorothiazide before she retired); dorzolamide hydrochloride, timolol maleate (DORZOLAMIDE HYDROCHLORIDE AND TIMOLOL MALEATE) taken for glaucoma from an unspecified start date and ongoing (been about a year that she has been using the Dorzolamide/Timolol); latanoprost taken for glaucoma from an unspecified start date and ongoing (has been using the Latanoprost for longer than she has been using the Dorzolamide/Timolol); acetylsalicylic acid (ASPIRIN (E.C.)) taken for an unspecified indication from an unspecified start date and ongoing (she has been taking an aspirin daily religiously for about 6 months); famotidine taken for gastroesophageal reflux disease from an unspecified start date and ongoing (has been taking Famotidine for a couple of years); hydrocodone taken for pain from 2005 and ongoing. The patient experienced sore arm on 08Apr2021 with outcome of recovered on Apr2021, arm swollen on 08Apr2021 with outcome of recovered on Apr2021, everything in vision went white on 08Apr2021 with outcome of recovered on 08Apr2021, felt weak and sick on 08Apr2021 with outcome of recovered on Apr2021, swelling and pain on right side of body on 09Apr2021 with outcome of recovered on Apr2021. The events were described as everything went white: patient reported that everything went white in her vision while she was sitting and waiting after receiving her first dose of the Covid-19 vaccine. She thought that it may have just been her glaucoma. The white out of her vision lasted for 5-10 seconds and then her vision returned to normal. Felt weak and sick: when she left the vaccination facility on 08Apr2021, the sun was beating down and she got real sick. She got into her friend's vehicle and upon arriving home, the patient was unable to get out of the car because she felt like she was about to faint. She sat in the air conditioning in her friend's vehicle for 30 minutes. She was still feeling weak and sick but she went inside her house and got into bed. Swelling and pain on right side of body: when she woke

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up on 09Apr2021, the whole right side of her body to include her face, arm, hand, and foot, were all very painful and very swollen for about 3 days. She has had multiple surgeries on the right side of her body and all of the sites were very painful. Felt weak and sick: she started sweating a lot while she sat in her friend's truck on 08Apr2021 after the first dose of the Covid-19 vaccine. She sat in her friend's truck for 30-40 minutes with the air conditioner running full force and felt a little better. She still felt weak and sick, but she went inside because her friend needed to leave. She took off her clothes and tried to eat some soup, but just got into bed and stayed there. Swelling and pain on right side of body: the swelling and pain was really bad for 3-4 days and eventually went away. The pain and swelling gradually diminished. The bones in her hands, knees, thighs, and feet were all very painful. She has a piece of wire that holds her foot to her leg and a spot on her thigh that was affected when she was being given pain blocks and the provider kept missing the site. She has rheumatoid arthritis in her hands, arms, and shoulders as well as a herniated disk in her neck. Patient reported that all of that was hurting and hurting at the same time. Felt weak and sick: patient reported that it took awhile to start coming back to herself. It took about a week and a half until she finally felt back to normal. The patient reported that she should have gone to the doctor or emergency room when she experienced side effects following the first dose of the Covid-19 vaccine. She didn't want to go to the hospital because her immune system wasn't right and she didn't want to catch anything. Information on Lot/Batch number was available. Additional information has been requested.

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| 1329514 | 5/19/2021 | MT | 43 | M | 4/30/2021 | 4/30/2021 | fainted; fell to the floor; hit his head; This is a spontaneous report from a contactable pharmacist. A 43-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), intramuscularly, administered in the left arm on 30Apr2021 at 12:15 PM (Batch/Lot Number: EW0172) as the 2nd dose, single for COVID-19 immunization. The vaccination facility type was reported as the pharmacy/drug store; the vaccine was not administered at the military facility. The patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on an unspecified date. Relevant medical history included past experience with fainting on an unknown date. The patient had no known allergies. The patient's concomitant medications were not reported. The patient had vaccination on 30Apr2021 and then proceeded to the front of the store to check-out. On 30Apr2021 at 12:20 PM, he fainted and fell to the floor and hit his head. The 911 was called immediately. The reporter checked the blood pressure and gave patient some water. The paramedics arrived and took over. The patient refused paramedic transport to hospital. The patient's father picked him up from the store. It was unknown if the patient has ever had an adverse event following any previous vaccine. The patient underwent lab tests and procedures, which included blood pressure with unknown results on 30Apr2021. The outcome of the events was unknown. Information on the batch/lot number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of event Faint cannot be excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate. |

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| 1330550 | 5/19/2021 | IL | 17 | M | 5/18/2021 | 5/18/2021 | PT HS NIXETY OF NEEDEL AND BLOOD, HE HAD FAINTED AFTER LAST VACCINE HE HAD. TODAY HE FELT NAUSEUS AND VOMITED. AFTER VOMITING HE FLET BETTER. HE WAITED 30 MINUTES IN WAITING AREA AND FELT NORMAL. PARENTA WERE WITH HIM THE WHOLE TIME. |

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| 1329496 | 5/19/2021 | CA | 60 | F | 4/9/2021 | 4/1/2021 | I have been sick; couldn't eat anything down; lost consciousness; Trigeminal neuralgia attack; Trigeminal neuralgia attack; massive vertigo attack; eye was so swollen; This is a spontaneous report from a contactable consumer (patient). This 60-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 09Apr2021 (at the age of 60-year-old) (Batch/Lot number was not reported) as single dose for COVID-19 immunisation. Relevant medical history included trigeminal neuralgia, head injury, pulmonary problems, severe migraine and tumor in lymph node. Concomitant medications were not reported. On 09Apr2021, the patient lost consciousness; in Apr2021, she experienced trigeminal neuralgia attack, massive vertigo attack and eye was so swollen; on an unspecified date she experienced also sickness and couldn't eat anything down. The patient specified that right after she got the injection, they make you to sit there for 15 minutes to see. She lost consciousness, it was like they gave her a shot before you go on for surgery and the doctor had come over, they had to wake her up. She didn't know what happened, so that was the first thing and the doctor said that's out of all the 1000's of people they vaccinated she was the first one that passed out right after the injection. So, she thought may be that should be noted somewhere and she didn't get a headache that she has a condition called Trigeminal neuralgia which was extremely painful and it's like only 3% of the population get it and it's usually caused after major head injury, was the very next day her shot was on the Friday and then Saturday the pain was terrific and she had the trigeminal pain for a week, took a week to go away and then right after that the next week she had a massive vertigo attack. And she really didn't know all these things or side effects from her head injury. But her conditions are pretty rare, you only get them if you've got massive concussions and fractured skull and stuff like that which happened a long time ago. So she didn't know if the shot had anything to do with it. She has pulmonary problems so she was getting it no matter what because she can't go anywhere hery Pulmonologist won't let her leave the house unless she has to go to a doctor or an emergency room. And she did go to the emergency room because her pain medication wasn't working at all |

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(Unspecified medication). She used to have migraine but after the head injury the migraine went away which she was very happy because she had severe migraine. What she didn't know was this Trigeminal neuralgia the nerve pain. The consumer further specified that she was so happy with the vaccine and she mean she doesn't care what the normal side effects are, she didn't have any other side effects her arm never hurts, she never had any fatigue or headache but she didn't know it was odd, the very morning she woke up Saturday she was in excruciating pain, its nerve pain that went down to the jaw, right under her eye and over the forehead and it's the most extremely painful thing that people get. She takes medication (Unspecified medication) daily to try to control it but sometime the pain is really really bad. She had been sick for the 3 weeks, she did not think anything had to do with the vaccine except the trigeminal. But it could have caused a massive vertigo attack which lasted 8 or 9 days. Today was the first day she was eating food in a week because she couldn't eat anything down. The patient was on a lot of steroids, she was reducing but she was still very plump so she thinks it's about 270 pounds right now. At the time of the report, the outcome of the events was unknown. The information on the batch number has been requested.

1329897 5/19/2021 NY 36 F 5/18/2021 5/18/2021 Systemic: Fainting / Unresponsive-Severe

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| 1329462 | 5/19/2021 | IN | 28 | F | 5/2/2021 | 5/2/2021 | skin pain; Nausea; Unable to sleep; Stomach pain; Diarrhea; Passed out from pain; Very extreme joint, muscle, organ, skin pain in every cell of body; 40 hours later, joints are still nearly unbearably sore; Very extreme joint, muscle, organ, skin pain in every cell of body; Headache; This is a spontaneous report from a contactable consumer (patient) A 28-years-old female patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) via an unspecified route of administration, administered in Arm Right on 02May2021 (reported as at 15:30) (Batch/Lot Number: Unknown) as 2ND DOSE, SINGLE for covid-19 immunization. The patient had no known medical history or allergies. Historical Vaccine includes 1st Dose of bnt162b2 on 11Apr2021 at 15:30 in right arm. Concomitant medications included amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL), paroxetine hydrochloride (PAXIL [PAROXETINE HYDROCHLORIDE]). No other vaccines were given within 4 weeks. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination the patient had not been tested for COVID-19. On 02May2021 at 02:00 the patient experienced passed out from pain, very extreme joint, muscle, organ, skin pain in every cell of body, 40 hours later, joints are still nearly unbearably sore, headache, skin pain, nausea, unable to sleep, stomach pain, diarrhea. Therapeutic measures were taken as a result of very extreme joint, muscle, organ, skin pain in every cell of body, headache. The clinical course was reported as follows Very extreme joint, muscle, organ, skin pain in every cell of body. Passed out from pain, Headache, Nausea. Pain only became slightly tolerable after taking 400 mg of both ibuprofen and acetaminophen nearly every 4 hours for the first 32 hours. Unable to sleep. Stomach pain. Diarrhea. 40 hours later, joints are still nearly unbearably sore. Continued stomach pain and diarrhea. The clinical outcome of the events was reported as recovering. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up. |

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| 1329456 | 5/19/2021 | IL | 57 | F | 4/14/2021 | 4/29/2021 | <p>Bell's palsy; eyes pretty red; runny nose: second dose; eyes started bothering her, the right eye: second dose; her eye had a little burning sensation and was irritated; This is a spontaneous report from a contactable consumer (patient). A 57-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in Arm Left on 14Apr2021 11:30 (Batch/Lot Number: EW0151) as single dose for covid-19 immunization. The patient's medical history included she was a breast cancer survivor, its been 10 years, all she had was radiation and she also had Tamoxifen for 5 years, had a colonoscopy a couple of months, she had seasonal allergies, adverse event following prior vaccinations: when she was young, she would get vaccines and would always get a light fever and her arm would swell and turn red. The patient's concomitant medication was not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient received the first dose of BNT162B2 (lot number: ER8733) in left arm on 24Mar2021 10:45 for covid-19 immunization and experienced fainted for just a few seconds, heart rate was very fast and headache, wasn't feeling well and lost consciousness. The patient experienced bell's palsy on 01May2021, eyes started bothering her, the right eye, her eye had a little burning sensation and was irritated on 29Apr2021, on the 30Apr2021 eye was pretty red, runny nose on 30Apr2021. The clinical course as following: This past Wednesday was two weeks and then Thursday, her eyes started bothering her, the right eye. She thought it was seasonal allergies, because she has those, that kept bothering her and and she had a very runny nose. Saturday she woke up she felt like her face was kind of numb. She called the nurse and they told her she should go to the emergency room. She was diagnosed with bells palsy and so they gave her treatment and they explained to her what it was all about. She had been working out in the yard and she came in and her eye had a little burning sensation and was irritated. She thought it was because she was outside. She also had a runny nose. She says again, she thought it was seasonal allergies because she has that. Felt weird around her mouth, felt kind of numb: second dose: This past Saturday, she woke up and stated she felt</p> |

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weird around her mouth, it felt kind of numb, it was hard for her to drink, she couldn't smile correctly, her smile was lopsided, one side was droopy. Caller states this began 01May2021. She went to the emergency room that same day and they diagnosed her with bells palsy. She was discharged from the emergency room because this time the lady doctor gave her the procedure with a stroke. The doctor could tell that it was not a stroke because of the eye, the doctor did something with her finger, they say can you see my finger, can you touch your nose. The doctor told her what she had is bells palsy and prescribed some medication. The eye is worse, but she doesn't have a runny nose anymore. With her eye, she can raise the left one, but the right one not as much. They gave her a patch for the right eye. She has to wear it in the evening, because it doesn't close anymore. She has to wear it to sleep with and during the day she has to wear glasses and if she goes outside, she has to wear sunglasses. Her eye is not really irritated, just kind of stiff, it does not really do much, she did some exercises to try to stimulate the muscles. The eye is just there, it doesn't really blink, it is beginning to blink a little bit but when she tries to close both eyes, she can close the left but it's like she can't completely close the right, she has no control of that part of the face, it's numb. She clarifies her eye started on Thursday 29 Apr because it was the first day she was outside. on the 30 Apr it was pretty red but she kept working. On Saturday morning she worked and she had a runny nose then too. Caller states they gave her some medicine at the emergency room. That night, she took Acyclovir and after she took the first one, she didn't have a runny nose anymore. Her eye is a different kind of bother now, it doesn't burn, its just there. They told her to get artificial tears and put the patch on. When asked if her eye is improved, persisted or worsened, she says the eye is not burning anymore, it's just kind of stiff. Bell's palsy: Caller states it's ongoing, when she smiles its the same. Caller states it's lopsided and when she raises her eyebrows, she can raise the left one, but the right one only goes up a little bit, but not as much. Caller states it's persisting, it's not getting worse, not getting better. Caller states she just started the medicine yesterday. Acyclovir: It was 400mg 5 times a day by mouth, one tablet for 10 days. Methylprednisolone: the other thing they prescribed me

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was Methylprednisolone. She tried taking both the Acyclovir and the Methylprednisolone yesterday, but she had a really bad stomach ache and couldn't eat anymore. She had no appetite and her doctor, she told him she couldn't take both it is too much, so he just said she should continue the Acyclovir so she is not going to take the Methylprednisolone. The Methylprednisolone is a 4mg dose pack, 6 day thing. Yesterday she was supposed to take two before breakfast, 1 after lunch, 1 after supper and 2 before bedtime. She couldn't take all of that, it was too much. Today would have been different, it tapers off. The emergency room visit on 01May2021, they didn't do any testing, she just had observation. the doctor did this thing with her finger where she could see her finger and she pushed back and held onto the doctor's hands and showed her strength. she raised her eyes, closed her eyes, smiled, but no other testing was done. she had her second emergency room visit on 01May2021. Therapeutic measures were taken as a result of bell's palsy included Acyclovir and Methylprednisolone, for events of 'eyes started bothering her, the right eye', 'her eye had a little burning sensation and was irritated', and 'eyes pretty red' included artificial tears and put the patch on, no treatment received for runny nose. The outcome of the event Bell's palsy was not recovered, the outcome of the event runny nose was recovered on 01May2021, the outcome of the other events was recovered on an unknown date.

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| 1329454 | 5/19/2021 | IL | 57 | F | 3/24/2021 | 4/1/2021 | This is a spontaneous report from a contactable consumer (patient). A 57-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in Arm Left on 24Mar2021 10:45 (Lot Number: ER8733) as SINGLE DOSE for covid-19 immunisation. Prior Vaccinations within 4 weeks, no other vaccinations within four weeks prior to the first administration date of the suspect vaccine. Medical history included she was a breast cancer survivor, it's been 10 years, all she had was radiation and she also had Tamoxifen for 5 years. When she was young, she would get vaccines and would always get a light fever and her arm would swell and turn red. She verified she had this type of reaction with any vaccine she received. She also had a colonoscopy a couple of months ago. The patient's concomitant medications were not reported. She got a very bad headache on 02Apr2021, she woke up in the middle of the night and she got up, she thought her head was going to explode. She fainted on 03Apr2021 for just a few seconds, so she went to the emergency room on 03Apr2021 and they gave her a CAT scan, with dye and one without dye and everything was normal. They gave her some Advil through her IV to get rid of the headache and then she was okay. She said the night before she had a headache, she took a baby aspirin and she was better and went to sleep. Patient stated around 1 AM in the morning, she woke up and wasn't feeling well. She got up, she had a really bad headache, throbbing, seemed like it was going to explode, and she went to the bathroom. She called out to her sister, she was not feeling well and she lost consciousness there. A few hours later, her sister helped her to the living rom and she could not walk by herself, she was weak. She ate something later, she drank a lot of Gatorade and she got in touch with the nurse and the nurse told her to go to the emergency room they performed tests at the ER. She did not have any more headaches, the throbbing headache went away but the headache didn't completely go away. In the emergency room after all the testing, the doctor told her they were going to give her something similar to Advil through her IV and the headache went away. The fainting only happened that one time and ended right then and there, she thought because the headache was so bad. Patient |

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reported her heart rate was very fast. She stated they waited for her heart rate to stabilize they gave her Advil through the IV, the headaches went away and she slept and they allowed her to go home once everything was okay. Between the first and second doses patient was sensitive to hot and cold foods, she couldn't drink a hot cup of coffee. She thought she had a cavity, it was strange. She was eating everything lukewarm. She felt sharp pain on her right side. So she went to the dentist and the dentist thought it was more of a vein problem, they took x-rays and found two cavities and a cracked tooth, and they fixed it. First Visit to emergency room, CAT scan with and without dye, COVID test, EKG, Lung X-ray. Everything came back normal, it was negative. Patient has recovered completely from the headache on 03Apr2021 thanks to the Advil. She confirmed she recovered completely from the fainting on 03Apr2021. The outcome of other events was unknown.

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| 1329453 | 5/19/2021 | PA | 64 | M | 4/2/2021 | 4/2/2021 | fainted; fell and hit his head; fell and hit his head; felt lightheaded/Dizziness; blood clots in his lungs; he has a spot on his lung that they are monitoring; hypoacusis and has a new hearing aid; This is a spontaneous report from a contactable consumer (patient's wife). A 64-years-old male patient received the first dose bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE;), via an unspecified route of administration, administered in Arm Left on 02Apr2021 (at the age of 64 years old) (Batch/Lot Number: ER8733) as 1st SINGLE DOSE for covid-19 immunisation. Medical history included severe sleep apnea from 18Mar2021 (received a machine not long after), gout (diagnosed about four years ago) , ex-tobacco user from an unknown date to an unknown date (two pack a day smoker over thirty years). Concomitant medication included colchicine (COLCHICINE) 0.6 mg, 1x/day taken for gout, start date was not reported to Apr2021. The patient experienced blood clots in his lungs (hospitalization, medically significant) on 02Apr2021 (also reported as 02May2021). , fainted, fell and hit his head, felt lightheaded/dizziness on 02Apr2021, The patient was hospitalized from 2Apr2021 to 4Apr202. It was reported the patient experienced hypoacusis and has a new hearing aid on an unspecified date. Caller says her husband has new hearing aids, which is why he is not doing the report himself. Patient has a spot on his lung that they are monitoring on an unspecified date. The patient underwent lab tests and procedures which included blood test: results unavailable on an unspecified date , 'they did a couple tests' (details not provided) results unavailable on 02Apr2021, urine analysis: results unavailable on an unspecified date. Therapeutic measures were taken as a result of blood clots in his lungs included Thrombectomy on 02Apr2021. The clinical course was reported as follows on April 2nd her husband received his first dose of the Pfizer COVID-19 vaccine. Approximately an hour later they went to the market and he felt lightheaded, so instead of getting out of the car they sat there 20 minutes. He started to get out again then halfway out the door he fainted and fell down on the ground. She says he was out for, 5-10 minutes, clarified to not even a minute. Since he hit his head she called an ambulance, and they took him to PRIVACY in PRIVACY. They did a couple tests and said since it was so soon after getting the vaccine that they did not think |

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the vaccine had to do with his blood clots. Caller also stated he fainted because that was one of the side effects of the vaccine, but they were glad he got there since he had several blood clots in his lungs. On the same day (02Apr2021) he had a thrombectomy to remove the blood clots and put him on a blood thinner. Patient was admitted to the hospital April 2nd and was discharged April 4th. He is doing better, he is on a blood thinner now. She says there were a few doctors that had to weigh in on whether he should get the second dose, they decided it wouldn't affect it since the vaccine goes into his muscle. No other vaccinations on the same days as his Pfizer COVID-19 vaccinations or during the four weeks prior. Once they placed him on a blood thinner, they took him off Colchicine 0.6mg. He stopped taking Colchicine because they said the blood thinner doesn't work with that particular medication. It was also reported The patient is to schedule an appointment with a rheumatologist and a hematologist, they did blood work and a urine test and said he has a spot on his lung that they are monitoring. The clinical outcome of the event blood clots in his lungs was Recovered/Resolved with Sequel while the remaining events was unknown. The second dose bnt162b2 was administered on April 29th. LOT: ER8751, caller hopes that is a 5, the writing is very bad on there. The patient had no side effects from his second dose of the Pfizer COVID-19 vaccine.

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| 1329435 | 5/19/2021 | NV | 19 | F | 4/23/2021 | 4/25/2021 | lost vision in both eyes; passed out; dizzy; severe nausea set in with severe body pain; severe nausea set in with severe body pain; worst migraine of my life; low blood pressure; This is a spontaneous report received from a contactable consumer (patient). A 19-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration (at the age of 19-years-old), administered in Arm Left on 23Apr2021 13:00 (Lot Number: EW0169) as 1st dose, single for COVID-19 immunization. Medical history included anxiety, and allergies to mosquitoes, hotdogs, and sausage. The patient was not pregnant at the time of vaccination. Concomitant medications included citalopram and drospirenone, estradiol (EOS), IUD, daily supplements. The patient previously took oxycodone ("oxycodone") and percocet [oxycodone hydrochloride;oxycodone terephthalate;paracetamol] and experienced allergies. The patient, 48 hrs later, lost vision in both eyes, became dizzy, passed out multiple times. Later severe nausea set in with severe body pain. Went to Urgent Care the following day and was told side effects. That night had worst migraine of her life, low blood pressure, and continued nausea. Given some meds and sent home to rest. Took 2 full days to feel okay again. Onset date and time of events reported as 25Apr2021 13:00. The adverse events resulted in Emergency room/department or urgent care. Therapeutic measures were taken as a result of the events. Treatment received for the adverse events included Toradol, Benadryl, and Reglan. The patient underwent lab tests and procedures which included sars-cov-2 test: negative (Nasal Swab) on 27Apr2021. The outcome of the events was recovered with sequelae. The events "lost vision in both eyes" and "passed out" were considered as serious (medically significant). Facility where the most recent COVID-19 vaccine was administered was Clinic/facility. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has been tested for COVID-19. No follow-up attempts are possible, no further information is expected. |

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| 1329429 | 5/19/2021 | AZ | 33 | F | 4/10/2021 | 4/13/2021 | Nearly fainted while doing normal activity; Extreme dizziness; Leg muscle weakness; Weight on chest; Difficulty catching breath-lasting; This is a spontaneous report from a contactable consumer. A 33-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EW0155), dose 1 via an unspecified route of administration, administered into the right arm on 10Apr2021, at 16:30 as single dose for covid-19 immunization. Medical history included no significant findings. Concomitant medication included botulinum toxin type a (BOTOX) taken for an unspecified indication, start and stop date were not reported. No known drug allergies were noted. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 13Apr2021, at 19:30, the patient nearly fainted while doing normal activity, extreme dizziness, leg muscle weakness, weight on chest, difficulty catching breath-lasting were all noted. The events resulted in doctor or other healthcare professional office/clinic visit. Details were as follows: the patient nearly fainted while doing normal activity, had extreme dizziness, leg muscle weakness, weight on chest, difficulty catching breath-lasting more than seven days. Unspecified therapeutic measures were taken as a result of the events; treatment was also noted as still pending labs, to identify problem. There was no COVID-19 diagnosis prior to vaccination. Patient has not been tested for COVID-19 since vaccination. The outcome of events, nearly fainted while doing normal activity, extreme dizziness, leg muscle weakness, weight on chest, difficulty catching breath-lasting was recovered with sequelae; the patient recovered with lasting effects.; Sender's Comments: Based on chronological connection to the vaccine a causal relationship between event "Nearly fainted while doing normal activity" and BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE) cannot be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate. |

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| 1329169 | 5/19/2021 | TN | 67 | F | 3/12/2021 | 3/12/2021 | mentally overwhelmed; missed her 2nd dose; headache on and off; staggering fatigue/hard to stay awake where her eyes always wanted to close; felt uneasy; dizzy; she did not make it and urinated on the floor; passed out on the toilet; nervous; jittery feelings; Hands started to shake; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (passed out on the toilet) in a 67-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 040A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Arthritis (Left knee). Concomitant products included ACETYLSALICYLIC ACID (ASPIRIN (E.C.)), KETOROLAC and HYDROXYZINE for an unknown indication. On 12-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 12-Mar-2021, the patient experienced NERVOUSNESS (nervous), FEELING JITTERY (jittery feelings) and TREMOR (Hands started to shake). On 13-Mar-2021, the patient experienced LOSS OF CONSCIOUSNESS (passed out on the toilet) (seriousness criterion medically significant), DIZZINESS (dizzy), INCONTINENCE (she did not make it and urinated on the floor), FEELING ABNORMAL (felt uneasy), HEADACHE (headache on and off) and FATIGUE (staggering fatigue/hard to stay awake where her eyes always wanted to close). On an unknown date, the patient experienced EMOTIONAL DISTRESS (mentally overwhelmed) and PRODUCT DOSE OMISSION ISSUE (missed her 2nd dose). On 12-Mar-2021, TREMOR (Hands started to shake) had resolved. On 13-Mar-2021, LOSS OF CONSCIOUSNESS (passed out on the toilet) and INCONTINENCE (she did not make it and urinated on the floor) had resolved. At the time of the report, NERVOUSNESS (nervous), FEELING JITTERY (jittery feelings), DIZZINESS (dizzy), EMOTIONAL DISTRESS (mentally overwhelmed), FEELING ABNORMAL (felt uneasy), HEADACHE (headache on and off) and FATIGUE (staggering fatigue/hard to stay awake where her eyes always wanted to close) outcome was unknown and PRODUCT DOSE OMISSION ISSUE (missed her 2nd dose) had resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) |

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(Intramuscular) was unknown. Treatment of these events were not reported. Based on current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded.; Sender's Comments: Based on current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded.

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| 1329070 | 5/19/2021 | CA | 52 | M | 4/12/2021 | | CEREBROVASCULAR ACCIDENT; SYNCOPE; ACUTE KIDNEY INJURY; DYSSTASIA; BLOOD GLUCOSE INCREASED; BLOOD PRESSURE INCREASED; ASTHENIA; MUSCULAR WEAKNESS; BLOOD TEST; COMPUTERISED TOMOGRAM HEAD ABNORMAL; CONDITION AGGRAVATED; HYPOAESTHESIA; MAGNETIC RESONANCE IMAGING HEAD ABNORMAL; This spontaneous report received from a consumer via a Regulatory Authority Vaccine Adverse Event Reporting System (VAERS) concerned a 52 year old male. The patient's height, and weight were not reported. The patient's concurrent conditions included high blood pressure, and the patient had no history of diabetes. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, 1 total administered to right arm on 02-APR-2021 for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. Concomitant medications included enalapril for high blood pressure. On 12-APR-2021, the patient came from work in the morning and complained numbness in left side (hypoesthesia). The patient thought it was related to the weather getting warm and as he works in the night shift, he rested and increased his water intake. He was able to go to work on that night and returned home and continued to rest. On 13-APR-2021, the patient had no numbness, but had weakness in both his legs (muscular weakness). On 14-APR-2021, the patient experienced weakness throughout his body (asthenia), especially in his legs. On 15-APR-2021, the patient collapsed (syncope), he did not lose consciences but his legs gave out under him and he was not able to get up (dysstasia). The patient was taken to the hospital and was diagnosed with a stroke (cerebrovascular accident), increased blood glucose levels, acute kidney injury, and uncontrolled increased blood pressure. During his hospital stay, Blood test (result: not reported), Computerized tomogram head (result: abnormal), and Magnetic resonance imaging head (result: not reported) were performed. The patient was hospitalized for 5 days and was discharged on 19-APR-2021. On 24-APR-2021, the patient experienced another episode of stroke (cerebrovascular accident, condition aggravated) and was readmitted to hospital and |

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| 1328947 | 5/19/2021 | GA | 30 | F | 1/19/2021 | 2/10/2021 | <p>Blood test (result: not reported), Computerized tomogram head (result: abnormal) were performed. On an unspecified date, the patient visited emergency department. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from acute kidney injury, asthenia, blood glucose increased, blood pressure increased, cerebrovascular accident, computerised tomogram head abnormal, condition aggravated, dysstasia, hypoaesthesia, magnetic resonance imaging head abnormal, muscular weakness, syncope, and blood test. This report was serious (Hospitalization Caused / Prolonged, Life Threatening, and Disability Or Permanent Damage). Version created to amend previously reported information on 07-May-2021. Upon review the following information was amended: Labelling for event MUSCULAR WEAKNESS and ASTHENIA was updated from labeled to unlabeled in Core.; Sender's Comments: V1:20210514642- covid-19 vaccine ad26.cov2.s - Cerebrovascular accident, Syncope, Acute kidney injury, Asthenia, Blood glucose increased, Blood pressure increased, Computerized tomogram head abnormal , Condition aggravated, Dysstasia, Hypoaesthesia, Magnetic resonance imaging head abnormal , Muscular weakness, and Blood test. This event(s) is considered not related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: MEDICAL HISTORY,UNDERLYING DISEASE</p> <p>Dizziness, tachycardia, bells palsy, neck pains, fainting,, fainting after eating, trouble speaking, swollen lymph nodes, dysautonomia , chest pain, anxiety, weird stretchy feeling in the neck, diarrhea like morning sickness, nausea, spasms in throat while speaking</p> |

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1329513 5/19/2021

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Kidney stones/two kidney stones; Blackout; Fainting; Low blood pressure; Urinary tract infection; Tiredness; Vaccination adverse reaction/She had a slight reaction to the Pfizer COVID vaccine; Dizziness; Pinched nerve; Vomiting; This is a solicited report from a non-Pfizer sponsored program, received from a non-contactable consumer (patient). A 50-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), intramuscular on an unspecified date (Batch/Lot number was not reported) as UNKNOWN, SINGLE for COVID-19 immunisation and adalimumab (HUMIRA, Solution for injection in pre-filled pen), subcutaneous from an unspecified date (Batch/Lot number was not reported) at unknown dose for moderate to severe chronic plaque psoriasis. The patient's medical history and concomitant medications were not reported. On an unspecified date, the patient experienced kidney stones, blackout, fainting, low blood pressure, urinary tract infection, tiredness, vaccination adverse reaction, dizziness, pinched nerve, and vomiting. It was further reported that patient had two kidney stone, blackouts, low blood pressure, fainting, urinary tract infection, took adalimumab week early and was little tired, small reaction to COVID vaccine, dizziness and pinched nerve in neck. The patient stated that she made a mistake and took her adalimumab a week early and she was a little tired, but she felt fine after a day or so and now she feels better like she has more energy. She had been having fainting spells, physician thought it might be due to a pinched nerve in her neck. She had a bad urinary tract infection and in Mar2021 she had to have two kidney stones removed. She also had vomiting and low blood pressure. She had a slight reaction to the Pfizer COVID vaccine. It was unknown if she was enrolled in a COVID-19 Vaccine Trial. The reporter considered the event kidney stone as serious. The action taken in response to the events for adalimumab was not applicable. Therapeutic measures were taken as a result of kidney stones which included removal of two kidney stones in Mar2021. On an unspecified date, the patient recovered from urinary tract infection and vaccination adverse reaction and was recovering from tiredness. The patient had not yet recovered from kidney stones, blackout, fainting, and dizziness. The outcome of low blood pressure, pinched nerve, and vomiting was unknown.

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The reporter's causality for the events of blackouts, fainting, urinary tract infection, took adalimumab week early and was little tired unknown onset, small reaction to COVID vaccine and dizziness with Humira (adalimumab) was no reasonable possibility. AbbVie's opinion was that there was no reasonable possibility that the events of two kidney stone, blackouts, low blood pressure, fainting, urinary tract infection, took adalimumab week early and was little tired unknown onset, small reaction to COVID vaccine, dizziness and pinched nerve in neck are related to Humira (adalimumab). AbbVie's opinion was that there was a reasonable possibility that the event of took adalimumab week early and was little tired unknown onset was related to humira (adalimumab). The reporter's assessment of the causal relationship of the events kidney stones, low blood pressure, tiredness, dizziness, pinched nerve, and vomiting with the suspect product was not provided at the time of this report. Since no determination has been received, the case is managed based on the company causality assessment. Information about the lot/batch number has been requested.; Sender's Comments: Based on available information and currently known drug safety profile, a possible contributory role of bnt162b2 can not be excluded for the reported events blackout, fainting, low blood pressure, tiredness, vaccination adverse reaction, dizziness, pinched nerve and vomiting. The other reported events kidney stones and urinary tract infection more likely represented intercurrent illnesses, but not related to bnt162b2. Case will be reassessed when additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and investigators, as appropriate.

1330117 5/19/2021 CA

14 F

5/18/2021

5/18/2021

Systemic: Allergic: Difficulty Breathing-Mild, Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Medium, Systemic: Hypotension-Mild, Systemic: Shakiness-Mild, Systemic: Tachycardia-Mild, Systemic: Weakness-Mild

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| 1331231 | 5/19/2021 | FL | 41 | F | 5/19/2021 | 5/19/2021 | Patient passed out approximately 10 minutes after getting her shot. She was given a bottle of water (by her spouse). EMS was called and evaluated patient. She declined further care and left with her husband once she felt better. |
| 1330458 | 5/19/2021 | TX | 81 | M | 4/1/2021 | 4/2/2021 | Vaccine was given on 4/1 and the next day nauseated, dry heaves, cannot eat and lives on protein shakes and he's lost 20lbs and he's weak and been in the hospital twice and the doctors cannot find why. He has passed out four times. He is a cancer survivor but nothing shows that the cancer has returned. |
| 1330444 | 5/19/2021 | | 17 | F | 5/7/2021 | 5/7/2021 | 2nd dose Pfizer vaccine administered patient was in Observation Area and c/o of sweating and dizziness. Patient fainted for about 2 seconds. Patient arousable and VS were within normal ranges, blood sugar was 68 when being cared for by EMS. Pt states she has had this history of reaction before to vaccines. She had not eaten or drank anything since around 8pm the night before. Patient given water and a food and stated she felt better. Patient remained in Obs area for an additional 40 minutes with EMT, RN and Physician oversight. |
| 1330439 | 5/19/2021 | CA | 34 | M | 5/19/2021 | 5/19/2021 | Patient warned of previous vaso-vagal syncope. Patient was placed in supine position for vaccine administration and about 1 min afterward became anxious and passed out. He was unconscious for 10 sec and awoke, sweaty, weak. He was not confused, did not seize or lose bowel/bladder continence. |
| 1330418 | 5/19/2021 | | 12 | F | 5/19/2021 | 5/19/2021 | Patient reported history of syncope episode with another vaccine in the past. Patient has history of seizure disorder. At 10:10am, patient was sitting with her mother when she started to convulse sitting up right in a chair. She also vomited while convulsing for about 15seconds. Full consciousness regained. |
| 1330387 | 5/19/2021 | MD | 13 | M | 5/19/2021 | 5/19/2021 | Vasovagal syncope a few minutes after receiving shot. Waiting to check in to observation area and fainted. LOC but immediately awake, A&O. LEs elevated, cool compress to neck. HR, BP checked, stable. Rested and resolved. Home with dad. |

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| 1330351 | 5/19/2021 | IL | 22 | F | 5/19/2021 | 5/19/2021 | Patient reported before the vaccine was administered that she had a history of fainting upon receiving vaccines in the past. As predicted, she fainted within seconds of administering the Janssen vaccine. While unconscious, patient had a few mild head/neck twitches which then progressed to 2-3 full body twitches/spasms before regaining consciousness. Total time unconscious with less than 1 minute. Once fully awake and alert, patient informed me that she had a history of a seizure once before. We gently laid her on the floor and I took her vitals. Vitals were low with BP 90/49, HR 49, and O2 90%. She continued to lay on the floor for approximately 10 minutes before checking her vitals again. At that time, vitals were better with HR 60 and O2 99; I was unable to retake her BP at that time, but patient claimed that it usually was on the low side. She called her mother who agreed to come stay with her to keep watch for more events at her home. A family friend was also called to come pick her up and drive her home. Before leaving, I strongly advised patient to see a doctor to check everything out. Patient just moved here and claims to not have a primary at either location. |
| 1330314 | 5/19/2021 | CA | 15 | F | 5/19/2021 | 5/19/2021 | Pt had syncope x 1 postvaccination followed by seizure x 2. Pt recovered spontaneously after 3-5 seconds. No labored breathing. Alert and oriented x 3. Pt brought to ER. |
| 1330225 | 5/19/2021 | OH | 31 | F | 4/12/2021 | 4/12/2021 | Within 15 mins I was sweating and nausea, shaking, I passed out for less than 30 secs. I was shaking. |
| 1329891 | 5/19/2021 | NJ | 12 | M | 5/18/2021 | 5/18/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Mild, Systemic: Vomiting-Medium |
| 1330130 | 5/19/2021 | PA | 15 | M | 5/18/2021 | 5/18/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient received vaccine and passed out. Father reported after event that patient has passed out from needles and previous vaccines and did not notify the pharmacist prior to administration. Patient recovered quickly and remained in store for 20 minutes post event with no reported issues. Father denied need to call 911 and patient was responsive within 5-10 seconds. |
| 1329895 | 5/19/2021 | MD | 16 | F | 5/18/2021 | 5/18/2021 | Systemic: Fainting / Unresponsive-Severe |

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| 1330114 | 5/19/2021 | MI | 30 | M | 5/18/2021 | 5/18/2021 | Roughly 5-10 minutes after receiving the vaccine, patient fainted and began seizing for about 30 seconds. 911 was called, but patient came too and denied ambulance. Patient then vomited a couple minutes after. Patient reported he had not eaten anything and he was given orange juice and water. Patient waited another 30 minutes and reported feeling better. denied any further medical treatment. |
| 1330099 | 5/19/2021 | MS | 23 | M | 4/21/2021 | 4/21/2021 | After receiving Moderna vaccine, pt came to 15 minute wait area. once here, pt stated he started getting a headache. The headache stopped , then pt began feeling extremely tired and shaky. Broke out into cold sweat. Never passed out. Pt his arms felt lie they were "asleep" and fingers on his left hands felt like he could not move them, stiffened . No respiratory distress listed VS taken |
| 1330091 | 5/19/2021 | NY | 18 | F | 5/17/2021 | 5/17/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Mild |
| 1330026 | 5/19/2021 | GA | 13 | M | 5/18/2021 | 5/19/2021 | A few minutes after receiving the vaccine, the patient fainted. The mother caught her son in her arms and we were both able to lay him on the floor safely without hitting his head. He came to within a few seconds. He remained in the pharmacy area for approximately 20 more minutes for observation. He was feeling back to normal before leaving. |
| 1330010 | 5/19/2021 | NV | 17 | M | 5/18/2021 | 5/18/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient fainted a few minutes after getting shot but regained concisousness in less than a minutes |
| 1329988 | 5/19/2021 | FL | 21 | F | 5/18/2021 | 5/18/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Nausea-Medium, Additional Details: patient fainted and vomiting after receiving vaccine, ambulance was called patient was evaluated and vitals were within normal limits. Patient was contacted 6 hours after event and stated she was feeling much better. patient was observed after vaccine for 1 hour |

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| 1329982 | 5/19/2021 | MD | 22 | M | 5/18/2021 | 5/18/2021 | Systemic: Confusion-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Nausea-Mild, Additional Details: Patient said he was not feeling well. When I responded to him he said he did not feel good. I told him to put his head between his knees, but before he could do it, he became non-responsive. He remained seated as I shook him gently asking if he was ok, his eyes were open. When he became responsive, he said he must have fallen asleep. He said he felt nauseated. He was sweating. We called 911. The paramedics came and checked vital signs. His BP was 110/68, blood glucose was 107.Pt left on his own. |
| 1329946 | 5/19/2021 | CA | 15 | F | 5/18/2021 | 5/18/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Shakiness-Mild |
| 1329929 | 5/19/2021 | NH | 27 | F | 3/21/2021 | 3/22/2021 | On March 22 2021, I had leg cramps that felt like Charlie horses, I had a fever of 102 and I missed work. On March 24 I went to my doctor because my legs were still bothering me. That same night I ended up experiencing extreme dizzy spells, I fainted. On March 25 called my doctor I told them my symptoms were getting worse, the office made me a follow up appointment for April 2 for dizzy spells and fatigue. My symptoms continued to get worse, I had a tele visit April 5. Then, I started developing a dry cough. I called again that same day 4/5 for shortness of breath and went in to my doctors office 1:10pm. They did a chest xray. April 6th I had another tele appointment for anxiety Because I started developing anxiety from all my symptoms. April 7th I called again I had blood in my urine and back pain, It was very alarming because my last period was & years ago. April 7th I went to an Urgent Care . April 8th it got really bad. I went emergency room, I felt like I had a lump in my throat and experiencing some chest tightness, my pulse was 101 beats per minute, heart 118, BP was 143/106 I presented with unspecified Right Bundle Branch block and I ended up tachycardia, they did a CT scan of my chest. the doctor gave me Valium & Hydroxyzine. At the hospital I started dry heaving and vomiting. April 9th saw a new doctor still very nauseated and I was experienced nausea and heart palpitations, and rapid heart. |

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| 1330526 | 5/19/2021 | FL | 27 | M | 5/19/2021 | 5/19/2021 | patient took vaccine went over to post vaccination area and fainted. Patient immediately woke up in cold sweats. Sat for 30 minutes and felt better. |
| 1330208 | 5/19/2021 | NC | 45 | F | 4/10/2021 | 4/11/2021 | Starting about noon the next day I was walking outside and completely passed out cold, hit head on the way down. When I came to everyone was standing around me and told me not to move. I was unconscious about 10 sec. Everything went white. An ambulance was called, it took them a while to show up, evaluated inside ambulance, everything was normal. EMT advised that they didn't think I needed to go to the ER. |
| 1331213 | 5/19/2021 | AL | 73 | F | 4/28/2021 | 4/29/2021 | Patient's daughter called today wanting to report an adverse event that she believed was related to mother's covid vaccine. Patient received first vaccine 3/27 and on 4/4 had to go to the ER with severe dizziness. This incident was not reported to the pharmacy until today. Patient received 2nd dose on 4/28. On 4/29, the ambulance was called by patient's husband because the patient had passed out. When she got to the ER, they determined that the patient had a seizure and she was admitted to the ICU. The patient does not have any history of seizures. She is still currently in the hospital but was moved to a regular room on 5/10 or 5/11 (daughter did not know the exact date). She is still having effects such as cannot feed herself and daughter said that communication is VERY limited. |
| 1328714 | 5/18/2021 | WA | 25 | M | 5/18/2021 | 5/18/2021 | WITHIN SEVERAL MINUTES OF RECEIVING THE VACCINATION THE PATIENT PASSED OUT, REGAINING CONSCIOUSNESS WITHIN 1 MINUTE |

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| 1325799 | 5/18/2021 | SC | 68 | M | 2/20/2021 | 2/20/2021 | In under two minutes, fainted / Believed to be vasovagal syncope; Stomach hurting so bad that felt heart; Chest discomfort; had Diarrhea; Immediate post-injection reaction; Felt very nauseous; Vomited; This regulatory authority case was reported by an other health care professional and describes the occurrence of SYNCOPE (In under two minutes, fainted / Believed to be vasovagal syncope) in a 68-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Nose congestion (For about 2 weeks.) since February 2021. Concomitant products included PAROXETINE, MELOXICAM, DIPHENHYDRAMINE HYDROCHLORIDE (BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE]), VITAMIN C [ASCORBIC ACID], COLECALCIFEROL (VITAMIN D [COLECALCIFEROL]), ZINC, ASCORBIC ACID, QUERCETIN (QUERCITIN), LISINOPRIL, FISH OIL (OMEGA 3 [FISH OIL]), CURCUMIN and PHENYLEPHRINE HYDROCHLORIDE (SUDAFED PE) for an unknown indication. On 20-Feb-2021, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 20-Feb-2021, the patient experienced SYNCOPE (In under two minutes, fainted / Believed to be vasovagal syncope) (seriousness criterion medically significant), ABDOMINAL PAIN UPPER (Stomach hurting so bad that felt heart), CHEST DISCOMFORT (Chest discomfort), DIARRHOEA (had Diarrhea), IMMEDIATE POST-INJECTION REACTION (Immediate post-injection reaction), NAUSEA (Felt very nauseous) and VOMITING (Vomited). At the time of the report, SYNCOPE (In under two minutes, fainted / Believed to be vasovagal syncope), ABDOMINAL PAIN UPPER (Stomach hurting so bad that felt heart), CHEST DISCOMFORT (Chest discomfort), DIARRHOEA (had Diarrhea), IMMEDIATE POST-INJECTION REACTION (Immediate post-injection reaction), NAUSEA (Felt very nauseous) and VOMITING (Vomited) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 20-Feb-2021, Abdominal X-ray: unknown Results not reported.. On 20-Feb-2021, Blood test: unknown Results not reported.. On 20-Feb-2021, Chest X-ray: unknown Result not reported.. On 20-Feb-2021, |

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Computerised tomogram head: unknown No fall.. On 20-Feb-2021, Electrocardiogram: unknown Result not reported.. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications included unspecified joint supplement. It was reported that immediately after the administration of the vaccine, the patient fainted In under two minutes. The patient reported that there was no prior history of fainting. After regaining consciousness the patient reported severe nausea, an episode of diarrhea, vomiting, bad stomach pain which he felt was heart related and went to the emergency room where tests were conducted and he was there for four hours. No treatment information was provided.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

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| 1325904 | 5/18/2021 | MO | 65 | F | 2/6/2021 | 3/7/2021 | Collapsed; large hematoma on the back of head; feeling very weak; Woozy and Headachy; flat on my back on the bathroom floor; quite disoriented; memory of what happened next is a little hazy; attempted to get up once and was unsuccessful; Low Blood Pressure; gash open my front lip in the fall; Woozy and headachy; This spontaneous case was reported by a consumer and describes the occurrence of SYNCOPE (Collapsed) in a 65-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 016M20A and 036A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Dust allergy, Pollen allergy, Grass allergy, Ragweed allergy and Seasonal allergy since 1960. Concomitant products included CALCIUM, COLECALCIFEROL (CALCIUM WITH VITAMIN D3 [CALCIUM;COLECALCIFEROL]) for Osteoporosis. On 06-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 06-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 07-Mar-2021, the patient experienced SYNCOPE (Collapsed) (seriousness criteria hospitalization and medically significant), DIZZINESS (Woozy and Headachy), FALL (flat on my back on the bathroom floor), DISORIENTATION (quite disoriented), AMNESIA (memory of what happened next is a little hazy), DYSSTASIA (attempted to get up once and was unsuccessful), HYPOTENSION (Low Blood Pressure), LIP INJURY (gash open my front lip in the fall) and HEADACHE (Woozy and headachy). On 19-Mar-2021, the patient experienced ASTHENIA (feeling very weak). On an unknown date, the patient experienced HAEMATOMA (large hematoma on the back of head). At the time of the report, SYNCOPE (Collapsed), DIZZINESS (Woozy and Headachy), FALL (flat on my back on the bathroom floor), DISORIENTATION (quite disoriented), AMNESIA (memory of what happened next is a little hazy), DYSSTASIA (attempted to get up once and was unsuccessful), HYPOTENSION (Low Blood Pressure) and HEADACHE (Woozy and headachy) had resolved and ASTHENIA (feeling very weak), HAEMATOMA (large hematoma on the back of head) and LIP INJURY (gash open my front lip in the fall) |

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outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood pressure measurement: low (Low) 85/45. On an unknown date, Computerised tomogram: negative (Negative) brain bleed (negative). On an unknown date, X-ray: negative (Negative) negative. Treatment for the events included aspirin and intravenous saline. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 08-May-2021: updated concomitant medications, treatment information, and medical history.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

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| 1326114 | 5/18/2021 | CA | 60 | F | 4/9/2021 | 4/9/2021 | Massive vertigo attack; Severe migraine; can't go anywhere; pain medication wasn't working at all; Pain; couldn't eat anything down; eye was so swollen; Passed out right after the injection; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out right after the injection) in a 60-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 09-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 09-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (Passed out right after the injection) (seriousness criterion medically significant). On an unknown date, the patient experienced VERTIGO (Massive vertigo attack), MIGRAINE (Severe migraine), MOBILITY DECREASED (can't go anywhere), DRUG INEFFECTIVE (pain medication wasn't working at all), PAIN (Pain), FEEDING DISORDER (couldn't eat anything down) and EYE SWELLING (eye was so swollen). At the time of the report, LOSS OF CONSCIOUSNESS (Passed out right after the injection), VERTIGO (Massive vertigo attack), MIGRAINE (Severe migraine), MOBILITY DECREASED (can't go anywhere), DRUG INEFFECTIVE (pain medication wasn't working at all), PAIN (Pain), FEEDING DISORDER (couldn't eat anything down) and EYE SWELLING (eye was so swollen) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No concomitant list is provided. Treatment information was not provided. Based on current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded.; Sender's Comments: Based on current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded. |

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| 1326133 | 5/18/2021 | NY | 17 | F | 4/29/2021 | 4/30/2021 | Fainting/syncope; high fever; lightheadedness; This is a spontaneous report from a contactable consumer (patient). A non-pregnant 17-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in left arm on 29Apr2021 at 14:30 (at the age of 17 years old) (Lot Number: EW0171, unknown expiration) as 2nd dose, single for COVID-19 immunization. Medical history reported as none. No known allergies. The patient's concomitant medications were not reported. The patient also received first dose of BNT162B2 on 08Apr2021 at 16:30 in the left arm (at the age of 16 years old; Lot number: EW0150, unknown expiration) for COVID-19 immunization. The patient experienced fainting/syncope, high fever, and lightheadedness on 30Apr2021 at 06:45 AM. The events resulted in emergency room/department or urgent care visit. The patient received IV fluids as treatment for the events. No COVID prior to vaccination and was not tested for COVID post vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient is recovering from the events. Information on lot/batch number was available. Additional information has been requested. |

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| 1326134 | 5/18/2021 | CT | 53 | M | 4/23/2021 | 4/23/2021 | My lower extremities, from the knee down, are weak and sometimes it is hard to walk.; My lower extremities, from the knee down, are weak and sometimes it is hard to walk.; My knees also hurt; Dizziness; Skin was very pale and cold to the touch.; Profuse sweating.; Fatigue; Muscle Pain; Fainting 9 hours after administration; I had my first headache.; I had pins and needles in fingers 4 and 5 in the arm of vaccine administration; This is a spontaneous report from a contactable consumer (patient). A 53-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in Arm Left on 23Apr2021 11:30 (Lot Number: EW0170), at age of 53 years old, at single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient previously took asparagus for Allergy. Reported Event: Immediately after the vaccine, I had pins and needles in fingers 4 and 5 in the arm of vaccine administration. 3 hours after vaccine, I had my first headache. Severe headache, dizziness, fainting 9 hours after administration. During fainting episode, skin was very pale and cold to the touch. Profuse sweating. This was on the same day as vaccine administration. For the next 3 days, I laid in bed with fatigue, severe headache, and muscle pain. After 10 days, I still feel weak, I get tired after walking half a mile, and I have episodes of dizziness during the day. My lower extremities, from the knee down, are weak and sometimes it is hard to walk. My knees also hurt. This is still present 10 days after the vaccine. Outcome for events was unknown. Prior to vaccination, whether the patient was diagnosed with COVID-19 Was Unknown, and Since the vaccination, the patient has not been tested for COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No follow-up attempts are needed. No further information is expected. |

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| 1326140 | 5/18/2021 | MD | 33 | M | 4/27/2021 | 4/28/2021 | <p>concussion; lost consciousness; fell; hit my head on the bathroom floor; This is a spontaneous report from a contactable consumer (patient). A 33-years-old male patient received second dose of bnt162b2 (Pfizer-BioNTech COVID-19 Vaccine), at the age of 33-years-old, via an unspecified route of administration, administered in Arm Left on 27Apr2021 12:45 PM (Lot Number: EW0171) as single dose for covid-19 immunisation. Medical history included known allergies: Penicillin, syncope from an unknown date and unknown if ongoing (last episode 2008). Concomitant medication included minocycline hcl taken for an unspecified indication, start and stop date were not reported at 50mg. (patient received within 2 weeks of vaccination). Patient received first dose of bnt162b2 at the age of 33-years-old, administered in Arm Right on 06Apr2021 12:30 PM (Lot Number: EW0158) for covid-19 immunisation. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. In the middle of the night, patient woke up to use the bathroom. At some time, he lost consciousness, fell, and hit head on the bathroom floor. Patient regained consciousness around 3am. At the hospital, he was diagnosed with a concussion. Event start date was at 28Apr2021 01:00 AM. Events resulted in Emergency room/department or urgent care, Hospitalization. Days hospitalization was 1. Treatment received for the adverse event was Testing and observation. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient been tested for COVID-19. Covid test name post vaccination was BioFire, Type post vaccination was Nasal Swab, test date on 28Apr2021, test result was Negative. Events outcome was recovering. Information on Lot/Batch number was available. Additional information has been requested.</p> |

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| 1326153 | 5/18/2021 | NY | 27 | M | 5/1/2021 | 5/3/2021 | fainted; lost consciousness for a couple of seconds; burning pain that felt like needles on his shoulder, left arm and a little on the right side/extremely, burning pains across his back/He had burning pain on his shoulders, very sensitive, felt like a 3rd degree burn; felt like he could not stand and had to go to the floor, struggled to get up; arms were numb; thought he was having a heart attack; left arm weak; skin is hypertensive: back of neck feels like a third degree burn: if he moves the hair on his arms it hurts; left side of face is swollen; left side of face is swollen was reported as worsened.; skin is hypertensive: back of neck feels like a third degree burn: if he moves the hair on his arms it hurts; skin is hypertensive: back of neck feels like a third degree burn: if he moves the hair on his arms it hurts; left arm pain; This is a spontaneous report from contactable consumers (patient reported for himself, patient's mother). A 27-years-old male patient received bnt162b2 (BNT162B2; PFIZER-BIONTECH COVID-19 VACCINE), dose 1 intramuscular, administered in Arm Right on 01May2021 12:00 noon (Batch/Lot Number: EW0170; Expiration Date: 31Aug2021) as 1ST DOSE, 0.3 ML SINGLE for covid-19 immunization, at the age at vaccination of 27 years old. The patient's medical history and concomitant medications were not reported. The patient experienced thought he was having a heart attack(medically significant) on 03May2021 01:00 with outcome of unknown, skin is hypertensive: back of neck feels like a third degree burn: if he moves the hair on his arms it hurts (medically significant) on 03May2021 with outcome of not recovered, fainted (medically significant) on an unspecified date with outcome of unknown, lost consciousness for a couple of seconds (medically significant) on 03May2021 01:00 with outcome of recovered with sequelae on 03May2021, burning pain that felt like needles on his shoulder, left arm and a little on the right side/extremely, burning pains across his back/he had burning pain on his shoulders, very sensitive, felt like a 3rd degree burn (non-serious) on 03May2021 01:00 with outcome of unknown, felt like he could not stand and had to go to the floor, struggled to get up (non-serious) on 03May2021 01:00 with outcome of recovered with sequelae on 03May2021, arms were numb (non-serious) on 03May2021 01:00 with outcome of recovering, left arm pain (non-serious) on 03May2021 |

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with outcome of not recovered, left arm weak (non-serious) on 03May2021 01:00 with outcome of unknown, skin is hypertensive: back of neck feels like a third degree burn: if he moves the hair on his arms it hurts (non-serious) on 03May2021 01:00 with outcome of not recovered, skin is hypertensive: back of neck feels like a third degree burn: if he moves the hair on his arms it hurts (non-serious) on 03May2021 with outcome of not recovered, left side of face is swollen (non-serious) on 03May2021 01:00 with outcome of not recovered , left side of face is swollen was reported as worsened (non-serious) on 03May2021 with outcome of not recovered. The patient underwent lab tests which included computerised tomogram (brain CT): no results, electrocardiogram (EKG): no results, both on unknown date. Reported patient was in pain and his mom and dad didn't know what to do. He had sharp pains. No bruises. He remember lowering myself to fall. He didn't fall. It was a strange thing. When he went to the ER they didn't fine anything. He was still in the same amount of pain. Caller stated her son took the vaccine on Saturday. Thirty six hours later around 1:00am he started getting extremely, burning pains across his back. The patient stated he was coming out of the bathroom and felt like he couldn't stand and he had to go to the floor. He lost consciousness for a couple of seconds. Both arms were numb. He struggled to get up. He sat on the couch and then went upstairs after being in the basement. He had a burning pain that felt like needles on his shoulder, left arm and a little on right side. His skin was sensitive. The back of his neck feels like he has a third degree burn. This morning he went to the hospital. Initially said he fainted but clarified that he was speaking about losing consciousness. He had left arm pain. He thought he was having a hard attack. While at the emergency room today he had labs, a brain CT scan and an EKG. He does not have results to provide. Caller added that his skin was hypersensitive. It was like if he moves the hair on his arm it hurts. His parents noticed he has swelling on the left side of his face. The events require a visit to Emergency Room. No Prior Vaccinations (within 4 weeks). Information on Lot/Batch number was available. Additional information has been requested.

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| 1326156 | 5/18/2021 | FL | 38 | F | 4/22/2021 | 4/23/2021 | I felt like I was going to die.; Chills; headache; stomach upset; nausea; fever; fatigue; weakness; dizziness; vomiting; This is a spontaneous report from a contactable consumer (patient). A 38-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in Arm Left on 22Apr2021 16:00 (Batch/Lot number was not reported), at age of 38 years old, as single dose for covid-19 immunisation. The patient was not pregnant at time of vaccination. The patient previously took dose 1 via an unspecified route of administration, administered in Arm Left on 04Apr2021 09:00 AM (Batch/Lot Number: 1 as reported) as single dose for covid-19 immunisation. Medical history was none and no known allergies. Concomitant drugs within 2 weeks of vaccination was not reported. Reported Event as reported: "24 hours after I took my 2nd dose, I felt like I was going to die. Chills, headache, stomach upset, nausea, vomiting, fever did not go away with Tylenol, fatigue, weakness and I even passed out. I alternated the use of Tylenol and Ibuprofen and it didn't work. Today (03May2021), 10 days after my second dose, i still feel weakness, fatigue, dizziness, stomach upset and nausea and I went to Emergency Room. I did bloodwork today at the and the doctor said that everything is normal in my blood test. They even tested me for the covid, but the test was negative for Covid. I was feeling very well, and healthy before the second dose of the vaccine and now I never felt well again. Terrible and weird side effects." Events onset date reported as 23Apr2021 07:00AM, AEs resulted In: Doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care. Zofran used as treatment and still feeling bad Outcome for events was not recovered. The patient was not diagnosed with COVID-19 prior to vaccination, and Since the vaccination, the patient has been tested for COVID-19 with negative result. The patient did not receive any other vaccines within 2 weeks prior to the COVID vaccine. No follow-up attempts are needed; information about lot/batch number cannot be obtained. |

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| 1326626 | 5/18/2021 | CA | 16 | M | 5/17/2021 | 5/17/2021 | Systemic: Allergic: Difficulty Breathing-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Medium, Systemic: Shakiness-Mild, Additional Details: 911 was called for vitals after patient passed out. Paramedics stated that patient experienced syncope when standing up. also has history of anxiety. |
| 1328926 | 5/18/2021 | | 12 | M | 5/18/2021 | 5/18/2021 | Pt dad states that patient fainted upon receiving the vaccine. Evaluated by EMS-Refusal to transport. |
| 1325406 | 5/18/2021 | CA | 13 | F | 5/17/2021 | 5/17/2021 | After receiving the Pfizer covid-19 vaccine. During the 15 minutes waiting, patient's father took pt to the front of the store to buy ice cream. While he was paying the ice cream, pt fainted and hit head on the register counter. Ambulance was called. Store personnel and pharmacist check up on pt. She said she was feeling fine. No sign of short of breath or allergic reaction. Emergency personnel arrived and performed check up on pt. Pt stated she was fine and refused the ambulance or the trip to hospital for check up. Pt's dad sign waiver and release with emergency personnel and left store with pt. |
| 1328558 | 5/18/2021 | AL | 38 | F | 5/18/2021 | 5/18/2021 | Patient fainted within 5 minutes of vaccine administration. She came to within 15 seconds, at that time she was laid down in a supine position. Once she stabilized and identified who she was, where she was, and what had just happened, I sat her up and checked her blood pressure (113/60 at 10:12am). I stayed with the patient and continued to assess the situation and her until EMS arrived and took over care. |
| 1328539 | 5/18/2021 | IA | 57 | M | 5/17/2021 | 5/17/2021 | Patient experienced syncope/fainted and profuse sweating after receiving dose of J&J vaccine |

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| 1328524 | 5/18/2021 | CA | 30 | M | 5/18/2021 | 5/18/2021 | PT WAS SEATED, WAITING FOR 15 MINUTE MONITORING PERIOD POST VACCINE ADMINISTRATION. FELT DIZZY. REMAINED SEATED BUT PASSED OUT FOR A FEW SECONDS. CALLED 911. CAME TO, WAS ABLE TO TALK AND BREATHE BUT WAS SWEATY AND DIZZY AND PALE. SAT ON FLOOR SO HE WOULDN'T SLIDE OFF CHAIR IN CASE HAPPENED AGAIN. PARAMEDICS CAME, MONITORED BP, BLOOD SUGAR, EKG. HE HAD LOW BP BUT IT CAME BACK TO NORMAL IN FEW MINUTES. PARAMEDICS DETERMINED HE WAS OK TO GO HOME, DIDN'T NEED TO GO TO HOSPITAL |
| 1328513 | 5/18/2021 | CO | 15 | M | 5/18/2021 | 5/18/2021 | Within 3 minutes of vaccination, pt fainted. Immediately came to. Monitored for 20 minutes and then released pt as mom was comfortable with pt being ok. Pt experienced similar episode 2 years prior during x-rays. |
| 1328500 | 5/18/2021 | | 23 | F | 5/18/2021 | 5/18/2021 | patient passed out on floor and appeared to have seizure like symptom. Felt faint, dizzy, and flushed. called 911. Medical team arrived and patient proceeded to get nauseated and throw up. |
| 1328283 | 5/18/2021 | TX | 20 | M | 5/18/2021 | 5/18/2021 | Syncope with what appeared as a short seizure. Patient placed flat on floor and at that time he asked "Where am I"? Respiration good, pulse good, no discoloration, no swelling, and not cold or clammy. While tending to patient a tech-in-training called 911. First responders arrived approximately 5 or 10 minutes later and followed up with the patient. He states he has never had a reaction to a flu vaccine but does not like to see the shot being given. He said that he could feel the medicine going into his muscle and it made him feel weird and doesn't remember anything after that until he asked "Where am I"? He stayed another 10 minutes and said he felt fine. His brother drove him home. |
| 1328261 | 5/18/2021 | TX | 14 | F | 5/18/2021 | 5/18/2021 | immediately after the injection, pt appeared to have fainted, eyes closed, still breathing, body stiffed and jerked for a brief moment then became slouchy on the chair. we called 911 - as we waited for ems, pt opened eyes, said very sleepy, i kept her awake by taking about greys anatomy - ems arrived - mom wanted pt to be monitored at a facility - ems took pt away on stretcher. |

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| 1328250 | 5/18/2021 | VA | 12 | F | 5/18/2021 | 5/18/2021 | 1808-Child waiting in observation post vaccine and experienced vasovagal with syncope. Lowered to floor and feet elevated. Regained consciousness after 10 seconds. EMS on site arrived and assumed care. Child talking and able to answer questions accurately. 1812-BP 113/69 P 104 SPO2-96% 1818-113/59 P 105 S 1822-100/57 P 99 1827-103/55 P 95 1832-109/59 P 105 1838-104/58 P 102 Standing-1842-110/52 P 96 SPO2-98 Standing-1844-108/56 P 108 SPO2-97 Mother reports child played basketball outdoors for 1.5 hours prior to arriving at clinic. Ate a popsicle since lunchtime. Child departed EMS observation and care at 1848. |
| 1328224 | 5/18/2021 | NC | 17 | F | 5/18/2021 | 5/18/2021 | about 5 minutes after receiving injection, patient's BP dropped. She was sitting when it happened and we rushed over to put feet up. She was non-responsive for about a minute and then started to come back for syncope episode. Water was provided until ambulance arrived to check on patient. |
| 1328059 | 5/18/2021 | TX | 12 | M | 5/18/2021 | 5/18/2021 | Patient appear to have a mild seizure (faint, stiffness on the arm that got the vaccine injection, eye rolled) about less than 5 seconds. Patient became fully awake as being put to laying down on the floor. Patient was able to answer to all questions was asked. Patient stated that he was nervous and scared of getting the vaccine. Patient's mother stated that he had fainting history of seeing cut or bleeding. The event occur 30 seconds after received that vaccine. |

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| 1326225 | 5/18/2021 | | 30 | F | 4/29/2021 | 4/30/2021 | fainting; Severe stomach-flue like symptoms with diarrhea; Severe stomach-flue like symptoms with diarrhea; Aches/Body aches in core; Head-cold like symptoms with sinus pain; Head-cold like symptoms with sinus pain; fatigue; Wooziness; Body aches in core and legs; This is a spontaneous report received from a non-contactable consumer (patient). A 30-year-old non-pregnant female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Lot Number: EW0179), via an unspecified route of administration on 29Apr2021 (at age of 30 years old) as single dose for COVID-19 immunization. Medical history included known allergies: Sulfa drugs. There were no concomitant medications. The patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. No COVID prior vaccination. No COVID tested post vaccination. The patient experienced Severe stomach-flue like symptoms with diarrhea, fainting, aches. Head-cold like symptoms with sinus pain, fatigue, wooziness. Body aches in core and legs. All events on 30Apr2021. No treatment received for all events. The outcome of the events was recovered in 2021. No follow-up attempts are Possible. No further information is expected. |
| 1326522 | 5/18/2021 | NM | 18 | M | 4/30/2021 | 5/15/2021 | 5/15/2021 passed out while taking shower, and passed out 2nd time outside bathroom (witnessed), hit head on side of door, was seen in ER for head injury/ concussion Labs, EKG, Blood sugar, and Head CT scan done - normal results, referred to concussion doctor within 3-5 days |
| 1326629 | 5/18/2021 | MI | 15 | M | 5/17/2021 | 5/17/2021 | Systemic: Allergic: Difficulty Breathing-Mild, Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Hypotension-Severe, Additional Details: sweating profusely, EMS called and came to pharmacy, checked on pt and all clear for him to leave, parents had no problem and said they didnt need anything before they leave |

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| 1326677 | 5/18/2021 | GA | 54 | M | 4/19/2021 | 4/23/2021 | Woke up at 3:30am to extreme swelling in my left cheek, went to the bathroom to check it out and almost passed out. Went to the hospital and was checked for a stroke. No stroke detected. While during the exam, my tongue started to swell up and they decided to insert a tube for breathing. Woke up on Sunday after the swelling went down and the tube was removed. Was released from the hospital on Tuesday. Maintained a fever that week and on Friday, my fingers on my left hand and my left foot started to swell again, almost passed out. Went back to the hospital for observation and treatment for a staph infection from the first hospital visit. |
| 1326740 | 5/18/2021 | MN | 22 | M | 5/17/2021 | 5/17/2021 | Patient fainted after receiving his first dose of the Moderna vaccine. He was very nervous and breathing hard before the vaccine because he is afraid of needles. After receiving his vaccine he was standing in the vaccine area with the woman he was with. The woman was also receiving a vaccine. He was still very nervous about needles and I suggested that he wait in the post-vaccination area so he didn't have to witness the woman receiving her vaccine. While walking to the post-vaccination area the patient fainted. After fainting he woke up right away. Another pharmacist and a technician immediately went to check on him and assist him. Patient thinks that he fainted because of his fear of needles. |
| 1326686 | 5/18/2021 | CA | 21 | M | 5/17/2021 | 5/17/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Exhaustion / Lethargy-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Hypotension-Medium, Systemic: Seizure-Mild, Systemic: Shakiness-Medium, Additional Details: Patient was immediately nauseous after vaccination, but that resolved quickly. Minutes after sitting down for the observation period, patient seemed to jerk and looked like he was seizing. He did not have trouble breathing. He was lucid after going in and out of consciousness for a minute or so. He was hypotensive and pale, but after water and some candy, patient was feeling much better. After the 30min observation period, his blood pressure was up and he was able to walk without trouble. |

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| 1326694 | 5/18/2021 | CA | 23 | M | 5/17/2021 | 5/17/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Pt fainted 5 minutes after receiving the vaccine. Pt feels much better after getting water from the staff and getting rested for about 30 minutes. Pt said he does not need an ambulance, and he is doing ok |
| 1326699 | 5/18/2021 | IL | 26 | F | 5/17/2021 | 5/17/2021 | Site: Pain at Injection Site-Mild, Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Weakness-Mild, Additional Details: Pt told us she tends to faint when she gets shots. gave her the janssen shot and in 5 mins she told us she was about to faint. she became confused and started walking. technician went after her and she layed on the ground. called 911. took her bp. told them she did not eat today and most likely why she fainted. pt rested for additional 30mins. had some water and food. Felt better and left for home. called her back at 5pm to follow up. states she is feeling better just a sore arm. |
| 1326701 | 5/18/2021 | MA | 27 | F | 4/6/2021 | 4/6/2021 | Patient mailed letter stating she fainted after receiving vaccine. |
| 1326619 | 5/18/2021 | CA | 24 | M | 5/16/2021 | 5/16/2021 | Systemic: Fainting / Unresponsive-Mild |
| 1326713 | 5/18/2021 | NY | 19 | F | 5/17/2021 | 5/17/2021 | Systemic: Chills-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild |
| 1325441 | 5/18/2021 | NY | 59 | F | 5/15/2021 | 5/1/2021 | Uncontrollable shivering and freezing cold, 14 hours after shot. Fainting, 20 hours after shot. |
| 1326489 | 5/18/2021 | NJ | 57 | F | 2/12/2021 | 3/5/2021 | I fainted at the facility I was at 10 minutes after the shot. I've since had burning at the injection shot (daily, months later) and a pain in the left side of my breast. I am often dizzy with the ground feeling like it's moving. I fainted a second time after a dizzy spell a few weeks after the second shot/fainting episode. My heart is often racing post getting the vaccine. |
| 1325415 | 5/18/2021 | | 36 | F | 5/13/2021 | 5/13/2021 | Pt had syncopal episode with possible convulsion (passed out for about a minute, face turned purple, and had contractions of the arms and hands with sweating) about 10-15 minutes post injection. 911 called. Checked EKG, vitals, BG and was advised to go the ER but she refused for further evaluation. |

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| 1326237 | 5/18/2021 | CA | 66 | F | 4/27/2021 | | Faint; Heart problem; Whole left side just had pressure, pressure from all around my left breast and my back, down my arm, my ear; Headache; Don't really have the energy; This is a spontaneous report from a contactable consumer (patient). A 66-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration, administered in left arm on 27Apr2021 (Lot Number: ER8736) as single dose for COVID-19 immunisation. Medical history included thyroid, COVID (patient was almost 100 percent sure that she had COVID before but she did not know for sure because she had not been tested for antibodies). Concomitant medication included levothyroxine sodium (LEVOTHYROXINE NA) taken for thyroid. The patient stated she got the Pfizer shot on the 27Apr2021 and she had a reaction to it, heart problem and she really did not think that she might have had, she was almost 100 percent sure that she had COVID before but she did not know for sure because she had not been tested for antibodies. But she just really had a terrible effect and she did not know what was the next step. She meant her whole heart, she fainted, her whole left side just had pressure, pressure from all around her left breast and her back, down her arm, her ear. She had a headache and she gave it a couple days and she was feeling better today (03May2021) but she did not really have the energy. No treatment received. Due date for the next shot is 18May2021. Height and weight were reported as 5 (feet) 3 (inches), and 135 (pounds) (That's just an estimate per patient). Outcome of the events was unknown. |

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| 1326529 | 5/18/2021 | SD | 27 | M | 5/18/2021 | 5/18/2021 | About 10 minutes after receiving COVID vaccine, patient became lightheaded and nauseated. He states that he thinks he may have passed out because he was laying on the exam table. He tells this nurse that he has a history of becoming anxious and having nausea/lightheadedness and then passing out. He hasn't eaten anything today and didn't sleep well last night. He did drink some coffee this morning. He is pale. Vital signs: 98.0, 85, 99%, 130/81, 18. Patient did vomit small amount of brown colored liquid emesis and then states that he is feeling better. He was given water and a snack. Per doctor, patient was monitored for another 15 minutes. Patient states that he is feeling ok and he does not wish to be seen in urgent care at this time. He will return to clinic or ER as needed. |
| 1326550 | 5/18/2021 | TX | 59 | F | 5/18/2021 | 5/18/2021 | AFTER PATIENT WAS VACCINATED WITH JANSSEN VACCINE AND WAITED 15 MINUTES, SHE SAID SHE FELT FINE AND LEFT THE PHARMACY AREA TO SHOP. A LITTLE WHILE LATER A EMPLOYEE ASKED US TO HELP BECAUSE A LADY WAS GOING TO PASS OUT. WE WENT OVER AND TALKED WITH THE LADY AND WALKED HER TO THE PHARMACY. SHE WAS COMPLAINING OF SWEATY, CLAMY, LIGHT HEADED, DIZZY AND FELT LIKE SHE WAS GOING TO FAINT - VASOVAGAL SYNCOPE SYMPTOMS. WE HAD HER SIT DOWN, GAVE HER A BOTTLE OF WATER AND THEN HAD HER LAY DOWN. WE ALSO GAVE HER SOME COOKIES BECAUSE SHE WAS HUNGRY. WE ASKED IF SHE WANTED US TO CALL EMS BUT SHE REFUSED. AFTER LAYING DOWN FOR ABOUT 35 MINUTES HER HUSBAND CAME AND SHE WAS FEELING BETTER. HUSBAND TOOK LADY HOME. WE TOOK HER BP (112/67) AND PULSE (74) |
| 1326554 | 5/18/2021 | HI | 27 | F | 5/18/2021 | 5/18/2021 | pt was sitting in waiting area during 15 minute waiting period after shot and says she thinks she passed out for a couple minutes. she also reports feeling sweaty and anxious but anxiety is something she has had a problem with in the past getting vaccines |
| 1326558 | 5/18/2021 | CA | 14 | M | 5/18/2021 | 5/18/2021 | Vasovagal syncope with mild convulsion for 5 seconds. |

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| 1326616 | 5/18/2021 | NY | 20 | M | 5/17/2021 | 5/17/2021 | Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Seizure-Medium |
| 1326617 | 5/18/2021 | NY | 28 | M | 5/17/2021 | 5/17/2021 | Systemic: Fainting / Unresponsive-Severe |
| 1325402 | 5/18/2021 | OR | 15 | F | 5/13/2021 | 5/13/2021 | Patient bopped her head back and then forward (fainted for about one second) after receiving vaccine. Reports of low blood pressure and dizziness |
| 1327990 | 5/18/2021 | | 75 | M | 3/23/2021 | 3/24/2021 | 3/24 medical facility, admitted day after covid vaccine with syncope. Male with a history of PVCs who is coming into the hospital after a syncopal episode; patient reports in usual health, he had a second covid vaccine on 3/23, and start getting dizzy especially with movement on 3/24. On 3/24, he woke up and was going to the bathroom and then turned around to walk out of the bathroom and all of a sudden became lightheaded and dizzy. He said he ended up falling onto the ground not sure exactly how long he was out for but did not lose control of bowel or bladder function he had no chest pain. Stable course in the ER vital signs reviewed slightly elevated blood pressure. Extensive work-up was done. Normal saline bolus given. Chemistries unremarkable save for creatinine 1.32. Rest labs reviewed. He did meet gap alert criteria so CT C-spine CT head done no acute findings. EKG sinus tachycardia as ventricular trigeminy. No ST elevation. Discharged in stable condition. |

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| 1326473 | 5/18/2021 | PA | 34 | M | 5/18/2021 | 5/18/2021 | Prior to vaccination the patient reported that in the past he had passed out after giving blood. About a minute after administering the COVID-19 vaccine the patient reported feeling dizzy. He then passed out in the chair. We safely moved the patient to the floor. Then within approximately 15 seconds the patient sat up and then stood up on his own. We asked the patient to then be seated in the chair while he recovered. We called 911 as soon as he passed out. Patient was somewhat confused initially but quickly regained his bearings. He began sweating and said he was very hot. We checked his blood pressure and it was 100/80. Patient continued to recover and said he was feeling better. We had him wait until EMTs arrived. He told them he did not need any care. We took his blood pressure again and it was now 110/75. He said he felt well to go to the EMTs and pharmacist. |
| 1327185 | 5/18/2021 | NC | 13 | F | 5/15/2021 | 5/15/2021 | Patient Fainted and we called EMS. Patient was fine after resting for a few minutes |
| 1328038 | 5/18/2021 | NJ | 14 | F | 5/16/2021 | 5/16/2021 | Patient received vaccine and within 5 minutes was not feeling well. Patient fainted and then when conscious began vomiting. Patient also became very pale and clammy. Patient has experienced vasovagal symptoms before when having blood work done but not during vaccination. Patient also stated afterwards that she had not eaten any food all morning prior to receiving the vaccine. |
| 1327459 | 5/18/2021 | IA | 17 | F | 5/18/2021 | 5/18/2021 | Patient passed out as soon as she got to the waiting area post-vaccination. She was unresponsive for less than 15 seconds before waking up. She was breathing the whole time. We moved her to the ground to avoid any injury if she was to pass out again. We called paramedics who were at the pharmacy within 5 minutes. They checked vital signs and deemed she was ok. Patient walked out of the store on her own with her mother. |
| 1327404 | 5/18/2021 | WA | 18 | M | 5/10/2021 | 5/10/2021 | syncope episode following vaccine |
| 1327246 | 5/18/2021 | NC | 30 | F | 1/27/2021 | 1/27/2021 | Increased heart rate / tachycardia, vasovagal syncope, extreme fatigue, inability to exercise (was an avid runner before), vertigo / imbalance, nausea. |

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| 1327229 | 5/18/2021 | PA | 17 | F | 5/18/2021 | 5/18/2021 | patient fainted five minutes after receiving vaccine. regained consciousness and emts evaluated but did not have to go to hospital |
| 1327223 | 5/18/2021 | OK | 21 | F | 5/17/2021 | 5/17/2021 | pt received covid shot and was waiting her 15 minutes. about 5 minutes later she fainted and an ambulance was called and took her to the hospital. |
| 1327219 | 5/18/2021 | MO | 16 | F | 5/6/2021 | 5/7/2021 | fainting and lightheadedness starting day after receiving second dose |
| 1327215 | 5/18/2021 | NC | 15 | F | 5/18/2021 | 5/18/2021 | Patient Vomited and passed out. EMS was called and Patient recovered after resting and calming down |
| 1327200 | 5/18/2021 | NC | 14 | M | 5/15/2021 | 5/15/2021 | Patient vomited and fainted. We already had EMS here for his sibling. He was also fine after resting and calming down. |
| 1327488 | 5/18/2021 | PA | 18 | M | 5/17/2021 | 5/17/2021 | Two minutes after administration of J&J vaccine, patient asked this nurse for water and said, "I feel dizzy." Patient was diaphoretic and pale. Patient remained seated in chair. Felt this was for 15 minutes. His feet were elevated, cold compress to neck, fan directed at patient. Patient never lost consciousness. Took cold water and pretzels. BP at 14:57 was 104/76. Symptoms totally resolved by 1500. Patient and mother report a history of vasovagal fainting with previous blood work/exposure to needles. |
| 1327189 | 5/18/2021 | UT | 46 | F | 5/17/2021 | 5/17/2021 | Patient was vaccinated at 6:00pm and told to stay at the store until 6:15pm. At approximately 6:40, while sitting in her car, she passed out. She had a friend with her that either called 911 or drove her to the emergency room. |
| 1327491 | 5/18/2021 | CA | 23 | F | 4/10/2021 | 4/11/2021 | Pt presented to ER early the following am, with seizures. Pt reports having a small reactions immediately after vaccine administration. Pt reports muscle stiffness, eyes rolling back, shaking, diaphoretic. Pt also reports having a second episode of syncope when she arrived home. |

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| 1327135 | 5/18/2021 | VA | 14 | F | 5/17/2021 | 5/18/2021 | Daughter fainted 20 hours after vaccine. Was treated by school nurse who observed elevated heart rate (150 bpm). Eventually heart rate normalized; took daughter to pediatrician for further evaluation. Not clear if fainting was related to the vaccine but it has never happened to her before and the timing of the two seems odd. |
| 1327130 | 5/18/2021 | MD | 12 | F | 5/18/2021 | 5/18/2021 | PATIENT HAD HEADACHE AND FELT PASSING OUT BUT NEVER PASSED OUT |
| 1327119 | 5/18/2021 | NH | 37 | M | 5/1/2021 | 5/1/2021 | I fainted while sitting in the chair about 5 minutes or less after the shot. I felt myself not feeling well immediately after the shot. |
| 1327107 | 5/18/2021 | CA | 15 | F | 5/18/2021 | 5/18/2021 | 15 year old female found in supine position with feet elevated in vaccination area. Pt had a left upper lip injury (non-bleeding) , redness and slight swelling to left lateral eye area. She also had a less than dime sized abrasion to right knee. Pt was recovered from dizziness (syncope) and then placed into a wheelchair and placed onto a cot in the observation area with her feet elevated with a chair. VS 107/73 66 24 and an O2 sat of 99% on RA. Pt timid and somewhat afraid of passing out again. Chair was later removed and then pt sat up in bed with apprehension. She ate a bag of doritos and drank a half bottle of water (about 250 ml) She then stood up and denied any dizziness but insisted on sitting and/or lying down. She did sit back down for another 10 minutes and later stood up , denies any symptoms. Pt then ambulated to BR without help, MAEW, NAD, steady gait. She was a + o x 3, VS at 1431 111/69 74 22 with O2 sat of 99% on RA. Pt and mother given directions to change positions slowly allowing 30-60 seconds per position change. They both acknowledged this. Pt discharged home with sister and mother with direction to f/u with pcp as needed and to increase sodium and water intake today and tomorrow. No medical history Denies taking any medications Denies any allergies (name), site supervisor aware of situation. Vaccination Site |
| 1327053 | 5/18/2021 | IN | 15 | F | 5/18/2021 | 5/18/2021 | Patient received the vaccine with no issues. Approximately 5 minutes after the vaccine the patient fainted. They were seated on a chair and had multiple instances of syncope. |

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| 1327049 | 5/18/2021 | MA | 51 | F | 5/18/2021 | 5/18/2021 | patient sat down after the vaccine and about 5 minutes later passed out for about 30 seconds. EMS came out and checked her out. She refused to come with ambulance and stayed in the store until a relative came in to pick her up because she was afraid to drive. She left the store thereafter. |
| 1327010 | 5/18/2021 | NV | 52 | M | 5/15/2021 | 5/15/2021 | On 5/15/21 pt was in a drive through vax site. He says immediately after he got the vax he was trying to drive away from the vax site but he has to pull over since he was passing out. He came to so put his car in park and then passed out again. He said he was nauseated, dizzy, and lightheaded. He kept going in and out. He blew the horn and got someone's attention. EMTs loaded him into an ambulance then he started vomiting. They took him to the Medical Center. They did multiple tests. He was admitted for further testing which had normal results. Pt was discharged after about 28 hours. Pt says he could stand up about 4 hrs after inj but the symptoms lasted about 18 hours total. |
| 1326882 | 5/18/2021 | SC | 55 | M | 5/18/2021 | 5/18/2021 | After 5 minutes from giving the vaccine. Patient started to say he was getting dizzy. He lost coloration at first, but could speak just fine. Then a few seconds later he appeared to lost consciousness, his head fell back, and he started to have jerking movements. He was making noises that almost sounded like a snore to me right at first, but it was more than likely him gagging on saliva. 911 was called, and his symptoms continued for roughly 30-60 seconds. EMS took him to hospital where they diagnosed it as vasovagal syncope and just gave him some fluids. |

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| 1326840 | 5/18/2021 | NY | 49 | F | 5/18/2021 | 5/18/2021 | Allergic reaction to TDAP. cleared by med. evaluator, Spoke to patient. 30 min wait. While in recovery after 20 min after vaccine pt complained of "lump in throat and feeling warm" no LOC, no SOB AAO. No tongue swelling, no lip swelling + diaphoresis. Lung sounds clear = bilaterally, no wheezing no difficulty wheezing. MD assessed surmised mild anxiety Globus Hystericus. Left deltoid site benign no redness, no swelling, no hives no LOC, no syncope. Ice pack to back of neck. 1:55 pm VS 160/90, HR 96, resp 14 reg non labored, 99% O2 Sat. Monitored 45 min, water for hydration, provided reassurance no further complaints. 2:08 pm 130/85, HR 80, resp 12 reg non labored, O2 sat 99%. Pt stated "feel much better, I'm OK. OK'd to exit. walked to door. |
| 1326808 | 5/18/2021 | OH | 62 | F | 3/10/2021 | 3/10/2021 | Sudden rapid heart rate , sweat , nausea, light headed , almost passed out . Ems was called . vitals returned to normal while in ambulance . No further heart fluctuations. A month later tinnitus has begun . I?m currently being checked by an ENT to find out why . No previous tinnitus issues . |
| 1327191 | 5/18/2021 | | 68 | F | 2/9/2021 | 5/15/2021 | fall/syncope |
| 1327674 | 5/18/2021 | OH | 16 | F | 5/5/2021 | 5/6/2021 | Mother states that 18 hours post-vaccination her daughter fainted. She was taken to receive medical help and it was determined that her blood pressure was low and she was given IV fluids. Patient's blood pressure remained low for 11 hours. |
| 1326671 | 5/18/2021 | NJ | 14 | F | 5/17/2021 | 5/17/2021 | Systemic: Dizziness / Lightheadness-Medium, Additional Details: Right after immunization patient looked pale and thought she was going faint. This was a near syncope event. Patient did not actually faint. Told her to lay on the ground flat with legs elevated. She was monitored for 30 minutes and felt fine after. |

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| 1327986 | 5/18/2021 | NY | 13 | M | 5/18/2021 | 5/18/2021 | Received Vaccine, immediately became pale, clammy, diaphoretic, had near syncope episode, brought to mat to lie down, elevated feet on chair, AAO, no loc, no sob, ice pack to neck, front, back, and stomach, MD assessed surmised vaso vagal reaction occurred, patient came from a baseball game, Patients mom at the side, Vitals: 110/80, HR-60, regular and strong, respirations 12, regular nonlabored, O2 Sat 98%, After 10 minutes sat up and had water for hydration and snack for nourishment. Monitored for 30 minutes, provided reassurance, okay to exit with Mom after 30 minutes, provided education to mother regarding reaction |
| 1327966 | 5/18/2021 | MO | 12 | F | 5/18/2021 | 5/18/2021 | approximately 30 seconds after patient received this vaccine she fainted and fell to the floor. She regained consciousness but then began to vomit. Symptoms were short lived and 9 hours later she seems to be fine. |
| 1327843 | 5/18/2021 | TX | 20 | F | 5/17/2021 | 5/17/2021 | Patient fainted after getting the vaccine; she woke up and stated she was fine. Called EMS and they spoke to her but she did not want them to come. Followed up with patient next day and she stated she was fine as well |
| 1327790 | 5/18/2021 | NY | 20 | M | 5/18/2021 | 5/18/2021 | pt had vasovagal syncope, dizzy, passed out, sweating, hot and cold. 911 was called. Put ice on pt's neck, spoke to pt to keep awake, blood pressure taken, EMS took all vitals and blood sugar and EKG all normal. pt allowed to leave pharmacy with ride home from girlfriend. followed up with pt 1 hour later by phone, pt is feeling ok but tired. |
| 1327778 | 5/18/2021 | UT | 13 | F | 5/18/2021 | 5/18/2021 | Patient came to the pharmacy to receive 1st dose of the Pfizer covid vaccine. About 5 minutes later patient felt unwell. According to her mom she passed out for about 5 seconds then jerked up and passed out again for a few seconds and woke up. Mom was unsure but thought it looked like a mini seizure. Both pharmacist was informed and checked on patient. Patient was hot and sweating but breathing was fine. Patient was coherent and could talk. Patient was given water. Blood pressure check was 102/69. Patient remained sitting with head over legs as that made her feel better. EMT arrived at the scene and took patient away on a stretcher for further observation. |

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| 1327763 | 5/18/2021 | | 13 | F | 5/15/2021 | 5/15/2021 | At 1345, EMT found patient on ground. Patient's mother stated patient fainted and fell face first onto ground from chair. Patient was alert and oriented to person, place, time and situation. Patient stated she felt dizzy before she fainted. Patient reported no history of fainting, eating breakfast, and no chronic conditions. At 1350, patient vitals were blood pressure 124/80 mmHg, pulse 65 beats/minute, and SpO2 95%. At 1349, 911 activated. At 1353, paramedics arrived and assumed care. Patient's mother signed an Against Medical Advice form. Paramedics left scene at 1407. Lead RN educated patient and patient's mother on following up with primary care provider, signing up on v-safe, and signs/symptoms of when to seek emergency care. Patient left observation area with mother at 1409. |
| 1327736 | 5/18/2021 | IL | 13 | F | 5/18/2021 | 5/18/2021 | Patients is a 13 year old girl who came into facility to receive her Pfizer vaccine. She was nervous upon receiving her vaccine and after the shot was administered she stated she feels a little warm. The vaccinating pharmacist told her to sit and wait in the sitting area for 15 minutes after receiving the vaccine. A couple minutes after her vaccine was administered the girl started not feeling well and fainted in the store and her father caught her. We immediately called 911 and checked in with the young girl. The ambulance came and did a physical exam. They offered to take her to the hospital but the patient declined. Patient left the store shortly after with her father. |
| 1327726 | 5/18/2021 | PA | 63 | F | 5/18/2021 | 5/18/2021 | patient felt dizzy, lightheaded, passed out |
| 1327472 | 5/18/2021 | MN | 13 | F | 5/18/2021 | 5/18/2021 | Shortly after receiving vaccine patient fainted in waiting area. Ran to check on patient and she got up on her own accord. Helped patient and mom to a bench in the waiting area, had pharmacy technician grab some orange juice while pharmacist waited with patient and parents to monitor for other signs of reaction. |

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| 1327685 | 5/18/2021 | WA | 14 | F | 5/18/2021 | 5/18/2021 | Patient received her vaccine and took a seat in the waiting area. After about 10 minutes she fainted and fell off her chair. Patient's mom yelled after it happened and the pharmacist and rushed over to help. When the pharmacist got to the patient she was face down and when they turned her over she got up. She did not appear to have hit her head and regained consciousness quickly. 911 was called at the request of patient's mother and the patient did not leave in the ambulance. |
| 1328037 | 5/18/2021 | CA | 28 | M | 5/17/2021 | 5/17/2021 | 5/17/21 Patient given Janssen vaccine at 1859. 1905 : patient had an episode of syncope. BP:90/55, pulse: 50 1906: patient awake , alert and oriented.x4 1910: BP: 114/71, pulse 57. Alert and oriented x4 Patient reports a history of syncope and fear of needles. 1930: patient reports doing well. Vital signs stable, alert and oriented x4 |
| 1327661 | 5/18/2021 | VA | 15 | F | 5/18/2021 | 5/18/2021 | Systemic: Fainting / Unresponsive-Mild |
| 1327638 | 5/18/2021 | | 14 | F | 5/18/2021 | 5/18/2021 | Patient with syncope right after vaccination. Vitals stable. Patient given juice and crackers. Hadn't eaten today. Able to discharge patient home with mom. |
| 1327634 | 5/18/2021 | WA | 19 | M | 5/14/2021 | 5/14/2021 | Passed out about 2 minutes after the shot, about 10 steps from where he got the shot. |

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| 1327568 | 5/18/2021 | PA | 22 | M | 5/15/2021 | 5/15/2021 | Sequence of Events re Incident * Patient made his appointment via on- line scheduler * Patient came in, filled out his paperwork, made no mention of previous vaccine issue on paperwork * I performed the usual screening of patient, and when I asked him about any previous reactions to immunizations he stated that he had an ?issue with a TdaP shot 4 years ago and passed out in doctor?s office for several minutes.? He stated the MD told him that ?he had several other issues with the shot so the MD said it was a ?bad batch??. * I made sure that the patient was comfortable about getting the Covid shot and he agreed that he was fine to get it. At that time the patient did not seem overly nervous about receiving the shot. * I administered the shot to the patient and he went directly to the seats next to the pharmacy. I asked him to stay there because he had a past issue with another vaccine. * Approximately 2-3 minutes later, the patient came back, looked troubled and said he didn?t feel well and was feeling the same way as the other shot. I brought him back into the pharmacy immunization room, sat him down and put his head between his knees. I did a quick check on him to be sure he was breathing OK and that there was no apparent allergic reaction. * After a minute I brought his head back up and put patient into regular seated position. At no point did he completely lose consciousness or faint. I asked him at that point if he wanted me to call an ambulance or a family member and he declined. He sat there in the chair for approximately 15 minutes- part of the time his head was in his hands, part of the time looking at his phone. He asked for a glass of water and I got him one (he had completely drank it by the time he left). I kept checking on him and it seemed like every time he saw me check on him he put down his phone and put his head in his hands again. He could have been embarrassed by the situation, unsure though. I tried to make him as comfortable as possible. * After 15-20 minutes I asked him if he wanted me to call someone and he said at that point he wasn?t sure he wanted to drive home so he would call his mother to pick him up, which he did. * I sat down with him for a couple of minutes and explained that this was called a vasovagal response and was quite common (I even empathized with him by explaining that I have the same response when I get blood drawn at the doctor?s office). He |

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| | | | | | | seemed to feel a little better after I explained it to him. * His mother came in 15 minutes later and I brought her back as well. She explained the same thing happened at the MD office 4 years ago and that it was the Meningitis shot, not Tdap. I explained to them going forward that it would probably be best to get his immunizations at the doctor?s office so that he could lay down after the shot and they agreed. * He and his mother then walked out of the immunization room and left the building. He left under his own power and without assistance from his mother. I gave him a business card and asked him to call me on Sunday to let me know that he was feeling ok. | |
| 1327566 | 5/18/2021 | OH | 24 | U | 5/18/2021 | 5/18/2021 | Patient experienced a brief episode of syncope immediately after receiving the Janssen Covid vaccine on 5/18/21 at approximately 1pm. Patient was seated at the time. Patient slumped over and was unresponsive for approximately 5 seconds. Patient resumed consciousness right away and blood pressure and respirations were checked by local paramedics. patient seemed alert and well when he left the store just after 1:30pm. |
| 1327559 | 5/18/2021 | OH | 15 | F | 5/18/2021 | 5/18/2021 | Patient received her covid vaccine, while waiting for 15 minutes to be observed the patient fainted. Her mom noticed her eyes rolled back and started calling for help. We called 911 . Patient was placed on the ground carefully as we awaited for EMS to arrive. The patient was breathing, but had low blood pressure when EMS arrived. EMS took the patient to the hospital. |
| 1327528 | 5/18/2021 | ME | 21 | M | 5/18/2021 | 5/18/2021 | vaccine adm @ 12:35 pm 5/18/2021 ,first event occurred 12:37 pm (passed out/muscle weakness(slumping)/ when over has no memory of event total time 5-7 seconds, then alert some sweating. second event same as first occurred 5 minutes later(was given water after first event.) CALLED 911 ARRIVED 5-10 MINUTES AFTER SECOND EVENT. after exam bp/blood glucose/pules/O2 sat/all normal(per emt) patient walked out under own power |
| 1327514 | 5/18/2021 | VA | 38 | M | 4/14/2021 | 4/14/2021 | Patient fainted immediately following vaccination. Initial BP was 147/107; decreased to 132/88 within about 30 minutes and patient was released to home. |

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| 1327503 | 5/18/2021 | OH | 31 | M | 5/18/2021 | 5/18/2021 | Approximately 10 minutes after receiving the Janssen vaccine the patient walked up to the pharmacy counter and asked a technician if it was normal to feel clammy after the vaccine. Immediately after the patient passed out. |
| 1327496 | 5/18/2021 | OK | 33 | F | 5/18/2021 | 5/18/2021 | patient passed out shortly(3-5 minutes) after receiving her vaccine. Patient got dizzy, fuzzy then blacked out for about 30 seconds then came to. After a few minutes patient was feeling better and left about 20-30 minutes after incident. |
| 1327704 | 5/18/2021 | OH | 30 | M | 5/18/2021 | 5/18/2021 | patient fainted but recovered soon after |
| 1324481 | 5/17/2021 | CA | 13 | F | 5/17/2021 | 5/17/2021 | pt fainted after getting the shot. pt was dizzy and pale after the shot. pt blood pressure was normal then dropped quickly to 80/40 per nurse and then came back to normal. pt rested and was given water and candy afterwards. pt walked around store after wards and felt fine and went home with parent. |

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| 1324220 | 5/17/2021 | TX | 35 | M | 5/10/2021 | 5/10/2021 | The patient walked in to the pharmacy for a Janssen Covid vaccination along with family. Patient was advised post vaccination administration to sit in observation for 15 minutes but did not comply and as he was walking away from the pharmacy fainted. Parents reported he did not hit his head and pharmacy was alerted post fall of what had happened. We approached the patient as he was getting to his feet and we advised again for him to come back to pharmacy to sit in a chair for further observation. His parents told us he always has fainting issues post any vaccination or blood work (no prior issue reported to vaccinations on consent form). The patient continued to decline going back to pharmacy and as he walked fainted again, he was able to hold on to shopping cart which lessened severity of fall. Pharmacy staff advised him to remain on floor and after he regained consciousness he was able to answer accurately his name, where he was and what day of week it was. At that time a nurse not employed by Company was shopping near by and began to help care for the patient. The patient and his parents continued to decline calling an ambulance, and after several minutes sat against a wall. He was starting to sweat profusely and heart rate was rapid (approximately 145 bpm per nurse) so we had him remove his coat and provided a cool compress for his head and neck. He was breathing rapidly but was able to slow his respiration upon our direction. The patient did not seem to be improving and the nurse helping advised calling EMS which we did. The patient continued to lose consciousness for brief periods awaiting and during EMS aid. EMS ran the patients blood pressure, blood sugar and ran an ECG prior to taking patient away to hospital (results unknown to pharmacy as we stayed in area to provide information on patient vaccination administration but had no active assistance care at that time. |
| 1324735 | 5/17/2021 | SC | 39 | F | 5/17/2021 | 5/17/2021 | Patient passed out for a few seconds. When she woke up she broke out in a cold sweat and threw up. She said her arms tingled. |

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| 1324568 | 5/17/2021 | WA | 17 | M | 5/17/2021 | 5/17/2021 | PATIENT FAINTED FEW MINUTES AFTER RECEIVING THE VACCINE. HE LOOKED LIKE HE WAS HAVING A SEIZURE. IT LASTER FOR A BOUT 15-17 IN MY ESTIMATE. HE WAS ALERT AFTER AND ANSWERING QUESTIONS ABOUT HIS NAME, DOB AND WHERE HE WAS. TOOK HIS BLOOD PRESSURE TWICE-5 MIN APART AND IT WAS LOW. 113/58 AND THEN 102/50 TO MY RECOLLECTION. PARAMEDICS WERE CALLED IMMEDIETLY AND PATIENT HAD HIGHER BLOOD PRESSURE WHEN THEY WALKED IN. IT WAS "NORMAL". PATIENT TOLD US HE HAS A HISTORY OF VASOVAGAL SYNCOPE AND HE FAINTED BEFORE WHEN HIS BLOOD WAS DRAWN. HE SAID THAT IT SEEMED LIKE A SEIZURE BEFORE BUT CHECKED WITH NEUROLOGIST AND WAS NEVER DIAGNOSED WITH EPILIPSY. PT LEFT IN A STABLE CONDITION |
| 1324547 | 5/17/2021 | PA | 30 | F | 5/17/2021 | 5/17/2021 | PATIENT RECEIVED JANNSEN COVID VACCINE. TURNED PALE. FAINTED. VOMITED. COUGHED. PATIENT CONDITION RESOLVED AFTER 20 MINUTES. ACTUAL SYNCOPE LASTED MAYBE 1-2 MINUTES |
| 1324503 | 5/17/2021 | OR | 14 | M | 5/17/2021 | 5/17/2021 | Patient passed out immediately following administration of the vaccine to the left deltoid. His head fell backwards and limp. The Rph administering the vaccine moved in front of the patient and gently moved his head into an upright position. The patient had mild muscle spasms and twitches while passed out but when he regained consciousness he immediately began talking saying he was ok. Father came into the consultation room at that point and Rph explained what had occurred. Patient looked a little pale and eyes were having a hard time staying open so with the help of his dad Rph helped him down to the ground in the corner of the room so he could have back and head support from the wall. Patient was given a glucose tablet and water, and later orange juice. Patient stayed in the consultation room for about 20 minutes before leaving on his own and saying he was feeling much almost back to normal. |

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| 1324758 | 5/17/2021 | WA | 14 | F | 5/17/2021 | 5/17/2021 | AFTER GIVING THE SHOT PATIENT WAS SITTING ON CHAIR AND SUDDENLY COLLASPSE . SHE PASSED OUT FOR 15- 20 SECONDS AND WAS CONSCIOUS AFTERWARDS MEASURE HER BLOOD PRESSURE WAS LOW AROUND 87/57 , GAVE HER WATER AND SOME THING TO EAT AND MEASURE BLOOD PRESSURE AFTER 15 IMUTES IT WAS 111/82 |
| 1324483 | 5/17/2021 | CA | 14 | F | 5/17/2021 | 5/17/2021 | Patient received first Pfizer Covid-19 LOT #EW0167 vaccine, pt stood up with mother to go to obseration area. pt passed out and hit her head on floor. mother states pt loss of consciousness for 10 seconds. after pt axox4. Vitals taken, 106/64 bp, hr 85 and spo2 100% RA. pt brought to urgent care via wheelchair for further evaluation. pt able to walk with steady gait without assist to wheelchair. breathing equal and unlabored. no open wounds noted no medication given. |
| 1324201 | 5/17/2021 | | 16 | F | 5/17/2021 | 5/17/2021 | Patient fainted about 30 seconds after the vaccination. She regained herself after about 5 seconds. |
| 1324470 | 5/17/2021 | | 25 | M | 3/18/2021 | 3/18/2021 | Patient fainted after vaccine. Patient was placed on cushions with feet elevated for further evaluation. Set of VS taken . Neuro checks done q15 for three times. Neuro checks WNL. PT offered juice and granola bar, pt recovered quickly, observed for an additional 30 mins before released home. |
| 1324467 | 5/17/2021 | CA | 14 | F | 5/17/2021 | 5/17/2021 | 14 year old female with a CC of lightheadedness about 8 minutes after her first dose of Pfizer. States she also noted mild nausea. I asked the patient to elevate her legs and she states her symptoms resolved. I also had the patient drink more water at that time. No wheezing, no hives, no toungue, lips, or throat swelling. No vomiting. Vitals signs were stable, oxygen saturation 98%. EMS was not called and mother and patient decided not to go to ED for follow-up as the patient has a history of vasovagal syncope around needles and states this response is normal for her. |

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| 1324455 | 5/17/2021 | OH | 16 | F | 5/17/2021 | 5/17/2021 | Immediately after receiving vaccine patient stated that her entire hand was tinging and numb feeling. This was the hand of the arm the vaccine was administered in. Patient said no other symptoms of syncope were present and it was just the left hand with this issue. 10-15 min later she said for a short time it went up to elbow but did not last there. Had her stay an extra 15 min and by the time the patient left she said it was better. |
| 1324299 | 5/17/2021 | | 27 | M | 3/18/2021 | 3/18/2021 | Patient had a syncope event post vaccination, was caught by nurse before hitting floor. 911 was called and was assessed by the paramedics and the patient and was cleared to go home. Additional set of vitals -done and were WNL and patient was finally released and sent home. No further action taken |
| 1324288 | 5/17/2021 | WA | 14 | F | 5/17/2021 | 5/17/2021 | Syncope 5 minutes after the vaccination |
| 1324254 | 5/17/2021 | CA | 50 | U | 5/14/2021 | 5/14/2021 | syncope |
| 1324494 | 5/17/2021 | WA | 17 | M | 5/11/2021 | 5/11/2021 | Pfizer-BioNTech COVID-19 Vaccine EUA ; On 5/11/21, Patient experienced tingling in left arm minutes after the vaccine was injected (4:07pm). Patient became nauseous. While in the vehicle to go home, patient's breathing quickened. After this, patient's vision became blurry and he was unable to see. Patient also experienced hearing loss with ringing in ears. The father of the patient pulled the car over in case medical attention was needed. Patient eventually passed out for about 30 seconds (about 4:22). Patient recovered, but complained about fogginess (thinking was unclear and unfocused). The next day, on 5/12/21, the patient experienced chills and nausea without a fever. Currently, the patient is doing fine with no further symptoms. |

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| 1324773 | 5/17/2021 | NM | 37 | M | 5/17/2021 | 5/17/2021 | Pharmacist gave a Johnson + Johnson shot to the patient. After the shot the patient got up and sat down in a "Post-Vaccination waiting area" chair. A few minute later the patient got up and walked towards the pharmacy asking for water, as he was walking to the pharmacist the patient fainted, fell to the ground and bumped his head on the counter. Patient woke up a several second later confused and laid on the floor. Code white and 911 was called. Another pharmacist grabbed an ice pack and a bottle of water for the patient. Patient said he went to the dentist office recently and received a shot in the mouth and something similar happened as well. The patient did not disclose this information to the immunizing pharmacist. Patient told us to cancel the 911 call and asked to leave, the pharmacist recommended he stay a while longer so we can monitor him. Patient said he had no history of diabetes or seizures. Patient forehead was slightly red. |
| 1324804 | 5/17/2021 | CA | 15 | F | 5/17/2021 | 5/17/2021 | client felt lightheaded after receiving 1st Pfizer Covid Vaccine. Client received vaccine at 1717 and RN kept client in chair a few mins as client stated feeling nervous. PHN brought client water. Per client had only ate snack prior to appointment. Client able to transfer by herself to anti gravity chair. 1722 vitals: blood pressure 122/68, oxygen 98%, pulse 81. Per client feeling nausea, RN gave emesis bag. Client appeared diaphoretic and pale. Per Mother only medical history is seasonal allergies and client takes Zyrtec as needed. No history of fainting with vaccines in the past or allergies. Vitals at 1728: blood pressure 118/72, pulse 82, oxygen 97%. Per client symptoms still there, but improving. Vitals at 1733: blood pressure 120/70, pulse 83, oxygen 100%. Client stated lightheaded resolved, nausea still same. Client denied blurry vision, headache, warmth feeling. Vitals at 1738: blood pressure 118/72, pulse 80, oxygen 99%. Per client all symptoms resolved. Last vitals at 1743: blood pressure 114/80, pulse 76, oxygen 99%. Mother driving client home. Advised to follow up with provider and ER precautions given. After completing 30 min observation client left facility with steady gait at 1750. |
| 1324988 | 5/17/2021 | | 42 | M | 5/15/2021 | 5/15/2021 | Patient experienced syncope, fell onto the ground. 911 was called |

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| 1325009 | 5/17/2021 | MN | 69 | F | 5/17/2021 | 5/17/2021 | Patient state that she didn't feel well after the shot. She wanted to sit in the chair at the pharmacy versus standing. She walked over to the chair, sat down, within 5 minutes her husband alerted us that she had fainted and if the pharmacy staff could help her. Staff then proceeded to lay her down on the ground where a cooler was placed under her feet to keep them elevated, a cushion was placed under her head for comfort, and she was given a bottle of water when she became alert. She then rested for a few more minutes before getting up in her chair again. She then got in the chair after 10 minutes, waited another 20 minutes and then felt safe enough to go home afterwards. |
| 1325242 | 5/17/2021 | AZ | 91 | F | 3/1/2021 | 3/26/2021 | J&J vaccine, extremely dizzy, fainting spells, vertigo started on March 26, 2021. Went to ER after reaction becoming worse on April 8, resulting in falling outside in yard. Dr advised going to ER after visit on April 13. Symptoms were stroke and or blood clots. At hospital they took multiple tests but inconclusive if she had a stroke or blood clots. Took CT scan of brain looking for bleeding on the brain. They have all test results. Today still has vertigo, weakness, and fainting spells. |
| 1324215 | 5/17/2021 | | 28 | M | 3/18/2021 | 3/18/2021 | Patient fainted after vaccine. and felt numbness in cheeks. 911 was called. Patient came to in 45-60 seconds and no longer complained of any breathing issues or of feeling faint. Vitals were WNL. 911 was cancelled and patient was advised to see primary physician for follow up. |

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| 1324180 | 5/17/2021 | FL | 18 | M | 4/28/2021 | 4/29/2021 | Had the vaccine after working out. He came home and showered and then went to get vaccine at 6:30. He came home ate dinner and went to bed much earlier than usual around 9:30. Woke up with chills and fever around 8:30. Came downstairs and fainted. Said he felt dizzy. Stood back up and while I was taking his temperature he fainted again (fell backwards from standing position). Got him up he went to bathroom and collapsed on floor. Got him up and were headed to car to take him to the hospital and he collapsed again. Got him up again and the paramedics were called. They arrived and he had a blood sugar of 60 and they thought he may be dehydrated. He did not have fever when they arrived. They left. He ate some breakfast and was tired the remainder of that day and the next. |
| 1322908 | 5/17/2021 | MA | 44 | M | 5/16/2021 | 5/16/2021 | Patient had a syncope episode post vaccination. Patient had a know needle phobia and stated passed out one time when had blood drawn. |
| 1323380 | 5/17/2021 | OH | 24 | F | 5/15/2021 | 5/15/2021 | patient had fainted a couple minutes after receiving vaccine due to a panic attack from getting a vaccine and fell the floor. patient was observed and emergency squad was called to make sure patient was ok and was subsequently discharged from their services after observation. |
| 1323378 | 5/17/2021 | NM | 29 | M | 5/17/2021 | 5/17/2021 | 5 minutes after receiving vaccine, patient stated he didn't feel so good. Lost color in face and then fainted. Pt layed on floor for 5 minutes. A wet cloth was placed in forehead. Pt came back to feeling better then sat up on floor for a few minutes then sat in chair. Pt drank a bottle of water and called his brother for a ride. |
| 1323324 | 5/17/2021 | MI | 32 | F | 3/23/2021 | 3/24/2021 | I received the second dose of the vaccine at 28 weeks pregnant (estimated due date 6/18/21). The morning after receiving the vaccine I suddenly passed out while working from home and subsequently vomited after coming to. I called the doctor's office, and they recommended that I stay home and rest, and that if I continued to struggle with keeping food down that I should go to OB triage at the hospital. I felt weakened and feverish throughout the rest of the day and had similar symptoms at a lower level the following day. |

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| 1323302 | 5/17/2021 | FL | 18 | M | 5/5/2021 | 5/5/2021 | Patient fainted after receiving 1st dose of Moderna. He recovered after about 20 seconds. Pharmacist checked blood pressure several times and it was within normal limits. After 45 minutes of observation patient felt ok to go home. Pharmacy called an car service to take patient home since he walked to the store alone. |
| 1323208 | 5/17/2021 | | 77 | M | 1/22/2021 | 2/16/2021 | SYNCOPE FATIGUE |
| 1323170 | 5/17/2021 | FL | 18 | F | 5/14/2021 | 5/14/2021 | The patient fainted a few minutes after given the vaccine. The patient was pale and needed to stay in a flat position. The EMT was called and the patient was not taken to the hospital. The patient was feeling better after 30 minutes. The patient stated that she sometimes faints when giving blood. |
| 1323134 | 5/17/2021 | MD | 46 | M | 5/17/2021 | 5/17/2021 | Patient fainted after receiving Janssen Covid 19 vaccination while sitted for the mandatory 15 minutes observation time. Patient slumped on the chair. Patient was helped to the floor, wet paper towel placed on his head and he became conscious. We immediately dialed 911 for emergency help. Ambulance arrived shortly after and he was transported to the hospital . |
| 1323081 | 5/17/2021 | OH | 15 | F | 5/16/2021 | 5/16/2021 | After administration of vaccine the patient stood up quickly and passed out. The patient fell down and came to rather quickly. After she came to we helped her to a chair and sat her down, advised her to put her head between her knees, and got her some water that she requested. After a few minutes she appeared rather pale and went to ask her if she was ok and she asked for a trash can because she felt like she was going to be sick. We gave her a garbage bag and she did get sick in the garbage bag. We kept an eye on her for another 15-20 minutes and she stated that she felt better and that she thought she was ok to leave. We offered her help to her car but she denied it saying she would be ok with she walked slowly. Her father was with her the entire time. While talking with them the father did state that she had incidents like that in the past where she stood up too fast and got light headed and passed out. |

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| 1323063 | 5/17/2021 | MI | 18 | F | 5/15/2021 | 5/15/2021 | Patient experienced a syncope episode post vaccination. Patient laid down on the floor for about ten minutes, she drank water and was able to recover on her own. She also stated that this happens when she doesn't have anything to eat or drink. She refused us to call 911. She then waited for about 20 minutes in the observation area and was able to leave on her own |

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| 1323410 | 5/17/2021 | MA | 12 | M | 5/13/2021 | 5/13/2021 | From ED Note: 12 year old male with PMH of asthma on flovent, food allergies with epi-pen (has not required this) and pre-syncope/syncope who presents with concern for loss of consciousness and possible seizure-like activity following a COVID vaccine. Mom notes that he was in his usual state of health when he presented to COVID clinic to get his first vaccine. He got the Pfizer vaccine, seconds after getting in his left arm, mom noted that he looked very "wide eyed" and distraught. She notes that he slumped forward and had lost consciousness for approximately 5 seconds. She noticed shaking movements in his right arm and bilateral lower legs. She notes that his left arm was against her and therefore cannot comment on it. She notes that his eyes were closed. No tongue biting and no incontinence. No secondary trauma. She notes that when these 5 seconds were over he then had a period for about 30 minutes where he looked pale and was breathing heavy but was alert and answering questions. She notes that he has had presyncopal episodes and episodes of feeling faint when getting flu shots in the past. However, this time she noted that he had shaking which made her nervous for possible seizure activity. Patient denies any chest pain or headache prior to the symptoms. She came via ambulance for further evaluation. On arrival, he reports that he feels 90% back to his baseline. He notes that he does not feel quite ready to run around yet however denies any pains or discomforts, headache, weakness, numbness, or tingling. He had eaten a full breakfast prior to getting the shot. He had a normal night sleep and a normal day yesterday per mom. Medical History: as above Surgical history: none Family History: Reviewed and no pertinent related family hx pertaining to this visit Social History: Lives with family Allergies: food allergies Medications: flovent, epi-pen Immunizations: Up to date Medical Decision Making 12 year old male with PMH of asthma on flovent, food allergies with epi-pen (has not required this) and pre-syncope/syncope who presents with concern for loss of consciousness and possible seizure-like activity following a COVID vaccine. On arrival, he was alert, well-appearing, in no acute distress. His vital signs were normal for age on room air. His physical exam was very reassuring as above with a normal neurologic and cardiac evaluation. Differential includes vasovagal/syncope in the setting of a known |

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| | | | | | | stressful trigger vs seizure given report of shaking in his extremities. We feel the latter is significantly less likely given the timeline of the events. Has no known seizure activity nor any triggers per history (fever, trauma, etc.). He also has a normal neurologic assessment. At this time we will defer neurology consults given low concern for seizure. It is possible that this represents a side effect of the vaccine however we also feel that this is less likely given the fact that his symptoms have been seconds after receiving the vaccine. Nonetheless we reported the symptoms to the pharmacist who recorded it in the database. We attained an EKG showing a known incomplete right bundle branch block (unchanged from 2013) and a slightly prolonged QTC of 477 (previously 451). I encourage patient to stay well-hydrated, well rested in the setting of his suspected syncopal episode this morning. I also suggested that for further vaccinations, that he lay down on the table and drink/eat well prior. We provided strict return to ED criteria in the setting of worsening symptoms. All questions were answered at the time of discharge. Mom verbalized her understanding and agreement of the plan. He was discharged in a stable condition with mom at side. **After patient was discharged, cardiology called the follow-up team due to the prolonged QTC to ensure that we were aware. I contacted the patient's PCP to do a follow-up EKG in 1 month's time. | |
| 1322915 | 5/17/2021 | FL | 17 | F | 5/16/2021 | 5/16/2021 | THE PATIENT, AFTER RECEIVING ONE DOSE OF VACCINE, PASSED OUT AND WAS HAVING DIFFICULTY BREATHING, SHORTNESS OF BREATH, SWEATING. SHE WAS CONSCIOUS AT THE TIME THE EMS ARRIVED. |
| 1323043 | 5/17/2021 | MI | 18 | M | 5/15/2021 | 5/15/2021 | Patients experienced a syncope episode after 10 minutes from receiving the vaccine. He was able to gather himself on his own, |
| 1322903 | 5/17/2021 | VA | 37 | M | 5/16/2021 | 5/16/2021 | Systemic: Confusion-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Shakiness-Mild |
| 1322893 | 5/17/2021 | NC | 21 | F | 5/15/2021 | 5/15/2021 | Pt with syncope, vasovagal reaction immediately after injection. LOC x 3-5 seconds, no injury. Observed for 30 minutes, BP improved with oral hydration and recumbent rest. Released to homecare. |

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| 1322885 | 5/17/2021 | MI | 16 | F | 5/16/2021 | 5/16/2021 | Very shortly after receiving the vaccine the patient's head dropped down and she momentarily fainted. She was held in her seat so that she didn't fall out and was awakened only seconds later. She was kept in her seat for 15 minutes after the incident until she felt stabilized. She stood up slowly and assessed for balance and strength. She and her father felt she was stable enough to go home. |
| 1322876 | 5/17/2021 | MA | 14 | M | 5/16/2021 | 5/16/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Mom said patient lost consciousness for less than 10 seconds after injection for about 5 minutes, while sitting in observation area for 15 minutes, then patient started to feel better. Patient felt fine after sitting for 30 minutes |
| 1322854 | 5/17/2021 | PA | 17 | F | 5/16/2021 | 5/16/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: syncope/seizure like activity-Medium, Systemic: Hypotension-Medium, Additional Details: Patient experienced a syncope/fainting/hypotensive event immediately post vaccination that had characteristics of possible seizure activity. Patient regained consciousness after a few minutes and seemed disoriented but stable (still hypotensive). Transported to reading hospital (tower health) emergency room for evaluation |
| 1322844 | 5/17/2021 | OH | 12 | F | 5/16/2021 | 5/16/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: pt fainted (slumped over in chair) aprox 1 min after receiving the vaccine. she recovered within 60 seconds |
| 1322827 | 5/17/2021 | MA | 13 | F | 5/16/2021 | 5/16/2021 | Fainted within minutes, hot, dizzy. Lasted approximately 15 minutes. Headache appeared about 8 hours later and soreness. |
| 1322820 | 5/17/2021 | TX | 17 | F | 5/16/2021 | 5/16/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient was administered the Pfizer Covid Vaccine. A few minutes later, while watching her mom receive the vaccine she fainted. Patient was unresponsive for less than a minute. Upon regaining consciousness patient seemed to recover fully after resting and drinking some water. |

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| 1322561 | 5/17/2021 | NJ | | F | | 3/21/2021 | <p>FAINTED; EARACHE IN BOTH EARS; SUSPECTED COVID-19 INFECTION; This spontaneous report received from a White not Hispanic or Latino female patient of unspecified age. The patient's weight, height, and medical history were not reported. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number:1808609, expiry: UNKNOWN) dose was not reported,1 total, administered on 19-MAR-2021 on left arm for prophylactic vaccination. No concomitant medications were reported. On 21-MAR-2021, COVID-19 virus test confirmed Suspected COVID-19 infection. On an unspecified date, the patient experienced earache in both ears, fainted. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the earache in both ears, fainted and Suspected COVID-19 infection was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0:20210518581- covid-19 vaccine ad26.cov2.s -Fainted. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p> |
| 1324164 | 5/17/2021 | CA | 58 | F | 5/17/2021 | 5/17/2021 | <p>Patient immediately felt dizzy and fainted a few minutes after getting the vaccine. She had to lay down on the ground to prevent falling.</p> |
| 1322958 | 5/17/2021 | NY | 13 | F | 5/15/2021 | 5/16/2021 | <p>She fainted</p> |
| 1324118 | 5/17/2021 | MA | 14 | M | 5/17/2021 | 5/17/2021 | <p>Immediately after receiving vaccine, pt had a syncopal event with brief LOC. Caught by medical staff and lowered to the ground - placed supine with legs elevated. Pt quickly regained consciousness and was alert and oriented x3. Has a history of syncope with vaccines and medical procedures. Dad present. Vital signs obtained and noted to be WNL HR 84 NSR Spo2 98% on room air B/P 123/61 laying down 118/62 sitting Pt hydrated with juice and was able to sit up and ambulate freely. Stayed for an additional 15 minute of observation without incident and left for home with dad.</p> |

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| 1322917 | 5/17/2021 | IN | 18 | F | 5/12/2021 | 5/12/2021 | Site: Pain at Injection Site-Mild, Site: Redness at Injection Site-Mild, Systemic: Fainting / Unresponsive-Mild, Additional Details: pt fainted for a few mins, she came to it after a few mins. Paramedics was called in and the pt was checked out. pt stated that she did not eat all day, her blood pressure was low. she was fine after a few mins. |
| 1324146 | 5/17/2021 | CA | 13 | F | 5/16/2021 | 5/16/2021 | Shortly after receiving the vaccine patient fainted. 911 was called. Pt recovered and parent refused to have patient transported. |
| 1323415 | 5/17/2021 | OH | 18 | F | 5/17/2021 | 5/17/2021 | While the patient was sitting in the waiting area, she passed out and began displaying signs of seizing, making nonverbal noises and convulsing. She quickly regained consciousness after approximately 1 minute of lost consciousness. The pharmacist on duty then asked the patient if she had eaten and drank today, to which she responded that she had not. The pharmacist then provided a granola bar and water. The pharmacist also took the patient's blood pressure, measuring 92/58 mmHg with a pulse of 60 bpm. She then took a second reading 5 minutes later, measuring 112/68 mmHg. The patient quickly recovered and was able to leave without further medical attention. |
| 1324109 | 5/17/2021 | GA | 14 | F | 5/13/2021 | 5/13/2021 | Vasovagal Syncope @ 10:05 14 year old female. No breakfast or fluids in am before vaccination. EMT called BP 104/68 oxygen 99% HR 78 . BS 85. 10:14 seizure like behavior eyes roll back in head both arms constrict. BP 100/60 IV fluids started 100ml saline. 10:30 BP 104/70. (Per mother history of syncope four years ago after receiving an allergy shot.) alert and oriented x4 at 10:40. released to mother . |

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| 1324090 | 5/17/2021 | AZ | 15 | M | 5/17/2021 | 5/17/2021 | Shortly after exiting the pharmacy, the patient's dad came back to the pharmacy propping up his son. Stated his son got light-headed and almost fainted. The pharmacist had the patient come into the vaccine area, sat him down, and took his blood pressure (106/80). His breathing was monitored and when it checked out, the pharmacist gave a single dose of diphenhydramine 25mg. The patient drank 2 x 16oz of water. Paramedics were called as a precaution. The patient was able to walk out on his own. The pharmacist made a follow up call at 2PM and the father acknowledged that his son is doing fine. |
| 1324080 | 5/17/2021 | CA | 16 | M | 5/15/2021 | 5/15/2021 | about 5 minutes after administration pt fainted. pt was in the company of his mother who stated pt quickly regained consciousness. we offered to call the paramedics pt's mother refused reassuring us her son was fine. several hours later we tried contacting pt at the phone number listed on their file but could not reach the pt and could not leave a message |
| 1324070 | 5/17/2021 | MI | 13 | M | 5/17/2021 | 5/17/2021 | Patient became very pale eyes rolled behind head and was unable to keep head up. Fainted for a few seconds before waking up again. |
| 1324045 | 5/17/2021 | FL | 20 | F | 5/17/2021 | 5/17/2021 | patient fainted. smelling salts used, cold pack to neck area and pt put in lying position with feet up |
| 1324024 | 5/17/2021 | VA | 24 | M | 5/17/2021 | 5/17/2021 | PATIENT BRIEFLY FAINTED. CONSUMED 20 OZ SODA AND WATCHED FOR ADDITIONAL 15 MINUTES AND RELEASED. |
| 1324014 | 5/17/2021 | OH | 17 | F | 5/17/2021 | 5/17/2021 | PATIENT PASSED OUT IN DAD'S ARMS, CAME TO WHEN WE LAID HER DOWN SWEATINESS AND DIZZINESS RESOLVED ON ITS OWN |
| 1324012 | 5/17/2021 | CA | 62 | M | 4/19/2021 | 5/8/2021 | Acute trouble breathing followed by fainting/loss of consciousness. Chest compressions were started as paramedics were on the way. Paramedics worked on my dad for over 30 minutes but were unable to revive him. They stated he went into cardiac arrest. |
| 1323930 | 5/17/2021 | VA | 14 | F | 5/17/2021 | 5/17/2021 | client received first dose of pfizer covid 19 vaccine. walked over to recovery area and passed out. |

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| 1323514 | 5/17/2021 | GA | 54 | M | 5/14/2021 | 5/16/2021 | Son came into Health Dept this morning to report that his father began throwing up and having diarrhea Saturday morning(05/15/2021) which progressed through the day. States did not want to go to the Hospital but wanted to wait to see his MD at the Dialysis center on Monday (05/17/2021). On Sunday(05/16/2021) nausea and vomiting and diarrhea was worse and now with cough noted. States was washing his hands and fainted, EMS was called and he died that morning. |
| 1324153 | 5/17/2021 | UT | 18 | F | 4/7/2021 | 4/7/2021 | The night of the vaccine: body aches, intense chills, fever, night sweats, headache, insomnia The morning after: Passing out/fainting (loss of consciousness for a couple seconds), body aches, chills, headache. *Symptoms improved with sleep throughout the afternoon of the the day after. Body aches and weakness continued for about 4 days. |
| 1323469 | 5/17/2021 | NY | 16 | F | 5/15/2021 | 5/15/2021 | Pt passed out after first dose of Pfizer vaccine. Pt was wheeled to the EMS station where she passed out a second time. Pt VS at 11:08AM HR 54, BP 11/40. At 11:16AM HR 60, BP 90/60. At 11:32AM HR 66, BP 100/60. Pt was given cookies and water and appeared alright, she was released following last set of VS. |
| 1323612 | 5/17/2021 | CO | 19 | M | 5/4/2021 | 5/6/2021 | 19 year old male who presented to Medical Center with presumed syncope leading to an MVA. He was the restrained driver of a car that was involved in a rollover. He was admitted to the trauma service, had trauma and syncope workup initiated. Pt has had 2 prior episodes of syncope, once when seeing blood and the other after smelling a noxious odor, suspect vasovagal syncope. Pt reports not feeling well since receiving covid vaccine on 5/4, and had vomited x 2 the morning of the accident. Trauma evaluation revealed nasal bone fracture, remained of imaging negative. He will follow up with the trauma facial surgeon next week |
| 1323624 | 5/17/2021 | MI | 16 | M | 5/9/2021 | 5/9/2021 | Fainted 2-5 minutes after the injection. Came to quickly and recovered enough to walk out after a short rest. |

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| 1323630 | 5/17/2021 | TX | 41 | F | 3/31/2021 | 5/1/2021 | Ear infection Throat infection Nausea/vomiting Fatigue Diarrhea Then after antibiotics and Mucinex treatment with no improvements Severe headache sent me to ER with no findings other then doctors are thinking it is Viral meningitis that could be causing it. I am still having headache nausea and diarrhea and Almost passed out yesterday from cooking My activities are very light or I pass out. |
| 1323651 | 5/17/2021 | MI | 12 | M | 5/16/2021 | 5/16/2021 | Fainted soon after the injection. Came too soon after and walked out on his own. |
| 1323770 | 5/17/2021 | CA | 16 | M | 5/16/2021 | 5/16/2021 | Within 30 seconds passed out. Woke up and about 5 minutes later passed out again, with eyes open and could hear but couldn't talk. Epi Pen administered by Pharmacist around 8 minutes after shot. Taken by ambulance to ER |
| 1323792 | 5/17/2021 | TX | 14 | F | 5/17/2021 | 5/17/2021 | PATIENT HAD BEEN ON CHAIR MONITORING FOR 14 MINUTES WHEN SHE FAINTED. NOT CERTAIN IF SHE HAD A SEIZURE. HOSPITAL WAS CALLED TO THE SCENE AND SHE WAS TRANSFERRED TO HOSPITAL FOR OBSERVATION. PHARMACIST SPOKE TO PATIENT'S MOM THIRTY MINUTES LATER AND SHE WAS ENROUTE. MOM STATED SHE WAS DOING OKAY. |
| 1323647 | 5/17/2021 | PA | 17 | F | 5/17/2021 | 5/17/2021 | Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Mild, Systemic: Chest Tightness / Heaviness / Pain-Mild, Systemic: Fainting / Unresponsive-Medium, Additional Details: Patient waited 15 minutes after receiveing vaccine and felt fine, on the drive home the patient says she had some difficulty swallowing water that caused pain in her chest, then passed out momentarily, patient returned to the pharmacy where we checked her BP which was 107-67, patient mom was on the phone with her physician, monitored the patient for additional 10 minutes and patient said she felt well enough to return home. Gave patient chocolate bar since she had not eaten anything. |

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| 1323833 | 5/17/2021 | GA | 15 | F | 5/14/2021 | 5/14/2021 | AFTER COVID19 VACCINATION, PATIENT EXPERIENCED NUMBNESS, TINGLING, DIZZINESS, WEAKNESS, LIGHTHEADEDNESS AND DIAPHORESIS AT FOREHEAD. NO LOC, NO DIB, NO SYNCOPE, NO CHEST PAIN. AFTER 15 MINUTES PATIENT WAS ASYMPTOMATIC. LEFT WITH FATHER TO HOME AT 11:16 AM. VITAL SIGNS: 1100 BP 72/36, HR 88, RR 20 1105 BP 86/46, HR 84, RR 20 1110 BP 88/62, HR 82, RR 20 1115 BP 96/68, HR 80, RR 20 1116 BP 102/70, HR 82, RR 20 |
| 1321944 | 5/16/2021 | TX | 13 | M | 5/16/2021 | 5/16/2021 | Syncope, seizure lasting less than 5 min, vomiting |

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| 1321793 | 5/16/2021 | AZ | 69 | F | 3/26/2021 | 5/15/2021 | <p>Chief Complaint Fever History of Present Illness This is a 69 year old female with breast cancer status post left mastectomy, diabetes mellitus, hypertension, and past transient ischemic attack who presented to ED for fever. The patient reports that she began experiencing sudden onset of fever and chills last night (05/15/2021), and she additionally complains of persistent sore throat and cough beginning the previous week. She has undergone radiation and chemotherapy treatment for breast cancer in the past but these treatments have been suspended for several months with mammography performed on 03/10/2021 failing to identify any malignant growths. In the ED, the patient was found to have acute bronchitis due to COVID-19, fevers and systemic inflammatory response syndrome. Review of Systems Constitutional: Positive for chills and fever. HENT: Positive for sore throat. Respiratory: Positive for cough. Negative for shortness of breath. Cardiovascular: Negative for chest pain and leg swelling. Gastrointestinal: Negative for abdominal pain, diarrhea, nausea and vomiting. Genitourinary: Negative for dysuria. Musculoskeletal: Negative for gait problem. Neurological: Negative for syncope. All other systems reviewed and are negative. Vitals Blood pressure 123/75, pulse 95, temperature 37.1 °C (98.7 °F), temperature source Oral, resp. rate 29, height 1.651 m (5' 5"), weight 106.6 kg, SpO2 95 %. Physical Exam Vitals reviewed. Constitutional: General: She is not in acute distress. Appearance: Normal appearance. She is well-developed. She is morbidly obese. She is not ill-appearing. HENT: Head: Normocephalic and atraumatic. Nose: Congestion present. Mouth/Throat: Mouth: Mucous membranes are dry. Dentition: Abnormal dentition. Pharynx: Oropharynx is clear. Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Pulses: Normal pulses. Heart sounds: Normal heart sounds. Pulmonary: Effort: Pulmonary effort is normal. Breath sounds: Normal breath sounds. Chest: Comments: Port in place to the upper right chest. Abdominal: General: Bowel sounds are normal. There is no distension. Palpations: Abdomen is soft. Tenderness: There is no abdominal tenderness. Musculoskeletal: General: Normal range of motion. Cervical back: Normal range of motion and neck supple. Skin: General: Skin is warm and dry.</p> |

VAERS_ID RECVD STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1321810 | 5/16/2021 | TX | 16 | F | 5/15/2021 | 5/15/2021 | <p>Comments: Chronic venous stasis changes to the bilateral lower extremities. Decreased skin turgor throughout. Neurological: General: No focal deficit present. Mental Status: She is alert and oriented to person, place, and time. Plan Admit to hospital ? cardiac telemetry unit Continuous pulse oximetry and telemetry monitoring Control pain, nausea and vomiting as needed Respiratory treatments (MDI) and supplemental oxygen prn IVF hydration; serial neurological checks every four hours Initiate dexamethasone therapy 6 mg IV once daily Ascorbic acid, zinc sulfate, and vitamin D3 supplementation Serial BMP, Mag, CBC, hepatic panel; ESR/CRP, PT/INR Serial lactic acid and procalcitonin; check respiratory PCR Follow up on blood cultures as available; check urinalysis Electrolyte correction/replacement as indicated Fall precautions; PT/OT evaluations during this visit FSBS and SSI every AC/HS for glycemic control Resume selected home medications with hold parameters DVT prophylaxis ? SCDs only GI prophylaxis ? Famotidine</p> |
| 1321879 | 5/16/2021 | IL | 75 | F | 5/16/2021 | 5/16/2021 | <p>about 1 minute after receiving vaccine patient fainted for about 30 seconds. I touched her hand and she came to. Her husband came in to be with her and we gave bottled water. She sat in chair about 15 minutes and went home with her husband</p> |
| 1321909 | 5/16/2021 | VA | 21 | F | 5/16/2021 | 5/16/2021 | <p>Syncope ,temporary loss consciousness for less than 1 minute I think was so short.</p> |
| 1321951 | 5/16/2021 | IL | 16 | F | 5/16/2021 | 5/16/2021 | <p>Patient has a seizure history. Mother stated they have had numerous vaccines in the past without a problem though. Patient was waiting the period of time afterwards. Mother then stated she was having a reaction. Mother stated she is a nurse and said she believed the patient was having a seizure. Mother later was not sure if patient had fainted also since she was nervous about receiving the shot in the first place. After paramedics arrived, they took her glucose and was 77. Paramedics let mom then take patient home to get food.</p> |

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| 1321942 | 5/16/2021 | CA | 30 | M | 5/14/2021 | 5/14/2021 | COUPLE OF MINUTES AFTER RECEIVING THE VACCINE PATIENT GOT UP AND WALK UP TO THE REGISTER. DURING CONVERSATION WITH PHARMACIST PATIENT REMOVED HIS MASK AND SAID SOMETHING WHICH PHARMACIST DIDN'T HEAR OR UNDERSTAND. PATIENT FAINTED AND FELL ON THE FLOOR. AFTER FEW MINUTES PATIENT WAS ABLE TO MOVE AROUND AND COMMUNICATE. PARAMEDIC WAS CALLED AND TAKEN TO THE EMERGENCY ROOM FOR FURTHER EVALUATION. ACCORDING TO NURSE AT ER PATIENT WAS FINE AND DISCHARGED AFTER COUPLE OF HOURS OBSERVATION. TRY CONTACTING PATIENT MULTIPLE TIMES VIA PHONE AND EMAIL BUT UNABLE TO COMMUNICATE WITH PATIENT AS OF NOW. |
| 1321788 | 5/16/2021 | NY | 21 | M | 5/16/2021 | 5/16/2021 | Pt passed out for a minute after receiving vaccine . Got dizzy and fell off chair. EMS called and came. Pt left on own will after 1/2hr. |
| 1321963 | 5/16/2021 | CA | 15 | M | 5/15/2021 | 5/15/2021 | PATIENT WAS GIVEN THE COVID-19 PFIZER VACCINE @11:18AM. THEY WERE ASKED TO STAY 15 MINUTES AT THE WAITING AREA AND AROUND 11:21AM, HE FAINTED. I RAN TO THE PATIENT, HE WAS ALREADY CONSCIOUS BUT STILL CALLED 911. PARAMEDICS CAME 15 MINUTES LATER, HE WAS ALMOST RELEASED TO GO HOME BUT UPON STANDING UP, HE FAINTED AGAIN. HE WAS TAKEN TO HOSPITAL AND WAS DISCHARGED SAME DAY. |
| 1321584 | 5/16/2021 | TX | 15 | F | 5/5/2021 | 5/15/2021 | Systemic: Chills-Medium, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Medium, Systemic: Nausea-Medium, Systemic: Numbness (specify: facial area, extremities)-Medium, Systemic: Shakiness-Medium |
| 1321919 | 5/16/2021 | PA | 16 | M | 5/16/2021 | 5/16/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient seemed to have a fainting spell about 10 minutes after vaccine was given, patient came too and felt "sick to his stomach", patient stated he felt okay, but once paramedics came, mom wanted him to go to with them to the hospital. |

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| 1321744 | 5/16/2021 | TX | 15 | M | 5/15/2021 | 5/15/2021 | Syncope and alleged seizure as reported by mother and bystanders (Pharmacist did not witness event) |
| 1321674 | 5/16/2021 | MA | 17 | F | 5/3/2021 | 5/4/2021 | While sitting in class, suddenly passed out and vomited at the same time. Came to about 30 seconds later. No additional adverse affects after the episode. |
| 1321602 | 5/16/2021 | MS | 52 | M | 5/15/2021 | 5/15/2021 | Site: Pain at Injection Site-Mild, Systemic: Fainting / Unresponsive-Severe |
| 1321597 | 5/16/2021 | MN | 15 | M | 5/15/2021 | 5/15/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild |
| 1321588 | 5/16/2021 | MA | 16 | F | 5/15/2021 | 5/15/2021 | Systemic: Chills-Mild, Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Hypotension-Mild, Systemic: Shakiness-Mild, Systemic: Weakness-Mild, Additional Details: Paramedics/911 called, patient's parent refused transport to the hopsital. Patient waiting in recovery with NP and nurses, RPH to check |
| 1321964 | 5/16/2021 | CA | 14 | F | 5/15/2021 | 5/15/2021 | Patient fainted about 10 minutes after receiving first dose of Covid-19 vaccine. She was instructed to remain seated in the waiting room but got up and walked around the store with her parents and felt faint after walking for a minute or two. She passed out and was caught by her dad and gently laid down on the floor. Paramedics were called to check vitals as patient continued to feel drowsy for a few minutes. She was assessed by paramedics and released to parents after checking vitals, blood glucose, heart. She stated she was feeling better after several minutes of sitting or laying down. |
| 1321581 | 5/16/2021 | MD | 18 | F | 5/15/2021 | 5/15/2021 | Near Syncope Seen by EMT on site Discharged home with father at 1750 |
| 1321530 | 5/16/2021 | | 50 | M | 5/15/2021 | 5/15/2021 | DIZZINESS, COLD SWEAT, PALE, DIAPHORETIC, SYNCOPE (LAST 20 SECS), SEEN BY PARAMADICS, VSS, PROVIDED SNACK AND WATER, SX RESOLVED, REFUSED TRANSPORT, AMA SIGNED. |

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| 1321486 | 5/16/2021 | OH | 34 | M | 5/13/2021 | 5/14/2021 | Injection site: pain/tenderness General side effects: Nausea, weakness (full body), nearly fainting multiple times, headache, some confusion, dehydration, some difficulty breathing, tired even with rest, low fever |
| 1322035 | 5/16/2021 | NY | 46 | F | | | Pt got lightheaded and almost fainted after given vaccine. EMS called to store to assist pt. Pt eventually left on their own . |
| 1321590 | 5/16/2021 | CA | 17 | M | 5/11/2021 | 5/11/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: patient had second vaccine in series and fainted. fell face forward from chair and hit cheek and left eyebrow area. patient was laid down and told to put feet on chair. blood pressure and heart rate were lower than normal. patient was monitored for blood pressure and heart rate until vitals normalized. patient and careprovider declined emergency services offered. |
| 1322292 | 5/16/2021 | GA | 61 | M | 4/23/2021 | 5/1/2021 | Complained of chest pain at 3:50 pm may 15th. He went and layed down across his bed was coherent and talking, suddenly passed out. 911 was called and chest compressions were started. Ambulance arrived his condition was 60/40 bp and heart rate of 40. Taken to hospital where he never recovered and passed away. |
| 1322008 | 5/16/2021 | NY | 21 | M | 5/14/2021 | 5/14/2021 | Patient received vaccine, appeared to be fine, I went back into pharmacy and about 1-2 minutes later, patient fainted and fell onto the floor out of his chair. We called 911 immediately and they were here within 5 minutes. Patient continued going in and out of consciousness and they brought him to the hospital via Ambulance where he was later released that day. |
| 1321972 | 5/16/2021 | CA | 18 | F | 5/16/2021 | 5/16/2021 | PATIENT FAINTED WITHIN 5 MINUTES OF VACCINE, BUT REGAINED CONSCIOUSNESS QUICKLY. PATIENT APPEARED PALE. PATIENT REMAINED SEATED FOR 30 MINUTES AND PARAMEDICS ARRIVED TO CONDUCT EVALUATION OF PATIENT. |

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| 1322324 | 5/16/2021 | CA | 13 | F | 5/16/2021 | 5/16/2021 | client had syncope episode after receiving 1st dose Pfizer Covid Vaccine. Client received vaccine at 1336 and was standing next to vaccine station and Father as sibling was receiving vaccine. Within 3 minutes of standing client had syncope episode and hit back of head on floor. RNs responded. PHN called 911 at 1340. Per RN client collapsed and hit back of head, Father tried to hold on but was unsuccessful. As PHN was speaking with paramedics, client regained consciousness. Client stated she remembered feeling dizzy and then woke up on the floor. Client alert and oriented, pale and stated blurry vision. RN elevated legs. Vitals: blood pressure 130/90, pulse 102, oxygen 99%. Father denied any relevant medical history, medications, allergies or history of syncope. Client stated feeling dizzy, denied pain on head or rest of body. Paramedics arrived approximately 1346 and assumed care. After assessment Father signed AMA with paramedics. Client sat in anti gravity chair after paramedics left. EMT stayed with client. Vitals at 1412: blood pressure 120/80, pulse 85, oxygen 96%. Client stated feeling dizzy and head hurts when she moves. Blurry vision resolved. PHN spoke with parents to review ER precautions and advised to make follow up appointment with primary doctor. After sibling was done with observation, client left facility at 1425 with steady gait. |
| 1322279 | 5/16/2021 | FL | 12 | F | 5/16/2021 | 5/16/2021 | About two minutes after she received her shot she told us she was seeing black spots. Then she told me she couldn't see and she passed out. She started to regain consciousness and a little bit of blurred vision and then she began dry heaving. She was clammy and sweaty at that point but continued to improve after she drank some water. |
| 1322272 | 5/16/2021 | CA | 38 | F | 5/16/2021 | 5/16/2021 | patient passed out after receiving vaccine due to extreme fear of needles. 911 was called but when patient regained consciousness after 10-20 seconds, she had us cancel the ambulance. She then passed out a second time and we called the ambulance again. She regained consciousness but agreed to have them assess her. She declined to be transported to the hospital and was released after they assessed she was ok. |

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| 1322259 | 5/16/2021 | AL | 17 | F | 5/16/2021 | 5/16/2021 | Patient felt light headed and fainted. Patient was alert and aware immediately and did not sustain injury. Ambulance was called but patient did not end up needing. |
| 1322213 | 5/16/2021 | VA | 14 | M | 5/16/2021 | 5/16/2021 | Client received Pfizer # 1 @ 09:26 Hx of fainting w/ blood draws and injections in past but did not inform staff Mother present at all times Client had vasovagal episode with syncope within seconds of receiving vaccine Was unresponsive for < 15 seconds. Did not fall or slide off chair at vaccinator's table Taken to EMS area for observation via W/C BP/P 100/60, 60 lying, sitting and standing Client felt back to normal within minutes of episode EMS advised transport to hospital. Mother declined. Observed for 30 minutes in EMS area Client and mother left EMS area independently @ 10:00 |
| 1322209 | 5/16/2021 | UT | 18 | M | 5/16/2021 | 5/16/2021 | Patient fainted about 5 minutes post vaccine. We had them lay down for a moment and gave them water. Patient waited for 40 minutes after vaccine and recovered. |
| 1322172 | 5/16/2021 | OH | 20 | M | 5/16/2021 | 5/16/2021 | Patient fainted after receiving Janssen Covid-19 vaccination, immediate upon removal of syringe needle at 3:24 pm on 5/16/21. Patient recovered consciousness about 10-15 seconds later and complained of feeling dizzy and light-headed. Wet paper towels were applied to patient's neck wrist and forehead for 5 minutes but he still felt light headed. Patient then was instructed to lie on the floor and elevate his feet on a chair. After doing this for 5 minutes he felt well enough to sit in the waiting/observation area for another 10 minutes after which he felt well enough to leave. |

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| 1322151 | 5/16/2021 | VA | 15 | F | 5/16/2021 | 5/16/2021 | Pt was brought in by her father for her first dose of Pfizer vaccine. Prior to receiving the vaccine, her father asked her to let the writer know of her fear of needle and what occurs when she she has blood draws or vaccination. Patient states that she usually lays down because she feels faint and passes out at times. After she sat down, another chair was provided to rest her legs. Pfizer dose was administered and within a minute, she acknowledged that she about to passed out. She had a near syncopal episode with both arms contracting. She was carried from the chair to the floor. Her father, who was prepared for this, had ammonia with him and had the patient sniff it and she responded to it. She was observed for little over 30 minutes and walked out of the pharmacy stating that she felt well. Throughout the ordeal, she was responding appropriately. |
| 1322150 | 5/16/2021 | MI | 15 | F | 5/16/2021 | 5/16/2021 | Patient received injection and sat down in the waiting area with her Mom. Less than 5 minutes after the injection she fainted and appeared to have a small seizure , her mother shouted at her and shook her and she became conscious and vomited. 911 was called , they evaluated the patient and she went to the hospital. |
| 1322016 | 5/16/2021 | | 15 | M | 5/16/2021 | 5/16/2021 | Patient fainted post vaccine and was out for about 10 seconds, and then came to. After waiting 15 minutes, drinking some water, and eating a light snack, patient was fine. |
| 1322136 | 5/16/2021 | OH | 16 | F | 5/16/2021 | 5/16/2021 | Patient passed out within a minute of vaccination. Mother and I moved patient to a laying down position where she immediately woke up and knew where she was and what just happened. Declined any other symptoms. Mom said she passes out often after vaccinations. Patient was conscious carrying on a conversation like normal immediately after coming to. Over the next 30 minutes I tried to get patient to a sitting position to take her blood pressure but every time we tried she needed to lay back down because she felt like she was going to pass out. After trying this twice and being unsuccessful I had EMS called to check on patient to make sure nothing more serious going on. EMS came and took a couple blood pressures and pulses which were normal. Patient was starting to feel better. Walked out with EMS and planned on going home. |

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| 1322131 | 5/16/2021 | IN | 14 | M | 5/14/2021 | 5/16/2021 | Exhaustion Headache Lightheaded/dizzy Nausea Fainting |
| 1322120 | 5/16/2021 | CO | 13 | F | 5/16/2021 | 5/16/2021 | The patient fainted after vaccine administration. The patient was fine after about 30 minutes of sitting. |
| 1322089 | 5/16/2021 | IL | 15 | F | 5/16/2021 | 5/16/2021 | Patient received her first dose of the Pfizer COVID19 vaccine at approximately 12pm. Patient felt fine immediately after the vaccination and was instructed to sit and wait for 15 minutes. The immunizer, watched the patient sit down in a chair. A few minutes later the mother of that patient began screaming help, help. Patient had fainted, falling on the floor and hitting her head. I ran our to assist patient, I instructed my technicians to call 911. Patient was on the floor, shaking. I assisted her in rolling over. When she came to I helped her control her breathing and take deep breaths. I used I gauze pad to stop the bleeding on her head. I made sure she was lying flat on the floor. We gave her an ice pack to help with the numbness and tingling in her hands. The paramedics arrived and took patient to the hospital. |

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| 1322069 | 5/16/2021 | CA | 18 | M | 5/14/2021 | 5/14/2021 | <p>Patient (DOB 05-01-2003) received his 1st COVID vaccine (Pfizer, lot # EW0182 use by 5/15/21 at 0855) at 1539. The patient became pale approximately 30 seconds following the administration of the vaccine, EMT assisted the patient to the chair as he was standing up when he became pale, the patient loss consciousness for approximately 2 seconds. RN arrived at the station and assisted the patient to the ground, where he was placed in a supine position with his lower extremities elevated. The patients face mask was removed, he was alert and oriented to person, place, time, and situation. The patients color slowly returned to his face. Vitals were taken at 1540: BP: 155/70 (R arm, supine position), HR 70, RR 16, oxygen saturation at 97%, and pupils were equal. The patient had a history of fainting x 1 and his last meal was at 0800 and he stated, " I didn't drink that much today." Denied any chronic medical conditions, was not currently taking any medications, and denied any drug allergies. The patient was moved to the anti-gravity chair and he was given pringles and Gatorade. Vitals were retaken at 1545: BP 162/80 (R arm, sitting upright), HR 50, RR 16, oxygen saturation at 97%. Denied any dizziness, headache, chest pain, or vision changes. Vitals were retaken at 1553: BP 158/72 (R arm, sitting upright), HR 52, RR 16, Oxygen saturation at 97%. The patient was advised to eat a full meal prior to receiving his second COVID vaccine dose and to receive his 2nd dose in the anti-gravity chair. Vitals were retaken at 1558, BP 152/78 (R arm, sitting upright), HR 57, RR 16, and oxygen saturation at 98%. The patient was also given a bottle of water, as he did not consume many liquids during the day. The patient's color fully returned to his face and he denied any shortness of breath, dizziness, changes in vision, or difficulty swallowing. Vitals retaken at 1603, BP 150/75 (R arm, sitting upright), HR 60, RR 16, and oxygen saturation at 96%. The patient called his mother to pick him up, as we strongly advised him to not operate machinery/ a vehicle after fainting. The patient's vital signs were taken at 1608, BP 140/75, HR 60, RR 16, and oxygen saturation at 100%. The patient was advised to drink the entire bottle of water, as his blood pressure was slightly elevated and it was most likely due to being dehydrated, as he did not consume any fluid since 0800 earlier that day. The patient drank a bottle of water and his vital signs were retaken at 1614, BP 122/68 (R arm,</p> |

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sitting upright) and a respiratory rate of 15 breaths per minute. The patient's mother arrived on site around 1630 and spoke with RN and both EMT. RN instructed the patient about emergency precautions and to follow up with his primary care provider. RN also educated the patient about the importance of informing the healthcare provider about his history of fainting with the first vaccine, when receiving the second COVID Pfizer vaccine. Gave the patient V-safe information and reported the occurrence in VAERS. The patient had a steady and even gait when leaving the site with his mother at 1632.

Non-stop vomiting, fainting, I fell out of my bathtub and hit my head. The sickest I have ever been in my life. I thought I was dying. I would have never taken this dangerous life-threatening vaccine knowing this.

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| 1321992 | 5/16/2021 | TX | 16 | M | 5/16/2021 | 5/16/2021 | <p>Patient was given Pfizer Vaccine on 5/16/21 at 11:00-11:10am. I read through the patient medical history through the handheld and noticed there was "yes" on seizure history. I ask the mother what happened and she told me it was from the first incident with the Pfizer vaccine. At the time of the first incident the mother stated that patient fainted and convulsed upon regaining consciousness. Patient has had no history of seizures prior to then or had any big injuries that could trigger it. Patient's mother states physicians think it's triggered by anxiety and not a true seizure, so MRI or tests was not needed. Doctor recommended patient to come back if it happens again. With the information provided I used professional judgement and was on high alert with the patient. After administrating the vaccine to the patient, I monitored patient's vitals carefully. Patient was stable and I walked with him to his seat near the wall and left him with his family. About a few minutes later the mother told me to come to her aid. Patient had a 1 time continuous seizure for about 30 seconds-1minute. After regaining consciousness the patient said he did not remember getting the vaccine. Patient's mother was very concerned and under control and did not overreact to the situation. Also, I promptly relayed to (pharmacist) to call 911 and he called a member of management. While pharmacist was on the phone with 911 the patient regained consciousness. I monitored patient's vitals while I waited for a member of store management. Store management took a little bit longer to respond (5-10 minutes) but arrived to document the whole incident. About 30 minutes after the incident patient's vitals were stable and the ambulance was not needed and the family took him to the hospital to get monitored. Patient rode the electric wheelchair was escorted out by store management to the car.</p> |
| 1322382 | 5/16/2021 | FL | 12 | M | 5/16/2021 | 5/16/2021 | Fainted in chair about 3 minutes after shor was given |
| 1322137 | 5/16/2021 | FL | 59 | M | 5/16/2021 | 5/16/2021 | Patient slumped over the chair and passed out for a few seconds after the vaccine |

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| 1320021 | 5/15/2021 | CO | 29 | M | 4/28/2021 | 4/29/2021 | Fell unexpectedly; I injured my nose, tooth; I injured my nose, tooth; My arm pain is 7 out of 10; scared to get up.; This is a spontaneous report from a contactable consumer (patient). A 29-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; solution for injection) via an unspecified route of administration on 28Apr2021 at 16:15 (at the age of 29-years-old) as a single dose in the left arm for COVID-19 immunisation and ibuprofen (ADVIL) from an unspecified date to an unspecified date at an unspecified dose (2) and frequency for an unspecified indication. Medical history included anxiety/depression (mitigated with SSR) from an unspecified date and unspecified if ongoing. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient had no known drug allergies. Concomitant medications (taken within 2 weeks of vaccination) included escitalopram orally taken for an unspecified indication from an unspecified date to an unspecified date at 10mg, daily. The patient did not receive any other vaccines within 4 weeks prior to the COVID-19 vaccine. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; solution for injection) via an unspecified route of administration an unspecified date as a single dose for COVID-19 immunisation. On 29Apr2021 at 03:00 the patient experienced fell unexpectedly, I injured my nose, tooth, my arm pain is 7 out of 10 and scared to get up. The course of events was reported as follows: "Got up at 3am in the morning to take some Advil. Took 2 Advil then fell unexpectedly. Partner was awake and stated that I did not trip on anything. I did not have any previous dizziness or indications that I was going to faint (no night sweats, no stars or blurry vision, no muscle weakness). I injured my nose, tooth (no significant damage), and was scared to get up. My arm pain is 7 out of 10. I have no previous medical history of fainting after a vaccine." No treatment was received for the adverse events. The clinical outcomes of the events fell unexpectedly, I injured my nose, tooth, my arm pain is 7 out of 10 and scared to get up were recovered/resolved on an unspecified date in 2021. Since the vaccination, the patient had not been tested for COVID-19. The lot number for the vaccine, BNT162B2, was not provided and will be requested |

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| | | | | | | | during follow up. |
| 1320432 | 5/15/2021 | | 9 | F | 5/14/2021 | 5/14/2021 | Syncope, drunk water and been under observation. Looks great and let home with her father. Pulse 92 SPO2 98 BP 102/66 |
| 1320431 | 5/15/2021 | CA | 13 | F | 5/14/2021 | 5/14/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Additional Details: 13 year old female fainted when sitting during her 15 minute observation. she fainted when her mom was standing next to her. we put her on the floor and raised both of her feet. she became concious after 15 seconds. We gave her water and chocolate. we took her blood pressure and her reading was 95/71 with pulse of 78. we had her sit for an additioinal 15 minutes. After feeling ok she left with her parents. |
| 1320429 | 5/15/2021 | CA | 15 | F | 5/14/2021 | 5/14/2021 | Systemic: Allergic: Itch Generalized-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Nausea-Mild, Systemic: Shakiness-Mild, Additional Details: 5 Minutes after the vaccine, pt lost consciousness for a few seoncds. pt showed some jerking motion. Pt was given water and benadryl. About 30 minutes after the shot, pt fully regained consciousness and back to normal |
| 1320427 | 5/15/2021 | NC | 14 | F | 5/14/2021 | 5/14/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Hypotension-Medium, Systemic: Shakiness-Medium |
| 1320434 | 5/15/2021 | CT | 17 | M | 5/14/2021 | 5/14/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Weakness-Medium, Additional Details: patient felt dizzy and lightheaded and fainted off the chair. never lost consciousness. recovered after staying in laying down position with knees bent, then had a bottle of water and another drink. walked out after 40 minutes with mom |

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| 1320419 | 5/15/2021 | NC | 15 | M | 5/14/2021 | 5/14/2021 | Systemic: Fainting / Unresponsive-Severe, Additional Details: while patient was waiting out in the waiting area for their 15 minute monitoring session the patient passed out and fell to the floor. The patient did not injure himself with falling to the floor and woke up immediately after he passed out. We immediately put ice packs on him and had him drink a bottle of water while sitting on the floor and made him stay in the waiting area until his color came back in his face and felt fine to go home. He was extremely nervous about getting the vaccine. |
| 1320731 | 5/15/2021 | TX | 46 | F | 5/14/2021 | 5/14/2021 | Patient vomited and fainted after vaccination within 20 minutes of vaccination Patient was checked out by EMS and referred to hospital, but patient refused and went home |
| 1320417 | 5/15/2021 | TX | 16 | M | 5/14/2021 | 5/14/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Hypotension-Medium |
| 1320407 | 5/15/2021 | FL | 18 | M | 5/14/2021 | 5/14/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Nausea-Medium, Additional Details: paramedics came to check out patient and he was ok |
| 1320422 | 5/15/2021 | MN | 13 | F | 5/14/2021 | 5/14/2021 | Systemic: Fainting / Unresponsive-Mild |
| 1320893 | 5/15/2021 | IA | 15 | F | 5/15/2021 | 5/15/2021 | Patient went to sit 15 minutes for recovery post-vaccine with her mom. All of a sudden she said "My arm feels funny," then laid her head on her mom. Her mom said her eyes rolled back and she passed out and slid down the chair onto the floor. 911 was called, pharmacist ran to scene. Patient remained on floor, started puking. Told her to breath deep, offered water. She slowly started feeling better. Paramedics arrived and examined her. After about 30 minutes, patient left with mom. No ER needed. |

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| 1320442 | 5/15/2021 | OR | 14 | M | 5/14/2021 | 5/14/2021 | Systemic: Fainting / Unresponsive-Severe, Systemic: Nausea-Mild, Additional Details: Patient received injection and got up from chair. After standing for a few minutes he fainted and lost consciousness. His mom and I got him to the floor and he regained consciousness within a minute. He said he felt thirsty and nauseated. His mom gave him water. He laid on the floor for 20 minutes and then sat up for a few minutes. Then he walked out of the dressing room and left the store. |
| 1320450 | 5/15/2021 | HI | 14 | M | 5/14/2021 | 5/14/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient fainted 5 minutes after administration during 15 minute post-vaccine observation period. Per witnesses he slumped over to his left side and fell onto the floor to his left side losing consciousness briefly. He was assessed by immunizing pharmacist and nurse practitioner and was found to have normal regular pulse & was pale in color. He regained consciousness shortly after a few seconds, EMS came over and assessed him later and was deemed ok to go home after 30mins. |
| 1320674 | 5/15/2021 | MN | 63 | M | 5/13/2021 | 5/13/2021 | Patient passed out 30 minutes after getting the vaccine. He bumped his head and was transported via ambulance to hospital. He was kept overnight. All test results came back normal. Patient is currently wearing a heart monitor for 3 days. |
| 1320773 | 5/15/2021 | VA | 30 | M | 5/15/2021 | 5/15/2021 | Syncope. Pt sustained abrasion to right forehead. BP 140/90 initially, 120/80 when released from recovery area. |
| 1320781 | 5/15/2021 | MI | 16 | F | 5/15/2021 | 5/15/2021 | Syncope caused patient to lose consciousness and fall out of chair hitting her head. Paramedics were called to the scene but patient did not require additional medical assistance at the time. Follow up with PCP recommended. |
| 1320808 | 5/15/2021 | MD | 27 | M | 5/15/2021 | 5/15/2021 | Patient said that he sometime faint when receiving a vaccination, but proceed with the Janssen Covid-19 shot at 9:50a. Then, had a syncope episode at 9:52a. EMS at Amazon was called to tend to the patient while 911 was called. Patient left with the ambulance service. |

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| 1320330 | 5/15/2021 | AL | | M | | | 13 minutes after dose patient passed out.; This is a spontaneous report from a contactable consumer. A male patient of an unknown age received bnt162b2 (PFIZER BIONTECH COVID-19 VACCINE, batch/lot number unknown) via an unspecified route of administration on an unknown date at unknown dose, single for COVID-19 immunization. Medical history and concomitant medications were not reported. The patient received vaccine, 13 minutes after dose he passed out. The outcome of event was unknown. Information on the Lot/Batch number has been requested. |
| 1320138 | 5/15/2021 | TX | 42 | F | 4/23/2021 | 4/23/2021 | fainting; Extreme fatigue; chills; headache; insomnia; elevated resting heart rate; nausea; brain fog; This is a spontaneous report from a contactable consumer (patient). A 42-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot Number: EW0162), via an unspecified route of administration, administered in right arm on 23Apr2021 08:15 as 2nd dose, single for COVID-19 immunization. The patient's medical history included allergic to chocolate. The patient's concomitant medications were not reported. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot Number: ER8727), in the right arm on 02Apr2021 08:15 AM for COVID-19 immunization. The patient was not pregnant at the time of vaccination. Facility where the most recent COVID-19 was administered was clinic (Public Health Clinic/Veterans Administration facility). The patient did not receive any other vaccine within 4 weeks prior to the COVID vaccine. There were no other medications received within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The patient experienced extreme fatigue, chills, headache, insomnia, elevated resting heart rate, nausea, fainting, brain fog, all on 23Apr2021 at 13:00. These started about 5 hours after injection, worsened for about 35 hours, then improved over the next 48 hours. No treatment was received for the events. The outcome of the events were recovered on an unspecified date. Follow-up attempts are needed. Information about lot/batch number is available. |

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| 1320859 | 5/15/2021 | IL | 14 | F | 5/15/2021 | 5/15/2021 | pt fainted roughly five minutes after shot. She came to shortly after and was helped back into her chair. Pt complained of dizziness and numbness in her arms. Blood pressure was taken 79/56. Paramedics came and checked pt out . Pt was released to mom after being given water and sitting for 10 more minutes. |
| 1320591 | 5/15/2021 | MO | 13 | F | 5/14/2021 | 5/14/2021 | Daughter passed out after 5 minutes of receiving vaccine. She said she couldn't hear for a little bit as well. |
| 1320141 | 5/15/2021 | CA | 36 | F | 4/29/2021 | 4/29/2021 | Fainting 14 hours after shot; This is a spontaneous report from a contactable consumer (patient). A 36-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in the right arm on 29Apr2021 at 08:30 (batch/lot number: EW0173) as 2nd dose, single for COVID-19 immunization. Medical history included known allergies to penicillin. The patient was not pregnant. The patient's concomitant medications were not reported. Historical vaccine included BNT162B2 1st dose on 08Apr2021 at 09:30 (lot number: EW0158) administered in the right arm for COVID-19 immunization. Facility where the most recent COVID-19 vaccine was administered was public health clinic/veterans administration facility. No other vaccine in four weeks and no other medications in two weeks. The patient experienced fainting 14 hours after shot on 29Apr2021 at 23:15. No treatment was received for the adverse event. No Covid prior to vaccination. The patient was Covid tested post vaccination which included Covid test type nasal swab with unknown result on an unspecified date. The outcome of the event was recovered on an unspecified date. Information on the lot/batch number has been received. Further information has been requested. |
| 1320931 | 5/15/2021 | WA | 23 | M | 5/15/2021 | 5/15/2021 | Pt. fainted while walking from counseling room to observation area. Was able to get up and walk to chair, but did develop sweating, blurred vision, difficulty hearing for 5-10 minutes. Pt improved after drinking water, apple juice, and doing deep breathing. Paramedics called to assess pt. Pt. had past vaccine syncope reactions and BP was <120/80 when taken by paramedics. Pt was fine after 30 min and was picked up by his girlfriend to go home together. |

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| 1320935 | 5/15/2021 | MD | 16 | F | 5/15/2021 | 5/15/2021 | Patient fainted after vaccination. Patient was put into the wheel chair by the nurse and taken to observation area. Patient wake up and was alert and oriented. Patient was asked to sit for 30mins observation. Patient feels better. |
| 1319825 | 5/15/2021 | PA | 25 | M | | 5/12/2021 | FEELS HORRIBLE; SEVERE FLU LIKE SYMPTOMS; ALMOST PASSED OUT; This spontaneous report received from a consumer concerned a 25 year old male. The patient's height, and weight were not reported. The patient's concurrent conditions included work out. The patient received covid-19 vaccine (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, administered on 12-MAY-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 12-MAY-2021, the subject experienced severe flu like symptoms. On 12-MAY-2021, the subject experienced almost passed out. On 13-MAY-2021, the subject experienced feels horrible. The action taken with covid-19 vaccine was not applicable. The patient had not recovered from feels horrible, and the outcome of severe flu like symptoms and almost passed out was not reported. This report was non-serious. |

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| 1320021 | 5/15/2021 | CO | 29 | M | 4/28/2021 | 4/29/2021 | Fell unexpectedly; I injured my nose, tooth; I injured my nose, tooth; My arm pain is 7 out of 10; scared to get up.; This is a spontaneous report from a contactable consumer (patient). A 29-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; solution for injection) via an unspecified route of administration on 28Apr2021 at 16:15 (at the age of 29-years-old) as a single dose in the left arm for COVID-19 immunisation and ibuprofen (ADVIL) from an unspecified date to an unspecified date at an unspecified dose (2) and frequency for an unspecified indication. Medical history included anxiety/depression (mitigated with SSR) from an unspecified date and unspecified if ongoing. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient had no known drug allergies. Concomitant medications (taken within 2 weeks of vaccination) included escitalopram orally taken for an unspecified indication from an unspecified date to an unspecified date at 10mg, daily. The patient did not receive any other vaccines within 4 weeks prior to the COVID-19 vaccine. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; solution for injection) via an unspecified route of administration an unspecified date as a single dose for COVID-19 immunisation. On 29Apr2021 at 03:00 the patient experienced fell unexpectedly, I injured my nose, tooth, my arm pain is 7 out of 10 and scared to get up. The course of events was reported as follows: "Got up at 3am in the morning to take some Advil. Took 2 Advil then fell unexpectedly. Partner was awake and stated that I did not trip on anything. I did not have any previous dizziness or indications that I was going to faint (no night sweats, no stars or blurry vision, no muscle weakness). I injured my nose, tooth (no significant damage), and was scared to get up. My arm pain is 7 out of 10. I have no previous medical history of fainting after a vaccine." No treatment was received for the adverse events. The clinical outcomes of the events fell unexpectedly, I injured my nose, tooth, my arm pain is 7 out of 10 and scared to get up were recovered/resolved on an unspecified date in 2021. Since the vaccination, the patient had not been tested for COVID-19. The lot number for the vaccine, BNT162B2, was not provided and will be requested |

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| 1320052 | 5/15/2021 | IN | 20 | F | 4/29/2021 | 4/29/2021 | during follow up. fainted; very light-headed; This is a spontaneous report from a contactable consumer (patient). A 20-year-old female patient (not pregnant) received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EW0153) via an unspecified route of administration at left arm on 29Apr2021 10:45 (20-year-old at time of vaccination), at single dose, for COVID-19 immunization. The patient's medical history included anxiety, ADHD, and allergies to amoxicillin. Concomitant medications in two weeks included amphetamine aspartate/ amphetamine sulfate/ dexamphetamine saccharate/ dexamphetamine sulfate (ADDERALL) and Vitamin D3. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EW0153) via an unspecified route of administration at left arm on 07Apr2021 10:30 (20-year-old at time of vaccination), at single dose, for COVID-19 immunization. There was no other vaccine in four weeks. The patient was very light-headed and fainted on 29Apr2021 15:45. Adverse events resulted in Emergency room/department or urgent care. Prior to vaccination, the was not patient diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. Therapeutic measures were taken as a result of the events and included "Ruled out heart issue, checked blood sugar level". The outcome of the events was unknown. |

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| 1320080 | 5/15/2021 | FL | | F | 4/12/2021 | 4/14/2021 | <p>bump on her head; head throbs a little bit; it all swelled up; but she is scared to death; she couldn't get up; spinning; cold sweats; throw up; diarrhea; shaking / feels a little shaky on her feet; breathing heavy; when she passed out she has been semi-okay; extreme headache; gland at the base of her neck swelled up / lymph nodes in arm pit swollen; arm started throbbing; felt like she was being stabbed / get a little fuzzy; This is a spontaneous report received from a contactable consumer (patient). A 76 year-old female patient A 76-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), intramuscular, administered in Arm Left on 12Apr2021 10:45 (Batch/Lot Number: ER8729) as 2nd dose, single for covid-19 immunisation. Medical history included ongoing allergies to all kinds of bug bites, poison sumac-connected to mango trees allergy, allergic to sulphur/sulfur drugs, codeine allergy since 1985, iodine in 1980 (iodine was for CAT scan and she broke out in hives), hypoglycemia (From: Unknown To: Ongoing, this is under control,no medication, strictly diet), pericardial cyst (From: Unknown To: Ongoing, on heart disappeared for a while and now it's back-onset back around 1980s when she had CAT (computerized tomography) scan and stuff showed up in an X-ray they wanted to rule out things ;so she went from x-ray to CAT Scan and the MRI (Magnetic resonance imaging). Pericardial cyst never bothered her or anything, advised to go to the heart doctor every 5 years and it hasn't changed), spraining ankles and stupid stuff like that (From: Unknown To: Unknown), dizzy spells (From: Unknown To: Unknown, occurred years ago, at least 10 years she thinks-had some dizzy spells they never figured out why she was having those. She had some Craniosacral or Sacralcranio done, but the dizzy spells stopped after the Craniosacral or Sacralcranio was done). Historical vaccine included BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE) on 15Mar2021 at 10:30 IM on left arm and experienced weird feeling, tired, diarrhea and hives on left side of her neck. She also had the flu shot for the first time this year but was way before the BNT162B2 vaccine. Family Medical History included 2 grandmothers had strokes both on patient's father's and mother's side; mother had a heart attack and heart issues. Father had heart issues and diabetes. Patient's paternal grandmother had diabetes</p> |

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bad. It was reported that the patient received the second shot of BNT162B2 on 12Apr2021 at 10:45 am in left arm. She felt great right after she got the shot, she wasn't tired, had no side effects. Thirty-six hours later, at 22:00 the gland at the base of her neck swelled up; arm started throbbing; lymph nodes in arm pit swollen; felt like she was being stabbed; had extreme headache, really bad headache; she does not get headaches and felt like her head was going to blow off but the extreme headache was gone in few minutes. The swelling and everything else took a couple days. Those events she reported as directly from the shots. On 20Apr2021, a week exactly from when she had those effects, around 17:00 she got home from work, opened her front door and after that remembered nothing. No warning. When her awareness finally came, she was on the floor inside her house. She did not have any idea what happened. She had bump on her head, and her right hand all swelled up (she must have landed on it). She took care of herself and called her doctor the next day. Initially she didn't associate those events with the Covid-19 Vaccine right away. She had a CAT Scan (27Apr2021) and lab work (unknown date) and that all came back ok. On 28Apr2021, she went in for heart monitor. The heart monitor and testing were done to rule things out. Last night, she went to go to bed at 23:00, laid down and immediately in laying down the room started spinning; she had cold sweats; she knew she would throw up so she immediately went in the bathroom and threw up; had diarrhea; couldn't stay seated; after she got most of throwing up stuff handled she couldn't get up so she was lying on floor drenched with cold sweats; shaking; breathing heavy; still throwing up a little bit; fortunately she had a small rug on the floor where she lay until almost 03:30 until she felt enough that she could get up. She got in the tub, cleaned herself off and was in the bed by 04:00 and slept until 10:00 29Apr2021. She has never had this happen before. The last time she threw up was probably 30 years ago. The patient as not hospitalized. Outcome for loss of consciousness, vertigo, head injury, pain in extremity, cold sweat, vomiting, diarrhoea, hyperventilation, head discomfort, peripheral swelling and anxiety was unknown. Outcome for headache, lymphadenopathy and asthenia was recovered. Outcome for feeling abnormal and tremor was not recovered. The patient underwent lab tests and

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procedures which included computerised tomogram: came back ok on 27Apr2021, heart monitor: unknown results on 28Apr2021, lab work: came back ok on unknown date.

passed out/Loss of consciousness resulted in concussion; concussion; became dizzy; Was experiencing body aches; increased thirst following vaccination; This is a spontaneous report from a contactable physician for a patient. A 20-year-old female patient received second dose bnt162b2 (PFIZER COVID-19 VACCINE), intramuscular, administered in Arm Right on 28Apr2021 08:30 (Batch/Lot number was not reported) at single dose for COVID-19 immunisation. The patient previously received first dose bnt162b2 (PFIZER COVID-19 VACCINE), on an unknown date (Batch/Lot number was not reported) for COVID-19 immunization. The patient medical history was not reported. The patient was not pregnant at time of vaccination. Concomitant medications (received within 2 weeks of vaccination) included celecoxib (CELEXA), trazodone, oral contraceptive nos (reported as oral birth control) taken for an unspecified indication, start and stop date were not reported. The patient got up at 2am 29Apr2021 to use restroom, became dizzy and passed out. She was experiencing body aches and increased thirst following vaccination. Loss of consciousness resulted in concussion. The adverse events result in: Doctor or other healthcare professional office/clinic visit. The events did not result in death, cause/prolonged hospitalization, was not life threatening, disabling/incapacitating, congenital anomaly/birth defect. The patient was not diagnosed COVID-19 prior to vaccination. Since the vaccination, the patient had not the patient been tested for COVID-19. The patient did not receive treatment for the events. The outcome of the event was recovering. Information about lot/batch number has been requested.; Sender's Comments: Based on the information currently available, the event Loss of consciousness is considered most likely associated with intercurrent or underlying medical conditions, appears unrelated to the suspect drug.

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| 1320117 | 5/15/2021 | CA | 73 | F | 2/22/2021 | 3/31/2021 | <p>This is a spontaneous report from a contactable consumer. A 73-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL8982), dose 2 via an unspecified route of administration, administered in right arm on 22Feb2021 14:15 as 2nd dose, single for covid-19 immunisation. Medical history included hyper/hypothyroid, cardiac arrhythmia. Concomitant medications included metoprolol; acetylsalicylic acid (ECOTRIN); atorvastatin (LIPITOR); levothyroxine sodium (SYNTHROID); cetirizine hydrochloride (ZYRTEC). The patient previously took codeine, cepezine, sulfa medication, adhesives, all experienced allergies. The patient previously received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL9261) administered in right arm on 01Feb2021 14:15 for COVID-19 Immunization. On 31Mar2021 (20:00), the patient awakened by upper abdominal pain, rapid pulse, and sweating, experienced diarrhea. On 01Apr2021 the patient awakened with same symptoms, plus tachycardia, shortness of breath, clammy skin, lightheadedness, what felt like acid reflux/upper abdominal pain, and diarrhea. Upon walking, almost fainted. On 01Apr2021 17:00, the patient went to Urgent Care. She had abnormal bloodwork, rapid heart beat and shortness of breath/wheezing. EKG showed irregularities. Was told to proceed to the ER for more tests. On 01Apr2021 19:00, the patient went to Hospital. She completed ultrasound of abdomen, EKG, CT Scan, and other testing. Found evidence of cardiomegaly (1st time ever), elevated blood pressure, inflammation around the heart, liver, pancreas, and stomach. Also noted pulmonary edema. Told I could travel back to CA with compression socks and pain medication and Zofran. 05Apr2021, they ordered additional tests and referral to the Cardiologist. Still experiencing extreme fatigue. Events resulted in doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care. The patient received treatment (pain medication, zofran, referral to GI and cardio) for adverse event. There is no covid prior vaccination. The patient received covid tested post vaccination with Nasal Swab on 01Apr2021, result was negative. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Since the vaccination, the patient has been tested for</p> |

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| 1320155 | 5/15/2021 | CA | 24 | F | 5/1/2021 | 5/1/2021 | <p>COVID-19. The outcome of the events was not resolved.</p> <p>passed out; sweating; turned blue; This is a spontaneous report from a contactable other healthcare professional (hcp reporting for self). A 24-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Solution for injection, Lot Number: EW0173, expiry date not reported) via an unspecified route of administration, administered in left arm on 01May2021 18:00 (at the age of 24 years old) as first dose, single for covid-19 immunization. The patient's medical history was not reported. Prior to vaccination, the patient was not diagnosed with COVID-19. There were no concomitant medications. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. There were no other medications the patient received within 2 weeks of vaccination. On 01May2021 18:00, patient immediately started sweating after getting the shot then passed out within a couple minutes. Pharmacist told the patient that she turned blue and they injected her with EpiPen. Patient woke up after and felt fine. The events resulted in doctor or other healthcare professional office/clinic visit and emergency room/department or urgent care. The events were reported as serious medically significant. Since the vaccination, the patient was not tested for COVID-19. The patient recovered from the events reported on an unspecified date in May2021.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the events loss of consciousness, hyperhidrosis and skin discolouration cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.</p> |

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| 1320131 | 5/15/2021 | TX | 65 | M | 4/29/2021 | 4/29/2021 | Fainting,pain,itching,fatigue,headache,nausea, Lost of smell, short term memory off and on,; Fainting,pain,itching,fatigue,headache,nausea, Lost of smell, short term memory off and on,; Fainting,pain,itching,fatigue,headache,nausea, Lost of smell, short term memory off and on,; Fainting,pain,itching,fatigue,headache,nausea, Lost of smell, short term memory off and on,; Fainting,pain,itching,fatigue,headache,nausea, Lost of smell, short term memory off and on,; Fainting,pain,itching,fatigue,headache,nausea, Lost of smell, short term memory off and on,; Fainting,pain,itching,fatigue,headache,nausea, Lost of smell, short term memory off and on,; Fainting,pain,itching,fatigue,headache,nausea, Lost of smell, short term memory off and on,; Fainting,pain,itching,fatigue,headache,nausea, Lost of smell, short term memory off and on,; Fainting,pain,itching,fatigue,headache,nausea, Lost of smell, short term memory off and on,; This is a spontaneous report from a contactable consumer (patient). A 65-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in Arm Right on 29Apr2021 12:45 PM at the age of 65-years-old (Batch/Lot Number: Unknown) as 1ST DOSE, SINGLE for covid-19 immunisation. Medical history included Herniated discs L4,L5,S1,C4,C5C6C7, type 2 diabetes from an unknown date. Concomitant medications included apixaban (ELIQUIS); dipyridamole (METROPOLYN) and bupropion, all taken for an unspecified indication, start and stop date were not reported. The patient previously took lidocaine and experienced allergy. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. On 29Apr2021 01:15 PM, the patient experienced Fainting, pain, itching, fatigue, headache, nausea, Lost of smell, short term memory off and on. It was unknown if treatment received. The outcome of the events was resolving. Information on the lot/batch number has been requested. |

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| 1320248 | 5/15/2021 | NJ | 40 | F | 3/20/2021 | 3/29/2021 | fainting; POTS; Dysautonomia; This is a spontaneous report from a contactable consumer (patient). A 40-year-old female patient (non-pregnant at time of vaccination) received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration administered in the left arm on 20Mar2021 (Lot number: EP7534) as single dose for COVID-19 immunisation. Medical history included hypertension and depression, allergies to penicillin. Concomitant medications included fluoxetine hydrochloride (PROZAC), bupropion hydrochloride (WELLBUTRIN), labetalol. The patient previously took the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration administered in the left arm on 02Mar2021 (Lot number: EN6205) as single dose for COVID-19 immunisation. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient did not diagnose with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. Occurred on 29Mar2021, patient experienced dysautonomia: fainting and POTS. The adverse events resulted in Doctor or other healthcare professional office/clinic visit and Emergency room/department or urgent care. The outcome of events was not recovered. |

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| 1320159 | 5/15/2021 | MI | 28 | F | 5/1/2021 | 5/2/2021 | fainted; low blood pressure; fever; This is a spontaneous report from a non-contactable consumer (patient). A 28-year-old non-pregnant female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in the left arm on 01May2021 (Batch/Lot Number: Unknown) as 2nd dose, single dose (at the age of 28-years-old) for COVID-19 immunization. Medical history was not reported. The patient did not have concomitant medications: the patient did not have any other medications the patient received within 2 weeks of vaccination. The patient received the first dose of 12Apr2021 BNT162B2 for COVID-19 immunization. The patient did not receive any other vaccines within 4 weeks. On 02May2021, around 24 hours after receiving the second shot of COVID vaccine the patient fainted due to fever and low blood pressure. The patient required emergency room/department or urgent care. The patient did not receive treatment for the events. The patient was not diagnosed with COVID-19 and since the vaccination the patient has not been tested for COVID-19. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained. |

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| 1320160 | 5/15/2021 | FL | 23 | M | 4/29/2021 | 4/29/2021 | Sore joints; his butt is still a little sore from falling; dizziness/ light headed; fainting; pain in upper abdomen area; Sweating; Nausea; falling; This is spontaneous report from a contactable consumer (patient). A 23-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 29Apr2021 at 1 pm (around 12:20ish as reported) (Lot Number: FN6206) (at 23-year-old) at single dose in arm right for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. No history of all previous immunization with the Pfizer vaccine considered as suspect, no additional vaccines administered on same date of the Pfizer suspect, no prior vaccinations within 4 weeks, no family medical history relevant to AEs. The patient stated he is a pretty healthy guy. All day after getting the vaccine he was fine. He got the shot at like 1 came home took a nap, ate some dinner, and was playing XBOX with the boys when this happened. At around 10:30 pm on 29Apr2021 he went to rub, his stomach just above his belly button and it hurt. He said that he read on line that that area is called the pancreas or liver, it has a lot of names for that area when looking online. He stated it's the left upper abdomen area he felt pain when he pressed on it. It radiated really fast across his abdomen while he was on the phone with mother. The more he pressed the more the pain got sharper, and it radiated right across the abdomen, mainly above belly button not too much in lower abdomen, not much in upper abdomen. It was very sensitive. He didn't have to press hard to trigger the pain. It was almost like the area was inflamed. It happened really fast and that it was his upper stomach not so much the lower part of his abdomen. He felt dizziness and nauseous and like a silly boy he tried to run to the bathroom. He stated that he fell and fainted. His butt was still a little sore from falling. He said when he woke up, he was sweating like he had been out side all day. He did not recall sweating any time he fainted in the past. The side effects were gone after about ten minutes. He was really light headed and had the crazy sharp pain in abdomen for about ten minutes and then it was gone. He had never had that kind of pain. He was laying on the floor for a couple minutes. He went to get his phone, and then sat back down and was sweating. He still had pain at that time but it only lasted |

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about 10 minutes at most. He was still a little bit sore in some joints which was not unexpected. He confirmed that he had a little bit of sweating, and he fainted a little bit. Since the episode he hasn't felt any symptoms like that before, he has not had any pain like gastritis but he has had some random gastrointestinal things before. It's also reported nausea on 29Apr2021. No required to emergency room and physician office. He was on the verge of going to the ER while the pain was there. He was going to go until it stopped and to get checked out. No relevant test. The outcome of the events sore joints, dizziness and butt sore was unknown; for other events was resolved on 29Apr2021. No follow-up attempts are needed. No further information is expected.

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| 1320169 | 5/15/2021 | | 39 | M | 4/29/2021 | 4/29/2021 | Had 2 episodes of syncope; Shortness of breath; weakness; Fatigue; 80% O2 saturation on RA; Heart rate up to 180; Rash on his abdomen appeared; This is a spontaneous report received from a non-contactable pharmacist. A 39-year-old male patient received BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2, intramuscularly administered in left arm on 29Apr2021 08:45 (Batch/Lot Number: EW0172) (age at vaccination: 39 years old) as single dose for COVID-19 immunisation. Medical history included asthma from an unknown date and unknown if ongoing. On an unspecified date, prior to vaccination, the patient was diagnosed with COVID-19, unknown if ongoing. Since the vaccination, the patient had not been tested for COVID-19. He had previously received the first dose of BNT162b2 on 08Apr2021 08:00 (Batch/lot number: EWP0158) (age at vaccination: 39 years old) as single dose for COVID-19 immunisation. Concomitant medication(s) included albuterol (ALBUTEROL) inhaler, naproxen (NAPROXEN) and calcium carbonate (CALCIUM CARBONATE), taken for an unspecified indication, start and stop date were not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 29Apr2021, the patient developed shortness of breath, weakness, fatigue hours after administration of the vaccine. He had 2 episodes of syncope, 80% O2 saturation on room air (RA), heart rate up to 180. Rash on his abdomen appeared. The adverse events resulted in emergency room/department or urgent care. The patient was admitted to the hospital on an unspecified date in Apr2021. The outcome of the events was unknown. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Considering a plausible temporal relationship, a causal association between the reported events and suspect drug bnt162b2 cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate. |

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| 1320170 | 5/15/2021 | | 19 | M | | | seizure like movements; passed out; dizzy; nausea; This is a spontaneous report from a non-contactable healthcare professional (HCP). A 19-year-old male patient received BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date (age at vaccination: 19 years old) (Batch/Lot Number: ew0167) as single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination the patient had not been tested for COVID-19. The patient experienced dizzy, nausea, passed out, seizure like movements on an unspecified date. The outcome of the events was unknown. No follow-up attempts are possible. No further information is expected. |

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| 1320177 | 5/15/2021 | MN | | M | 4/30/2021 | 4/30/2021 | seizure; faint; feeling dizzy; drained again; his lips lost their color; difficulty hearing; nauseous; sweating profusely; This is a spontaneous report from a contactable pharmacist. An adolescent male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; Batch/Lot Number: Er8736), intramuscular, administered in Arm Left on 30Apr2021 20:30 as 1st dose, single for COVID-19 immunization. Medical history, none known. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The patient's concomitant medications were not reported. The patient reported no previous adverse events with prior vaccinations, specifically dizziness or fainting. After the shot he went to the bathroom, returned fairly quickly & reported feeling dizzy and quickly took a seat and thought he might faint. Soon thereafter he seemed to have a seizure. His eyes remained open but rolled back, he stayed upright but was unresponsive. They removed his mask & his mother & they kept talking to him. It ended after about 10 seconds & he asked how long he had been out. His color was momentarily better, but drained again & his lips lost their color. They asked if he had any difficulty breathing and he did not. He reported that he had difficulty hearing (like he had headphones on) & sweating profusely. His mother kept encouraging him to take deep breaths, they got him some water & asked if he had a history of hypoglycemia- he did not. They asked if they could get him a candy bar& they asked for a granola bar which they acquired. He was too nauseous to eat it & asked. The events started on 30Apr2021 20:30. No treatment was given. The outcome of the events was recovered.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the seizure and the other reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including EEG and head CT/MRI, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety |

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evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

passed out a total of 3 times; blood pressure went so high; This is a spontaneous report from a contactable consumer reporting for her sister-in-law's sister-in-law. An about 60-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date (Batch/Lot Number: Unknown) as unknown, single for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The reporter stated the patient's blood pressure went so high after she received the COVID-19 Vaccine, that she passed out a total of 3 times. She said she had no clue as to how patient's blood pressure was treated. The reporter thought the 3rd time of passed out from her blood pressure being high, the patient made her husband take her to the Emergency Room. She said adverse reaction occurred around the same time frame as hers, in either Feb2021 or Mar2021. The patient underwent lab tests and procedures which included body height: 5'6" or 5'7". The event outcome was unknown. Information on the lot/batch number has been requested.

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| 1320209 | 5/15/2021 | FL | | F | | | she passed out; she had swelling of her lymph nodes; cold chills; cold sweats; threw up; She thought she was going to have a heart attack; This is a spontaneous report received from a contactable consumer (patient). A female patient of an unspecified age received the second dose of BNT162B2 (Lot number and expiry date were not reported), via an unspecified route of administration on an unspecified date as single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient previously received the first dose of BNT162B2 on an unspecified date as single dose for COVID-19 immunization. The patient had minor side effects with the first COVID vaccine. With the second shot on unspecified date, the patient had swelling of her lymph nodes. A week later from the shot, she passed out. She has never passed out before in her life. This week two days ago, she had cold chills, cold sweats, and threw up. She was in the bathroom from both ends. She thought she was going to have a heart attack. She went to the doctor for a check-up. The patient had a CAT scan, and a heart monitor to rule out a TIA on unspecified date with unknown results. She cannot believe it because she is normally a healthy person. The outcome of the events was unknown. Information on the lot/batch number has been requested. |
| 1320222 | 5/15/2021 | CA | 36 | F | 5/14/2021 | 5/14/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Additional Details: Patient described feeling dizzy about 15 min after the vaccine. We had her lie down, offered her water & gatorade, monitored her. We took her BP and heart rate. We asked her if she could breathe- she said she could breathe ok. BP was 135/85 and heart rate was 79bpm which was normal. We had her continue lying down and complained that she was feeling worse after another 15min and wanted us to call 911. We did, 911 showed up, took her vitals again which were normal. No hospitalization reqd. |

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| 1320247 | 5/15/2021 | CA | 33 | F | 4/27/2021 | 4/28/2021 | <p>passed out; Severe abdominal pain; arm was very sore from the injection site; hit my head very hard; I felt the need to vomit; woozy; bruised; This is a spontaneous report from a contactable consumer reporting for herself. A 33-years-old female patient received bnt162b2 (BNT162B2), via an unspecified route of administration, administered in Arm Left on 27Apr2021 (Batch/Lot Number: EW0165) as single dose for covid-19 immunisation . The patient medical history and concomitant medications were not reported. The patient passed out on 28Apr2021 02:30 with outcome of recovering , had severe abdominal pain on 28Apr2021 02:30 with outcome of recovering , arm was very sore from the injection site on 28Apr2021 02:30 with outcome of recovering , hit my head very hard on 28Apr2021 with outcome of recovering , i felt the need to vomit on 28Apr2021 with outcome of recovering , woozy on 28Apr2021 with outcome of recovering , bruised on 28Apr2021 with outcome of recovering. Loss of consciousness was considered an Important Medical Event. Course of the event: The patient stated: At 2:20 am I woke up with severe abdominal pain, and my arm was very sore from the injection site. I got up to take Tylenol since i hadn't taken any yet. While I was trying to read the label I got very dizzy and I tried to walk back to my bed and I passed out onto the floor. When I woke up I felt like I had hit my head very hard, I slowly went back to my bedroom and passed out again and my husband found me unconscious And called 911. When I woke up I felt the need to vomit and have bowl movements so he took me to the bathroom. When the paramedics came I was conscious but very nauseous and woozy. Now I am bruised all over, the bridge of my nose where I hit my face, and knees and elbows". Follow up information has been requested.</p> |

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| 1320126 | 5/15/2021 | | | F | 4/22/2021 | 4/30/2021 | <p>passed out; Astronomical Headache; I got very dizzy and had dots; She got very dizzy and had dots; I just started spinning and broke out; I have a bump on her head; scrape on her knee; chills; Nausea; Vomiting; Diarrhea; I was severely cold; I was very sluggish; My chest feels congested; her head feels like it weighs 30 lbs; This is a spontaneous report from a contactable consumer (patient). A female patient of an unspecified age received bnt162b2 (BNT162B2 reported PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration on 22Apr2021 (Batch/Lot number was not reported) as first dose, single for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient reported that this past Wednesday (30Apr2021), she was getting severe chills, nausea, vomiting, and diarrhea. She took Dayquil because she still had the chills and she was severely cold. Yesterday (30Apr2021), she was very sluggish. She mentioned that her head feels like it weighs 30 lbs. on 30Apr2021. She added that her chest feels congested on 30Apr2021. This morning (01May2021), she was lightheaded and had an astronomical headache. She got very dizzy and had dots. She got up again to turn the tea kettle off and she just started spinning and broke out and went to the bathroom. When she went to the bathroom and went to squat on the toilet, she passed out. She doesn't know how long she was out. She has a bump on her head and a scrape on her knee. When she woke up, she was so cold, so she put on flannel pajamas. She also mentioned that she was scheduled for second one on next Tuesday (11May2021). She inquired if she can still get Covid after getting the vaccine. The outcome of the events was unknown. Information about lot/batch number has been requested.</p> |

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| 1321315 | 5/15/2021 | NV | 24 | M | 5/15/2021 | 5/15/2021 | Patient stated he had no previous problems with vaccines in the past. After I gave him the vaccine, I directed the patient to sit outside and wait 15 minutes per protocol. As soon as patient got up to walk to outside of vaccination room, he fainted and fell onto the ground hitting his head as well. Patient regained consciousness 5-10 seconds later. I had him sit upright against the wall, I directed my technician to call EMS, and I gave the patient some water. EMS arrived in about 5-10 minutes and they triaged the patient for about 20-30 minutes (given anti-nausea medication, IV fluids, and some other things I didn't see). Patient's parent ended up coming to pick up him, EMS was comfortable letting him leave without going to the hospital, EMS advised patient to seek medical attention if other problem arises. |
| 1321197 | 5/15/2021 | CA | 15 | F | 5/15/2021 | 5/15/2021 | Patient fainted within 5 minutes after injection. Patient experienced a syncope event passed out. Patient regain conscious within a minute. Patient may have injure her head upon falling. |
| 1321221 | 5/15/2021 | IL | 14 | F | 5/15/2021 | 5/15/2021 | Patient fainted due to vasovagal |
| 1321233 | 5/15/2021 | MN | 38 | M | 5/15/2021 | 5/15/2021 | Patient fainted 3min post vaccination, placed patients head between his legs, patient regained consciousness after 15 seconds. |
| 1321239 | 5/15/2021 | NY | 41 | M | 5/15/2021 | 5/15/2021 | Patient was given the vaccine. After sitting in a chair for a few minutes post vaccination, he said he felt dizzy and then fell over and hit the floor face first but had blacked out and did not remember fainting or passing out. He was bleeding because he had hit his face and his lip was split and his tooth was chipped. He also continued to be very dizzy, was extremely pale, and was sweating profusely. The EMT arrived about 20 minutes later and took him to the emergency room. |
| 1321240 | 5/15/2021 | CO | 18 | M | 5/15/2021 | 5/15/2021 | Patient received the vaccine and while sitting down within one minute he fainted and fell on the floor. He remained on the floor until paramedics arrived. Paramedics took his vitals and observed him for a period of time. They said it was fine for him to leave with someone else to drive him. While waiting for family to arrive the patient began to have a seizure. Paramedics returned and this time they took the patient for further care. |

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| 1321241 | 5/15/2021 | AZ | 18 | F | 5/14/2021 | 5/15/2021 | My daughter did not sleep all night, had fever & chills. Got up early in am & fainted on tile floor in kitchen. She was easily aroused after fainting. Helped her to a chair Then she had a seizure. It was very short lasting, then she vomited. She was very weak for 2 hrs. after that & she continued to slowly consume water & crackers. After getting her to bed she slept for one hour. Still too weak to go to bathroom alone. Improvement shown after 5 hrs of rest & fluids/some food. |
| 1321248 | 5/15/2021 | TX | 15 | F | 5/15/2021 | 5/15/2021 | In 2-3 minutes after injection patient fainted, she was conscious but dizzy, she was sweating a lot, her skin was pale and clammy, she felt nauseated and threw up |
| 1321255 | 5/15/2021 | | 17 | F | 5/14/2021 | 5/14/2021 | pt was very scared before vaccine, after vaccine passed out, i suspect syncope , came back fast sat and was fine |
| 1321185 | 5/15/2021 | CA | 15 | F | 5/14/2021 | 5/14/2021 | syncope with bilateral tonic/clonic movements. per parents, patient has history of vasovagal syncope following exposure to needles or lancets (vaccines, finger prick). approx 2 minutes following injection, patient lost consciousness, followed by several clonic movements bilaterally of upper and lower extremities. patient was transferred from chair to floor, legs were elevated. She regained consciousness quickly, was given water. When she felt better, she once again sat in a chair. After another 5 minutes (approx), she had another episode of loss of consciousness with increased tone of UE and LE bilaterally and also several clonic movements. She was again transferred to the floor, regained consciousness. She was more shaky and diaphoretic following the second episode but was otherwise aware and oriented. She was observed for another 30 minutes at the pharmacy and then left. |
| 1321311 | 5/15/2021 | | 17 | M | 5/15/2021 | 5/15/2021 | Near fainting, low blood pressure and low oxygen saturation |
| 1321419 | 5/15/2021 | MO | 30 | M | 5/15/2021 | 5/15/2021 | Syncope, loss of consciousness lasting about 5 secs, projectile vomiting and sweating |

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| 1321355 | 5/15/2021 | NE | 13 | F | 5/15/2021 | 5/15/2021 | Patient was sitting with her mother in front of the pharmacy for the 15 min waiting period after vaccination, and mom alerted us to "something going on here." I (pharmacist) went over to the patient and she appeared to be having a seizure, hands clenched, eyes rolled back in head, and she shook a small amount for a short period of time, though mom believes she just passed out. Mom and I protected head and held her in place, it was over within a few seconds. A Nurse Practitioner was in the clinic next door and we alerted her. Together, we laid her down, asked her questions, took pulse with pulse oximeter and blood pressure. All seemed within normal range. We called 911 due to appearance of seizure. Rescue squad came and evaluated her. |
| 1321362 | 5/15/2021 | CA | 18 | M | 5/15/2021 | 5/15/2021 | PATIENT FAINTED A FEW MINUTES AFTER RECEIVING THE SHOT AND WOKE UP AFTER A FEW SECONDS. WE LET THE PATIENT LIE DOWN AND ELEVATED HIS LEGS. WE ALSO ASKED PATIENT TO STAY FOR 30 MINUTES FOR OBSERVATION. |
| 1321365 | 5/15/2021 | OR | 22 | M | 5/15/2021 | 5/15/2021 | Pt passed out in chair about a minute or so after administration of vaccine. He brought along his girlfriend who was in the consultation room with him. Prior to administration, pt informed me that he was afraid of needles. After administration, we discussed the type of needle that was used (vanish point syringe) and the mechanism of how it works. He seemed anxious so I advised that it was ok for them to sit in the room for a few minutes instead of getting up to wait in the lobby, I left the door open for them. I walked back into the pharmacy and his girlfriend alerted me that he had passed out. He regained conscious within a few seconds. I advised he sit with his head between his legs, as he mentioned feeling light headed, feeling hot and sweaty. he threw up a little into the trash. pt sat in room for at least 30 minutes until he felt better. was given a few cups of water while sitting. did not leave until he felt comfortable and no longer light headed. pt mentioned that his last vaccine was about 2 years ago and the same response occurred then. |

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| 1321423 | 5/15/2021 | WA | 19 | M | 5/14/2021 | 5/14/2021 | Patient passed out for a few seconds 2-3 minutes after the vaccine. Complained of dizziness , sweating and unable to stand up. Patient's father, was with him at time of accident. His after caught him and prevented him from falling. Patient did not get hurt. Patient sat in front of vaccination room for about 20 minutes and left. I called to check on the patient the following morning at 9 AM and was told by patient father that patient is ok now. |
| 1321431 | 5/15/2021 | AR | 16 | M | 5/15/2021 | 5/15/2021 | Vaccine was administered to patient. Patient was walked to chair in waiting area and fainted. Once patient fainted, he immediately recovered. No treatment was necessary and left after 15 minutes |
| 1321453 | 5/15/2021 | MA | 14 | F | 5/15/2021 | 5/15/2021 | PATIENT FAINTED ABOUT 2 TO 3 MINUTES AFTER GETTING HER FIRST DOSE OF COVID VACCINE. NO INJURIES REPORTED. MOM AND PHARMACIST ASSISTED THE PATIENT, PARAMEDICS ARRIVED AT SCENE FOR EVALUATION. AFTER GETTING SOME FLUIDS AND SUGAR, PATIENT FELT BETTER. MOTHER REFUSED TO GO TO HOSPITAL. AFTER LONG OBSERVATION, PATIENT DEPARTED PHARMACY WITH HER MOTHER. |
| 1321457 | 5/15/2021 | CA | 14 | F | 5/15/2021 | 5/15/2021 | PATIENT FAINTED AND RECOVERED CONSCIOUSNESS WITHIN ONE MINUTE. OCURRED WITHIN 5 MINUTES OF BEING VACCINATED |
| 1320921 | 5/15/2021 | IL | 14 | F | 5/15/2021 | 5/15/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Exhaustion / Lethargy-Mild, Systemic: Fainting / Unresponsive-Mild |
| 1321292 | 5/15/2021 | MA | 42 | M | 5/15/2021 | 5/15/2021 | PATIENT FAINTED |
| 1320970 | 5/15/2021 | TN | 16 | M | 5/15/2021 | 5/15/2021 | Within approx. 5 minutes of receiving vaccine another patient (not related) alerted pharmacy staff to a patient "having a reaction" in our waiting area. When I approached the patient, he was staring ahead at his mother while she informed me that he experiences similar reactions when at the doctors office when he receives any shot. Before I approached he was passed out, but he was coming to when I arrived. He was able to speak, look at me, and move without delay within a minute and showed no further symptoms. |

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| 1321428 | 5/15/2021 | WA | 14 | F | 5/15/2021 | 5/15/2021 | Vasovagal syncope resulting in loss of consciousness for approximately 1/2 to 1 minute. Followed by nausea and multiple rounds of emesis over the course of the next fifteen minutes. Patient remained in pharmacy for approximately another 15 minutes before her mom and her felt she had recovered enough to leave under her own power. |
| 1321483 | 5/15/2021 | AR | 12 | F | 5/15/2021 | 5/15/2021 | Pt walked to waiting area and was light headed and pale. Pt fainted and immediately recovered. |
| 1321160 | 5/15/2021 | IL | 14 | F | 5/15/2021 | 5/15/2021 | 14 year old female fainted. alert and oriented X 0 not verbally responsive |
| 1320939 | 5/15/2021 | | 55 | F | 5/15/2021 | 5/15/2021 | Fainted |
| 1320948 | 5/15/2021 | TX | 14 | F | 5/13/2021 | 5/13/2021 | Approx. 5 min after vaccination patient started to feel dizzy. Technician went to retrieve ice packs and patient fainted. Pharmacist gently moved patient to her side on the floor and brought knees up to her chest while technician called 911. Patient regained consciousness after approx. 2 minutes before EMS arrived on scene. EMS took patient's blood pressure (hypotensive), administered saline drip in ambulance onsite then released patient to parents. Followed up with parents next day, patient was monitored at home and was feeling fine. Per EMS patient most likely was dehydrated. No prior history of event post vaccine. |

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| 1320991 | 5/15/2021 | LA | 18 | F | 5/15/2021 | 5/15/2021 | The patient informed me before giving the second dose of Moderna that she has fainted for every single vaccine she has ever been given including the first dose of Moderna. She stated it usually happens one to two minutes after receiving the vaccine and that she comes to within 10-15 minutes. Her father has been with her for every vaccination, and she just rests her head on his stomach. I informed the other pharmacist on duty of this and had EpiPen and smelling salts on hand just in case. We were all ready to react in case of any emergency. The patient did faint after sitting for a couple of minutes. She knew it was about to happen and her father stepped in to let her rest her head. We had her feet raised on a chair. She was still breathing the entire time, so we used smelling salts to bring her to which worked. She was out for close 10 minutes, but still breathing normally. The smelling salts enabled her to respond and nod that she was okay. When she came to, she asked for water and a sticker, which we gave her, and she acted as if nothing had happened and was all smiles. We did get a member of management to come fill out a report. |
| 1321005 | 5/15/2021 | AL | 16 | F | 5/15/2021 | 5/15/2021 | Patient fainted right after getting vaccinated - she has a history of fainting with needles |
| 1321022 | 5/15/2021 | NY | 13 | M | 5/14/2021 | 5/14/2021 | PATIENT'S PARENT ADVISED TO PHARMACIST PATIENT HAD FAINTING/PASSING OUT SYMPTOMS IN PAST WITH AN HPV VACCINE. PHARMACIST HAD PATIENT REMAIN SITTING AFTER VACCINATION. WITHIN A COUPLE MINS, PATIENT'S MOM FLAGGED DOWN PHARMACIST, REPORTING EXTREME SWEATING, NAUSEA, TROUBLE SEEING. PHARMACIST CALLED 911 AND EMS ARRIVED WITHIN 10 MINUTES TO MONITOR VITALS. PATIENT WAS RELEASED FROM EMS CARE AND ABLE TO WALK/LEAVE PHARMACY WITHOUT AN ISSUE. |
| 1321031 | 5/15/2021 | TN | 18 | M | 5/14/2021 | 5/14/2021 | Patient fainted after immunization. EMS was called and responded to evaluate the patient. No treatment was needed. The patient recovered consciousness within one minute but remained altered for 30 minutes then was fully back to normal. |

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| 1321040 | 5/15/2021 | SC | 16 | M | 5/15/2021 | 5/15/2021 | Within minutes of receiving the vaccine, the father says patient became slumped down in his chair, was drowsy, and he thought his son had passed out. Patient had become very pale in color, and his father says he was sweaty/warm to the touch. He was conscious, but wasn't very alert. |
| 1321128 | 5/15/2021 | IL | 15 | M | 5/15/2021 | 5/15/2021 | Patient felt dizzy, hot, nauseous and subsequently fainted approximately five to ten minutes after vaccine administration. He regained consciousness within a few seconds. They had him lay on the floor with feet elevated. Dizziness and lightheadedness resolved. He remained under observation for 30 more minutes. |

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| 1321144 | 5/15/2021 | CA | 14 | F | 5/14/2021 | 5/14/2021 | <p>Patient received the 1st COVID vaccine (Pfizer lot # EW0182 use by 5/15/2021) at 1455. The client had a history of fainting (x3) with intramuscular injections. The client reported eating lunch prior to arriving for her appointment. The client was vaccinated in the anti-gravity chair at 1455 by EMT. The client became very pale about 1 minute following the vaccination administration and she loss consciousness for 5 seconds, during this time she had 2 myoclonic contractions. RN and EMT immediately placed the patient in Fowler's position in the anti-gravity chair during the syncopal episode. The patient immediately regained consciousness and was alert and oriented to person, place, time, and situation. The patient remained in Fowler's position and vitals were taken at 1456: BP 125/95 (R arm), HR 45, RR 18, and oxygen saturation at 95%. The patient denied experiencing lightheadedness, shortness of breath, dizziness, nausea, headache, or blurry vision. The patient was given a juice box. The patient's color slowly returned. Vitals were retaken at 1505: BP 123/82 (R arm), RR 20, HR 50, oxygen saturation at 98%. The patient stated, " I usually feel really bad after I faint but this time I feel fine." Vitals at 1510 were as follows: BP 130/70, RR 18, HR 67, oxygen saturation at 100%. The patient was speaking in full sentences and laughing with her friend. Vitals taken at 1515: BP 125/ 68, RR 16, HR 68, oxygen saturation at 99%. The patient was positioned from a Fowler's position to sitting upright. The patient's color returned to her face and she denied any nausea, dizziness, blurred vision, double vision, or chest pain. Vitals were taken at 1520: BP 125/70, HR 82, RR 16, oxygen saturation at 99%. At 1524, the patient's blood pressure was 125/68 and HR was 58. The patient continued to deny any shortness of breath, dizziness, nausea, or vision changes. The patient's heart rate was taken at 1531, HR 55 and again at 1536, HR 62. The patient's mother stated her daughter was currently taking an antibiotic for acne (dosage and name unknown) and denied having any drug allergies or chronic medical conditions. RN instructed the patient and her mother about emergency precautions and to follow up with their primary care provider. RN, also educated the patient and her mother about the importance of informing the healthcare provider about her history of fainting with injections when receiving the second COVID Pfizer vaccine. Gave the patient's mother V-safe</p> |

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| 1321141 | 5/15/2021 | CA | 15 | F | 5/1/2021 | 5/15/2021 | information and reported the occurrence in VAERS. The patient had a steady and even gait when leaving the site with her mother at 1537. |
| 1321141 | 5/15/2021 | CA | 15 | F | 5/1/2021 | 5/15/2021 | 15 year old female syncope s/p Pfizer first dose Covid19 vaccination at 1300 . Pt was with both parents Assisted fall to ground Approximate LOC of 10 seconds No injuries Laid down supine with legs elevated. After about three minutes pt placed in W/C and placed in cot in supine position. Initial VS 99/56 71 12 98% O2 sat on RA Ate a bag of potato chips and drink one bottle of water (118 mL) Ambulated to BR by self, steady gait, maew, nad, a+o x3. Given instructions to patient and parents to increase salt intake and water intake and to lay down immediately if dizziness returns. Repeat VS at 1320 97/64 67 16 99% on RA Pt is asymptomatic at this time. DCd home with parents and to f/u as needed with pcp and to inform staff of syncope for 2nd vaccination, |
| 1321139 | 5/15/2021 | AZ | 18 | M | 5/12/2021 | 5/12/2021 | ABOUT AN HOUR AFTER THE SHOT, TIRED AND WEAK. ARM SORE. NEXT DAY WEAK, DIZZY, COULDN'T GET FULL BREATH....NEEDED BREATHING TREATMENTS ALL DAY, HARD TO LIFT ARM, TRIED TO WALK BUT FAINTED AND CRASHED INTO A WALL. |
| 1321042 | 5/15/2021 | CO | 14 | F | 5/15/2021 | 5/15/2021 | Pt received vaccine while seated and when she stood to go to observation area she experienced syncope and fell supine to tile floor. No LOC, was A&Ox4 immediately. Pale, strong pulses, RRR P 60's, unlabored resp effort. BP not evaluated. Some nausea, no vomiting. Exam of head revealed mild TTP with no open wound, swelling, or depression. Pt responded to rest and required no intervention. Pt was monitored x 60 mins with full resolution of sx and discharged to home in good condition. |

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| 1321132 | 5/15/2021 | CA | 14 | M | 5/15/2021 | 5/15/2021 | Adverse event: RN called to vehicle by father who was yelling for help. Once RN arrived at vehicle opened passenger door to find patient fluttering eyes after father stated he had just passed out. Patient was clammy, pale, and diaphoretic. RN advised patient to take slow deep breaths. Patient followed instructions, stated his name and said he felt 'funny'. Pulse taken and was HR 58. Then vehicle was moved to the side and vital signs were taken at 1301. BP 82/42, HR 80, RR 13. Patient was alert, oriented and answered questions appropriately. Treatments: RN and Charge RN present and spoke to both Father and patient about potential contributing factors to episode. Patient given water and gatorade. Able to finish bottle of gatorade and stated his symptoms had improved. Second set of vitals taken at 1324. BP 116/72, HR 82, RR 16. Patient also stated he had a banana for breakfast. Advised patient to stay hydrated, eat lunch, and rest. Advised father to reach out to pediatrician if any further events or questions about today event |
| 1321099 | 5/15/2021 | IL | 12 | M | 5/15/2021 | 5/15/2021 | pt received Pfizer covid 19 vaccine with mom in the room. Less than 5 minutes later, step dad reported that patient passed out and hit his head on the side. Pt was bleeding from the left forehead. A technician called 911. I wiped blood from the injury and applied a gauze and instant ice pack. pt was breathing and fully responsive. pt denied any other pain or discomfort other than the injury on the forehead and injection site pain in the arm. |
| 1321097 | 5/15/2021 | CT | 0 | M | 5/15/2021 | 5/15/2021 | Patient passed out approximately 5 minutes after receiving covid-19 first dose vaccine. Mother alerted pharmacy staff. Pharmacist went out to provide assistance and 911 was called. Patient was alert and responsive. Urgent care doctor from next door arrived to provide assistance. Patient laid down on the ground until paramedics arrived. We got patient water, Gatorade and neck rest to make him comfortable. While the patient was awake and responsive, he turned pale but no cpr or epi-pen were needed. Paramedics took patient with them after event. Patient was fine during administration of the vaccine and walked out with no problems or questions. |

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| 1321089 | 5/15/2021 | PA | 22 | M | 5/14/2021 | 5/14/2021 | After patient received vaccine, another patient shouted that he needed help. Came back out of pharmacy to find patient passed out but he came to quickly. He was very pale, sweating and complaining of nausea. Got patient ice packs, water and Gatorade and after about 20 minutes patient was feeling well enough to leave with his father. |
| 1321084 | 5/15/2021 | CT | 14 | F | 5/15/2021 | 5/15/2021 | Patient got up from receiving shot and fainted on the ground-patient hit his head. EMS was called. Patient turned very pale and nausea, patients arms was swelling. Patient started to return to conscience but remained unwell. EMS did an evaluation. Father took son to hospital |
| 1321044 | 5/15/2021 | CT | 15 | F | 5/15/2021 | 5/15/2021 | patient fainted and was dizzy and pale |
| 1317246 | 5/14/2021 | PA | 20 | M | 5/14/2021 | 5/14/2021 | Patient passed out for less than 5 seconds after receiving the immunization. |
| 1317535 | 5/14/2021 | MI | 18 | M | 5/13/2021 | 5/13/2021 | Patient has history of vasovagal syncope / seizure and told us in advance. When he was administered the vaccine, he passed out for just a short period of time and had a minor seizure (approx. 5 seconds). |
| 1317240 | 5/14/2021 | CA | 15 | F | 5/13/2021 | 5/13/2021 | Pt experienced fainting spell right after vaccination. BP 107/73; HR 68; RR 16; T 98.4 & pt stable and d/c'd home with father |
| 1317439 | 5/14/2021 | WY | 46 | M | 3/26/2021 | 3/26/2021 | Approximately 6 minutes after vaccination, patient experienced a syncopal event and passed out. He became nauseated after the event then vomited. Pt was seen in the emergency department, patient admitted to hospital for overnight observation. |
| 1317317 | 5/14/2021 | FL | 26 | M | 5/14/2021 | 5/14/2021 | Systemic: Fainting / Unresponsive-Severe, Additional Details: pt fainted and fell to floor, was bleeding from nose- was picked up by ambulance following |
| 1317352 | 5/14/2021 | | 26 | F | 5/14/2021 | 5/14/2021 | Patient reports fainting after receiving any inject. |
| 1317420 | 5/14/2021 | SC | 13 | M | 5/14/2021 | 5/14/2021 | Patient fainted for a few seconds and regained consciousness quickly. We gave him some water and he was fine. |

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| 1317265 | 5/14/2021 | CA | 38 | M | 5/11/2021 | 5/11/2021 | Ten minutes after receiving my 1st dose I passed out and hit my head on the floor! Causing multiple bruises on my face and head! I was unconscious for 30 seconds, and while unconscious my eyes started to role to the back of my head. When I became alert I was on the floor and I couldn?t breathe! While on the floor gasping for air I vomited twice! 911 was called and an EKG was done on site! It showed that my heart rate was low, and I was transported to hospital ER department. Multiple test were done on me and everything came back perfect! No high blood pressure, not a diabetic, and no Permanent head damage. |
| 1317449 | 5/14/2021 | OH | 12 | F | 5/13/2021 | 5/13/2021 | The patient was given the pfizer vaccine and then was standing watch her brother gets his. She all the sudden fainted and dropped to the floor. We rushed over and put her feet in the air on a chair and checked her BP and pulse (115/70, 71). She didn't look pale or sweaty or any other symptoms per patients response. We gave her an ice pack for head and had her lay down for 15mins. I repeated the BP/pulse and still WNL. |

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| 1317588 | 5/14/2021 | FL | 36 | F | 5/14/2021 | 5/14/2021 | Patient had a reaction immediately after the JJ vaccine. Patient passed out for 10-15seconds, her body stiffened up, she felt hot and then cold and started sweating excessively. Patients eyes closed briefly and then opened. Patient then became conscious and was unaware what had happened. Patient is not on any medication and had not eaten all morning. After administering the vaccine a small amount of blood came out. I gave her a cotton ball to apply on the area and to hold. After 20-30 seconds she said she felt faint and hot all of a sudden. Her body then went limp and her eyes began to close. Her body then stiffened up for a few seconds. After shouting her name a few times she regained consciousness and was able to talk. she didn't realize what had happened. Her body was fine again but she had urinated during the episode. Upon speaking to the patient I learnt that she was nervous about the vaccination and she had felt dizzy in the past when giving blood. I observed the patient over the next 45 minutes. Her speech was fine, she was still a little light headed. She was in her seat for 40 minutes, then I asked her to stand and to move a little to see how she was. She was able to walk a bit but then sat down as she still felt light headed. She than sipped on water and continued talking and seemed to get some energy back. |
| 1317489 | 5/14/2021 | KS | 54 | F | 5/14/2021 | 5/14/2021 | Patient was given johnson and johnson vaccine and immediately felt lightheaded and faint. She laid down on the floor. I went to get cool wet papertowels and upon returning she was unresponsive. I immediately had staff call for an ambulance. Patient came to before needing to administer the epipen or diphenhydramine. Patient denied throat swelling or pain and was alert x3. EMS checked her out and determined it was just a fainting episode, which the patient admitted to having frequently in the healthcare setting. Patient was able to walk out of the pharmacy and is feeling fine now. |

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| 1317580 | 5/14/2021 | VA | 15 | M | 5/14/2021 | 5/14/2021 | pt received first dose of Pfizer COVID vaccine. 2-3 minutes after the shot was completed, I was alerted that someone has "passed out" in the designated waiting area. upon arriving at the scene, I saw his mother holding him and helping him to the floor. she states he had fainted---she states he did not lose consciousness, did not fall, and did not hit his head. I called 911 and stayed with him the whole time until the rescue squad arrived. parent states pt has never had a reaction to a vaccine previously, has no health conditions, no allergies to food or drugs. upon arrival, rescue squad gathered information. a mutual decision was made between parent and rescue squad not to take patient to hospital; they walked him to the vehicle |
| 1317223 | 5/14/2021 | ME | 56 | F | 5/14/2021 | 5/14/2021 | Patient recieved vaccination, within 5 minutes she reported not feeling well. She was seated and briefly passed out. She was shaky and sweating. Paramedics were called. Patient was evaluated in ambulance. Within 30 min of initial reaction patient returned to pharmacy feeling well as her reaction had passed. |
| 1316515 | 5/14/2021 | KS | 34 | F | 5/13/2021 | 5/13/2021 | Systemic: Confusion-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Nausea-Severe, Systemic: Seizure-Severe, Systemic: Vomiting-Severe, Additional Details: patient had a seizure when she was 12 after taking hep b vaccine (22 years ago). Patient had no reaction from COVAX dose 1. |
| 1317597 | 5/14/2021 | IL | 16 | F | 5/14/2021 | 5/14/2021 | Patient received vaccine, 1-2 minutes later stated she was feeling dizzy and passed out and began to seize. 911 was called. patient was monitored and given water and an icepack upon regaining consciousness. Paramedics did a physical assessment, including checking blood pressure and blood sure. Patient's guardian refused going to hospital. After 30 minutes patient and guardian went home as patient stated she felt fine. Pharmacy planning to follow up with patient the next day. |

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| 1317456 | 5/14/2021 | CA | 17 | F | 5/13/2021 | 5/13/2021 | Episode of syncope in observation area. No s/sx of distress. AOx3. Given water, assisted to stretcher & sx resolved (BP 118/75; HR 71; RR 16; O2 sat 100%). No health hx or medications. Released from vaccine site with mother |
| 1316539 | 5/14/2021 | MO | 29 | M | 5/13/2021 | 5/13/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Additional Details: pt sat down after receiving vaccine and felt faint within the next minute, slouched over in the chair and woke up on his back on the floor. pharmacist reported pt was sweating but alert immediately after this incident. pharmacist assisted pt and pt ambulated into clinic with assistance and was supine for 10 minutes and sitting for 10 additional minutes. BP 118/76, pulse 79, spo2 98% and heart rhythm regular. pt ambulated out of clinic without problems, all symptoms resolved. |
| 1317916 | 5/14/2021 | CA | 14 | F | 5/1/2021 | 5/13/2021 | Approximately 4 minutes after administration of vaccine, patient fainted and was caught by parent and gently laid on ground. Patient was monitored by pharmacist until paramedics arrived. Patient woke up quickly and was in good spirits and left the store on her own after being monitored by paramedics. Followed up with parent the next day and she was doing well with no adverse effects except for a mild sore arm. |
| 1317640 | 5/14/2021 | CA | 18 | M | 5/13/2021 | 5/13/2021 | Dizziness, syncope. No prior meal eaten. BP 116/77; HR 64; RR 18. Water & crackers given; vital signs stable. Advised to eat lunch & hydrate. Pt stable & released from vaccination site |

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| 1315986 | 5/14/2021 | CA | 24 | M | 5/13/2021 | 5/13/2021 | On Thursday May 13th, 2021, patient arrived to receive his first Pfizer vaccination. Patient was vaccinated and sent to the observation area. At 1342, the patient stated, " I feel dizzy, like I might pass out," to EMT observer. EMT observer immediately assisted the patient to the gravity chair. The patient's vital signs were taken: BP 110/72, HR 84, RR 15, oxygen saturation at 96% . The patient was alert and oriented to person, place, time, and situation. The patient was given water and stated, " I feel so much better after sitting in this chair." No loss of consciousness or syncope occurred. The patient was given a bottle of water. Co-lead, assessed the patient, who was alert and oriented to person, place, time, and situation, was in no apparent distress, and was speaking in full sentences. No pallor or diaphoresis was observed. Vitals were taken at 1347: BP 108/70, HR 63, RR 14, oxygen saturation at 99%. The patient took off his mask to reduce anxiety. Denied any history of fainting. or having any known drug allergies. Vitals were retaken at 1352: BP 120/68, HR 63, RR 14 ,oxygen saturation at 98%. The patient was offered a granola bar but denied it, as he ate around 1230. Patient denied any shortness of breath, blurry vision, lightheadedness, dizziness, itching, nausea, or facial flushing. The patient stated, " I feel totally fine." Vitals were retaken at 1357, BP 120/70, RR: 14, HR 63, and oxygen saturation at 98%. Notified patient to inform the vaccinator about his reaction when returning for his second Pfizer dose. Vital retaken at 1402, BP 125/ 68, RR 14, HR 63, 98% oxygen saturation. The patient felt comfortable to drive home and left the site at 1405. The patient left the site with an even and steady gait. |

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| 1316184 | 5/14/2021 | CA | 16 | F | 4/23/2021 | 4/24/2021 | she fainted; hit her head; This is a spontaneous report from a contactable consumer (patient's mother) reported that a 16-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EW0171), via an unspecified route of administration, administered in arm left on 23Apr2021 (at the age of 16-years-old) as 1st dose, single for Covid-19 immunisation. The patient's medical history and concomitant medications were not reported. On 24Apr2021, she fainted and hit her head. Clinical course details was reported as the patient got her Pfizer COVID vaccine on Friday (23Apr2021), and she fainted on Saturday (24Apr2021), knocked her head on counter and was knocked out. The doctor was taking her to ER. The patient was not yet admitted to the hospital, since when the patient's mother called they were going there (hospital) now. The doctor had her blood drawn to find out what was going on. The patient underwent lab tests and procedures included weight: 58.97 (no unit), and height: 157 (no unit) both on an unspecified date. The patient was scheduled on 15May2021 for 2nd vaccine. The outcome of the events was unknown. No follow-up attempts possible. No further information expected. |

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| 1316212 | 5/14/2021 | NC | 87 | F | 2/9/2021 | 2/10/2021 | left side weakness; Elevated troponin levels but no sign of heart attack; patient became so weak that she could not stand or walk , even with assistance; transient ischemic attack; gallstones; Endometrial cancer; headache; migraine; goiter; hypothyroidism; high blood pressure; Slurred speech; This is a spontaneous report from a contactable consumer (Patient's daughter). An 88-year-female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in Deltoid Right on 09Feb2021 17:00 as 2nd dose, single for covid-19 immunisation. Medical history included Type 2 diabetes from 08Jan2016 to an unknown date (diabetic retinopathy). Concomitant medications included latanoprostene bunod (VYZULTA) from an unspecified start date and ongoing. The patient previously took dose 1 of bnt162b2 (PFIZER- BIONTECH COVID-19 VACCINE, Lot no Lot number : EL3247), anatomical location was left arm for Covid Immunization on 16Jan2021(Age at the time of vaccination was 87years 10 months). On 10Feb2021 at 19:00, Patient felt unwell, fainted and could not stand due to weakness. Elevated troponin levels but no sign of heart attack, 08Mar2021at 19:00, she had transient ischemic attack resulting in left side weakness and slurred speech. Endometrial cancer, gallstones, headache, migraine, goiter hypothyroidism and high blood pressure. On 10Feb2021. Patient became so weak that she could not stand or walk even with assistance and received treatment for these events. She was incapable of even holding her head up properly before hospitalization, she was basically dead weight and as treatment had IV fluids, shot to prevent blood clotting. In hindsight, patient probably experienced a transient ischemic attack on 10Feb2021. She wasn't taken to the hospital until 12 hours after the weakness started. and ER physician didn't check to see if she was weak on one side of her body. AE required to visit to emergency room. Patient was hospitalized 1st time from 10feb2021 to until 18Feb2021 and 2nd time from 09Mar2021 until to 16mar2021. The outcome for the event transient ischemic attack, slurred speech, left side weakness, gallstones, endometrial cancer, headache, migraine, goiter, hypothyroidism, high blood pressure was unknown and for the event patient became so weak that she could not stand or walk, even with assistance and elevated |

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troponin levels but no sign of heart attack was recovered. Additional information is requested.

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| 1316347 | 5/14/2021 | CA | | M | | 4/1/2021 | STROKE; PASSED OUT; DIZZINESS; DID NOT FEEL WELL; HEARTBURN; HEADACHE ON THE FRONT LEFT SIDE; RECURRENT SEIZURE; This spontaneous report received from a patient concerned a male of unspecified age. The patient's weight, height, and medical history were not reported. The patient received COVID-19 VACCINE AD26.COV2.S (suspension for injection, unknown, batch number: 1805029, expiry: UNKNOWN) dose was not reported once a total on left deltoid, administered on 28-MAR-2021 11:00 for prophylactic vaccination. No concomitant medications were reported. On 30-MAR-2021 patient went to the hospital because patient did not feel well and was given seasick pills. Two days later patient was still not feeling well and went to hospital, where the doctor said that patient having a Stroke, and patient in the middle of a Stroke. The doctor administered intravenous to patient .The patient was hospitalized for 3-4 days then transferred to Hospital (where patient is insured) and was hospitalized for 4-5 day. On an unspecified date in 2021, the patient had recurrent Seizure .Three days in a row and then one day rest and then it came back again, basically for the month came different times. Patient said his eyes would roll back to his head. On unspecified date in 2021, patient had dizziness and passed out and went to hospital where they said they should have never released patient. Patient was hospitalized for 2 days and did work up. Then hospital took patient back and they didn't do what hospital did. Patient mentioned feeling better at hospital with the treatment they provided him but when hospital cared for patient, they did not use the same. Patient also mentioned that he was sent to rehab to learn how to walk. Patient had experienced heartburns but they did not give him medication for heartburn. Patient was upset and got his friend to buy Antacid for him and he took it with relief. Patient used a walker/cane to get around and was perfectly fine before. On unspecified date in 2021 patient experienced headache on the front left side of the head (like someone is stepping). The action taken with COVID-19 VACCINE AD26.COV2.S was not applicable. The outcome of the headache on the front left side, dizziness, recurrent seizure, heartburn, stroke, passed out and did not feel well was not reported. This report was serious (Hospitalization Caused / Prolonged, and Other Medically |

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| | | | | | | | Important Condition).; Sender's Comments: V0: 20210507602-COVID-19 VACCINE AD26.COVID-19 S-stroke, recurrent seizure, passed out, dizziness. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s). 20210507602-COVID-19 VACCINE AD26.COVID-19 S-did not feel well. This event(s) is labeled per RSI and is therefore considered potentially related. |
| 1316520 | 5/14/2021 | PA | 13 | F | 5/13/2021 | 5/13/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: patient fainted as stood up waited about 30 minutes, drank some water said felt fine after about 10 minutes |
| 1316525 | 5/14/2021 | NE | 13 | M | 5/13/2021 | 5/13/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Exhaustion / Lethargy-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Hypotension-Medium, Additional Details: PATIENT PASSED OUT, HAD SYNCOPE, EMT WAS CALLED AND CAME TO EVALUATE. BP DROPPED BUT CAME BACK. MOM WAS WORRIED. |

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| 1317151 | 5/14/2021 | CA | 61 | M | 4/3/2021 | 4/15/2021 | For the first two weeks, there was only mild headache and fatigue. But on day 12 (or 13) following the shot, my husband had severe abdominal pain and black, tarry poop. He passed out on the toilet in the middle of the night and hit his head, woke up in a puddle of blood (from hitting his head). He was severely lightheaded, short of breath, could not walk. He had to crawl back to bed. He continued to have severe lightheadedness, shortness of breath, muscle aches, abdominal pain, and also ringing in his ears. He called me early Saturday morning and told me what happened and that he called out from work. (We do not live together. He is 280 miles away because of his job.) That man has called out sick only one time since I've met him in 1998; so when he told me he did not go to work, I knew it had to be really bad. I drove up there ASAP the same day, and I took the pulse oximeter with me. His oxygen levels were all over the place. They were usually better (like high 70s to low 80s) while he was lying down. When he would sit up or stand up, the number would plummet, reading so low I thought he was going to die. One time his finger was so cold that it took me 4 tries to get a reading. It read at 55, but I realize that might be because his finger was too cold. |
| 1316561 | 5/14/2021 | MA | 39 | F | 5/4/2021 | 5/4/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Counseled patient. She said she ate very little before the vaccination. She fainted for a couple minutes and had to lie down. She informed pharmacy staff. I went over to her and offered her a bottle of water and stayed with her for approximately 10 minutes until she felt fine. She said after a couple minutes and drinking some water she felt fine. She stayed sitting in the vaccination/observation area for 10 more minutes. She was at the store for approximately 45 mins and waited 30 min after shot |
| 1316865 | 5/14/2021 | TX | 18 | F | 5/5/2021 | 5/13/2021 | 8 days after injection I had a delayed hypersensitivity reaction (?covid vaccine arm?), symptoms included firmness and a red patch on my upper arm near the injection site. The following morning, I woke up feeling well with the rash still on my arm (no change). 2 hours later I began feeling dizzy and fainted. I was unconscious for 5 to 10 seconds. When I woke up, the rash had vanished and the firmness was gone. No signs of the reaction were present after waking. |

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| 1316922 | 5/14/2021 | CT | 37 | M | 5/7/2021 | 5/7/2021 | Patient fainted after administration of his vaccine. It was only a few seconds and when he opened his eyes he stated he usually only faints after giving blood. We held him the full 30 minutes for observation and he did not experience any other adverse reaction |
| 1317019 | 5/14/2021 | IL | 17 | M | 5/14/2021 | 5/14/2021 | Patient fainted after leaving vaccination administration room and passed out on the floor. Patient was conscious and 911 was called and arrived. Patient did not leave in ambulance and was doing fine. |
| 1317024 | 5/14/2021 | NC | 13 | F | 5/14/2021 | 5/14/2021 | My daughter passed out 2 times within 5 minutes of receiving her first dose. She complained of being nauseous after both fainting episodes. We gave her water and orange juice and she ultimately felt better after about 25 minutes of resting. |
| 1317026 | 5/14/2021 | OR | 24 | M | 5/10/2021 | 5/10/2021 | immediately after vaccine: pre-syncope symptoms (lightheaded, perspiring, felt cold). 15 minutes later pulse 60 bpm (normal for pt). 30 minutes post vaccination pt reported feeling normal. called pt 5/12 to check in and he reported normal fatigue, and having experienced nausea for 2 hours |
| 1316519 | 5/14/2021 | MN | 15 | F | 5/13/2021 | 5/13/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: Tinnitus-Medium, Systemic: Visual Changes/Disturbances-Medium, Additional Details: Fainted immediately after administration & came to within 1 minute. Vision impairment & plugged ears for approx 10 minutes afterwards. She remained in the observation area for 30 minutes and was fully recovered when she left the store. |

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| 1318574 | 5/14/2021 | ME | 18 | M | 5/14/2021 | 5/14/2021 | The patient fainted approximately 3 minutes after receiving the vaccine. I caught him before he fell out of his chair, and he regained consciousness within about 5 seconds of me tapping on his shoulder. We got him some water immediately and he was able to speak to me, but he continued to nod off in his chair over the next couple minutes. We got him to lay on the floor with his legs elevated and a damp cloth across his face. As soon as he made it safely to the floor he had fully regained consciousness and held a conversation with me. I had him stay on the floor in that position for about 10 minutes. When he felt like he had his full strength back he went back to his chair and sat there for another approximately 10 minutes and continued to drink his water. At that point I let him walk around the area with my supervision and he still felt strong so he left the pharmacy. |
| 1318204 | 5/14/2021 | MO | 13 | F | 5/14/2021 | 5/1/2021 | Pt exhibited an episode of syncope/lightheadedness directly after the vaccination. Counseled patient about the risks of standing after a vaccination. Immediately gave Benadryl to the patient upon initial assessment. |
| 1318245 | 5/14/2021 | ME | 14 | F | 5/14/2021 | 5/14/2021 | After about a minute or so, Pt. felt pretty warm/hot in the room and started saying that she could not see/vision was blurry and she started turning pale/yellow. The room was stuffy so we moved from the vaccination room to the waiting room but the symptoms (vassalage syncope) seemed to progress so we brought her into the pharmacy where there was enough room for her to lie down. We had a fan run directly on her & within a few minutes the EMTs were present and they checked her out initially & they decided to bring her to the ambulance & checked her vitals. They asked her mom if she wanted to bring her to the hospital as her vitals were all normal. Mom decided to bring her just in case to make sure everything was okay and get her checked again as a safety precaution/parental concern. |

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| 1318439 | 5/14/2021 | CA | 16 | F | 5/14/2021 | 5/14/2021 | ADVERSE EVENT: DIZZINESS/ SYNCOPE AND NAUSEA, PATIENT ALSO TURNED PALE DURATION OF 15 MINUTES. TREATMENT: MONITORED PATIENT ENTIRE TIME AND PROVIDED SUPPORTIVE THERAPY. GAVE PATIENT WATER OUTCOME: PATIENT RECOVERED IN 15 MINUTES AND WAS OBSERVED FOR AN ADDITIONAL OF 15 MINUTES (30 MINUTES TOTAL) AND PATIENT WAS RELEASE TO THE CARE OF HER GUARDIAN |
| 1318442 | 5/14/2021 | CA | 12 | F | 5/14/2021 | 5/14/2021 | Patient received the vaccine, and 5 minutes later when walking out of the consultation room she fainted and hit her head on the high machine. |
| 1318529 | 5/14/2021 | WA | 26 | F | 5/14/2021 | 5/14/2021 | Patient fainted in waiting area after receiving immunization. Patient experienced visual disturbances seeing black spots, left sided chest pain, and arm tingling. Checked patient blood pressure, elevated her legs, applied cold ice pack behind her neck. Called 911 and paramedics arrived on time. |
| 1318202 | 5/14/2021 | VA | 26 | F | 5/14/2021 | 5/14/2021 | Pt became very hot, light headed, nauseous, and almost passed out. We sat her on the floor and checked pt's BP and monitored her until she felt better. She refused emergency services and left on her own choice after she felt better. |
| 1318570 | 5/14/2021 | MI | 15 | F | 5/14/2021 | 5/14/2021 | PATIENT FAINTED WHEN STANDING UP OUT OF CHAIR AFTER VACCINATION REGAINED CONSCIOUSNESS IN SECONDS AFTER SITTING DOWN |

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| 1318869 | 5/14/2021 | WA | 46 | M | 5/14/2021 | 5/14/2021 | Patient got faint, cold and clammy about five minutes after his vaccination and was visibly pale. When we went to assist him he asked to lay on the floor, before we could help him to this position he fainted, we got him on the floor and on his side, within about twenty seconds he woke up and was very aware of his situation. We applied ice packs under his neck and on his forehead. After about twenty minutes he sat up and started to gain his color back. At this point he told us he had fainted before after a flu shot and donating blood. Several minutes later he was able to stand up and sit in a chair. Cold packs were continued and he drank a bottle of orange juice. Twenty minutes later he said he was back to normal just felt weak like after a work out. He wanted to use the restroom and was escorted, showed no additional signs or symptoms at this point, and wanted to go home. |
| 1318584 | 5/14/2021 | PA | 23 | M | 5/14/2021 | 5/14/2021 | pt experienced syncope after vaccine administration. Monitored for 20 mins and pt seemed fine. No other reactions/ symptoms |
| 1318637 | 5/14/2021 | OR | 30 | M | 5/14/2021 | 5/14/2021 | Patient fainted after injection. He stated he has a history of fainting with any vaccine, not because of vaccine but because of fear of needles. Patient laid on floor until he felt better then moved to a chair outside the imz room to continue monitoring. He fainted again and was moved back to imz room. He laid on the floor for about 10 minutes until he felt better then moved back to chair outside room. Remained there for 20 minutes and felt he was fine to leave. |
| 1317705 | 5/14/2021 | OK | 15 | F | 5/14/2021 | 5/14/2021 | Patient fainted after the needle was removed. She quickly regained consciousness. Blood pressure was low. She waited 15 min. Blood pressure was good. Pt felt fine. She left with her Dad. |
| 1318905 | 5/14/2021 | CO | 12 | M | 5/14/2021 | 5/14/2021 | Patient received their first Pfizer Covid vaccine and while his sibling was receiving her vaccine approximately two minutes later the patient fainted and fell on the floor and hit his head. |
| 1317863 | 5/14/2021 | MI | 19 | M | 5/14/2021 | 5/14/2021 | Vasovagal syncope occurred while standing, approximately 5 minutes after administration. |

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| 1319503 | 5/14/2021 | CO | 13 | F | 5/14/2021 | 5/14/2021 | Patient was walking around the pharmacy approximately 10 minutes after receiving her first COVID vaccine where she felt lightheaded and passed out into a shelf. By the time pharmacist and technician were with the patient, the patient was awake and oriented. Offered to call 911, both patient and mother refused. Gave patient a Gatorade and a chair to relax before leaving the store. Patient was able to walk out on her own and felt fine. |
| 1318563 | 5/14/2021 | MA | 15 | F | 5/13/2021 | 5/13/2021 | PT got shot was with mom, seemed ok. Sat down to wait the 15 minutes, at about 7 minutes after sitting fainted. |
| 1317768 | 5/14/2021 | | 36 | M | 5/14/2021 | 5/14/2021 | Fainted Spasms like seizure (20 seconds) |
| 1318957 | 5/14/2021 | KY | 16 | F | 4/26/2021 | 4/26/2021 | Within 5-10 mins post-injection pt became pallor, sweaty, dizzy and had a vasovagal episode while sitting in her chair. Pt exhibited jerking motions and then quickly had a syncope episode lasting <1 min. Pt was lowered to the ground during the episode. No trauma occurred. Pt mother beside pt entire time. During this time a pulse ox was put on pt and her legs were elevated. Pulse ox remained 96-98%. After waking, water and wet rag was given to pt and pt moved to reclined chair after 5 mins. Pt remained pallor and dizzy x15mins, after 40 mins pt was able to walk and leave the clinic. Mother stated in past that pt had a vasovagal episode after the Gardasil vaccine. |
| 1318043 | 5/14/2021 | WA | 16 | F | 5/12/2021 | 5/12/2021 | received vaccine and stood up. During walking out of room, fainted and potentially had seizure as she fell. Head hit the ground. Stayed awake, alert after she fell. Generally knew who, what, when, where and that she just had vaccine. EMS called who arrived and transported to ER for evaluation. |
| 1317735 | 5/14/2021 | NC | 14 | F | 5/14/2021 | 5/14/2021 | Immediate syncope lasting about 15 seconds with 5 seconds of tonic-clonic activity and brief emesis. Normal mental status within 30 seconds. Initial heart rate 50, and BP 90/60, recovered to normal with BP 100/60 and heart rate 70 within 30 minutes. No signs of allergic reaction or anaphylaxis. Taking fluids and felt well upon discharge. |
| 1317797 | 5/14/2021 | WA | 13 | M | 5/14/2021 | 5/14/2021 | Patient Fainted |

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| 1317843 | 5/14/2021 | TX | 14 | F | 5/14/2021 | 5/14/2021 | Patient fainted after received her 1st dose of vaccine |
| 1317855 | 5/14/2021 | CA | 32 | M | 5/10/2021 | 5/10/2021 | vasovagal syncope, all of pt symptoms were resolved within 15 min after laying down |
| 1317910 | 5/14/2021 | CA | 14 | M | 5/14/2021 | 5/14/2021 | PATIENT FAINTED . He has an history of fainting according to grandmother. he was sweaty and pale. paramedic came and his blood pressure was 120/70 heart rate 70. no problem now |
| 1317941 | 5/14/2021 | | 31 | F | 5/14/2021 | 5/14/2021 | syncope. Evaluated by EMS-Cleared |
| 1317946 | 5/14/2021 | WA | 15 | F | 5/14/2021 | 5/14/2021 | Patient fainted while sitting in a chair after receiving the vaccine. After checking on her, she was responsive and was nervous about receiving the vaccination. |
| 1317956 | 5/14/2021 | KY | 17 | F | 5/14/2021 | 5/14/2021 | Patient given dose @ 6:00 pm, mother stated prior that she had passed out with HPV vaccine in past. Had patient lay back while giving vaccine and after 5 minutes she stated she felt fine and proceeded to waiting area. After sitting in chair in waiting room, patient fainted, return to previous state by 6:20. |
| 1317985 | 5/14/2021 | IL | 34 | F | 5/14/2021 | 5/14/2021 | Patient was given vaccine at about 2:30 pm and then about 2:32 pm the patient became unresponsive in the chair. Patient was covered in sweat and had low blood pressure (101/65) upon regaining consciousness. Gave the patient an ice pack to cool her down and she began to regain color in her face and her blood pressure returned to 130/82 before she left. Patient did state that this is not the first time she has passed out around a needle. |
| 1317986 | 5/14/2021 | CA | 13 | M | 5/13/2021 | 5/13/2021 | Patient received the vaccine and was completely fine immediately following. We walked around the store, conversed, and 10-12 minutes after injection he had syncope and generalized tonic clonic seizure for minutes. We were transported 911 to Hospital ED where he had normal labs, normal brain MRI, and consultation with Peds Neuro. He was post-ictal for 30+ minutes to follow the incident. He has secondary trauma to his R temporal and occipital bones and likely a mild concussion resulting from the fall. |

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| 1317734 | 5/14/2021 | IL | 12 | F | 5/14/2021 | 5/14/2021 | Patient Vomitted and Fainted for couple secs. No signs of distress or SOB observed. Patient stated "that she is ok". Patient discharged home. |
| 1318016 | 5/14/2021 | WI | 32 | M | 5/14/2021 | 5/14/2021 | Patient received a Johnson & Johnson vaccine today. Shortly afterwards while waiting in pharmacy area, we were alerted that the patient was unresponsive by his wife. Immediately responded to patient. Code white called and management responded. Tried to get him to wake up, he opened his eyes but immediately closed them again. I attempted to keep him alert and eyes open. This proceeded to go on for several minutes. Ice packs were placed on neck and wrists. Feet elevated. Once patient was alert and oriented, water was provided and patient was instructed to take small sips. Patient was kept in pharmacy area for additional 15 minutes once he was back to normal. Patient stated that when he passed out, he felt tired, couldn't see or hear. |
| 1318037 | 5/14/2021 | CA | 15 | F | 5/14/2021 | 5/14/2021 | Patient felt dizzy and fainted after 4 minutes of receiving the Pfizer COVID-19 vaccine. Pt immediately woke up, no change in level of consciousness. Patient awake, alert, and oriented to name, place, time, and situation. Vital signs were within normal limits. BP 96/54, HR 71, SpO2 99% in RA. Patient left ambulatory with mother in stable condition after 40 minutes of monitoring and observation. |
| 1314017 | 5/13/2021 | NY | 21 | M | 5/13/2021 | 5/13/2021 | pt passed out for a minute or so---quickly regained consciuosness |
| 1313576 | 5/13/2021 | MN | 33 | M | 5/12/2021 | 5/12/2021 | Site: Itching at Injection Site-Mild, Site: Redness at Injection Site-Mild, Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Severe, Systemic: Exhaustion / Lethargy-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Nausea-Medium, Additional Details: he was fainted right after the shot. my tech called 911 and i stayed with him. after 1 minute he was responding but still needed medical attention. i waited with him until paramedics come. |

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| 1313579 | 5/13/2021 | PA | 20 | F | 5/12/2021 | 5/12/2021 | Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Mild, Systemic: Hypotension-Mild, Systemic: Visual Changes/Disturbances-Medium, Additional Details: immunization given on 5/12/2021 at pharmacy at approximately 5:25p. about 3 minutes later patient complained of lightheadness and black spots covering her vision. in an attempt to help her lie down, when patient was repositioning, she went limp and passed out for a few seconds. vitals were checked by rph. 911 was called. patient was cleared and went home on her own record. patient has driver friend |
| 1313582 | 5/13/2021 | FL | 19 | F | 5/12/2021 | 5/12/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: fainted upon standing but was responsive-Severe, Additional Details: patient got up to go to bathroom and fainted but was responsive. mother came picked her up, patient was drinking gatorade |
| 1313603 | 5/13/2021 | NE | 32 | M | 5/12/2021 | 5/12/2021 | Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Additional Details: patient became unresponsive/fainting while sitting in the chair. |

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| 1313733 | 5/13/2021 | NC | 71 | F | 2/26/2021 | 2/27/2021 | <p>She got her vaccine, felt fine, the shot didn't hurt until probably about 6 hours later she began to feel not sick, but not totally well, feeling blah. Through the night, she did not sleep well, probably awake as much as sleeping. In the middle of the night her husband was up and she said she felt as if she had the virus, as well as her husband. She ate about 1/3 of a bowl of oatmeal, and it did not make her feel better. She did not have any energy and hurt as if she had had a bad fall. She had periods of her head floating away, strange feeling. She got up to move and continued to have light headed spells and felt if she held her head back she would pass out. She then walked into the kitchen as she was thirsty and her stomach unsettled, went to the fridge and then does not remember anything other than her son being at the house. Her husband called him, and it was 15 minutes while she was out before she regained consciousness. They told her they called 9-1-1 and went to the bathroom and the paramedics checked her out and recommended for her to go to the hospital. She was transported to the ER, and based on the info they had they checked her for a stroke. They sent her for a brain scan. The Dr. told her that she had a healthy brain. They monitored her and was in the ER until that evening, she was then transferred to a room and put on a motion and heart monitor to keep check on her. She did not have anymore episodes of syncope and checked her out and told her that everything was WNL. They were trying to find out what caused her blackout spell. She asked if she could take the 2nd vaccine, and he told her that she needed it. She came home on Monday evening after being discharged. She had no energy until the last week or so since that episode. She still has a brain fog, trouble just thinking and makes quilts for hospice patients and was able to complete that task last week. Her brain fog is better and her fatigue is improving.</p> |

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| 1313738 | 5/13/2021 | NC | 71 | F | 2/26/2021 | 2/27/2021 | She got her vaccine, had no problems. Went home felt tired and ate some oatmeal but only about 1/3 of what she normally eats. She went to bed and woke up and told her husband that she had flu like feeling. She got up to move and continued to have light headed spells and felt if she held her head back she would pass out. She then walked into the kitchen as she was thirsty and her stomach unsettled, went to the fridge and then does not remember anything other than her son being at the house. Her husband called him, and it was 15 minutes while she was out before she regained consciousness. They told her they called 9-1-1 and went to the bathroom and the paramedics checked her out and recommended for her to go to the hospital. She was transported to the ER, and based on the info they had they checked her for a stroke. They sent her for a brain scan. The Dr. told her that she had a healthy brain. They monitored her and was in the ER until that evening, she was then transferred to a room and put on a motion and heart monitor to keep check on her. She did not have anymore episodes of syncope and checked her out and told her that everything was WNL. They were trying to find out what caused her blackout spell. She asked if she could take the 2nd vaccine, and he told her that she needed it. She came home on Monday evening after being discharged. She had no energy until the last week or so since that episode. She still has a brain fog, trouble just thinking and makes quilts for hospice patients and was able to complete that task last week. Her brain fog is better and her fatigue is improving. |
| 1313848 | 5/13/2021 | MO | 23 | M | 5/12/2021 | 5/12/2021 | VASOVAGAL SYNCOPE- PATIENT PASSED OUT. PATIENT CAME TO MOMENTS LATER. |

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| 1314304 | 5/13/2021 | CO | 19 | F | 3/27/2021 | 3/28/2021 | First symptoms were fever of 103.5 at midnight on the 28th. I called the RA on call in my university department and they called PD - to come and make sure I was okay. For 36 hours, I felt terrible - couldn't do anything. About 1 1/2 to 2 weeks later, I started getting really severe back pain that made it hard for me to do things - even sitting in a chair caused so much pain or walking or standing for long periods of time made me light headed because it was intense pain. There was one instance, when I nearly passed out from the pain but I didn't as I called for help for someone to catch me. It kind of moves around - the pain - sometimes it's a along my spine and sometimes it's low below my shoulder blades. I'm still having this pain. It's not on the same pain scale as it was a couple of weeks ago. It's more manageable right now. I do stretches and some medications and there are a couple of patches - Salontas - that my dad uses that he recommended I try to use for backaches. I am calling my doctor today to make an appointment. |
| 1314170 | 5/13/2021 | AL | 32 | M | 5/11/2021 | 5/11/2021 | Patient began sweating profusely approximately 10 minutes after his vaccine. He went to his parent's car and asked his father to turn on the air conditioning as he was hot. he then passed out in the back seat of the car. His mother came inside and asked for assistance. I grabbed an epi-pen and ran outside to the car. Patient was breathing and had a pulse rate of 64. He aroused shortly after I began asking him if he could hear me and asked if he could tell me his name. He was pale (notably his lips were quite pale) and confused. He could not say his name but could nod appropriately to questions when asked. We immediately called EMS for assistance. They arrived within 4-5 minutes and transported the patient to hospital. |
| 1313511 | 5/13/2021 | MA | 30 | M | 5/12/2021 | 5/12/2021 | Systemic: Fainting / Unresponsive-Medium, Additional Details: Patient has a history of fainting with medical procedures. We called 911 Paramedic responded observed patient took patient's blood pressure waited 15 minutes told patient he should not drive. Patient said he was fine declined medical transport said he was OK to walk home. |

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| 1312661 | 5/13/2021 | CA | 18 | M | 5/12/2021 | 5/12/2021 | <p>Pt. received the first COVID vaccine (Pfizer, lot # EW0182 and use by date is 05/13/21 at 0930am) around 1123am. LVN, administered the Pfizer vaccine and approximately 10 seconds after the vaccine was administered, the patient became pale and the patient loss consciousness for approximately 4 seconds. LVN ensured that the patient did not fall off the chair while RN (and Co-Lead), RN (Lead Vaccinator), and EMT observer, immediately ran to assist LVN with assisting the patient to the ground. The patient was alert and oriented when the nurses assisted him to the floor and had him lie in a supine position with his legs elevated. The patient was alert and oriented to person, place, time, and situation. Vital signs were immediately taken at 1124 when the patient was supine on the ground with his legs elevated: blood pressure of 112/58 (right arm, supine) , heart rate of 48 beats per minute, respiratory rate of 16 breaths per minute, and 100% oxygen saturation at room air. The patient denied any headache, nausea, or dizziness. The patient was moved to the gravity chair and was placed in Fowler's position. The patient was given Gatorade, as the patient did not eat or drink anything prior to being vaccinated. Vitals were taken at 1131: BP 114/78 (Right arm, sitting) , 66 beats per minute, 16 breaths per minute, and 100% oxygen saturation at room air. Alert and oriented to person, place, time, and situation. Denied any history of fainting . Denied taking any medications or having any chronic medical conditions. The patient continued drinking Gatorade and was offered a granola bar, the patient did not have any known allergies to medications, foods, or dust. At 1141, vitals were retaken, BP 122/87 (Right arm, sitting), HR 63, RR 16, and 100% oxygen saturation at room air. The patient denied any chest pain, shortness of breath, lightheadedness, dizziness, or headache. The patient ate a breakfast biscuit at 1148. At 1153 the patient was positioned from a Fowler's position to sitting upright in the gravity chair. Instructed the patient to have a friend or family member drive him home, the patient then called a friend to transport him home. RN, went over the V-Safe app with the patient and instructed him to eat breakfast and drink fluids the next time he arrived for his 2nd Pfizer vaccine. RN also instructed him to inform the vaccinator the next time he is vaccinated (for his second dose), to inform him/her about his history of fainting with his first</p> |

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| | | | | | | | dose. The patient's vitals were taken at 1158 when he was sitting upright, BP: 138/80 (right arm), HR 67, RR 15, and oxygen saturation at 99%. RN instructed the patient about ER precautions and to follow up with his primary care provider. The patient's vital signs were taken a final time at 1210, BP 122/78, RR 16, HR 67, and 100% oxygen saturation at room air. The patient's ride arrived on site around 1215, and the patient had a steady and even gait when ambulating to the vehicle, where he was driven home by a friend. |
| 1313840 | 5/13/2021 | FL | 35 | M | 5/9/2021 | 5/10/2021 | Monday 5/10 felt fatigued, Tuesday 5/11 Diaphoretic and nauseous, 5/12 Syncope/Weakness, 5/13 Weakness, called 911 and brought to emergency room |
| 1313508 | 5/13/2021 | VA | 21 | F | 5/12/2021 | 5/12/2021 | Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Exhaustion / Lethargy-Medium, Systemic: Fainting / Unresponsive-Medium, Additional Details: Patient was unresponsive for 5 minutes. Pharmacy called 911 and the EMT took her out of the building. |
| 1313289 | 5/13/2021 | IL | 32 | M | 5/12/2021 | 5/12/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Hypotension-Medium, Additional Details: Patient received vaccine. Had not eaten anything that day prior to vaccination. Said he felt tired and closed his eyes for a minute but lost control of his bladder. Seemed shaky and sweaty. Blood pressure taken was low 90/50 initially at 222pm. Gave patient water and a protein bar. Blood pressure at 238pm 109/72. Blood pressure at 253pm 119/86. Seemed much improved after 30 minutes. |
| 1313286 | 5/13/2021 | CA | 23 | M | 5/12/2021 | 5/12/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium |
| 1313277 | 5/13/2021 | IN | 36 | M | 5/12/2021 | 5/12/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium |

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| 1313254 | 5/13/2021 | WA | 87 | F | 3/29/2021 | 3/30/2021 | <p>passed out 24 hours after the first shot; heartrate went to 99; freezing; chills off and on; Wiped out, Fatigue; freezing ,chills off and on; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (passed out 24 hours after the first shot) in an 87-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 025A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No medical history was provided by the reporter. Concomitant products included TRIAMCINOLONE ACETONIDE (NASACORT), FLUTICASONE PROPIONATE (FLOVENT), LISINOPRIL, ASCORBIC ACID, ERGOCALCIFEROL, NICOTINAMIDE, RETINOL, RIBOFLAVIN, THIAMINE HYDROCHLORIDE (VITAMINS [ASCORBIC ACID;ERGOCALCIFEROL;NICOTINAMIDE;RETINOL;RIBOFLAVIN;THIAMINE HYDROCHLORIDE]) and PRAVASTATIN for an unknown indication. On 29-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 30-Mar-2021, the patient experienced LOSS OF CONSCIOUSNESS (passed out 24 hours after the first shot) (seriousness criterion medically significant), HEART RATE INCREASED (heartrate went to 99), FEELING COLD (freezing; chills off and on) and CHILLS (freezing ,chills off and on). 30-Mar-2021, the patient experienced FATIGUE (Wiped out, Fatigue). On 30-Mar-2021, LOSS OF CONSCIOUSNESS (passed out 24 hours after the first shot) had resolved. On 06-Apr-2021, FEELING COLD (freezing; chills off and on) and CHILLS (freezing ,chills off and on) had resolved. At the time of the report, HEART RATE INCREASED (heartrate went to 99) outcome was unknown and FATIGUE (Wiped out, Fatigue) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Electrocardiogram: result not mentioned (Inconclusive) result not mentioned. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Treatment included discontinuation of glipizide. Company comment: This case concerns an 87-year-old female with a serious unexpected event of loss of consciousness, and non-serious unexpected heart rate increased, feeling cold, and expected fatigue, chills. Based on current available</p> |

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information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. This case was linked to MOD21-070319 (Patient Link). Most recent FOLLOW-UP information incorporated above includes: On 16-Apr-2021: No new information On 04-May-2021: Updated outcome of fatigue, added route of administration of suspect drug.; Sender's Comments: This case concerns an 87-year-old female with a serious unexpected event of loss of consciousness, and non-serious unexpected heart rate increased, feeling cold, and expected fatigue, chills. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.

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| 1313190 | 5/13/2021 | HI | 28 | F | 5/12/2021 | 5/12/2021 | <p>Patient received second covid shot from technician certified to vaccinate. Tech knocked on door, because when patient went to stand she felt like putting her head between her legs and fainting. I went in there and it looked like previous episodes of fainting I have seen so I tried to calm her and have her breath while patient was getting the blood pressure machine. Patient then fainted again a little more intensely, but still not alarming me that much. She came to and again I was talking with her to try to keep her alert. I asked her how she was feeling. She said she was extremely hot (she kept repeating this), that she had a headache, and asked for water. I told her we couldn't give her food or water until she felt better. We now had blood pressure monitor on her and it wouldn't read her pressure or pulse it kept saying error. I just used it on another patient with high blood pressure and it had been functional. I had been manually holding her pulse and it was strong and normal. Then she fainted again and started shaking. the shaking quickly stopped. She woke up and said that she couldn't see. I asked tech to call 911, while I stayed with her and kept assessing her. Tech got the headset got 911 on the phone and turned the phone over to me. I asked her to grab another blood pressure monitor. We tried again and at 3:55pm it was 88/50 and pulse of 66. I was talking 911 and responding to all questions over the phone. I had to ask the patient for the responses (many COVID related questions). I told the lady her blood pressure and the lady said I don't need to know any of that. She wanted me to keep asking the patient questions. The blood pressure was 87/49 and pulse of 65 at 3:58. Now the EMT had arrived and assessed her. They said she fainted and she said she did not want to go with them. So they left. The patient remained at pharmacy for 45 to 90 min more until she was sure she felt okay enough to catch an uber home. I called her at 8:43pm and she said she feels much better, has eaten, and is with her boyfriend in case she experiences anymore ADRS. Upon asking who her primary physician is she said she last saw a doctor in another country. She said her md only speaks another language. I asked her to call her MD and report to her in a different language what happened since I am unable to speak with her.</p> |

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| 1313061 | 5/13/2021 | NY | 62 | F | 3/25/2021 | 3/25/2021 | having faint spells; blood pressure is a little bit higher than normal; Feeling kind of funny; had severe headache; This is a spontaneous report from a contactable healthcare professional, the patient. A 62-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot ER8727, second dose) solution for injection intramuscular in the left arm on 25Mar2021 (at the age of 62-years-old) as a single dose for COVID-19 vaccination. Medical history included thyroid disease (diagnosed with probably 20-21 years ago) and blood pressure increased (takes blood pressure medicine). Concomitant medication included hydrochlorothiazide for blood pressure increased began taking this 4 or 5 years ago. Historical vaccine included BNT162B2 (first dose, lot EN6200) for COVID-19 vaccination on 04Mar2021 with no adverse effect reported. On 25Mar2021, the patient was feeling kind of funny and had a severe headache. In Apr2021, the patient had faint spells and blood pressure was a little bit higher than normal at 137/80 which began after the second dose Pfizer Covid Vaccine. The patient stated she never felt like fainting before in her life. Her blood pressure was never over 150 and can't keep blood pressure under 130 for some reason. The outcome of the events feeling kind of funny and headache was unknown. The outcome of the events faint spells and blood pressure was a little bit higher was not recovered. Information on batch number has been requested.; Sender's Comments: Based on chronological connection to the vaccine a causal relationship between event faint spells and BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate. |

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| 1312664 | 5/13/2021 | IL | 59 | F | 3/14/2021 | 3/14/2021 | 10 minutes after receiving injection felt body heating up like blood was boiling, sweating eventually passed out. 8 weeks later still low energy levels and lengthy sleeping times |
| 1312633 | 5/13/2021 | WA | 20 | F | 5/12/2021 | 5/12/2021 | PATIENT WARNED ME THAT HE HAS A NEEDLE PHOBIA, I GAVE HIM THE VACCINE, HE TOLD ME THAT HE DID BETTER THAN OTHER TIMES, HE STAYED SITTING ON THE CHAIR, THEN HE SAID THAT HE FEEL NAUSEATED AND WANTS COLD WATER, THEN HE FAINTED, I CALLED FOR HELP, HIS MOM WAS OUTSIDE THE CLINIC IN THE LOBBY, WE CALLED HER, WE ALSO CALLED 911. HE STARTED WAKING UP AFTER LIKE 5 MINUTES, 911 WERE HERE AND CHECKED HIM, HE WAS OK, ALL HIS VITAL SIGHNS WERE NORMAL, HE LEFT THE PHARMACY WALKING WITH HIS DAD AND MOM. |
| 1312630 | 5/13/2021 | TN | 26 | F | 5/12/2021 | 5/12/2021 | PT PASSED OUT AND FELL TO FLOOR FROM THE CHAIR SHE WAS SITTING IN. |
| 1312620 | 5/13/2021 | CA | 28 | M | 5/12/2021 | 5/12/2021 | patient felt fainting after vaccine ,was placed down on the floor and was awake until paramedics arrived and checked patient and started to feel better and left the store with a family member |
| 1314306 | 5/13/2021 | MI | 16 | F | 5/12/2021 | 5/12/2021 | The patient felt tired and describes her eyes going dark, then passed out a few minutes after vaccination. She was vaccinated and then left the immunization room to sit down for a 15 minute waiting period. When she went to sit down, she collapsed on the floor. Her mother assisted her into a chair. She continued to be incoherent and have her eyes rolling back into her head for a few minutes. We used a cool cloth on her forehead and the back of her neck. The parents requested that we call 911. EMS arrived shortly and evaluated her. Heart rate, blood pressure, pulse ox, blood sugar and chest sounds were all within normal range. The patient stated that her arm felt heavy and "funny". She then stated that her tongue felt funny. EMS evaluated her tongue and said it looked normal. To err on the side of caution, she was taken to the hospital to determine whether or not she was having a delayed onset anaphylactic reaction. This patient has no history of seizures. |

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| 1315187 | 5/13/2021 | CA | 69 | F | 4/1/2021 | 5/3/2021 | Unknown date of vaccination, physician asked for this to be reported, possibly related to Covid vaccine. Patient admitted to hospital with syncope and bilateral pulmonary embolism. Patient treated and discharged home after 2 days |
| 1312996 | 5/13/2021 | | | F | | | This is a spontaneous report from a contactable consumer (reporting for cousin of mother). A female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: UNKNOWN) via an unspecified route of administration on an unspecified date as a single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient passed out either the next day or shortly after receiving dose of BNT162B2 on an unspecified date, a medically significant event. The outcome of the event, passed out was unknown. Information on the lot/batch number has been requested. |
| 1315448 | 5/13/2021 | CO | 14 | M | 5/13/2021 | 5/13/2021 | Near syncope. Monitored in clinic. Vitals stable. Self-resolved after 5 minutes. Monitored for 30 minutes |
| 1315148 | 5/13/2021 | CA | 18 | F | 5/8/2021 | 5/8/2021 | Pt received vaccine soon after began to c/o syncope episodes. Pt able to walk to cot and lay down. No SOB noted. Pt cold and clammy. 911 called paramedics out to assess pt refused to go to hospital. after 30 minutes pt began to feel better. 1st set V/S 530 pm p-88, 02 sat 97, BP 104/80 waited 1.5 hrs for husband to pick pt up. Pt stable no c/o no distress able to ambulate on own home with husband. |

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| 1315708 | 5/13/2021 | CA | | F | | 4/10/2021 | <p>CEREBRAL HEMORRHAGE IN HER HEAD/ DIZZINESS/ LOOSE HER BALANCE/ VOMITED/ HEADACHE; BLOOD PRESSURE WAS HIGH; FAINTING; TEMPORARY BLINDNESS; BROWN SPOTS ON FINGER; EYES ALSO HURT; EYE FEELS HEAVY; EYE PRESSURE FROM THE BACK; FATIGUE/ STILL FEEL TIRED; FEELS WEAK; NAUSEA; SHAKING BECAUSE SHE WAS COLD; CHILLS; This spontaneous report was received from a patient and concerned a 53 year old White (Hispanic or latino) female. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 202A21A, expiry: unknown) dose was not reported, administered on 10-APR-2021 to left deltoid for prophylactic vaccination. No concomitant medications were reported. On 10-APR-2021, the patient experienced shaking because of cold, chills, nausea. On 11-APR-2021 patient felt nauseous. On an unknown date the patient had fatigue and headache. On 17-APR-2021, the subject experienced fainting. On 22-APR-2021 patient felt dizzy, vomiting, and was losing balance periodically and got admitted to emergency room; On admission the patient was diagnosed with high blood pressure and cerebral hemorrhage in head due to high blood pressure and patient kept in emergency room under observation. On 24-APR-2021 patient was discharged but still experienced headaches when she returned home. On 30-APR-2021 the patient again visited emergency room and was prescribed unspecified blood pressure medications and Tylenol (paracetamol). On an unknown date, the patient had brown spots appeared on left hand (on top of her middle) the spots covered about half of middle finger. The patient described the headaches as it felt like something was moving inside her head which started on the back of head and right side and moved slowly around which hurt a lot. She mentioned her eyes also hurt. On 05-MAY-2021 the patient visited hospital and reported that they cannot do anything to the headaches. On an unknown date the patient eyes are heavy feels like something is pushing her eye and had temporary blindness Patient was prescribed with butalbital-caffeine with Tylenol for headache; that headache subsides away for 4 hours and comes back. On an unknown date the patient feels tired</p> |

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| | | | | | | | up and weak. Treatment medications (dates unspecified) included: butalbital/caffeine/paracetamol, and paracetamol. The patient recovered from fainting, and vomited, was recovering from shaking because she was cold, had not recovered from chills, fatigue, headache, brown spots on finger, eye feels heavy, eye pressure from the back, and temporary blindness, and the outcome of nausea, dizziness, blood pressure was high, cerebral hemorrhage in her head, eyes also hurt, loose her balance, still feels tired and feels weak was not reported. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: V0: 20210514047-covid-19 vaccine ad26.cov2.s-Cerebral heamorrhage, High blood pressure, Fainting, Temporary blindness. These events are considered unassessable. The events has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the events. |
| 1315655 | 5/13/2021 | CA | 15 | M | 5/13/2021 | 5/13/2021 | Pt fainted shortly after receiving vaccine, 911 called immediately, BP fluctuating rapidly, pt was mostly awake but not alert. Paramedics took out in ambulance with Dad |
| 1315196 | 5/13/2021 | VT | 23 | M | 5/13/2021 | 5/13/2021 | 4 minutes after receiving vaccine pt sitting in chair slumped or and fainted falling to floor. Awoke immediate. Alert and oriented x3. No complaints of pain. Ambulance called and assessed pt. Pt refused to go in ambulance. Pt given water to drink. Sat in vaccine for 1 hour. Able to stand with steady gait. Pt reported had worked a 10 hour day and probably did not drink enough water. |
| 1314333 | 5/13/2021 | NY | 14 | F | 5/13/2021 | 5/13/2021 | Pt received vaccine and developed syncope less than 30 min after administration |
| 1315185 | 5/13/2021 | CT | 34 | F | 5/13/2021 | 5/13/2021 | Patient fainted. Given water and lemonade and requested patient to remain in place for 30 minutes. Episode passed, patient reported feeling fine. |

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| 1315875 | 5/13/2021 | TX | 18 | F | 5/13/2021 | 5/13/2021 | Patient passed out while on her 15 minutes of observation after the vaccine , she woke up quickly and threw up ,she was conscious , her dad was with her all the time, we offered her the first aids , she was feeling well after approximately 20 minutes. |
| 1314964 | 5/13/2021 | KS | 23 | M | 5/13/2021 | 5/13/2021 | Shortly after receiving the vaccine patient felt light headed and removed mask. He then passed out falling forward in chair and hitting his head he then went into convulsions. Quickly came to and was able to walk out with EMS. |
| 1314953 | 5/13/2021 | MI | 15 | F | 5/13/2021 | 5/13/2021 | Patient fainted after getting Covid-19 Pfizer immunization. She recovered right away and she seems to have no effects from the fainting or the shot. She said she has fainted in the past and she is afraid of needles but she did not mention that at the moment of answering the questioner. |
| 1314946 | 5/13/2021 | PA | 27 | M | 5/13/2021 | 5/13/2021 | Patient recieved J&J COVID vaccine, after 1 minute was transitioned to the 15 minute waiting area. Upon arriving at the chair, patient fainted and fell to the floor, patient was out for approximately 20 seconds and came to. I then asked the patient if he hurt or felt injured, assessed his alertness he was alert and oriented x 3. He transitioned to chair under own power and was speaking with me, his eyes then rolled back in his head for approximately 10 seconds went out again. At this time we called the ambulance, they came to assess patient, patient refused transport to hospital and left under his own power. |

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| 1314943 | 5/13/2021 | CA | 14 | F | 5/13/2021 | 5/13/2021 | 14 y/o female presented to observation after receiving covid-19 pfizer vaccine c/o of dizziness and expressing syncope after lying down for ten minutes in the vaccination station. Pt V/S as follows; at 1332; 79/49 53 12 and O2 100% RA in supine position with legs elevated. Pt continued to express dizziness. Pt reposition to seating after ten minutes. Pt V/S as follows at 1340; 86/50 57 16 and O2 100% RA. Pt provided water and chips. Pt reposition to standing after ten minutes. Pt V/S as follows at 1350; 76/45 57 16 and O2 100% RA. Pt express feeling dizzy after standing. Pt advised to reposition to sitting. Pt V/S while sitting at 1400 are as followed 85/55 53 16 and O2 100%. Pt then advised to stand and try to ambulate once ready. Pt stands and expressed they felt fine and was ready to ambulate. Pt ambulated thirty feet without assistance. Pt VS after standing and ambulating at 1209 as followed; 84/54 63 18 and O2 100% RA. Mom stated PCP reports SBP of 90 in March via phone. Pt and Pt mother advised to follow up with PCP prior to playing Baseball next day. Pt DC after displaying steady gait after ambulating, eating chips, drinking a full bottle of water Pt stating "no longer feeling dizzy" and VS taken at 1409. Supervisor notified. |
| 1314923 | 5/13/2021 | CA | 14 | M | 5/13/2021 | 5/13/2021 | 14 year old male pt presented with syncope episode upon walking from vaccination room to the observation area, LOC for 2-4 seconds, pt placed in supine position with elevated feet, woke up immediately. Pt did not hit head and was assisted to into wheelchair and place on cot. 2:25pm vitals: BP 66/48 P 92 SpO2 98 on RA. Pt history obtained from father, no history of allergies but does have needle related anxiety. Pt supine with feet elevated, ate bag of chips, juice box and water. VS at 2:33 BP 98/65 P 65 when sitting. Pt ambulated, alert and oriented x3, and final VS at 2:38 at BP 94/62 P 76. |
| 1314700 | 5/13/2021 | OH | 22 | M | 5/13/2021 | 5/13/2021 | Patient became light headed and had a syncope reaction and fainted, and came to attention immediately as we approached him. He then vomited 10 minutes post syncope reaction. |
| 1315684 | 5/13/2021 | CO | 40 | M | 5/13/2021 | 5/13/2021 | Severe syncope, shaking, low blood pressure |

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| 1314913 | 5/13/2021 | NC | 42 | M | 5/13/2021 | 5/13/2021 | 5/13/21 around 11:30 am Patient received vaccination. Patient directed to post exposure waiting area. Patient after sitting down under a minute started to slouch and fainted. Fell on floor with side of head hitting floor. Patient passed out and then less then 10 seconds later gradually became alert. Patient did not want to lay on floor and was positioned in chair. 911 Call placed and EMS responded approximately 8 to 10 minutes later. Patient declined being sent to hospital. EMS took blood pressure and made sure patient was okay. Patient signed waiver with EMS |
| 1314377 | 5/13/2021 | NY | 0 | M | 5/11/2021 | 5/11/2021 | Pharmacist administered Janssen vaccine, pateint left the vaccination room and was waiting by the pharmacy for the patients vaccination card and fainted onto the floor. Pharmacist attended to the patient on the floor, i called 911. 911 showed up and the patient refused any real medical attention since he did not have insurance. Patient left under his own will. |
| 1314653 | 5/13/2021 | NE | 14 | M | 5/13/2021 | 5/13/2021 | Fainting, patient fainted after administration and was being monitored for 30 minutes sitting down in our pharmacy. |
| 1314710 | 5/13/2021 | WA | 23 | F | 5/13/2021 | 5/13/2021 | Patient received vaccine and fainted. Significant other was with patient at the time and reported patient "convulsing". Patient reported feeling numb and tingly at extremities and hyperventilating. Patient was sweating and extremely anxious. EMT arrived, assessed patient, and escorted patient out of facility. |

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| 1314722 | 5/13/2021 | CA | 50 | F | 4/7/2021 | 4/7/2021 | <p>Within 5 minutes from receiving my J&J vaccine, I went to sit down and I started feeling very hot in my body. My heart started to race, had chest discomfort and had trouble breathing, my trachea closed up, had blurry vision and pain in my chest. I felt like I could not breathe and when the nurse came over to ask me I could not speak to her, I went into a shock and I was placed on the floor and I could not hear anything nor could open my eyes, from my hips down to my feet I could not feel anything, my legs went completely numb and I had a syncope. What I was told from the nurse that I was given an Epi-pen to help with my reaction. When I came back my body was having convulsions, felt my head spinning, had pain in my chest that so very intense and the nurse got me up and took me to a nearby ambulance and the EMT staff placed like a heart monitor because my heart was racing super fast. I also felt heaviness in my chest and inside the ambulance I was given two injections on my left arm and when I slowly started coming back, I was already at the hospital. I was at the hospital from 2pm to 4:30pm more less being monitored. At the hospital x-ray of the chest was performed as well as lab work and I was discharged home. When I got home, I still did not feel good, I felt heaviness to my chest, still have trouble breathing and get chills during the night. I also could not stand up and have a nerve sensation to my body and the chest pain to my left side is still very present. I have blurry vision, dizziness, headaches, and my heart-beat continues to race very fast. I get headaches, have abdominal pain and I peed blood few times then that's when I was able to pee, my abdominal pain was painful like having a baby. On Friday 04-08-2021, I again went to the hospital because I had fallen to the floor on my kitchen floor and my daughter took me to the hospital. I let the nurse staff know that I still have continued chest pain and pressure, difficulty breathing and headaches, dizziness and they monitored and gave me three pills as medication. I was discharged home about 5pm with a referral to see a neurologist due to my chest pain, blurry vision, dizziness and fever which I had these past three weeks. I do not know why I felt all these symptoms after my J&J vaccine.</p> |

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| 1314819 | 5/13/2021 | CA | 26 | F | 4/28/2021 | 4/28/2021 | After receiving the vaccine about five minutes later my Chest became very heavy and painful my throat felt like I?m knot closing and I passed out I was woken up at the site but I was unresponsive all I remember was them telling me to stay awake the ambulance is on the way I became very nauseous |
| 1314755 | 5/13/2021 | NH | 29 | F | 5/13/2021 | 5/13/2021 | Patient had difficulty breathing, fainted, gasping for breath, given epinephrine injection in thigh, started to become conscious and breath more easily, then started vomiting. Called 911 in meantime. Patient taken to hospital. |
| 1314775 | 5/13/2021 | VA | 13 | F | 5/13/2021 | 5/13/2021 | The patient fainted approximately 10 to 15 minutes after receiving the vaccine. She and her father walked to the front register and were waiting in line when she fell. We called 911 and monitored her closely until they came. The patient was coherent and talking and said she was not in pain. Paramedics came and took her to the hospital. |
| 1314780 | 5/13/2021 | WA | 29 | M | 5/13/2021 | 5/13/2021 | Pt recv'd Covid-19 J&J vaccine. Aprox 5-10 minutes after shot pt passed out in wife's arms. Our Technician dialed 911. We assisted in lowering him to the ground. I elevated his feet slightly and he slowly came back. Pt stated he was slightly dizzy but felt fine for the most part. Ems arrived and took over care. |
| 1314744 | 5/13/2021 | KS | 19 | M | 5/13/2021 | 5/13/2021 | pt fainted approx 2 minutes after vaccination while sitting in waiting area. 911 was called. Pt was placed supine and was unconscious for approx 60 seconds with involuntary movements of arms and upper body consistent to passing out (not seizure like in intensity). confused, clammy/nauseas upon awakening, remained supine for 2-3 minutes. upon sitting up pt became dizzy and laid down again. paramedics arrived began assessment. BP, EKG, BG all normal. pt reports not having eaten today, also reports congenital heart defect that was corrected surgically while an infant. Mother arrived and decision was made in conjunction with paramedics to take pt to hospital for further eval based on his symptoms of lightheadedness/nausea continuing. |

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| 1314859 | 5/13/2021 | PA | 25 | F | 5/13/2021 | 5/13/2021 | patient laid down because becoming light headed, never passed out but was "jittery", BP and HR remained within normal range |
| 1309971 | 5/12/2021 | NY | 22 | M | 5/11/2021 | 5/11/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Severe, Systemic: Hypotension-Medium, Systemic: Nausea-Severe, Systemic: Tachycardia-Severe, Additional Details: Pt has vaso-vagal reaction: syncope, low blood pressure, increased pulse, profuse sweating |
| 1309974 | 5/12/2021 | FL | 21 | F | 5/11/2021 | 5/11/2021 | Systemic: Fainting / Unresponsive-Mild |
| 1309980 | 5/12/2021 | TX | 27 | M | 5/8/2021 | 5/8/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Seizure-Mild, Systemic: Shakiness-Mild, Additional Details: Patient fainted and had seizures like symptoms along with cramps. Patient fainted for less than a minute. Was breathing and talking soon afterwards. 911 was called. |
| 1309982 | 5/12/2021 | TX | 42 | M | 5/11/2021 | 5/11/2021 | Systemic: Confusion-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Severe, Systemic: Nausea-Severe, Systemic: Vomiting-Severe, Additional Details: patient was given jassen vaccine. during 15 minutes observation. patients appeared to black out for 3 seconds. patient can breath ok. no epipen injection was given. after 30 min. patient is coherent. BP 117/75. normal sinus rythm. 911 was called. Patient stated that he doesnt want to go to the hospital and doing fine. Patient had pee himself. |
| 1310064 | 5/12/2021 | FL | 61 | M | 5/8/2021 | 5/8/2021 | Patient fainted and fell on the floor, as soon as he left the room to wait in the observation area for 15 minutes. He was conscious and oriented, We called 911, they took care of him and got him out of the store. He didn't go to the hospital, and said that he felt much better as soon as they gave him water. |
| 1309990 | 5/12/2021 | IL | 33 | M | 5/11/2021 | 5/11/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Mild, Systemic: Headache-Mild, Systemic: Tingling (specify: facial area, extremities)-Mild |

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| 1309955 | 5/12/2021 | CA | 30 | F | 5/10/2021 | 5/10/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Additional Details: pt stated "im going to pass out" rn help her to floor she recovered immediatly. gave water and candy. pt forgot to mention and document history of passing out or black out after immunization. pt is fine and doing well |

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| 1309295 | 5/12/2021 | KY | 18 | M | 3/30/2021 | 4/29/2021 | <p>Passed out; Hallucination; Chest tightness; Sore arm; Headache; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out) and HALLUCINATION (Hallucination) in an 18-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 039B21A and 008B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 30-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 29-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 29-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (Passed out) (seriousness criterion hospitalization), HALLUCINATION (Hallucination) (seriousness criterion hospitalization), CHEST DISCOMFORT (Chest tightness), PAIN IN EXTREMITY (Sore arm) and HEADACHE (Headache). At the time of the report, LOSS OF CONSCIOUSNESS (Passed out), HALLUCINATION (Hallucination), CHEST DISCOMFORT (Chest tightness), PAIN IN EXTREMITY (Sore arm) and HEADACHE (Headache) outcome was unknown. Patient was hospitalized due to vehicular accident. Concomitant product use was not provided by the reporter. No treatment information was provided. The patient received both scheduled doses of mRNA-1273 prior to the events, therefore action taken with the drug in response to the events was not applicable. Based on current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded.; Sender's Comments: Based on current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded.</p> |
| 1310065 | 5/12/2021 | TX | 19 | M | 5/11/2021 | 5/11/2021 | <p>Patient felt dizzy about 1-2 minutes after receiving the vaccine. He was on his way to the chair in the waiting area when he fainted and fell into a Lysol display.</p> |
| 1309989 | 5/12/2021 | TX | 18 | M | 5/11/2021 | 5/11/2021 | <p>Systemic: Fainting / Unresponsive-Medium</p> |

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| 1309950 | 5/12/2021 | CT | 21 | F | 5/11/2021 | 5/11/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Nausea-Medium |
| 1309948 | 5/12/2021 | PA | 27 | M | 5/4/2021 | 5/4/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Severe, Systemic: Hypotension-Severe, Additional Details: Pt asked for some water then tilted his head back and passed out. He was very warm and sweaty. My technician and I lowered him to a exercise mat where he recovered. I offered him water and a granola bar. He drank the water, declined the bar. Pt was observed in waiting area for 30 min. I suggested he call a friend or family member to pick him up, he said he was ok to drive. |

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| 1309531 | 5/12/2021 | TX | 39 | F | 2/4/2021 | 4/21/2021 | blood pressure drop; nearly fainted; chest pain; jaw pain; loss of vision; Multiple bilateral pulmonary embolisms in my lungs; This is a spontaneous report from a contactable consumer (patient). A 40-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection) (at 39 years of age), via an unspecified route of administration, administered in arm left on 04Feb2021 (Batch/Lot Number: EN6202) as 2nd dose, single for COVID-19 immunisation. Medical history included MTHFR blood clotting gene mutation. Concomitant medications included citalopram, metoprolol, omeprazole and minastein fe24, all taken for an unspecified indication, start and stop date were not reported. Historical vaccine included BNT162B2 (lot number: EN9581) dose 1 on an unknown date (also reported as 04Feb2021) 01:00 PM in left arm for COVID-19 immunisation. The patient was not pregnant. The patient did not have any other vaccine within 4 weeks prior to the COVID vaccine. She was not diagnosed with COVID-19 prior to vaccination. She had not been tested for COVID-19 prior since vaccination. It was reported that 6 weeks after the second dose on 21Apr2021 12:00, the patient had a blood pressure drop, nearly fainted, chest pain, jaw pain, loss of vision. She went to emergency room (ER), they did tests and found multiple bilateral pulmonary embolisms in her lungs. The adverse events resulted in Emergency room/department or urgent care. Therapeutic measures were taken as a result of the events, Eliquis (reported as 'Eloquis') blood thinners given. The patient was hospitalized for the events for one day. The outcome of the events was not recovered. Information on the batch lot/batch number has been obtained. |

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| 1309527 | 5/12/2021 | AR | 49 | M | 2/3/2021 | 2/3/2021 | <p>have some clots; Neuropathy; autoimmune disorder; Fell and hit elbow and 3 ribs on left side; lost 6 (lbs) pounds/Within 2 months, he has lost 47 lbs and eats all the time and is still losing weight; falling; felt super strong; dizziness; failed all the tests for motor skills for his arms and legs; Fell and hit elbow and 3 ribs on left side; Fell and hit head; Sensory nerves are all gone; Fatigue; scabs; delusional; tore tendons in between ribs; They are tender(ribs); hurting all over; Cannot walk or lift anything; chest pain; his arm was sore a little; Left arm injection site pain; Disoriented; This is a spontaneous report from a contactable consumer (patient). A 49-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 1 intramuscular, administered in left arm on 03Feb2021 (batch/lot number and expiration date not reported) at the age of 49 years old, as 1ST DOSE, SINGLE for COVID-19 immunisation. Medical history included COVID-19 from Dec2020 to an unknown date, vascular disease, bilateral stents placement, cataracts since he was born. Concomitant medication included gabapentin taken for an unspecified indication from an unspecified start date and ongoing. On 04Feb2021, the patient experienced left arm injection site pain. The patient experienced dizziness, falling, and couldn't go to work on unspecified date. He was treated by his (MD) physician, was given a CT scan, echocardiogram, and found to have some clots. He stated he has a history of vascular disease and had bilateral stents placed a year ago. He was placed back on an aspirin/Plavix regimen and referred to a neurologist because he has no motor skills anymore. He stated he failed all the tests for motor skills for his arms and legs. He was advised not to take the second dose of the vaccine and was diagnosed with neuropathy and autoimmune disorder (caller does not specify which disorder). He reported being positive for Covid-19 in Dec2020. He wanted to know what else he can do for his symptoms and is offering to be tested by Pfizer for treatment. The symptoms come in really hard seven days later. He actually had to go to the (ER) emergency and they worked on him and a whole string of doctors. He went to the emergency room and something was going on and wanted him to go to a family practitioner. They sent him to vascular, neurological and now they want to send him to a research center. It was a</p> |

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whole week after receiving vaccine before he began having symptoms. With the neuropathy and autoimmune, he cannot work like he did. He can hardly walk. Unspecified autoimmune was diagnosed last week. He can't remember the name of it. They told him not to take second one because the first one did what it did to him. It hurt a little and it was quick. The next day (04Feb2021), he said his arm was sore a little. He is only taking 4 medications and they looked it up. He did not think they were relevant. He was disoriented and fell and hit his head a couple of times. They ran an MRI on his head trying to figure that part out. That was done last week. He doesn't know the date and said it may have been on Friday. Results were good. The date he was disoriented was Wednesday 03Feb2021, when he took the shot. He has been disoriented and has been that way ever since. They kept him for 15 minutes to make sure no one passed out. He has been disoriented since then. He could not think clearly, and he could not do his job. He tore tendons in between ribs. He first thought he actually broke his ribs, but did not. There were two different falls. He cannot feel feet or anything. His motor skills are OK but when they did neuropathy test, they put needles in and shocked him to make his motor fire. His reflexes were really bad. He fell and hit elbow to keep from falling on face and twisted going down hitting 3-4 ribs on left side. It has been over 3 weeks now for his ribs. They are tender but they are not like the initial blow. It feels like they are healing. He fell and hit head a week ago. He was unsure of the exact date. He did not go to the emergency room with this one because the bed caught him. He fell and hit his head. All he has left is scabs. He cannot walk or lift anything (11Feb2021). That next Wednesday, he got ready to go to work and was so delusional and could not go in. He slept from 5:30 all that day and all that night. Then Thursday, he gets up and goes to work and goes slower, just to see what happened on Wednesday. He had fatigue and was disoriented. He did not provide start date or outcome for fatigue. He walked in and said either call an ambulance or he would go home. He went home and that was the last day of work. He then stated he laid in the car for 30 minutes and he said he is going to the emergency room. He went straight there that day. He had stents put in lower part of his body a year before. The neuropathy and

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the autoimmune kicked in 7 days later after the shot. The reason he went to the ER is because he thought it was his stent. He had bilateral, 4 of them. He was having chest pain and hurting all over on 11Feb2021. He thought he was having a heart attack. He was seen in the emergency room and released. It depends on how far he goes, how the chest pain worsens. Right now, he is ok, but when he gets up and moves around, it does the same thing. Within 2 months, he has lost 47 lbs and eats all the time and is still losing weight. He was about 200 something and was kind of built and now is skin and bones. He lost 6 (lbs) pounds within a week and is eating like crazy. Sensory nerves are all gone. If hit with a baseball bat and he would not feel it. It came on slowly almost that he did not know it was happening. That is why they want to send him to Privacy for a research center and he does not want to go. He never had this happen before. ER or physician's office required: 1st date was on Thursday, 11Feb2021, when he went to Privacy. He was having chest pain and hurting all over. He thought he was having a heart attack. He was released. The patient stated he wanted to change the information he had provided since he was not in his right mind since he had taken the wrong medication dose than the doctor had given him. He stated the medication dosage he wanted to change was for Amiripyin. He stated he wanted to say he told the representative the symptoms he had experienced was enhanced which they were yesterday because he was trying to fight everything and stay awake. COVID 19 vaccine: he stated the doctor did not want him to take the second dose of the vaccine. He stated one of the symptoms he had experienced after the vaccine that he wanted to change the outcome for is the neuropathy. He stated he is back to where he used to be and yesterday it was bad he could hardly walk or talk. He stated also the other symptoms he wanted to change the outcome for is the autoimmune. The patient has not recovered from neuropathy, autoimmune disorder, disoriented, can't walk or lift anything, chest pain, and sensory nerves all gone; while outcome of the remaining events was unknown. Information on the lot/batch number has been requested.

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| 1309381 | 5/12/2021 | MN | 18 | M | 5/10/2021 | 5/11/2021 | Patient stated that at 3am the following day he was cold, sweating and weak. He got up and fell on the floor twice and passed out twice. The whole episode lasted 5 to 10 minutes. The rest of the day he was tired, but not to the extent of the 3am episode. |
| 1309308 | 5/12/2021 | UT | 18 | F | 5/3/2021 | 5/3/2021 | passed out; Anxiety; right now she has trouble breathing; nauseous; This spontaneous case was reported by a non-health professional (subsequently medically confirmed) and describes the occurrence of LOSS OF CONSCIOUSNESS (passed out) in an 18-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 007C2LA) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No medical history was provided by the reporter. Concomitant products included FLUOXETINE for an unknown indication. On 03-May-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 03-May-2021, the patient experienced LOSS OF CONSCIOUSNESS (passed out) (seriousness criterion medically significant), ANXIETY (Anxiety), DYSPNOEA (right now she has trouble breathing) and NAUSEA (nauseous). On 03-May-2021, LOSS OF CONSCIOUSNESS (passed out) and NAUSEA (nauseous) had resolved. At the time of the report, ANXIETY (Anxiety) and DYSPNOEA (right now she has trouble breathing) had not resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Treatment of events at was reported as medic was about to give oxygen. The patient did not know if it was her oxygen or heart rate that was low but she became conscious. Patient is worry about taking second dose. She asked if something bad will happen if she stopped at first dose. |

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| 1309288 | 5/12/2021 | NC | 46 | F | 4/9/2021 | 4/10/2021 | <p>hyperthyroidism; Tachycardia/Increased heart Rate; fainted; Sweaty; Clammy; Dehydrated; extremely fatigued; Nausea; Bad Headache; This spontaneous case was reported by a pharmacist (subsequently medically confirmed) and describes the occurrence of HYPERTHYROIDISM (hyperthyroidism), TACHYCARDIA (Tachycardia/Increased heart Rate) and SYNCOPE (fainted) in a 46-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 032821A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Syncope in March 2020 and COVID-19 virus test positive on 16-Feb-2021. Concomitant products included MAGNESIUM OXIDE, ASPIRIN [ACETYLSALICYLIC ACID], UBIDECARENONE (COQ 10) and COLLAGEN for an unknown indication. On 09-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 10-Apr-2021, the patient experienced HYPERTHYROIDISM (hyperthyroidism) (seriousness criterion medically significant), TACHYCARDIA (Tachycardia/Increased heart Rate) (seriousness criterion medically significant), SYNCOPE (fainted) (seriousness criterion medically significant), HYPERHIDROSIS (Sweaty), COLD SWEAT (Clammy), DEHYDRATION (Dehydrated), FATIGUE (extremely fatigued), NAUSEA (Nausea) and HEADACHE (Bad Headache). At the time of the report, HYPERTHYROIDISM (hyperthyroidism), TACHYCARDIA (Tachycardia/Increased heart Rate), SYNCOPE (fainted), HYPERHIDROSIS (Sweaty), COLD SWEAT (Clammy), DEHYDRATION (Dehydrated), FATIGUE (extremely fatigued), NAUSEA (Nausea) and HEADACHE (Bad Headache) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 10-Apr-2021, Blood pressure measurement: 120/80 mmhg (normal) 120/80. On 10-Apr-2021, Heart rate: 108 bpm (High) 108 bpm. On an unknown date, Blood pressure measurement: 110/60 mmhg (Low) 110/60. On an unknown date, Blood thyroid stimulating hormone: elevated (High) Elevated. On an unknown date, Electrocardiogram: normal (normal) normal. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown),</p> |

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the reporter did not provide any causality assessments. On an unknown date, T3 and T4 investigations were done; however, results were pending. Treatment medication included Tylenol. This case concerns a 46-year-old female with serious unexpected events of hyperthyroidism, tachycardia, syncope, and nonserious unexpected hyperhidrosis, cold sweat, dehydration, and nonserious expected fatigue, nausea, headache. Latency 2 days after first dose mRNA-1273. Event outcomes unknown. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.; Sender's Comments: This case concerns a 46-year-old female with serious unexpected events of hyperthyroidism, tachycardia, syncope, and nonserious unexpected hyperhidrosis, cold sweat, dehydration, and nonserious expected fatigue, nausea, headache. Latency 2 days after first dose mRNA-1273. Event outcomes unknown. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.

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| 1309180 | 5/12/2021 | FL | 62 | F | 4/1/2021 | | <p>SORES IN MOUTH; DRY MOUTH; TONGUE RAW BLEEDING; STABBING TO FEET; TINGLING; LEG CRAMPS; MUSCLE PAINS; ABDOMINAL PAIN; TEMPERATURE CHANGES CHILL ON AND OFF THEN REALLY HOT THESE COME AND GO; BLURRED VISION THERE TO VERTIGO; MULTIPLE SOMATIC COMPLAINTS; STOMACH GETS NAUSEATED; COULDN'T SLEEP; VERTIGO; PASS OUT FAINTING FEELING; This spontaneous report received from a patient concerned a 62 year old female. The patient's height, and weight were not reported. The patient's pre-existing medical conditions included no allergy reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 205A21A, and batch number: 205A21A expiry: UNKNOWN) dose was not reported, administered on 11-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On APR-2021, the subject experienced couldn't sleep. On APR-2021, the subject experienced vertigo. On APR-2021, the subject experienced pass out fainting feeling. On APR-2021, the subject experienced blurred vision there to vertigo. On APR-2021, the subject experienced multiple somatic complaints. On APR-2021, the subject experienced stomach gets nauseated. On APR-2021, the subject experienced temperature changes chill on and off then really hot these come and go. Laboratory data included: Chest X-ray (NR: not provided) chest x-ray was clear, Diagnostic ultrasound (NR: not provided) saw nothing, and Laboratory test (NR: not provided) looked very good. On 11-APR-2021, the subject experienced abdominal pain. On 13-APR-2021, the subject experienced muscle pains. On 15-APR-2021, the subject experienced leg cramps. On 30-APR-2021, the subject experienced tingling. On 30-APR-2021, the subject experienced stabbing to feet. On 01-MAY-2021, the subject experienced sores in mouth. On 01-MAY-2021, the subject experienced dry mouth. On 01-MAY-2021, the subject experienced tongue raw bleeding. Treatment medications (dates unspecified) included: meclizine hydrochloride/nicotinic acid. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from leg cramps, abdominal pain, muscle pains, sores in mouth, dry mouth, tongue raw bleeding, tingling, and stabbing to feet, and the outcome</p> |

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| | | | | | | of multiple somatic complaints, temperature changes chill on and off then really hot these come and go, stomach gets nauseated, couldn't sleep, vertigo, pass out fainting feeling and blurred vision there to vertigo was not reported. This report was non-serious.; Sender's Comments: V0 Medical assessment comment not required as per standard operating procedure as the case assessed as non-serious. |
| 1310833 | 5/12/2021 | TX | 19 | M | 5/11/2021 | 5/11/2021 Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild |
| 1310834 | 5/12/2021 | AZ | 25 | F | 4/7/2021 | 4/7/2021 was feeling ill, weak, said she was having some kind of reaction to shot, fainted was taken by ambulance to the hospital , she got a concussion, broke her nose and chipped tooth, was in the hospital 3 days |

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| 1309312 | 5/12/2021 | NC | 22 | M | 3/23/2021 | 4/20/2021 | Headache; Chills; Vertigo; Nausea; He threw up for about 20 minutes; He feels odd here and there; Random onset on backpain now, in the lumbar area; He almost passed out; Heart beat was 130; Fever of 100.6; This spontaneous case was reported by a non-health professional (subsequently medically confirmed) and describes the occurrence of LOSS OF CONSCIOUSNESS (He almost passed out), HEADACHE (Headache), CHILLS (Chills), VERTIGO (Vertigo), NAUSEA (Nausea) and VOMITING (He threw up for about 20 minutes) in a 22-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 046B21A and 037A21B) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 23-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 20-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 20-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (He almost passed out) (seriousness criterion medically significant), VERTIGO (Vertigo) (seriousness criterion hospitalization), NAUSEA (Nausea) (seriousness criterion hospitalization), VOMITING (He threw up for about 20 minutes) (seriousness criterion hospitalization) and TACHYCARDIA (Heart beat was 130). On 20-Apr-2021 at 10:00 PM, the patient experienced HEADACHE (Headache) (seriousness criterion hospitalization) and CHILLS (Chills) (seriousness criterion hospitalization). On an unknown date, the patient experienced FEELING ABNORMAL (He feels odd here and there), BACK PAIN (Random onset on backpain now, in the lumbar area) and PYREXIA (Fever of 100.6). At the time of the report, LOSS OF CONSCIOUSNESS (He almost passed out), HEADACHE (Headache), CHILLS (Chills), VERTIGO (Vertigo), VOMITING (He threw up for about 20 minutes), TACHYCARDIA (Heart beat was 130), FEELING ABNORMAL (He feels odd here and there), BACK PAIN (Random onset on backpain now, in the lumbar area) and PYREXIA (Fever of 100.6) outcome was unknown and NAUSEA (Nausea) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 20-Apr-2021, Body temperature: 100.6 |

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| | | | | | | (High) 100.6. On 20-Apr-2021, Heart rate: abnormal (abnormal) Resting heart rate was 130. Additionally irregular heartbeat reported.. Patient got to the hospital where he was given pain medication and medication for vertigo. He was in the hospital for 6.5-7 hours. When he was discharged nausea went away and it took him 48 hours after ER visit to feel normal. Concomitant medication information not provided. Action taken with mRNA-1273 in response to the events was not applicable. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. This case was linked to US-MODERNATX, INC.-MOD-2021-114588 (E2B Linked Report).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. US-MODERNATX, INC.-MOD-2021-114588:dose 1 | |
| 1311964 | 5/12/2021 | DE | 31 | F | 5/12/2021 | 5/12/2021 | Pt Came to outdoor clinic and received Janssen Vaccine in a her left arm seated in a chair. Five minutes later patient felt dizzy and passed out. Patient was lowered to the floor and woke back up immediately. Pt remained in a lying position and was slowly helped up into a sitting position. Pt stated she felt dizzy once again and passed out. Pt again immediately came to and stated she was embarased. Pt remained alert and oriented inside the trailer in lying position. Vital signs stable @5:45pm , BP 100/60, P66 ,T96.7, P66. EMS called to the scene . Vitals taken again at 6:00pm BP 110/70, P55, POx 99. Pt refused to be transported to the hospital and said she feels fine . Pt left with her boyfriend at 6:15 pm |
| 1312611 | 5/12/2021 | CA | 17 | F | 5/12/2021 | 5/12/2021 | Patient was in recommended observation and was on the phone with her father and told him she began to feel nauseous. Shortly after she leaned forward from the chair and fell to the ground passed out. Her blood pressure was checked immediately and found to be 121/81. She was immediately responsive and said she still felt nauseous and light headed. EMT was called and they arrived within 10 minutes. Her father also arrived on scene. EMT determined that no serious medical treatment was required and patient left with her father to drive her home. |

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| 1310340 | 5/12/2021 | IL | 17 | M | 5/12/2021 | 5/12/2021 | patient was found to have fainted in the waiting area. Reports hitting his head, but was conscious by the time we examined him. A+Ox3, vision intact, speaking normally, complaining of slight pain where he hit his head |
| 1312592 | 5/12/2021 | CA | 18 | M | 5/12/2021 | 5/12/2021 | Attendee was found laying on his back on the floor of the observation area and appeared pale skin, eyes open. breathing effortlessly. Attendee was assessed by me and I asked him his name. No response. Said Hello, can you hear me? Attendee responded "yes". I asked patient to tell me how he was feeling and he said I feel dizzy. Blood pressure was taken 152/ 66 pulse 76 SpO2 98%. Attendee informed he appeared to have fainted. Stated he did not have any symptoms or problems like this after first dose. States he did have breakfast. Remembers walking to chair after shot and was watching Anime on his phone and then I asked him if he could hear me. Patient denies SOB, chest pain, no S/S of swelling, itching , redness, denies headache. Sat up with assistance on floor. Offered saltine crackers and Nestle sugar water which he drank. Patient stood with assistance back to chair. No symptoms of nausea, vomiting, headache or dizziness. Second BP taken 132/66 Pulse 66, SPO2 99%. Attendee reported he drove himself to clinic. Advised to call for ride home. Patient called his father who arrived and identified to pick him up at 11:58. Observed patient until father came and answered questions from father. Home care instructions reiterated. Attendee walked to exit by me. |
| 1312456 | 5/12/2021 | IA | 35 | M | 5/3/2021 | 5/4/2021 | Death. While driving patient passed out and was found by County Sheriffs Office. EMT was called and could not save patient. M.E. Declared patient dead at 7:20 PM on May 4, 2021 |
| 1311968 | 5/12/2021 | IN | 29 | M | 5/12/2021 | 5/12/2021 | WITHIN 5 MINUTES OF RECIEVING THE VACCINE THE PATIENT FAINTED. MYSELF AND ANOTHER PHARMACIST SAFELY GOT HIM TO THE GROUND. WE TOOK HIS BLOOD PRESSURE WHICH WAS FINE. WE BELIEVE IT WAS JUST FAINTING DUE TO GETTING A VACCINE. WE GAVE HIM WATER AND GATORADE AND WITHIN 10 MINUTES HE WAS BACK TO NORMAL. |

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| 1311736 | 5/12/2021 | PA | 25 | F | 5/12/2021 | 5/12/2021 | PATIENT FAINTED (SYNCOPE) 8 MINUTES AFTER INJECTION |
| 1311728 | 5/12/2021 | FL | 81 | F | 2/19/2021 | 2/20/2021 | Syncope leading to fall 24 hours post vaccine Deep venous thrombosis 2 weeks post vaccine |
| 1311667 | 5/12/2021 | WA | 33 | F | 4/7/2021 | 4/8/2021 | The day after the vaccine I was sitting at work at 11:00am and I got a wave of lightheadedness and nausea. I passed out when I tried to stand and I was taken by ambulance to the ER. There were no identifiable problems. I was 23 weeks pregnant. I still felt a little lethargic for another week and then I was fine. I have not had any other problems. Due Date- 07/31/2021 Pregnancy-First pregnancy |
| 1311530 | 5/12/2021 | TX | 18 | F | 5/12/2021 | 5/12/2021 | Patient's boyfriend called over and stated she was reported feeling faint, lightheaded, dizzy, looked pale in the face and broke out into sweats and with cold clammy skin. I had her sit in head down position for several minutes and started to monitor her vitals. Prior to vaccine pt was having severe anxiety and has a history of syncope with blood draws. After several mins of her sitting with ehr head down I checked her blood pressure and it was elevated 155/109 mmHg. 10 minutes later pt felt a little better but started to feel faint and dizzy again. I called emergency sevices and EMS arrived at the scene, assessed the patient and diagnosed her with anxiety/syncope. She opted out from going to the hospital with them. She left the store at 1:01 pm and felt alot better and stated she had an appt with her PCP at 3pm to further seek medical treatment if deemed necessary |
| 1311518 | 5/12/2021 | PA | 23 | M | 5/12/2021 | 5/12/2021 | patient fainted for several seconds after receiving vaccine, emts called as a precaution |
| 1310989 | 5/12/2021 | IL | 45 | M | 4/20/2021 | 4/28/2021 | patient was Diagnosed with Pulmonary Embolism after her second covid vaccine. patient symptoms were dyspnea and syncope . Patients treatment is to take Eliquis everyday. |
| 1310837 | 5/12/2021 | NY | 34 | M | 5/12/2021 | 5/12/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Tingling (specify: facial area, extremities)-Medium |

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| 1311976 | 5/12/2021 | GA | 37 | M | 5/12/2021 | 5/12/2021 | Couple of minutes after injecting Janssen covid-19 vaccine to the patient, I was alerted to help patient. I found him passed out on the chair, face pale, forehead sweating. I talked to him trying to get a response. I called out to my tech to call 911. patient was now somewhat awake. a nurse was in the store and she helped me. we got blood pressure monitor. nurse applied ice pack beyond head. Initial blood pressure was 99/14 pulse 45, couple minutes later, blood pressure 104/65 pulse 62. patient is now awake and aware of surroundings. we had him drink juice. blood pressure 128/71 pulse 81. fire rescue came and patient is now totally coherent. patient did not want to go to ER. blood pressure 121/69 pulse 70. patient and family waited for a while and left. |
| 1311477 | 5/12/2021 | OR | 18 | M | 5/12/2021 | 5/12/2021 | Patient was turning around to look at their brother, then suddenly fainted and fell on the floor. Patient got up soon after. |
| 1310872 | 5/12/2021 | PA | 32 | M | 5/12/2021 | 5/12/2021 | Site: Pain at Injection Site-Mild, Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: pt fainted-Medium, Systemic: Flushed / Sweating-Medium |
| 1310977 | 5/12/2021 | | 38 | M | 5/12/2021 | 5/12/2021 | Syncope x2 |
| 1311012 | 5/12/2021 | FL | 57 | F | 4/8/2021 | 4/8/2021 | 15 to 20 minutes after the shot I got very hot/clammy, weak and confused the employee health nurse came to check on me and told me to come to her office and I passed out. I was taken to the ER and kept there approx. 5 hours. I was extremely weak, could not lift my head and had trouble forming thoughts and words. They gave me medication via IV's and observed me. I started to feel better after about 4 hours after the vaccine, but have had more headaches than usual after receiving it. I still have some issues with being upset and anxious about the reaction and if it will have long term adverse effects on me. I will never get another vaccine of any type again. |

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| 1311189 | 5/12/2021 | TN | 46 | M | 5/12/2021 | 5/12/2021 | Patient fainted post vaccination. Patient was seated in our post vaccine area in a chair with arms. Within a few minutes patient collapsed into the floor, was hot/sweating and a little disoriented. Patient regained consciousness, applied wet compress and rested in a seated position with head down. Began feeling better. Patient provided with a bottle of water. Patient remained on our site for another 30 minutes until felt better and stable. |
| 1311195 | 5/12/2021 | FL | 18 | M | 5/12/2021 | 5/12/2021 | Pt received vaccine and sat down in observation and passed out after 3 mins in observation. Pt monitored for an additional 30 minutes then cleared by medical professional to go home with parent. |
| 1311232 | 5/12/2021 | AZ | 51 | F | 5/8/2021 | 5/8/2021 | Hives appeared on torso within 2 hours of vaccine administration. By the evening of the vaccine, hives/rash spread to entire body and fever set in. Fever of 102 degrees reported and low grade fever continues as of 5-12-21. The patient fainted within 24 hours after vaccination and EMT was called. Syncope lasted just under one minute. No tests were ordered but she was prescribed an EPINEPhrine injector and PredniSONE to treat and she is scheduled for a follow up on 5-17-2021. |

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| 1311467 | 5/12/2021 | PA | 80 | F | 3/9/2021 | 3/10/2021 | Patient received Moderna COVID-19 vaccine #1 on 02/09/2021. Patient received Moderna COVID-19 vaccine #2 on 03/09/2021. Patient admitted to hospital 03/10/2021 through 03/11/2021 due to syncope on 3/11/2021. Patient had gotten up out of bed to go to the bathroom, called out to her husband then had syncopal episode and fell to the floor. According to husband, she had loss of consciousness for 5 minutes. Per husband and EMS, she then had another syncopal episode after taking a few steps and then collapsed. No urinary incontinence. Syncope occurred day after receiving 2nd dose of COVID-19 vaccination. CT brain as well as CT cervical spine negative for acute abnormality or cervical fracture. Hemodynamically stable. Cardiac enzyme negative x 2. EKG negative for acute abnormality or arrhythmia but with baseline abnormalities. Suspicion was that symptom was due to vasovagal reaction to 2nd dose of COVID19 vaccine. Notably husband also reported that on 02/23/2021 patient was showering, and he then heard her calling out. He found her undressed and wet in the living room area confused. She did not know where she was. Patient also with history of TIA in 05/2020. patient with history of mild dementia. |
| 1306548 | 5/11/2021 | GA | 23 | F | 4/30/2021 | 4/30/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient's roommate called and stated she fainted briefly and asked what she should do. We told her to take benadryl and and to the ER but they didn't. We called back to try and see how she was doing and she never picked up the phone again. |
| 1306601 | 5/11/2021 | CA | 33 | M | 5/10/2021 | 5/10/2021 | Systemic: Chills-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Hypotension-Medium, Systemic: Seizure-Severe |

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| 1306559 | 5/11/2021 | OH | 21 | M | 5/8/2021 | 5/8/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Hypotension-Severe, Additional Details: Approximately 5-10 min after dose was administered the patient fainted and hit his head against the wall. He regained consciousness almost immediately. Patient was laid on his side. He was given water and crackers. The clinic nurse took him in for an appointment. His blood pressure was noted to be low. After he was determined to be stable his mother came to the pharmacy to pick him up and take him to the urgent care for further eval. He stated he had been fasting for 24 hours prior. |
| 1306553 | 5/11/2021 | NY | 46 | M | 5/10/2021 | 5/10/2021 | Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Severe, Systemic: Hypotension-Medium, Systemic: Nausea-Medium, Systemic: Seizure-Medium |
| 1306555 | 5/11/2021 | PA | 31 | F | 5/10/2021 | 5/10/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: Total event time 3 minutes max-Medium, Systemic: Hyperventilation-Medium, Additional Details: Immediately after withdrawal of the vaccination needle, the patient began to hyperventilate, then became unresponsive without her eyes closing, and leaned into her mother (who was standing next to her) from a seated position. The patient's arms became straight and tense, and she made a snoring/snorting noise. Pharmacy staff called 911. The patient came to and started to speak per her mother, and requested us to cancel the emergency services call. She was fully aware, normal breath and speech. |
| 1306552 | 5/11/2021 | NJ | 49 | F | 5/10/2021 | 5/10/2021 | Systemic: Allergic: Anaphylaxis-Medium, Systemic: Allergic: Difficulty Breathing-Severe, Systemic: Chest Tightness / Heaviness / Pain-Medium, Systemic: Exhaustion / Lethargy-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Weakness-Severe |

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| 1306575 | 5/11/2021 | UT | 46 | M | 5/10/2021 | 5/10/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Hypotension-Medium, Additional Details: Patient fainted after receiving vaccine, he tipped forward in his chair and hit his head on counter in front of him. 2 minor laceration on forehead and cut upper lip. Pt unconscious for less than 1 minute. Blood pressure taken about 5 minutes later and was 65/40. 911 was called and paramedics arrive on scene. Care was transferred to them |
| 1306584 | 5/11/2021 | MD | 50 | F | 5/10/2021 | 5/10/2021 | Systemic: Fainting / Unresponsive-Severe, Additional Details: patient unresponsive while very stiff for several minutes. has happened before with bloodwork. |
| 1306667 | 5/11/2021 | ME | 59 | M | 5/3/2021 | 5/3/2021 | He got his vaccine, was in the store at the meat counter and then had a visual effect as people were looking at him funny, and things went from black/white to black/gray/white and passed out (told he had a seizure and on film at the grocery store), then woke up in the back of the ambulance on the way to the hospital. In the hospital he was given an injection to slow his heart rate down, said that he drank a pot of coffee and then had another 16 oz coffee after that. He was not admitted, treated in the ER, fed him and was discharged home and then walked about 1/2 mile to his truck at the supermarket, and finished his shopping. He has been a little tired since then, has been taking it easy and not pushing himself too hard and not working too many hours. |
| 1306586 | 5/11/2021 | FL | 60 | M | 5/10/2021 | 5/10/2021 | Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Severe, Systemic: Nausea-Medium, Systemic: Seizure-Mild, Systemic: Shakiness-Medium, Systemic: Vomiting-Mild |
| 1306597 | 5/11/2021 | AR | 23 | M | 5/8/2021 | 5/8/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Nausea-Mild, Systemic: Shakiness-Mild, Additional Details: Patient was laid flat to avoid fainting and recovered within 15 minutes |
| 1306545 | 5/11/2021 | OH | 23 | M | 5/10/2021 | 5/10/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Medium, Systemic: Hypotension-Medium, Additional Details: never unresponsive |

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| 1304908 | 5/11/2021 | PR | | F | | | Reflex syncope (vasovagal reflex); Decreased blood pressure 60/40; This is a spontaneous report from a contactable consumer (parent). A 26-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration, on an unspecified date (Batch/Lot number was not reported) as single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced decreased blood pressure 60/40 and reflex syncope (vasovagal reflex) on unspecified date. The clinical outcome of decreased blood pressure 60/40 and reflex syncope (vasovagal reflex) was unknown. Information about lot/batch number has been requested. |
| 1306588 | 5/11/2021 | NY | 21 | M | 5/10/2021 | 5/10/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Mild, Additional Details: Collapsed about 1 minute after receiving shot for about 30 seconds. Called 911 and paramedics arrived. He was able to walk out without assistance. |
| 1306543 | 5/11/2021 | NJ | 31 | F | 5/10/2021 | 5/10/2021 | Systemic: Allergic: Difficulty Breathing-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Hypotension-Medium, Systemic: Vomiting-Severe, Systemic: Weakness-Medium |
| 1306533 | 5/11/2021 | CT | 28 | M | 5/10/2021 | 5/10/2021 | Systemic: Chills-Mild, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Nausea-Medium, Systemic: Vomiting-Mild |
| 1304847 | 5/11/2021 | CA | 70 | F | 5/10/2021 | 5/10/2021 | After patient received the vaccine of Janssen I saw a hand shake. When I was going over side effect patient's hand was shaking more. I asked the patient if hand shaking was normal she stated no and she passed out. I was able to her upper body from falling. I asked her husband to hold her and I got an epinephrine 0.3mg Lot # 026a20aa exp 02/22. I injected epi into her left thigh. patient woke up after 20 second but she didn't have any memories what happened |

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| 1306113 | 5/11/2021 | PA | 49 | F | 5/1/2021 | 5/8/2021 | I have had 4 terrible days after the vaccine that I had to spend in bed. I had horrific severe headaches at the front of my head and at the back starting in less than 24 hours after the vaccine. On the next day I had a fever added to these headaches. I couldn't open eyes and light hurt my eyes. I had a loss of appetite and huge weakness. I couldn't walk and had literally to crawl to the bathroom. When I stood up from my bed I almost fainted. After 96 hours after vaccine I still have nausea and headaches that diminished a bit. Fever disappeared only after 96 hours. Still I'm very weak, have nausea and can't really do anything except being in bed. I have never had anything like that in my life after a vaccine. and I'm in perfect health and don't smoke, don't drink any alcohol, doing regular gym and my BMI is normal |
| 1305693 | 5/11/2021 | CT | 48 | M | 4/23/2021 | 4/24/2021 | passed out; felt dizzy; Felt fatigue; headache which lasted about 10 hours; This is a spontaneous report from a contactable consumer report for self. A 48-year-old male patient received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EW0170), via an unspecified route of administration, administered in left arm on 23Apr2021 08:30 as single dose for covid-19 immunisation. None Medical history reported. No covid prior vaccination. No other vaccine in four weeks, no Other medications in two weeks. Patient received first dose of bnt162b2 (Lot number=ER8733) on 26Mar2021 03:30 PM in left arm. About 20 hours (on 24Apr2021 04:00 AM) after injection felt dizzy, passed out. Felt fatigue and headache which lasted about 10 hours. No treatment received, Patient recovered from the events. Patient has not been tested for COVID-19 Since the vaccination. |

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| 1305647 | 5/11/2021 | IL | 27 | M | 4/10/2021 | 4/10/2021 | I received the first dose of the Pfizer vaccine. During the 15 minute evaluation, i felt nauseous, hot/sweaty and my vision got blurred to the point i passed out on the floor. After I regained conscio; I received the first dose of the Pfizer vaccine. During the 15 minute evaluation, i felt nauseous, hot/sweaty and my vision got blurred to the point i passed out on the floor. After I regained conscio; I received the first dose of the Pfizer vaccine. During the 15 minute evaluation, i felt nauseous, hot/sweaty and my vision got blurred to the point i passed out on the floor. After I regained conscio; I received the first dose of the Pfizer vaccine. During the 15 minute evaluation, i felt nauseous, hot/sweaty and my vision got blurred to the point i passed out on the floor. After I regained conscio; I received the first dose of the Pfizer vaccine. During the 15 minute evaluation, i felt nauseous, hot/sweaty and my vision got blurred to the point i passed out on the floor. After I regained conscio; I received the first dose of the Pfizer vaccine. During the 15 minute evaluation, i felt nauseous, hot/sweaty and my vision got blurred to the point i passed out on the floor. After I regained conscio; I received the first dose of the Pfizer vaccine. During the 15 minute evaluation, i felt nauseous, hot/sweaty and my vision got blurred to the point i passed out on the floor. After I regained conscio; This is a spontaneous report from a contactable consumer. A 27-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), dose 1 via an unspecified route of administration, administered in the left arm on 10Apr2021 at 15:00 (Batch/Lot Number: EW0158) at 27-years-old as a single dose for COVID-19 immunization. The patient did not receive any other vaccine within four weeks of the suspect vaccine. The patient's medical history was reported as none. There were no concomitant medications received within the two weeks of vaccination. The patient experienced: "I received the first dose of the Pfizer vaccine. During the 15-minute evaluation, I felt nauseous, hot/sweaty and my vision got blurred to the point I passed out on the floor. After I regained consciousness (medically significant, hospitalization) on 10Apr2021 at 15:00. Reported Event: The patient received the first dose of the Pfizer vaccine. During the 15-minute evaluation, the patient felt nauseous, hot/sweaty and their vision got blurred to the point where the patient passed out on the floor. After, the patient regained consciousness with the assistance from the doctors and nurses there. The patient passed out again within minutes. After the second time, the patient was placed on a stretcher and sent to the emergency room for further testing. The patient reported that he had no history of medical conditions. The patient stated "all because of my vaccine hospitalization, I acquired a |

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(some amount) medical bill. I would like to discuss assistance for handling this. I have all of the paperwork as proof. It's very unfortunate to pay this amount due a shot." Pfizer received an adverse event letter from withheld directed to Department, on 03May2021. Customer Verbatim: "On Saturday, 10April2021, I received the first dose of the Pfizer vaccine. During the 5-minute evaluation, I passed out on the floor. After I regained consciousness, I passed out again within minutes. After this, I was taken to the emergency room. I have no history of medical conditions. All because of my vaccine hospitalization, I acquired a (some amount) medical bill. I would like to discuss assistance for handling this. I have all of the paperwork as proof. " It was reported that the events required an emergency room visit and physician office visit. The patient was hospitalized due to the events from 10Apr2021 to an unknown date for 1 day (as reported). It was reported that no therapeutic measures were taken. The clinical outcome of the events was recovered on an unspecified date. The patient was not tested for COVID post vaccination. No follow-up attempts are possible; information about batch/lot number cannot be obtained.

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| 1305643 | 5/11/2021 | NY | 39 | F | 4/24/2021 | 4/25/2021 | <p>passed out; ran a fever fluctuating between 103F and 106 F (measured on three different thermometers) from 700 to 1030; severe nausea; dizziness; headache that made it impossible to sit up without vomiting; headache that made it impossible to sit up without vomiting, could not keep down liquids other than water; This is a spontaneous report from a contactable consumer or other non hcp. A 39-year-old non-pregnant female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) (Batch/Lot Number: ER8735), dose 2, via an unspecified route of administration in the left arm on 24Apr2021 at 16:30 (at the age of 39-years-old) as a single dose for covid-19 immunisation. Medical history included asthma from an unknown date and unknown if ongoing. The patient's concomitant medications were not reported. No other medications were received within 2 weeks of the vaccination. The patient did not receive any other vaccines within 4 weeks prior to the vaccination. The patient previously received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) (batch/lot number: Unknown), dose #1, via an unspecified route of administration on an unspecified date as a single dose for COVID-19 immunization and experienced no adverse effects. Prior to the vaccination, the patient was not diagnosed with COVID-19. On 25Apr2021, the patient ran a fever fluctuating between 103F and 106F (measured on 3 different thermometers) from 0700 to 1030. She experienced severe nausea, dizziness and a headache that made it impossible to sit up without vomiting. The patient could not keep down liquids other than water. She passed out at 1030 and woke at 1400. Her fever was then at 100.1F at 1400 to 1830 and would not drop further despite cold showers and Tylenol. The patient called urgent care once she could sit up at 1830 and increased the Tylenol dosage. She stated she never had this high of a fever for this sustained time period in her life. The adverse events resulted in an emergency room/department or urgent care visit via Telehealth. The patient underwent lab tests and procedures which included body temperature (25Apr2021): fluctuating between 103F and 106F from 0700 to 1030 and body temperature (25Apr2021): 100.1F at 1400 to 1830. Clinical outcome of events ran a fever fluctuating between 103F and 106F (measured on 3 different thermometers) from 0700 to 1030. She</p> |

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experienced severe nausea, dizziness, headache that made it impossible to sit up without vomiting, could not keep down liquids other than water and passed out at 1030 and woke at 1400 was unknown. It was also reported that since the vaccination, the patient had not been tested for COVID-19. Follow up needed, further information has been requested.

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| 1305028 | 5/11/2021 | MA | 78 | F | 4/20/2021 | 4/21/2021 | <p>If she walks little bit then she felt she passed out; After 2 weeks, she had shortness of breath; Dizziness; Vomiting; Chills; Headache; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of LOSS OF CONSCIOUSNESS (If she walks little bit then she felt she passed out) in a 78-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Allergy to antibiotic (all cillins), Drug allergy (ibuprofen (MOTRIN)), Sulfonamide allergy (trimethoprim/sulfamethoxazole (BACTRIM)), Allergic to cats and Asthma. Concomitant products included DILTIAZEM, LISINOPRIL and ISOSORBIDE MONONITRATE (IMDUR) for an unknown indication. On 20-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 21-Apr-2021 at 3:00 AM, the patient experienced DIZZINESS (Dizziness), VOMITING (Vomiting), CHILLS (Chills) and HEADACHE (Headache). On 03-May-2021, the patient experienced LOSS OF CONSCIOUSNESS (If she walks little bit then she felt she passed out) (seriousness criterion medically significant) and DYSPNOEA (After 2 weeks, she had shortness of breath). At the time of the report, LOSS OF CONSCIOUSNESS (If she walks little bit then she felt she passed out) had resolved and DYSPNOEA (After 2 weeks, she had shortness of breath), DIZZINESS (Dizziness), VOMITING (Vomiting), CHILLS (Chills) and HEADACHE (Headache) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Oxygen saturation: normal (normal) Normal. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. The patient received her first dose of Moderna COVID-19 vaccine on 20-APR-2021. After two weeks, she had shortness of breath and "if she walks little bit then she felt she passed out." The patient's health care provider did some test (unspecified) and everything came out normal, her lungs are clear and her oxygen level is normal. Treatment information was not reported.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of these events,</p> |

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a causal relationship cannot be excluded.

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| 1305008 | 5/11/2021 | KS | 85 | M | 3/24/2021 | 4/22/2021 | Fainted; Left rib cage injured; Aches in the bones; Ill; Fell face first into the floor, fell on my hands; Bruised his hand; Face injured; Left hip and knee is injured; Nausea; Aches in the joints; This spontaneous case was reported by a non-health professional (subsequently medically confirmed) and describes the occurrence of SYNCOPE (Fainted) and CHEST INJURY (Left rib cage injured) in an 85-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 042821A and 003821A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included COVID-19 (Patient spent 50 days in the hospital) from October 2020 to 04-Dec-2020. On 24-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 21-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 22-Apr-2021, the patient experienced SYNCOPE (Fainted) (seriousness criterion medically significant), CHEST INJURY (Left rib cage injured) (seriousness criterion medically significant), BONE PAIN (Aches in the bones), ILLNESS (Ill), FALL (Fell face first into the floor, fell on my hands), CONTUSION (Bruised his hand), FACE INJURY (Face injured), JOINT INJURY (Left hip and knee is injured), NAUSEA (Nausea) and ARTHRALGIA (Aches in the joints). At the time of the report, SYNCOPE (Fainted), CHEST INJURY (Left rib cage injured), BONE PAIN (Aches in the bones), ILLNESS (Ill), FALL (Fell face first into the floor, fell on my hands), CONTUSION (Bruised his hand), FACE INJURY (Face injured), JOINT INJURY (Left hip and knee is injured), NAUSEA (Nausea) and ARTHRALGIA (Aches in the joints) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 22-Apr-2021, Cardiac function test: normal (normal) normal (heart was ok). No relevant concomitant medications were provided. On 22 Apr 2021, patient experienced aches in his joints and bones, he was becoming ill and had nausea which triggered emergency and needing to go to bathroom. He was heading to the bathroom, he fainted and fell face first into the floor. He injured his face, fell on his hands. He had bruised his hand. His left rib cage and left hip and knee was injured. He went to the Emergency Department |

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| | | | | | | | where he was told his heart was ok, he was not delirious and consciousness was ok. He stated, it has now been a week and the bruising is still there and the stiches will be coming off tomorrow. No treatment information was provided. Action taken with mRNA in respect to the events was not applicable. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. However, the events face injury, contusion, fall, chest injury and joint injury is unlikely related to m-RNA 1273.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. However, the events face injury, contusion, fall, chest injury and joint injury is unlikely related to m-RNA 1273. |
| 1306345 | 5/11/2021 | MA | 24 | M | 5/10/2021 | 5/10/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Additional Details: patient passed out after about 7 minutes. Was unconscious for about 2 minutes. had a pulse and was breathing but Paramedics were called but patient recovered and denied further treatment |
| 1304874 | 5/11/2021 | AK | 35 | M | 5/10/2021 | 5/10/2021 | Patient received vaccine and was waiting in front of pharmacy for his allotted time. I noticed his head was down and he was kind of sunk in his chair. Went out to assist him, but he had fainted. I grabbed his shoulder and shook him for about 30 seconds and he came to. He was a little disoriented and pale and pulse was fast. he refused us calling for an ambulance. I directed him to sit on the floor. We sat and talked for about 30 minutes until he felt well enough to drive home |
| 1304857 | 5/11/2021 | MO | 29 | F | 4/1/2021 | 4/26/2021 | Chest pains, irregular heartbeat, chills, cold hands, nauseous, light headed/fainting, sweats |

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| 1306702 | 5/11/2021 | PA | 23 | M | 5/8/2021 | 5/8/2021 | Client received his vaccination during a drive though clinic. Immediately after receiving his vaccine he developed lightheadedness and dizziness. Client did not experience syncope. A paramedic was on site and assessed client at 1250. Client did not require medical intervention . He was offered water and his dizziness was resolved by 1300. HR was 72 . Client was able to drive out of the parking lot by 1305. |

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| 1305026 | 5/11/2021 | OH | 56 | F | 3/25/2021 | 3/25/2021 | almost passed out; blood pressure was 40/60; tired after the shot.; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (almost passed out) in a 56-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 006B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No medical history was provided by the reporter. The patient's past medical history included Breast cancer (11 years ago). Concomitant products included VENLAFAXINE, ROSUVASTATIN and LEVOTHYROXINE for an unknown indication. On 25-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 25-Mar-2021, the patient experienced LOSS OF CONSCIOUSNESS (almost passed out) (seriousness criterion medically significant), BLOOD PRESSURE DECREASED (blood pressure was 40/60) and FATIGUE (tired after the shot.). At the time of the report, LOSS OF CONSCIOUSNESS (almost passed out), BLOOD PRESSURE DECREASED (blood pressure was 40/60) and FATIGUE (tired after the shot.) outcome was unknown. Not Provided DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood pressure measurement: 40/60 Low. On an unknown date, Heart rate: 50 (Low) went down. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Treatment details were not provided. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested This case was linked to US-MODERNATX, INC.-MOD-2021-103634 (E2B Linked Report).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested US-MODERNATX, INC.-MOD-2021-103634:Case for dose 2 |

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| 1308207 | 5/11/2021 | TX | 40 | M | 4/20/2021 | 5/7/2021 | #2 Moderna Vaccine given on 4/20/21 On 5/7/21 patient became SOB before syncope to cardiac arrest, event was witnessed and CPR started immediately. Patient expired 45 min later at Medical Center. |
| 1306722 | 5/11/2021 | PA | 19 | M | 5/8/2021 | 5/8/2021 | Client received vaccine through a drive through clinic. He was in passenger side of car. His mother was driver. Immediately after receiving the J&J vaccine he reported pain in his arm after vaccination and then he developed nausea and dizziness . No syncope noted. Immediately upon start of symptoms, a EMT was on site and assessed client. He was provided with water and his symptoms resolved within 10 minutes of start of symptoms. Client stayed for his 15 minute observation time and was able to leave after the 15 minutes with his mother. |

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| 1305769 | 5/11/2021 | NY | 56 | F | 4/22/2021 | 4/22/2021 | she thinks may be blood clot or a muscle but not really sure; passed out; very anxious and nervous; her heart is beating fast and she is nervous.; burning sensation in her ear; tiredness; headache; heaviness on her back and chest on the left side; heaviness on her back and chest on the left side; no appetite; nauseous; diarrhea; throbbing is almost like a band-aid is too tight. If she rubbed her hand across her thigh she could feel crushing and throbbing; her heart is beating fast and she is nervous.; sharp pain in her thigh/pinching sensation on inner thigh; sick; throbbing; muscle pain; weird sensation; throbbing sensation to the left side of her belly button/It was like at her stomach; fever of 100.3F; had a feeling of heat on her neck, face, and ears; redness and itchiness at the injection site; redness and itchiness at the injection site; the injection was large, red, hot, and itchy; the injection was large/ the swelling went down; dizzy; This is a spontaneous report from a contactable consumer reported herself. A 56-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 22Apr2021 (Batch/Lot number was not reported) as 1st dose, single for covid-19 immunisation. Medical history included disability, obese, covid-19 when she was sick with COVID last year, she has never been that sick. she thinks she made it through because she owns a nebulizer and can say her lungs have never felt like they were full of fluid. If anything, they felt heavy. It was heavy in her back and chest. She also had a fever. She guesses she would be considered obese. Concomitant medications included paracetamol (TYLENOL). The patient received the first dose of the Pfizer COVID vaccine last week and she has experienced several side effects and is very anxious and nervous. She experienced redness and itchiness at the injection site, pinching sensation on inner thigh that she thinks may be blood clot or a muscle but not really sure, fever of 100.3F from 24Apr2021, burning sensation in her ear, tiredness, headache, heaviness on her back and chest on the left side, no appetite, nauseous, diarrhea, had a feeling of heat on her neck, face, and ears, throbbing sensation to the left side of her belly button from 26Apr2021 and she felt dizzy from 22Apr2021. The patient stated there was a bad connection and she was having difficulty hearing. The patient was a little nervous. Maybe this was a |

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psychosomatic issue and she was thinking of things too much. She was sick for 5 weeks. She was never in the hospital or intubated. The site where she had the injection was large, red, hot, and itchy. It was from 22Apr2021 (Thursday) for the next maybe 3 days. Now the color is diminishing, the color is going down more like to pink and smaller and it not itching anymore. Once in a while she got a pinching sensation on her inner thigh ever since she had the injection. In the last couple days, she has been feeling a that a little more. She wanted to make sure it was not a symptom of a blood clot. She doesn't feel short of breath. She was nervous talking the call handler so that is why she is talking fast. She doesn't want to feel so sick like she did last year when she had it in March or April. She wanted to know that it's not a symptom of a blood clot. It was a throbbing pinching pain that goes and doesn't come back for a little bit, but it might come back a little bit later. It happened when she woke up. She has no swelling in her legs or thighs or anything else. She says she would not be talking this fast, but her heart was beating fast and she was nervous. She tended to be an anxious and nervous person. The patient never had blood clot issues. She wanted to make sure with everything that she has heard about Pfizer she hasn't heard of anyone having blood clot issues. She had to read to calm herself down a bit. It is a sharp pain with throbbing that comes and goes. She didn't read where it could be a blot clot, she just wanted to know. She is horrible at running to the hospital when she feels something because she gets so nervous and she thinks knowing is better because she's a realist. It takes her a minute to go to the hospital to figure it out. If she continues to feel like this she and her daughter will go to the emergency room. It is 5 blocks away. It is a small little hospital and they will be able to ease her mind. It could be her nerves getting to her too. Her fever got up to 100.3 and that was only on Saturday, 48 hours after the vaccine. Once she took Tylenol it was gone and didn't return again. She took her temperature; it was a beeping one. She always says she would take like 2 out of 3, and every time she took it went up. She felt a weird sensation of burning in her ears, the same as when she first had Covid, feeling like a fever. It brought her back to a bad place and it freaked her out. She is on disability and has people go to the store for her. She did that for 3 to 4

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months. She is not agoraphobic, but she hadn't gone out until she got the vaccine. It took her all day to get back home because she loves the outdoors. It is kind of sad, and she knows she is not the only one who experienced that. She was able to actually stay at home, and when she went out, she wanted to stay. She still has her second dose to take, not everyone in has this and she doesn't want to feel that sick again. Eventually she will perish away one day, from God knows what but a slow death of not being able to breathe she cannot picture for herself or anybody else. She tries not to watch the news, it was depressing, because it is all over the news, she tries to stay in the loop. She was tired and had a headache. She took Tylenol and slept for an hour or hour and half. When she woke up she felt heaviness on her back and chest on the left side, and as she moved around more it was on her back and less on her chest. It was the same as she felt when she had Covid. She didn't have any aches or pains. The other thing was she had no appetite for the next 3 days. Every time she woke up, she felt extremely nauseous but had nothing to vomit. For the next 3 days or 72 hours, she had diarrhea. If she ate anything, she was in the bathroom. On 24Apr2021 (Saturday) after 48 hours she started to feel the heat in her neck and face and ears like right on her ears. She was talking to her daughter and her daughter said these are normal. Where she got the injection was itchy and a little more red. She told herself not to scratch it in her sleep, she is one of those people if something itches, she scratches. What she would do is rub her arm up and down on the site. It was almost the size of an 8 ounce tomato sauce can or maybe the size of a baseball. Then the third day it got redder. In her sleep she was rubbing her arm because it got itchy. Today the swelling went down, the color is like a light pink, and the size is also minimized. The fever lasted that night. She took her temperature again the next day and it was 97.9. That is usually what it is when she wakes up. She is not just tired; she is exhausted and feels like she has to go to sleep. Her daughter came with her granddaughter who is a baby, and she didn't know how to tell them. She was happy to see them but so exhausted. She worries about the sharp pain in her thigh. The other thing is she started getting pain in the middle of her thigh, her inner thigh. A sharp pain with like a throbbing is almost like a band-aid

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is too tight. If she rubbed her hand across her thigh, she could feel crushing and throbbing. She can feel it from touching the area. She had this before like when she is stretching. It started maybe 3 months ago and went away but then after she took the injection and heard about thing, she worried about a blood clot with Johnson & Johnson, not that she would know because she has never had a blood clot. It could be psychosomatic and all working in her head. It started the last 2 days when she woke up, she felt fine and as she was lying in bed, she started feeling a sharp throbbing pain that eventually goes away. She has no swelling of her legs or thighs, and her daughter said it looks fine. She is semi-terrified of hearing bad news. It takes her longer to go to the hospital. If she starts feeling worse, she will be there in no time. She does not want to wait until it is worse, but she does not want to spook herself into going. She suffers from anxiety. She definitely had the fever not like she was just tired it was like she was exhausted. She got up early and would take a little nap because she was doing a bunch of stuff. That hasn't happened, but that's her. It will be 2300 when she goes to sleep. She was doing a bunch of stuff and felt like she just needed to take a nap. Maybe it is part of that too, but usually she doesn't feel tired like this. After her daughter left, she read something on her phone and passed out. When she woke up, she saw she actually dropped her phone. Her thigh is now not a pinch but more a little bit of a muscle pain. Now it is not like the inner thigh, it is more behind the thigh now, but not below the knee, right behind the thigh, closest to the knee but not on the knee. It is the same thing as if the middle had gone behind her thigh a bit. The little pillow on her chair is not helping anything either. It feels like it maybe muscular, its deep feeling. It feels like it could be muscle, if she rubs it, she can feel it. When asked has it improved persisted or worsened, caller states it is there, but it is dull. She can say there is pain, but it is a little duller just because it is more in the muscle. It is hard to explain, it was not the same throbbing pain but there is a dull pain, it goes around the chunkier part of her thigh, like the inner thigh. When she rubs it there is pain but a dull pain. When she rubs it, it feels better but she can still feel the site where it hurts. When she rubs it, it is still located right in the lower middle going toward her knee but not at the knee, maybe

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3 to 4 inches away from the fold of her knee, almost at the center of her thigh almost. Almost like a dull muscle ache, there is a bit of throbbing with it. She will go to the doctor if something weird happens and will call back when they have an idea of what happened to her. This will sound crazy. The next thing she felt was a light throbbing where her belly button is but more to the left side, but not at the belly button. It was like at her stomach, not right at the belly button but right on the same line as her belly button but more at her waist. It was a small throbbing started today about an hour ago. She is hoping it is gas. Her fever went away pretty fast. She was on the phone and took her temperature to tell what it was. The woman said to take some Tylenol. It went from 99.9 to 100 to 100.3. She thought oh no. That was the highest she saw. Then eventually it started going down to 99.4, and then by morning it was back to normal. She only took Tylenol the one time. She is thinking maybe it is from being nervous and causing her body to heat up. She doesn't know she is just thinking. She thinks the fever went away the same day within an hour to 2 hours. She also wasn't drinking enough water. When asked if her fever has recovered completely or with last effects, caller states that is fine now, her temperature today was 99.4 without the fan on, she says she thinks that was pretty normal. When she first wakes up it is 97.9 usually. There was also a 98.4. The redness and itching at the injection site started 3 hours after the injection. She took her 2 sons with her. She took it and then her son took it. They said to wait 15 minutes. As soon as she stepped out, she looked up and felt so dizzy. It looks like when in summer and it seems to be boiling hot, that is how it got for her. Things got blurry. It was not like she was going to black out, but she had to close her eyes because the room was going to spin. She knocked back on the door and took a seat, so she sat down because she was not feeling right. When she gets nervous, she chews gum as a coping mechanism. Her son got some gum for her. She felt better but kind of nervous waiting for 15 minutes to go by, what if she felt dizzy again. She let 20 minutes go by and she got up and was fine. She wanted to be out of there and in the cool air outside. That is the first reaction that she had. She is one of those people that feel so nervous she is sure that happens that they feel like, oh they are so nervous, and they read so

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| | | | | | | | much, and it is in our faces everyday no matter what. Maybe it had nothing to do with the injection, maybe more that she was so nervous, but it was a weird sensation after. She knows when people first started getting the COVID vaccine, people were just like falling to the ground, she was like that would be terrible. She went with high expectations and was also nervous. Her heart was beating, and she could hear her own heartbeat. She still feels tired and like she can go take a nap now. She asks if that is normal. She would rather talk to Medical Information now. She is over this statistics part of it. She doesn't feel a release, she is just giving her information and she doesn't feel any better. Outcome of the event throbbing sensation to the left side of her belly button/It was like at her stomach was not recovered; of the event dizzy was recovered; of the events the injection was large, red, hot, and itchy/ the swelling went down, tiredness was recovering; of the other events was unknown. Information about lot/batch number has been requested. |
| 1308940 | 5/11/2021 | MN | 18 | M | 5/10/2021 | 5/11/2021 | Woke up feeling warm, nauseous, feverish, had a headache. Went to the bathroom and felt dizzy, blacked out and fainted approximately 12 hours after vaccine. |
| 1308507 | 5/11/2021 | TX | 18 | M | 5/11/2021 | 5/11/2021 | Patient fainted about 2-3 minutes after receiving first Pfizer COVID vaccine. Instantly awoke and remained upright and breathing regularly. Fainted again after another 2-3 minutes of being awake. 911 was called and EMTs arrived. Vitals were normal and patient declined to go to the hospital with EMTs. Patient stayed for another 15 minutes inside the store. |
| 1308278 | 5/11/2021 | | 36 | F | 4/8/2021 | 4/8/2021 | I fainted 2 times after receiving the shot |
| 1308187 | 5/11/2021 | WA | 21 | M | 5/11/2021 | 5/11/2021 | Patient fainted. Patient fell onto floor and hit face. Paramedics arrived and transported to hospital due to low blood pressure. Determined to be a response to stress of vaccination. Patient needed stitches to repair cut in lip from fall. |
| 1308048 | 5/11/2021 | | 18 | F | 5/11/2021 | 5/11/2021 | patient fainted immediately after vaccine was administer |

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| 1307860 | 5/11/2021 | TN | 56 | M | 5/10/2021 | 5/10/2021 | some time between 4:30 and 5:00 PM (1-1.5 hours after the vaccination) Patient felt bad and went to take his BP with a monitor. He passed out before he took it and woke up face down in carpet with a bloody nose and had urinated on himself. He called his daughter for help. Upon her arrival, he passed out several times, complained of severe headaches, had severe vomiting, has trouble breathing, pain shot up up his neck and face, his BP reading was around 83/60 with a heart beat of 45. The Ambulance service arrived and confirmed he was having an active stemi heart attack. He was taken to hospital where the heart attack was confirmed again and he was taken immediately to the Cath Lab to have a stent placed. He was placed in ICU |
| 1307746 | 5/11/2021 | CO | 26 | F | 5/11/2021 | 5/11/2021 | Pt sat down after vaccine. Became dizzy within 10 minutes. She briefly fainted where she was unresponsive. When she started responding she was very nauseous and vomited. She stayed sitting and we provided gatorade. She was feeling better 30 minutes later and left the vaccine location |
| 1307716 | 5/11/2021 | CA | 71 | M | 2/17/2021 | 2/18/2021 | Headaches- Intense and consistently reoccurring- most prominent at both temples on head and sometimes start on top of head, both sides all the way down the neck- have had now for 3 months- started day after 2nd vaccine on 2/17/21 Constipation- started the week after 2nd vaccine (2/17/21) and had not resolved- have had to use stool softners, laxatives and now prescription (Linzess) to regulate Orthostatic Hypotension- Diagnosed on 4/25/21 after he fainted, lacerated his head and ended up in ER. Fell one more time (4/27/21) and went to ER again. Is now unable to stand more than 2-3 minutes before fainting. Cardiologist ran heart stress test on 5/4/21 and we are awaiting results. |
| 1307674 | 5/11/2021 | WA | 18 | F | 5/11/2021 | 5/11/2021 | Patient experienced syncope and fainted after leaving the immunization area. She hit her face and was treated by paramedics and released. Followed up with her at 1:00pm and she stated she was fine although tired. |

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| 1307545 | 5/11/2021 | MD | 39 | M | 5/11/2021 | 5/11/2021 | During 15 minutes post-monitoring period: COVID-19 Vaccine Adverse Reaction Reaction due to: First dose of vaccine Symptoms: Dizziness/Lightheadedness, Syncope How long after administration did the symptoms start?: Immediately (within 15 minutes) Previous reaction to prior vaccines: Patient denies similar previous reactions Interventions: PO fluids, Report to VAERS submitted, Additional monitoring, Other (comment) (BP monitoring, given food and drink, rest, 911 was initiated at the time of the event. EMT arrived, checked VS) If reassessed, patient's condition: Improved Disposition: Other (comment) (Pt's symptoms improved upon rest, food, and hydration. Declined ER transport. Advised to call 911 if any symptoms return.) Initial BP laying 101/61 15 minute BP 119/84 BP by EMS when sitting 134/84 P 63 |
| 1307477 | 5/11/2021 | | 21 | F | 5/11/2021 | 5/11/2021 | patient fainted twice |
| 1307461 | 5/11/2021 | NJ | 33 | M | 5/10/2021 | 5/10/2021 | Patient nearly fainted shortly after receiving the vaccine. He turned pale and his head dropped. EMS was called to the scene. The pharmacist gave the patient some water and he came around before EMS got there. EMS checked the patient and determined his vitals were okay. Patient did not need to be transported to the hospital. Patient did not have any known allergies. Patient did not know how they would react to the vaccine as they did not have insurance and did not usually get vaccines or routine blood work. |
| 1307006 | 5/11/2021 | TX | 17 | F | 5/11/2021 | 5/11/2021 | Few minutes after Pfizer 1st dose injection, patient felt lightheaded and fainted. |
| 1306788 | 5/11/2021 | FL | 21 | M | 5/7/2021 | 5/7/2021 | Syncope, vomiting, fever, chills, loose stools. |
| 1308295 | 5/11/2021 | PA | 16 | F | 5/11/2021 | 5/11/2021 | Patient fainted |
| 1307419 | 5/11/2021 | TX | 23 | M | 5/10/2021 | 5/10/2021 | VASO VAGAL RESPONSE, FAINTING, ABNORMAL JERKING MOVEMENTS |

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| 1306948 | 5/11/2021 | OH | 30 | M | 5/7/2021 | 5/8/2021 | Friday, I received the shot at 3:30pm. I got home around 5:00pm and I started to not feel not feel well at all around 8:00pm. I woke up Saturday feeling dizzy and weak just like the night before. Saturday evening I let my dog out and when I turned around to go inside I fainted and feel on my face. |
| 1306929 | 5/11/2021 | ME | 40 | M | 5/11/2021 | 5/11/2021 | Pt experienced syncope episode directly after administration; Slow collapse to the floor; no associated trauma; Regained consciousness within 10-15 seconds; AxO within 1-2 minutes; BP 138/90; initially bradycardic in the 50's and increased in the 80's within 2 minutes; Blood glucose 130; Pt stated he did not eat any breakfast; Pt denied any discomfort after the episode; PO fluids and cracker tolerated well. Released after 15 minutes of monitoring without any issues. |
| 1307090 | 5/11/2021 | MI | 52 | M | 5/11/2021 | 5/11/2021 | Patient got dizzy/and light headed and passed out in the chair. I noticed the patient holding his head and went over and talked to him. He was feeling light-headed and sweaty. We put his feet up in the chair and he briefly passed out for about 10 seconds. He came around quickly and we gave him a drink. He sat for about 10-15 minutes longer and we made sure he was feeling good before he left. |
| 1307100 | 5/11/2021 | VA | 18 | F | 5/11/2021 | 5/11/2021 | Vasovagal syncope |
| 1307340 | 5/11/2021 | NC | 18 | M | 5/11/2021 | 5/11/2021 | Site: Pain at Injection Site-Medium, Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Exhaustion / Lethargy-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Headache-Medium, Systemic: Hypotension-Medium, Systemic: Numbness (specify: facial area, extremities)-Medium, Systemic: Seizure-Severe, Systemic: Tachycardia-Medium, Systemic: Tingling (specify: facial area, extremities)-Medium, Systemic: Weakness-Medium, Additional Details: Patient was given COVID vaccine and moved to another chair to be observed. Upon sitting in other chair, he almost immediately went stiff, began convulsing, and then went unconscious. Patient came to, 911 was called, and patient was transported to ER. |

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| 1307306 | 5/11/2021 | AZ | 36 | F | 5/11/2021 | 5/11/2021 | PATIENT FAINTED SHORTLY AFTER THE INJECTION, BUT THEN REGAINED CONSCIOUSNESS SHORTLY AFTER I ATTENDED TO HER BY SITTING HER UP AND CALLING 911. I WAS READY TO ADMINISTER CPR AND EPI. |
| 1307322 | 5/11/2021 | FL | 24 | M | 5/11/2021 | 5/11/2021 | patient fainted immediately after receiving the shot |
| 1307331 | 5/11/2021 | VA | 18 | F | 5/10/2021 | 5/10/2021 | Site: Pain at Injection Site-Mild, Systemic: Dizziness / Lightheadness-Mild, Additional Details: RECOVERED ABOUT 5 MINUTES AFTER FAINTING. 911 WAS CALLED. PT RECOVERED IN 5 MINS |
| 1307371 | 5/11/2021 | CA | 29 | F | 4/6/2021 | 4/29/2021 | Three weeks later getting fainting spells, light headed, dizzy, left arm numbness and tingling, vertigo. |
| 1307172 | 5/11/2021 | PA | 18 | M | 5/11/2021 | 5/11/2021 | Immediately after vaccine administered, his eyes rolled back in his head, placed him on the ground and he regained consciousness. BP 120/87, hr 72. He said he only slept a few hours and had a history of fainting after flu shot. He ate a snack and drank water and felt much better . He left after 30 minutes observation. |
| 1307352 | 5/11/2021 | NY | 24 | F | 5/10/2021 | 5/10/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Hypotension-Mild, Systemic: Seizure-Mild, Additional Details: patient fell over and passed out a few minutes after administration, possible seizure occurred. EMT services were called and patient declined to go with them. |
| 1302071 | 5/10/2021 | TX | 27 | M | 5/6/2021 | 5/6/2021 | During the 15 Observation Patient passed out and fell out of the chair. Patient was unresponsive for approx 30 seconds. He had seizure. Patient be came alert and responsive confused for about 2 minutes. After becoming more alert. Patient stated he has had this happen before when we was giving blood. Patient had not eaten anything before coming to get vaccine as well. 911 was called. BP was 160/80, pulse 60, O2 sat 97% . Patient refused to go the hospital. Stated he felt fine now. I observed him for another hour before letting him leave our facility. |

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| 1302140 | 5/10/2021 | NH | 54 | F | 5/10/2021 | 5/10/2021 | Pt has a history of vasovagal syncope and actually required transport to the hospital for a prolonged hypotensive episode after her first dose of Moderna last month. Shortly after vaccination, pt had a syncopal event. Initial BP was in the 60s systolic. HR 52, and SP0298%. After an extended observation period, she became more alert and BP was noted to be 90/60. Repeat HR was 62. Symptoms were mostly resolved when the pt elected to go home with a family member. |
| 1302147 | 5/10/2021 | FL | 74 | F | 4/28/2021 | 4/28/2021 | syncope, body aches, nausea |

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| 1302212 | 5/10/2021 | NY | 44 | F | 5/7/2021 | 5/7/2021 | Chills and fever began about 8 hrs after second shot on Friday afternoon. Normal baseline temp is 97 - temp was up to 101.5 overnight/early Saturday morning. Symptoms predominantly fever and fatigue all day Saturday, with temp hovering around 100.7-101.5 during the day. I expected symptoms like this based on others' experiences. The reason I am reporting is that I briefly passed out right around the 24 hour mark. I had eaten very little (a banana and two eggs that morning) but was drinking a fair amount of fluids, and had basically slept most of the day. Around 1:30PM, I woke up, took my temperature, and was surprised to see it read 101.5 - I felt cooler or at least I felt less uncomfortably warm than I had when it read higher. I got up, reheated some soup, and just as I was pouring it in the bowl, was hit with an overwhelming wave of nausea and dizziness such that I thought I wouldn't make it to the bathroom. En route, I bumped into a piece of furniture with my right arm. I remember grabbing my arm and the next thing I knew, I was lying on the hallway floor. I must have slid down somehow, because I didn't have any head pain or bump to the head - and managed to get to the bathroom. After a time, the nausea passed without vomiting, I made it back to bed, fell asleep, and felt better enough when I woke two hours later to eat some soup. I continued to drink a lot of fluids and had a smoothie before bed. My temperature peaked at 102.3 that night before bed. Overnight Saturday, I sweat through two shirts. My temperature Sunday morning was 99.1 and I noticed some low-level "COVID rash" at my injection site before bed Sunday night. I woke this morning (Monday) at 5AM to discover I had sweat through another shirt, but my temp was finally back to 97.1. Again, I wouldn't have reported this as out of the ordinary, if I hadn't briefly passed out. I should say that Saturday (day after my shot) was also the first full day of my period. I don't know if it was fever, blood sugar, cramps, vertigo, or the virus - but that particular wave of nausea and dizziness at 24 hours was really intense. I wouldn't have reported this if I hadn't briefly passed out |
| 1302173 | 5/10/2021 | GA | 18 | F | 5/8/2021 | 5/8/2021 | Pt passed out for few minutes, had seizures like symptoms |

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| 1302182 | 5/10/2021 | PA | 17 | F | 5/10/2021 | 5/10/2021 | syncope in observation area after vaccination, was sent to hospital for further evaluation |
| 1302039 | 5/10/2021 | FL | 52 | F | 5/8/2021 | 5/8/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Nausea-Mild, Additional Details: pt fainted few minutes after shot. called 911 pt was alert after few minutes , ems came and checked pt had nausea.per patients husband pt anxious when she get shot and fainted inthe past several time. patient did nt want to go to hospital so she went to home |
| 1302222 | 5/10/2021 | NH | 30 | M | 5/4/2021 | 5/4/2021 | Patient presents via EMS for altered mental status after a syncopal episode. Per EMS, coworkers heard a loud noise and found him face down on the floor unresponsive shortly after receiving 1st Moderna vaccine (history of vasovagal syncope in the past per chart). Per bystanders pt HR in the 30s, but 60s upon EMS arrival. Upon arrival, pt answering yes/no questions appropriately, but limited history given. |
| 1302158 | 5/10/2021 | GA | 18 | M | 5/8/2021 | 5/8/2021 | Pt passed out just after getting the vaccine for 2 minutes |
| 1302037 | 5/10/2021 | CO | 31 | F | 5/9/2021 | 5/9/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient experienced lightheadedness, then passed out for about 20 seconds at around noon on 05/09/2021. Patient has recovered. Paramedics were called. Patient refused to go with paramedics. |

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| 1302035 | 5/10/2021 | CO | 18 | M | 5/7/2021 | 5/7/2021 | Systemic: Chills-Mild, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Hypotension-Medium, Systemic: Nausea-Mild, Systemic: Visual Changes/Disturbances-Mild, Additional Details: DURING SYNCOPE EPISODE, PATIENT STATED HE "COULDN'T SEE". VISION RETURNED AFTER LESS THAN 1 MINUTE. PATIENT WAS UNCONCIOUS FOR LESS THAN 30 SECONDS. AFTER LAYING DOWN FOR 1 MINUTE, I RETURNED PATIENT TO CHAIR AND MONITORED BLOOD PRESSURE. PATIENT WAS HYPOTENSIVE FOR 20 MINUTES. PATIENT BECAME HEMODYNAMICALLY STABLE AFTER 20 MINUTES USING 4 SEPERATE READINGS 5 MINUTES APART EACH. PATIENT'S FATHER ACCOMPANIED PATIENT AND OPTED TO TAKE HIM HOME AFTER HE WAS STABLE. |
| 1302029 | 5/10/2021 | IL | 22 | M | 5/9/2021 | 5/9/2021 | Systemic: Fainting / Unresponsive-Severe, Systemic: Vomiting-Medium, Additional Details: patient fainted shortly after receiving covid-19 vaccine. pts legs were propped and he gained conciousness fairly soon. paramedics were called, they checked on pt and found all vitals to be normal. pt was given option to go to hospital but declined. he sat in chair for another 30 mins and then felt strong enough to walk. he walked a few times around pharmacy and then felt comfortable going home with mother. |
| 1302027 | 5/10/2021 | NJ | 26 | F | 5/9/2021 | 5/9/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: Nausea-Medium, Systemic: Seizure-Mild, Additional Details: Patient receieved vaccine. After about 5-10 minutes the patient stated she was very nauseous. I went to grab a trash can for her and within the 20 seconds or so it took to grab she had what seemed like a single muscle spasm or convulsion then she slid out of her chair onto the floor. She was breathing and coherent right away however she did not remember getting on the floor. Called 911 and EMS came out and took her vitals. She stated she felt fine afterward and did not go with them. |

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| 1302012 | 5/10/2021 | CA | 37 | M | 5/9/2021 | 5/9/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Mild, Additional Details: Pt was seated after the vaccine in observation area. He stood up saying he had to use the bathroom. He proceeded to faint and was caught. He passed out and then came around seconds later. BP check and pulse were normal. Had him lie down with legs raised. Gave water and cookie. He stayed about 45 min. He was driven home later. Called his home at end of day and said he was sleeping but fine. |

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| 1301747 | 5/10/2021 | PA | 55 | M | | 5/1/2021 | PASSED OUT; SEVERE ABDOMINAL CRAMPY PAIN; CRACKED HEAD; This spontaneous report received from a patient concerned a 55 year old male The patient's height, and weight were not reported. The patient's concurrent conditions included seasonal allergies, and penicillin drug allergy. The patient received COVID19 VACCINE AD.26.COV2.S (suspension for injection, route of admin not reported, batch number: 202a21a, expiry: UNKNOWN) dose was not reported, 1 Total administered administered on 29-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On 01-MAY-2021, Saturday evening the patient experienced so severe pain, patient passed out, did not eat anything and did nothing out of ordinary that could have caused the severe abdominal crampy pain and hit his head (cracked head), sending patient to the ER (emergency room). It was reported that, he did not eat anything and did nothing out of ordinary that could have caused the severe abdominal and he did not know 100 percent that it comes from vaccine but nothing else was any different in his live other than vaccine. In ER they did laboratory tests included full blood test, chest X-ray, electrocardiogram and magnetic resonance imaging (MRI) of head and abdomen was normal (NR: not provided for all labs). The action taken with COVID-19 VACCINE AD26.COV2.S was not applicable. The patient recovered from severe abdominal pain on 02-MAY-2021, and the outcome of passed out and cracked head was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: 20210505687-JANSSEN COVID-19 VACCINE-Passed out -This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event. |
| 1301656 | 5/10/2021 | IL | 21 | F | 5/4/2021 | 5/4/2021 | fainting, eyewitness reported seizure (patient also had scrapped left shoulder) |
| 1301622 | 5/10/2021 | MN | 70 | F | 4/15/2021 | 4/15/2021 | Pt reported that she fainted after getting her COVID 19 vaccine (she did not know the manufacturer, nor has a lot #). She also stated that when she went to the hospital she was told that she had "multiple mini-strokes" She also tested positive to COVID 19 and required treatment. |

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| 1302248 | 5/10/2021 | FL | 52 | M | 5/5/2021 | 5/8/2021 | Pt vaccinated on 5/5/21. On 5/6/21 he developed fatigue, body aches and chills. In the early morning of 5/8/21 (around 3am), he woke up from a sleep in his armchair and stood up, at which time he lost consciousness and passed out, hitting his head. He does not recall anything after that until he woke up in bed in the morning. |
| 1302026 | 5/10/2021 | NJ | 26 | F | 5/9/2021 | 5/9/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: Nausea-Medium, Systemic: Seizure-Mild, Additional Details: Patient received vaccine. After about 5-10 minutes the patient stated she was very nauseous. I went to grab a trash can for her and within the 20 seconds or so it took to grab she had what seemed like a single muscle spasm or convulsion then she slid out of her chair onto the floor. She was breathing and coherent right away however she did not remember getting on the floor. Called 911 and EMS came out and took her vitals. She stated she felt fine afterward and did not go with them. |
| 1301990 | 5/10/2021 | CA | 68 | F | 5/8/2021 | 5/8/2021 | Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Medium, Systemic: Exhaustion / Lethargy-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Hyperventilation-Medium, Systemic: Tachycardia-Mild, Systemic: Weakness-Mild, Additional Details: post 20mins vaccination |
| 1304151 | 5/10/2021 | IL | 47 | M | 5/7/2021 | 5/9/2021 | Patient was found at home Saturday afternoon passed out. Patient was rushed to the hospital where it was discovered he had a blood clot. He is going to hospitalized for a few days per patients mother. |
| 1302264 | 5/10/2021 | CA | 35 | U | 5/9/2021 | 5/9/2021 | COUGHING, THEN SYNCOPE, DIAPHORETIC. CODE GREEN CALLED, PARAMEDICS CAME. PROVIDE WATER, SX RESOLVED, NO TRANSPORT. |
| 1301994 | 5/10/2021 | FL | 25 | F | 5/4/2021 | 5/4/2021 | Pt. fainted right after getting vaccinated. B/P 110/70, HR 74, R 19. Pt stated, "I faint most of the time when I see needles." At 3:10 pm pt. stated, "I feel better now." Pt. is alert and oriented x4. 3:26 pm pt stated, "I'm ok now I want to go home." Pt. went home at 3:25 pm. |

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| 1304697 | 5/10/2021 | CO | 33 | M | 5/10/2021 | 5/10/2021 | A few minutes after administration the patient went to leave the room where he got his vaccine. He stood up turned to ask another question about the vaccine and then fainted. He was out for about 15 seconds. He awoke disoriented and sweaty. I gave him water and some glucose tablets. He said he felt fine after that. i have called to follow with him and he says he feels fine |
| 1304189 | 5/10/2021 | CA | 17 | F | 5/10/2021 | 5/10/2021 | Pt felt dizzy after the 1st dose of Pfizer vaccination. As I was walking out to check on her, she fainted. She regained conscious immediately. I gave a small soda to drink and she threw up after but she didn't faint again. She felt better right after she threw up and stated that this never happened before. After about 45 minutes, pt stated that she felt much better and wanted to leave with her dad. |
| 1303937 | 5/10/2021 | PA | | F | | 3/1/2021 | FAINTED; DIZZINESS; DID NOT FEEL RIGHT; This spontaneous report received from a patient via a company representative concerned a female of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, 1 total, administered on MAR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. In MAR-2021, the patient has received vaccine. After 5 minutes, the patient fainted and hit head. Later, after few days, the patient felt faint and dizzy. She was taken by ambulance to the hospital to be checked out. Patient did not feel right for a whole week after. Patient is receiving many medical bills for ambulance and the hospital and would like to be compensated since it's from vaccine. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the fainting and dizziness was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210503181-covid-19 vaccine ad26.cov2.s-Fainted. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s). |

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| 1303907 | 5/10/2021 | IA | 45 | F | 2/16/2021 | 3/1/2021 | Started with increased heart rate, fatigue and shortness of breath. Didn't go to Dr until April 23, 2021 & April 26, 2021, syncope, multiple large bilateral pulmonary Emboli & DVT & right heart strain |
| 1303634 | 5/10/2021 | AK | 26 | M | 5/10/2021 | 5/10/2021 | Administered vaccine in left arm at 11:46 AM . about 11:48 patient said he felt lightheaded. I got up to get patient a Gatorade and he began to snore. I realized he had passed out . I held his arm and said his name he immediately jerked awake and did not know where he was or what he was doing. He drank some Gatorade and ate a couple of chocolate kisses. He began to have cold sweats that lasted a few minutes. I sat with him in counseling room for 15 minutes and then he sat in waiting room until he felt better. He did not feel that he needed further attention or medical assistance. |
| 1303626 | 5/10/2021 | VA | 58 | F | 5/10/2021 | 5/10/2021 | after patient waited allotted time in pharmacy under supervision, as patient was walking out of store she fainted |
| 1303602 | 5/10/2021 | CA | 17 | F | 5/10/2021 | 5/10/2021 | Pt felt like she was going to vomit 2 mins after administration, then fainted as being assisted to gurney to lie down. |
| 1303535 | 5/10/2021 | CT | 29 | M | 5/10/2021 | 5/10/2021 | Patient received vaccine at around 11am. After waiting around for a few minutes he stated he was light headed. I went over to observe and gave patient some water. He was starting to sweat and turned very pale. 1 minute later he passed out. I brought him to the floor from his chair and he starting shaking and 'seizing" for about 10-15 seconds. We used pressure on his chest to try to "snap" him out of it. After about 15 seconds of "seizing,not breathing normally and his left arm completely locked up" he came to and did not know where he was for about 2-3 minutes. After about that time he started to realize where he was and recognized his wife who was assisting. EMS was called and arrived shortly, He was lucid and knew where he was and started to feel normal again. EMS checked his vitals and they were normal. Patient refused to go to hospital and EMS released him to his wife. I checked on patient 4 hours later and he had no ill effects and stated he felt just like he did before receiving the vaccination. |

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| 1302664 | 5/10/2021 | DC | 34 | M | 5/10/2021 | 5/10/2021 | Patient experienced light headedness, dizziness and passed out for about 2-3 seconds. Minor convulsions during unconsciousness. |
| 1304458 | 5/10/2021 | CO | 37 | M | 5/10/2021 | 5/10/2021 | At 4:05pm, patient fainted 5 minutes after vaccine administration and came to within 10 seconds but fell onto floor. 911 was called immediately by pharmacy staff. EMT arrived within 10 minutes. Patient was alert while waiting for first responders to arrive. First responders took over at 4:15pm. Patient was advised to seek medical attention after leaving store, but was not escorted to ER by first responders. Patient walked out himself, and went to see his doctor at hospital at 5pm. |
| 1303268 | 5/10/2021 | CT | 20 | F | 5/10/2021 | 5/10/2021 | Patient passed out and body started to shake. within less than a minute patient regain consciousness. |
| 1302281 | 5/10/2021 | FL | 34 | M | 5/10/2021 | 5/10/2021 | 34 y/o male with no known medical history, who presents with seizure like activity lasting 2-3 seconds post vaccination. Patient states that this is his second vaccination in the two-dose series. Patient denies previous reaction with the first vaccination. Patient states that he fears needles. Patient was witnessed with upper arm stiffening, convulsions and syncope lasting 2-3 seconds. RNs lowered patient to the ground with legs elevated. Patient regained consciousness within seconds. Patient was not post ictal. Patient denies headache, sore throat, difficulty breathing or itch. Patient vitals (151/79 BP, 98% O2, 74 HR, 14 Resp, Glucose 125, EKG NSR). Fire rescue was called. Patient was placed in wheelchair and taken to private area where he was further assessed by the Paramedics, NP and RN. Patient was noted to be diaphoretic. Water provided and patient placed in Trendelenburg position. Fire rescue arrived. Patient refused to be transported to the ER, although it was advised by the NP. Fire rescue did not have the patient sign out AMA. AMA form provided and signed, witnessed by the NP. Patient aware of risk involved with no seeking further medical evaluation, such as worsening adverse reaction, subsequent seizures, cardiac event, MVA and/or death. Patient verbalized understanding. Patient ambulated to his car without difficulty. |

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| 1302276 | 5/10/2021 | PA | 17 | M | 5/7/2021 | 5/7/2021 | Approximately 10 minutes after vaccination, patient began jerking and passed out. Patient was placed on the floor and vitals were taken which were normal. After approximately 10 minutes, patient was brought to sitting position and after a few minutes began jerking movements and felt faint. After approximately 10 minutes, patient was walked to a chair but after a few minutes he again began jerking and felt faint. Patient was returned to the floor. Parents refused transport to the hospital. Father helped patient to the car and he was placed in the back seat lying down. Father stated he may take him to the ER if he seems like he needs it. |
| 1302665 | 5/10/2021 | IN | 72 | M | 4/30/2021 | 5/1/2021 | Got up in the middle of the night and passed out. EMS called and taken to hospital. Was there for 1 week and then transferred to another hospital facility nearby. |
| 1302792 | 5/10/2021 | CA | 71 | F | 4/28/2021 | 4/28/2021 | Syncope and whole body flushing one minute after vaccine was given, lasting a couple of minutes. Patient walked upstairs to primary care provider to be monitored for 30 minutes. |
| 1302859 | 5/10/2021 | FL | 62 | F | 5/10/2021 | 5/10/2021 | Patient felt dizzy and fainting 2-3 minutes after vaccine. Her breathing was normal. Pharmacist gave her 5 ml of benadryl (12.5mg/5ml). Patient start responding within 1 min, Mean while pharmacy call 911. Paramedics arrived and check all symptoms ,BP and ECG. BP was little elevated and ECG came normal. |
| 1302872 | 5/10/2021 | FL | 17 | F | 5/10/2021 | 5/10/2021 | Dizziness, followed by brief syncope, all resolved within 2 minutes. She fell out of chair on to ground and immediately woke. Sweaty and pale, placed cool compress on back of neck and gave her a cold water to drink. She remained upright on the floor for approximately 5 minutes until she felt like she was fully recovered. Her father was present the entire time. She stated that she had no injuries or pain from falling out of chair. No rashes, bruising or bleeding observed. Mgr came over and patient's father declined to file a report for injury. |
| 1302873 | 5/10/2021 | IL | 16 | F | 5/10/2021 | 5/10/2021 | Patient had anxiety about getting the second shot and had fainted on the first dose of pfizer. After the shot the patient thought she might faint, never did. Patient was hot, anxious and then vomited. 911 was called |

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| 1302607 | 5/10/2021 | WI | 39 | F | 5/1/2021 | 5/3/2021 | Low grade fever for two days until 5/3. Went to ER with severe nausea, muscle pains. Fainted in ER waiting room. Was extremely sick for three days with nausea, pain, low energy and side effects. Am still having leg muscle pain on 5/10 as well as low energy, being unable to sleep, no appetite, depression. Went to Urgent Care on 5/10, vitals are good |
| 1301000 | 5/9/2021 | NY | 16 | F | 5/7/2021 | 5/8/2021 | 20 hours after receiving the vaccine I felt very dizzy and nauseous for a moment and then fainted and was unconscious for a minute. I had developed a fever about 8 hours after receiving the vaccine, but by the time I fainted the fever was pretty much gone. |
| 1300763 | 5/9/2021 | NJ | 17 | M | 5/8/2021 | 5/8/2021 | Site: Pain at Injection Site-Mild, Additional Details: Patient was waiting after the his first covid shot and he was talking with his parents, they had a conversation for 5 minutes and then the patient fainted, fell down, had seizure for few seconds and then woke up in few seconds. Patient was sweating, feeling hot. He was breathing normal. Face was red. 911 was called. Patient had no issues with needles. HR was 104. Patient felt better after 10-15 mins and left with his parents. No hospitalization needed. |
| 1300781 | 5/9/2021 | CO | 35 | M | 4/29/2021 | 4/29/2021 | Site: Bruising at Injection Site-Mild, Site: Itching at Injection Site-Mild, Site: Pain at Injection Site-Mild, Site: Redness at Injection Site-Mild, Site: Swelling at Injection Site-Mild, Systemic: Fainting / Unresponsive-Medium, Additional Details: Patient fainted just after admisntration, he passed out for less than 10 second , all of the first aid requirments done, vitals were normal called 911 and they arrived at the location in 5 mintutes , patient monitored for about 30 minutes after and walked out the store himself |
| 1300796 | 5/9/2021 | IL | 26 | M | 5/8/2021 | 5/8/2021 | Systemic: Confusion-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild |

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| 1300789 | 5/9/2021 | AR | 62 | M | 5/8/2021 | 5/8/2021 | Site: Pain at Injection Site-Medium, Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Nausea-Medium, Systemic: Tingling (specify: facial area, extremities)-Medium, Additional Details: Tingling was only located in fingers and hands. Patients Blood Pressure after event was recorded at 106/58. Patient states he naturally runs lower blood pressure and heart rate. Also mentioned that he has a fear of needles.. Patient is now responsive and feeling better. |
| 1300784 | 5/9/2021 | NY | 36 | M | 5/8/2021 | 5/8/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Nausea-Severe, Systemic: Numbness (specify: facial area, extremities)-Medium, Systemic: Shakiness-Medium, Systemic: Tingling (specify: facial area, extremities)-Medium |
| 1300779 | 5/9/2021 | CA | 22 | M | 5/8/2021 | 5/8/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Additional Details: pt witness previous pt receive vaccine and was nervous, we offered to reschedule him, but he insisted on getting the vaccine anyways |
| 1300778 | 5/9/2021 | CA | 24 | M | 5/8/2021 | 5/8/2021 | Site: Redness at Injection Site-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Seizure-Severe, Additional Details: pt did not have reddness or pain at site, but fainted and had a seizure |
| 1300772 | 5/9/2021 | TN | 41 | M | 5/8/2021 | 5/8/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Fainted. Responded after about 10 seconds. Has history of fainting / abscent seizures. Pulse and blood pressure normal immediately after incident ocured. |
| 1300766 | 5/9/2021 | PA | 18 | F | 5/8/2021 | 5/8/2021 | Systemic: Confusion-Severe, Systemic: Exhaustion / Lethargy-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Feeling of passing out, in and out of consciousness, general weakness, sweats, weakness in breathing-Severe, Systemic: Flushed / Sweating-Severe, Systemic: Nausea-Severe, Systemic: Weakness-Severe |

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| 1300758 | 5/9/2021 | IL | 17 | F | 5/8/2021 | 5/8/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Shakiness-Severe |
| 1300756 | 5/9/2021 | TX | 16 | M | 5/8/2021 | 5/8/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Medium, Systemic: Seizure-Medium |
| 1301041 | 5/9/2021 | MO | 17 | F | 5/9/2021 | 5/9/2021 | Syncope following vaccination. Patient reported blurry vision, dizziness. Had patient rest with feet elevated and gave patient bottle of water. Observed patient for 30 minutes. After 30 minutes patient reported feeling back to normal. |
| 1300799 | 5/9/2021 | IL | 26 | M | 5/8/2021 | 5/8/2021 | Systemic: Confusion-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Visual Changes/Disturbances-Mild, Additional Details: Patient went unresponsive approximately 30 seconds after vaccine administration, was unresponsive for a total of 30 seconds, his neck and face were flush, pupils were dilated and his eyes wandered. He woke up confused. |
| 1300770 | 5/9/2021 | CA | 28 | F | 5/7/2021 | 5/7/2021 | Site: Pain at Injection Site-Mild, Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient regained consciousness within one minute. Her blood pressure was 107/78 mmHg and heart rate was 62 bpm. She was fully recovered and left the pharmacy after 30 minutes. I follow-up with the patient on 05/08/2021. Patient said she was fine after she left the pharmacy and only had soreness at the right arm. |

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| 1301381 | 5/9/2021 | PA | 27 | F | 4/6/2021 | 4/6/2021 | Symptoms started 15 min after receiving Moderna vaccine, nausea, chills, on and off leg numbness, fatigue. Syncope on 4/14/2021, work up in ER negative. Hospitalization 4/19-4/20/2021 with chest pain and severe headache. EKG in ER abnormal (T wave inversion, long QT), repeat EKG next day wnl. CT chest for chest and CT head both wnl. Diagnosed with UTI. Started on Pantoprazole and Famotidine for GI symptoms (epigastric pain, bloating). On Sunday 4/25/2021 left arm numbness and weakness, another ER visit was told Cervical radiculopathy. Still severe fatigue, muscle, and joint pain, on and off numbness of the left arm, muscle twitching, GI symptoms. All labs and imaging wnl. |
| 1300794 | 5/9/2021 | OR | 38 | M | 5/8/2021 | 5/8/2021 | Site: Pain at Injection Site-Mild, Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: close to fainting several times-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Hyperventilation-Mild, Systemic: Nausea-Medium, Systemic: Shakiness-Medium, Systemic: Tingling (specify: facial area, extremities)-Medium, Systemic: Weakness-Medium, Additional Details: Specifically tingling in Hands. Patient was very disoriented and appeared close to fainting a couple of times post vaccination. Was closely monitored for 30 minutes. He did not think it was due to being nervous, he was slightly nervous before the vaccine, but nothing of concern. |

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| 1301105 | 5/9/2021 | NY | 24 | F | 5/9/2021 | 5/9/2021 | Patient was a walk-in COVID-19 applicant. She filled out her form and told me she's very scared of needles and has fainted in the past from getting a vaccine. I asked whether she was comfortable receive vaccine at pharmacy setting and she said she really wanted the Janssen COVID-19 vaccine to avoid getting two shots. She appeared calm and the administration of the vaccine went smoothly without any issues. During the 15 minute observation period, patient's mother and technicians alerted me she has fallen over. I quickly instructed by technician to call 911, while the other paged CODE WHITE and I rushed to the patient. Her father helped me lie her down on their back (supine) and I elevated the patient s feet onto the chair. I took of her mask to listen to make sure she was breathing and she quickly regained consciousness and looked right at me. I had her take some deep breaths for me to make sure airways were clear and helped her sit down in a chair. I asked her to stay an additional 15 minutes to ensureshe is feeling fine. She decline emergency personnel from coming to the store. She was fine and left the store after 15 minutes. I will follow up with her to make sure she's doing well on 05/10/21. |
| 1301513 | 5/9/2021 | WA | 17 | F | 5/8/2021 | 5/8/2021 | This writer received the following report: Adverse Event: Guest reports that she passed out and this was her first time. (Vital Signs: SPO2-99%, P-60) Treatment: AID called - Juice and water provided - EMT's arrived and assessed. (Vital Signs: SPO2-100%, P-60, B/P-90/54). No further treatment indicated. Outcomes: EMT's assessed no further treatment indicated and they released guest to the care of her mother. Guest and her mother were informed if this event occurs to go to the nearest emergency room and report to her PCP. |

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| 1301329 | 5/9/2021 | FL | 33 | F | 5/9/2021 | 5/9/2021 | Patient was given her shot, she got up and sat down in the nearest observation chair, then immediately said she was dizzy and thought she was going to pass out. I went to her and she repeated that she was about to pass out. When her head started to roll back I was able to hold her by her shoulders. Her eyes rolled back and her head dropped back and she started convulsing. She lost consciousness for about 10 seconds. When she came to she didn't know what was happening. She was very sweaty by this time. I asked if she had a history of seizures or had ever fainted before and she answered no. EMS was called. I checked her BP and it was 84/41. The patient tried to stand to assist with finding her husband in the store but I told her she had to sit until EMS arrive. We offered her water and orange juice and she asked for both. When the husband got there we asked him if she has a history of fainting or seizures and he said this has happened multiple times, mostly as a result of seeing blood. He said she hasn't had seizures but she has had tremors when this has happened. I checked her BP again and it was 116/88. She was feeling a lot better. EMS arrived and she was stable by that point. They recommended that she go to the hospital, but patient opted not to go. |
| 1301313 | 5/9/2021 | CO | 18 | F | 5/9/2021 | 5/9/2021 | Patient passed out after receiving second Pfizer vaccine |

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| 1301301 | 5/9/2021 | LA | 69 | F | 4/6/2021 | 4/7/2021 | The injection site felt "achey" immediately after the injection and this discomfort lasted several hours despite my gently massaging the band-aid site. My left arm felt "heavy" for the rest of the day. Within 18 hours of vaccination, I was awoken from sleep shaking violently. I thought that someone was shaking me violently. When I realized that my body was shaking so, I wrapped myself in a comforter; then I passed out or went back to sleep. When I was aware of myself again, I was too hot wrapped in the comforter and removed it. I was very concerned about what had happened to me so I moved slowly getting up and starting my day. I live alone so there was no one to help or advise me. For the next few days, I rested often, not sleeping, just feeling the need to lay about. By week 2 after the injection, I was "dragging" but not sleeping. When I laid down, my mind roamed about, when I tried to read or engage in meaningful activities were not successful. By week 3, I have full-blown insomnia. I go to bed at 4 am to be awake for hours while in bed, then being exhausted during the day. I am normally active, but I do not have the stamina to do what I love such as mowing my own lawn and working in garden. My heart rate jumps to 122 after 10-20 minutes of activities when in the past I could work steadily for 40 minutes and my heart rate never get above 90 beat per minute (I wear a charge 2 watch that monitors exercise parameters.) I had to stop to rest up to 4 times to complete the yard work that I could normally complete in less than 40 minutes. Currently, I have "hay fever" symptoms: itchy runny nose, tickle in the throat with dry cough, tired, runny eyes and frontal headache; I take benadryl and other allergy medicines. I have poor sleep habits. |
| 1301278 | 5/9/2021 | NC | 18 | M | 5/9/2021 | 5/9/2021 | Patient had a episode of syncope around 5 minutes of receiving the vaccine. Patient quickly recovered in less than a minute and then returned to normal around 10 minutes. |
| 1301259 | 5/9/2021 | WI | 16 | M | 4/15/2021 | 4/15/2021 | Patient fainted in store about 5 minutes after receiving vaccination, patient seemed anxious when vaccine was given |

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| 1301228 | 5/9/2021 | SC | | U | | | Right arm/hand swole Dizziness Chest pain Chest tightness Passed out at time of reaction Fever Trouble breathing Headache Muscle aches Joint aches Fatigue Weakness Couldn't stand/walk at time of reaction |
| 1301214 | 5/9/2021 | NY | 22 | M | 5/9/2021 | 5/9/2021 | Pt fainted after ~2-3 minutes of sitting on a bench. Moved to the floor and resting against hard surface. Pt was warm and sweating. Came back to in about 1 min. BP was normal. Gave water and food. Pt is resting until ride comes to pick him up. |
| 1301162 | 5/9/2021 | PA | 33 | M | 5/8/2021 | 5/9/2021 | A few minutes after patient was vaccinated he started to feel clumpy , cold sweat,feel like fainting " feeling of thing starting to close in" but alert and in a sitting position. He was talking the entire time. A few minutes later he said he starts to feel better. |
| 1301145 | 5/9/2021 | CT | 19 | F | 5/8/2021 | 5/8/2021 | The patient fainted about 20 seconds after I gave her the vaccine. I lowered her to the floor and was going to lay her on her side when she regained consciousness. She then felt nauseous and stayed on the floor for about 15 minutes. She never vomited. She started drinking her beverage and felt better in about 25 minutes. She communicated that she did not need further medical attention and I agreed. |
| 1301118 | 5/9/2021 | NY | 40 | M | 5/8/2021 | 5/8/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium |
| 1301251 | 5/9/2021 | HI | 24 | F | 5/9/2021 | 5/9/2021 | About 3 minutes after vaccine administered noticed patient hand twitching, asked if they were okay and got a head nod, then patient went unresponsive and fainted. Called for help and called 911. Laid patient down and elevated her legs and in a few seconds after patient came too. When the EMT got here checked her BP and it was low, observed her for about 5-10 minutes and her BP went up to normal. Patient left after about 30 minutes feeling fine |
| 1301107 | 5/9/2021 | NC | | M | 5/9/2021 | 5/9/2021 | PATIENT FAINTED IMMEDIATELY FOLLOWING INJECTION. FULLY RECOVERED AFTER INCIDENT |

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| 1301116 | 5/9/2021 | NY | 23 | F | 5/8/2021 | 5/8/2021 | Systemic: Chills-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive- Mild |

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| 1298904 | 5/8/2021 | MI | 73 | F | 2/1/2021 | | <p>Passed out 3 times after Moderna vaccine; hair thinning; dry skin and nose; dry skin and nose; muscle spasm in back; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out 3 times after Moderna vaccine) in a 73-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product PALBOCICLIB (IBRANCE) for Breast cancer. Concurrent medical conditions included Breast cancer, Acute cystitis, Anxiety, Lipid metabolism disorder NOS, Unspecified disorder of thyroid, Dizziness, Giddiness, Hyperlipidemia, Hypokalemia, Pure hypercholesterolemia, Thyrotoxicosis, Acquired hypothyroidism, Urinary tract infection, Drug allergy (Allergy to Amoxicillin), Drug allergy (Allergy to Sulfa) and Drug allergy (Allergy to Penicillin.). Concomitant products included DOCOSANOL (ABREVA), ANASTROZOLE, ATORVASTATIN CALCIUM, CALCIUM CARBONATE, COLECALCIFEROL (CALTRATE +VIT.D), MECLIZINE HCL, PROCHLORPERAZINE MALEATE, ZOLEDRONIC ACID MONOHYDRATE (ZOMETA) and LEVOTHYROXINE SODIUM (SYNTHYROID) for an unknown indication. In February 2021, the patient started PALBOCICLIB (IBRANCE) (unknown route) 125 milligram. On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced LOSS OF CONSCIOUSNESS (Passed out 3 times after Moderna vaccine) (seriousness criterion medically significant), ALOPECIA (hair thinning), DRY SKIN (dry skin and nose), NASAL DRYNESS (dry skin and nose) and MUSCLE SPASMS (muscle spasm in back). At the time of the report, LOSS OF CONSCIOUSNESS (Passed out 3 times after Moderna vaccine), ALOPECIA (hair thinning), DRY SKIN (dry skin and nose), NASAL DRYNESS (dry skin and nose) and MUSCLE SPASMS (muscle spasm in back) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. The patient reported that the co-suspect drug Ibrance (palbociclib) was taken once daily for 21 days. The patient reported</p> |

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| 1299292 | 5/8/2021 | UT | 52 | M | 4/1/2021 | 4/4/2021 | <p>that she went to ER (emergency room) for "passing out". No treatment information was provided. Very limited information regarding these events has been provided at this time. The patient's medical history and con meds are confounders.; Sender's Comments: Very limited information regarding these events has been provided at this time. The patient's medical history and con meds are confounders.</p> <p>This is a spontaneous report from a contactable consumer (patient's husband). A 52-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), dose 2 intramuscular, administered in Arm Right on 01Apr2021 14:00 (Lot Number: ER8727) as SINGLE DOSE for COVID-19 immunization. The patient previously took BNT162B2 (lot number: EN6198) in the right arm via intramuscular dose 1 on 10Mar2021 14:00 for COVID-19 immunization at 52 years old and experienced passed out, fell to floor and was unresponsive for multiple minutes, syncope, feeling of nausea and lightheadedness before passing out and mild sore arm. The patient's medical history and concomitant medications were not reported. Three days post vaccination, the patient experienced dizzy potential syncope on 04Apr2021 20:00, BP was 115/70 and heart rate: 48 bpm. The outcome of the events was unknown. No follow-up attempts are needed. No further information is expected.</p> |

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| 1299204 | 5/8/2021 | MA | 49 | F | 4/5/2021 | 4/5/2021 | Nose bleeds; Fainted; Insomnia; headache; Chills; This is a spontaneous report from a contactable consumer (patient). A 49-year-old female patient (non-pregnant) received first dose of BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine; lot number: ER8737), via an unspecified route of administration, administered in left arm on 05Apr2021 18:45 (at the age of 49-years) as single dose for COVID-19 immunization. Medical history included migraine and known allergies to sunflower oil, chamomile, mold, and dogs. The patient is not pregnant at the time of the vaccination. Concomitant medications included atenolol and rizatriptan benzoate (MAXALT). The patient has no other vaccine in four weeks. The patient previously had allergies to hydroxyethyl methacrylate, sodium pentothal, and erythromycin. The patient was not tested for covid post vaccination. The patient experienced insomnia and headache for three days, and chills on and off for over a week on 05Apr2021 at 21:00. The patient also experienced fainted on 06Apr2021 and nose bleeds lasting 15-45 minutes on 07Apr2021, 14Apr2021, 20Apr2021, and 23Apr2021 (patient never get nose bleeds previously). The patient received pain and antibiotics medications as treatments. The outcome of the events was unknown. No follow-up attempts are possible. No further information is expected. |

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| 1299223 | 5/8/2021 | MI | 45 | M | 4/14/2021 | 4/15/2021 | nearly fainted twice; I've been having weird pains in several spots inside my muscles all over the place in my legs, feet, arms, neck, chest, face and even my left hand ring finger tip. It's pain that is in spots, it feels; I've been having weird pains in several spots inside my muscles all over the place in my legs, feet, arms, neck, chest, face and even my left hand ring finger tip. It's pain that is in spots, it feels; pains in chest; catching my breath; very cold and clammy; This is a spontaneous report from a contactable consumer (the patient). A 45-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Lot number EW0169), via an unspecified route of administration, on 14Apr2021 at 11:30 (at the age of 45-years-old) as a single dose in the left arm for COVID-19 immunization. Medical history included cardiac disorder from an unknown date and unknown if ongoing, irregular heart beat and depression from an unknown date and unknown if ongoing. Concomitant medication included metoprolol (METOPROLOL) taken for an unspecified indication, start and stop date were not reported. The patient did not have any other vaccines within four weeks prior to the vaccination. The patient stated that when he first got the shot he actually nearly fainted twice and had to lay on the floor for a while. It was very scary, he thought he was going to die. He got very cold and clammy and had pains in chest and had a hard time catching his breath. They checked his vital signs a couple times and said they looked good. But he still felt sick and they said if he did not feel better soon they may have to call for an ambulance for him. Eventually he felt better enough to where he was able to get up off the floor and on handicap cart to drive out of there. Also, he's been having weird pains in several spots inside his muscles all over the place in his legs, feet, arms, neck, chest, face and even his left hand ring finger tip. It's pain that is in spots, it feels like mini-charley-horses that lasts anywhere from 20 something to 30 something seconds. Now it's mostly continuous pains in his thigh muscles between his legs. And a pain in one spot in his left arm bicep. This has been happening for days." The patient experienced "nearly fainted twice" on 15Apr2021 with outcome of not recovered, chest pain, got very cold and clammy and had a hard time catching his breath on 15Apr2021 with outcome of not recovered. He also |

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| 1299238 | 5/8/2021 | NY | 52 | F | 3/19/2021 | 3/20/2021 | <p>reported that he has been having weird pains in several spots inside his muscles all over the place in his legs, feet, arms, neck, chest, face and even his left hand ring finger tip. it's pain that is in spots, it feels starting on 15Apr2021 with outcome of not recovered. The patient underwent lab tests and procedures which included unspecified investigation: myalgias on an unspecified date . Therapeutic measures (unspecified) were taken as a result of the events.</p> <p>I fainted(the day after 1st dose); When I regained conscious I started to feel numbness and tingling in both arms and hands and few minutes later on both legs and feet.; My blood pressure was 89; When I regained conscious I started to feel numbness and tingling in both arms and hands and few minutes later on both legs and feet.; pain in joint; I have been feeling burn; This is a spontaneous report from a contactable consumer. A 52-years-old non-pregnant female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection, Lot Number: EN6204) via an unspecified route of administration, administered on left arm on 19Mar2021 08:45 (Batch/Lot Number: EN6204) and second dose via an unspecified route of administration, administered on left arm on 09Apr2021 09:15 (Lot Number: EP7533) as single dose, for covid-19 immunization. The patient Medical history was not reported. Prior to the vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19.The patient concomitant medications were not reported. On 20Mar2021 02:00 PM, the patient fainted after the 1st dose. Her blood pressure was 89. When she regained conscious, she started to feel numbness and tingling in both arms and hands and few minutes later on both legs and feet. Since then, she had been feeling burn and tingling in her hands and feet. Some pain in her joint. The paramedic asked her to walk and then It went away on that moment. The patient underwent lab tests and procedures which included blood pressure measurement was 89. The patient did not receive any treatment for the events. The outcome of the events was reported was recovered /Recovered with lasting effects. Information about Lot/Batch number is obtained. Additional information has been requested</p> |
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| 1299239 | 5/8/2021 | PA | 54 | F | 4/25/2021 | 4/25/2021 | Fainted; low pulse oxygen level; Fainted; low pulse oxygen level; This is a spontaneous report from a contactable consumer. A 54-year-old, nonpregnant, female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE) dose 1 at a health clinic facility, via an unspecified route of administration, administered in left arm on 25Apr2021 11:45 AM (age at vaccination: 54 years; Batch/Lot Number: ER8736) as single dose for COVID-19 immunization. Medical history was reported as none and patient had no known allergies. The patient's concomitant medications were not reported. Patient had not received any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination the patient was not diagnosed with COVID-19 and since the vaccination patient had not been tested for COVID-19. The patient experienced fainted; low pulse oxygen level on 25Apr2021 11:45 am. No treatment was given. Patient recovered on an unspecified date from fainted; low pulse oxygen level. |

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| 1299243 | 5/8/2021 | CT | 26 | M | 3/30/2021 | 3/31/2021 | <p>passed out/unconscious; This is a spontaneous report from a contactable consumer (patient). A 26-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), dose 1 via an unspecified route of administration, administered in Arm Right on 30Mar2021 06:00 (Lot Number: ER8732) as SINGLE DOSE and dose 2 via an unspecified route of administration, administered in Arm Right on 22Apr2021 06:00 (Lot Number: ER8736) as SINGLE DOSE for COVID-19 immunization. Medical history included penicillin, amoxicillin and sulfa drugs allergy from an unknown date and unknown if ongoing. The patient's concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. It was reported that after both doses of the vaccine, the patient had a regular evening and a full night's sleep. On 31Mar2021 07:00, the patient stated, "When I woke up and walked to the bathroom, I passed out both times. I was unconscious for a minute and was helped up, but passed out again and woke up a minute later. Emergency medical services were contacted both times". The events resulted in visit in emergency room/department or urgent care. The outcome of the event was recovered on unspecified date. No follow-up attempts are needed. No further information is expected.</p> |

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| 1299280 | 5/8/2021 | WA | 59 | F | 4/22/2021 | 4/1/2021 | little heart palpitations; felt really warm; felt like she was on fire; Nauseous; she was white as a ghost; felt cold; Dizzy; bruised her tailbone; Passed out; from when she fell she has a knot on the back of her head, and her back has a kink; from when she fell she has a knot on the back of her head, and her back has a kink; This is a spontaneous report from a contactable consumer (patient). A 59-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) dose 1 via an unspecified route of administration, administered in left arm on 22Apr2021 17:36 (Lot Number: EW0161) (at age 59 years old) as single dose for covid-19 immunisation. Medical history included diabetic from an unknown date and unknown if ongoing diagnosed in 2001-2002. The patient's concomitant medications were not reported. She did not get any other vaccinations yesterday or in the last four weeks. She says she has started no other new meds recently. The patient stated she got her first dose on 22Apr2021 and was perfectly fine, she didn't feel anything. She says when she went to bed a few hours later, she felt really really warm like she was sunburnt or something. She says she slept, then woke up around midnight and got up and thought maybe she had to go to the bathroom. She says she felt nauseous and thought she was going to be sick so she went back to the bathroom and she was white as a ghost, and felt cold and dizzy. She says she was feeling like she was gonna pass out, so she thought her sugar levels had dropped really low, so she went downstairs to check them then woke up on the floor, she had passed out. She says she came to, and checked her sugar and it was normal, 110, so she is assuming she passed out due to the shot. She says her first dose was injected around 17:36, and it was a few hours later when she went to bed around 09:00-9:30PM and got into bed when she kind of felt like she was on fire. She says she did no treatment; she went to sleep. She says from when she fell she has a knot on the back of her head, and her back has a kink in it. She says she is sure she has also bruised her tailbone. As of 23Apr2021, she doesn't feel warm or anything now, she just has little heart palpitations that is all, and those have stayed about the same. Outcome of the events was unknown. |

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| 1299333 | 5/8/2021 | AL | 59 | F | 4/12/2021 | 4/14/2021 | <p>Passed out; Pressure in her head; Major headache; Fatigue/ tiredness; Stress/fatigue headache; This is a spontaneous report from a contactable consumer (patient herself) via a medical information team. A 59-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, Lot number: ER8730, NDC number: Unknown, Expiration date: Unknown), via an unspecified route of administration in left arm on 12Apr2021 at 09:30 (at the age of 59-year-old) as a single dose for COVID-19 immunisation and asthmatic. The patient's medical history included rheumatoid arthritis (diagnosed three months ago), sleep disorder, blood pressure, blood pressure increased, PTSD (post-traumatic stress disorder). Patient's medical history (including any illness at time of vaccination) was none. Concomitant medications included trazodone (Strength: 25 mg) orally taking for years at 25 mg, once a day for sleep disorder, losartan (Strength: 25 mg) orally taking for 4 years at 25 mg, once a day for blood pressure, acetylsalicylic acid (ASPIRIN) orally taking for 4 years 81 mg, once a day for blood pressure increased, hydroxychloroquine (Strength: 200mg) orally taking for two months at 200 mg, once a day for rheumatoid arthritis, leflunomide (Strength: 10 mg) orally taking for two months at 10 mg, once a day, sertraline orally taking for 4 years at 50 mg, once a day for PTSD (post-traumatic stress disorder); All ongoing. The patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, Lot number: EN6206, NDC number: Unknown, Expiration date: Unknown), on 22Mar2021 at 15:30 as a single dose in left arm for COVID-19 Immunization and asthmatic. Family history was none. Prior vaccinations (within 4 weeks) was none. No additional vaccines administered on same date of the Pfizer suspect. On 14Apr2021 she reports developing a headache that has been ongoing since then, 14-16 days total. She also reports fatigue. She has been seen by doctors and had CT scans and bloodwork, the doctors think it was a stress/fatigue headache. Caller indicated she didn't think the symptoms were vaccine related but wants to rule everything out. Enquired what information do we have for duration of headache after vaccination. Caller indicated she had already spoken to a nurse with safety. Caller</p> |

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was a 59-year-old female reporting a headache that started 2 days after her second dose of the Pfizer COVID-19 vaccine, with symptoms that have been ongoing for 14-16 days. Response: Provided information from fact sheet that 55.1% of patients reported headache in the clinical trials, and that data was coming from the 7 days after either dose. Enquired how long side effects last. Which states adverse events typically start 1-2 days after vaccination and resolve shortly thereafter; Also spoke from CDC data which indicates adverse events might be more intense after the second dose. Referred back to healthcare professional for additional assessment and treatment. Consumer calling regarding the Pfizer COVID-19 vaccine. Reports she got the second shot 12Apr2021 and a couple of days later she got pressure in her head that has turned into a major headache. States and it has been a major headache. Reports she has been to the emergency room and her primary care doctor. Adds she had a CT scan, and bloodwork till she looks like a pin cushion, and everything was coming back fine. Adds she was tired all the time and could not get rid of the headache. Her question; Mentions she was looking at the side effects and saw tiredness and headaches a couple of days after; but enquired have we had any complaints about them lasting so long. Clarified she received the second dose of the Pfizer COVID-19 vaccine on 12Apr2021 at 09:30 AM in the left arm. A couple of day later the headache started; and the tiredness started at the same time. Tiredness was reported as worsened. She got the shot at PRIVACY. Adds she has missed two weeks of work and she could sleep 24 hours a day if the headache would let her. Adds she was 60 years old and takes a lot of medication; she tries not. Primary/prescriber: States the rank was major; she thinks her doctor was on maternity leave; Product: Pfizer COVID-19 vaccine; treatment first dose of the vaccine 22Mar2021 at 15:30 PM in the left arm. Lot EN6206; provides lot number for both doses from vaccination card but does not see NDC, expiration date or dose. This past Sunday the headache got so bad that she passed out in her living room and her 72-year-old husband called 911. She was taken to the (PRIVACY) Hospital and they did the CT scan and the blood work that was normal. She went home and tried to go to work on Monday and that only lasted 3 hours. No investigation assessment. No

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relevant test. The adverse events require a visit to emergency room but not admitted to the hospital and visit to physician office as she saw a doctor at the base on Monday, she had doctor's excuse to be off on Monday and Tuesday, so she called and got a walk-in appointment for Thursday. They did more blood work, and it came out great. The patient underwent lab test and procedure which included blood work: Normal, CT scan: Normal on an unspecified date. The outcome of the event passed out was recovered on an unspecified date in 2021, unknown for the event pressure in her head and not recovered for the other events. No follow-up attempts are needed. No further information is expected. Lot number obtained.

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| 1299289 | 5/8/2021 | MD | 27 | F | 4/24/2021 | 4/25/2021 | <p>Woke up with extreme nausea in middle of the night (2:30 AM) and passed out/fainted in the restroom. Unsure of how long episode lasted.; Woke up with extreme nausea in middle of the night (2:30 AM) and passed out/fainted in the restroom. Unsure of how long episode lasted.; Woke up with extreme nausea in middle of the night (2:30 AM) and passed out/fainted in the restroom. Unsure of how long episode lasted.; This is a spontaneous report from a non-contactable consumer (patient). A non-pregnant 27-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), dose 2 via an unspecified route of administration, administered in the left arm on 24Apr2021 at 09:00 (Batch/Lot Number: EW0164) at 27-years-old as a single dose for COVID-19 immunization. The patient did not receive any other vaccine within four weeks of the suspect vaccine. The patient did not have COVID prior to the vaccination. Medical history included Ehler-Danlos Syndrome, migraine, gastroparesis, and fibromyalgia; all from an unknown date and unknown if ongoing. Concomitant medications included colecalciferol (VITAMIN D); gabapentin (MANUFACTURER UNKNOWN); promethazine (MANUFACTURER UNKNOWN); ascorbic acid, betacarotene, calcium sulfate, colecalciferol, cyanocobalamin, ferrous fumarate, folic acid, nicotinamide, pyridoxine hydrochloride, retinol acetate, riboflavin, thiamine mononitrate, tocopheryl acetate, zinc oxide (PRENATAL VITAMINS); all taken for an unspecified indication, start and stop date were not reported; received within two weeks of the suspect vaccine.. The patient previously took bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) for COVID-19 immunization (Lot number: RE8732; Anatomical Location: Arm Left; Dose Number: 1) on 03Apr2021 at 27-years-old. On 25Apr2021 at 02:30, the patient experienced: woke up with extreme nausea in middle of the night (2:30 am) and passed out/fainted in the restroom. Unsure of how long episode lasted. (medically significant); with no treatment taken. The clinical outcome of the events was recovered on an unspecified date. The patient was not tested for COVID post vaccination. No follow-up attempts are possible. No further information is expected.</p> |

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| 1299315 | 5/8/2021 | AK | 16 | M | 3/31/2021 | 3/31/2021 | Too trashed to train for his sport/described as too weak to train; Swelling; Loss of taste and smell to some extent; Brain fog; Swollen glands; Loss of taste and smell to some extent; Leg pain; Joint pain; passed out/hit the floor, put a big bump on his head; passed out/hit the floor, put a big bump on his head; Redness; Chills; Fever; Too sick to get out of bed; Shortness of breath; Headache; Muscle pain; Tiredness/Fatigue; Pain in the arm; 2 inch diameter raised circle at injection site; could not barely remember his name; tried to study but just wasn't there, head on desk. Still has difficulty focusing; This is a spontaneous report from a contactable consumer (patient's father). A 16-year-old male patient received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot: ER2613 and expiry: Jul2021), via an unspecified route of administration in right arm on 31Mar2021 14:30 (at the age of 16-year-old) as single dose for covid-19 immunisation. Vaccination was taken because he was going back to school. The vaccine was not administered at a military facility. No additional vaccines administered on same date of BNT162B2 and no prior vaccinations (within 4 weeks). The patient received first dose of bnt162b2 (Lot: EN6199, Expiry: Jun2021) on 10Mar2021 at 13:30 in right arm (at the age of 16-years-old) as single dose for covid-19 immunisation and experienced loss of taste and smell and joint pain, all events started in Mar2021. Medical history included mild allergy to Birch pollen (which everybody has, but nothing else/patient tested for allergies, and had no significant allergies, they thought he might be because he spilled a sugared soda behind his bookcase in his room and there was mold growing so they thought he might be allergic to mold, so they tested for allergies and he has no allergy to mold) and ongoing vitamin supplementation. Family Medical History included Sarcoidosis with mother. Concomitant medications included vitamin d3 for vitamin supplementation from 2020 (about a year ago) and ongoing; ascorbic acid, rosa canina fruit (VITAMIN C) for vitamin supplementation from an unspecified date (several years ago) and ongoing and an unspecified ongoing multivitamin from an unspecified date (several years ago) at 1 taken daily for vitamin supplementation. On 31Mar2021, the patient experienced pain in the arm at 17:30, tiredness at 20:30, shortness of breath, |

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headache at 22:30 and muscle pain at 22:30. On 01Apr2021, the patient experienced fever at 00:30, chills at 01:30, redness at 02:30, leg pain at 08:30, fatigue (ongoing) at 02:30, joint pain at 08:30, too sick to get out of bed and passed out and hit the floor, put a big bump on his head at 05:30 (about 15 hours after second dose, patient was at the kitchen table with his head between his knees trying to breathe, passed out, hit the floor and put a big bump on his head). On 02Apr2021, the patient experienced brain fog at 14:30, swelling at 14:30, swollen glands at 02:30, loss of taste and smell to some extent at 14:30 and too sick to get out of bed. On day 2 (02Apr2021) and was still about pushing 100 degrees Fahrenheit and on 21Apr2021 (after 21 days) sometimes over sometimes less. On the following Monday (05Apr2021), he struggled back to school after 5 days, but came home early. He has just been trashed, too trashed to train for his sport, further described as too weak to train, he hadn't trained for 3 weeks. He still has a fever. His local doctor did not have any suggestions other than he should take acetaminophen and ibuprofen alternately to get rid of the headache and fever. In 2021, the patient experienced 2-inch diameter raised circle at injection site and disappeared after 10 days and there was a time he could not barely remember his name, tried to study but just wasn't there, head on desk. Still has difficulty focusing and doing his calculus. It was reported that the time to recover from any exertion seems to be longer by a lot. On 01Apr2021, body temperature reached 103 degrees Fahrenheit. The patient tried to do a few things like a week ago just because he couldn't stand to be in the house anymore he took a bike out for about 15 minutes and was just trashed from that experience and took 3 days to recover. The events did not require emergency room visit nor physician's office neither hospitalized. The outcome was recovered from loss of consciousness, head injury on 01Apr2021; from illness on 02Apr2021; from headache on 04Apr2021; from chills on 06Apr2021; from pain in arm and fatigue on 07Apr2021; from erythema on 11Apr2021; from ageusia and anosmia on 14Apr2021; from lymphadenopathy on 16Apr2021; from arthralgia on 17Apr2021; from myalgia on 18Apr2021; from leg pain on 21Apr2021; from vaccination site swelling in 2021; then recovered with sequel from dyspnoea on 05Apr2021

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19 F

4/21/2021

and from swelling on 07Apr2021; then recovering from pyrexia, feeling abnormal; then not recovered from asthenia and unknown for the remaining events.

I almost fainted; Nausea; Feeling sick and throw up; Feeling sick and throw up; felt very light headed/dizzy; Ear pain (right); This is a spontaneous report from a contactable consumer (patient). A 19-year-old female patient received first dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), via an unspecified route of administration in arm left, on 21Apr2021 at 18:00 (Lot Number: EW0162), as single dose, for COVID-19 immunisation. Medical history was not reported. Concomitant medication included unspecified nasal spray. The patient experienced almost fainted (medically significant) on an unspecified date with outcome of unknown, nausea (non-serious) on an unspecified date with outcome of unknown, feeling sick and throw up (non-serious) on an unspecified date with outcome of unknown, felt very light headed/dizzy (non-serious) on an unspecified date with outcome of unknown, ear pain (right) (non-serious) on an unspecified date with outcome of unknown. No follow-up attempts are needed. No further information is expected.

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| 1299202 | 5/8/2021 | TX | 17 | M | 4/22/2021 | 4/22/2021 | Fainting twice the next morning; Tachycardia (up to 145 bpm); somewhat disoriented for about 24 hours; Chills and fever starting that evening; Chills and fever starting that evening; Very lightheaded; This is a spontaneous report from a contactable consumer (patient). A 17-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 2 via an unspecified route of administration, administered in right arm on 22Apr2021 15:00 (Batch/Lot number was not reported) at the age of 17 years old, as single dose for COVID-19 immunisation. The patient's medical history was not reported. Concomitant medications included colecalciferol, fish oil (VITAMIN D WITH OMEGA 3); saccharomyces boulardii (FLORASTOR); and multivitamins; all taken for an unspecified indication, start and stop date were not reported. Historical vaccination included bnt162b2 on 01Apr2021 (product=COVID 19, brand=Pfizer, Lot number=ER8737, Administration time=03:00 PM, Vaccine location=Right arm, Dose number=1, age at vaccination=17 years) for COVID-19 immunization. On 22Apr2021 20:00, the patient experienced fainting twice the next morning, tachycardia (up to 145 bpm), somewhat disoriented for about 24 hours, chills and fever starting that evening, and very lightheaded. No treatment was given for the events. The patient was recovering from the events. The patient was not diagnosed with COVID prior to vaccination and has not been tested for COVID since the vaccination. Information on the lot/batch number has been requested. |

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| 1298904 | 5/8/2021 | MI | 73 | F | 2/1/2021 | | <p>Passed out 3 times after Moderna vaccine; hair thinning; dry skin and nose; dry skin and nose; muscle spasm in back; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out 3 times after Moderna vaccine) in a 73-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product PALBOCICLIB (IBRANCE) for Breast cancer. Concurrent medical conditions included Breast cancer, Acute cystitis, Anxiety, Lipid metabolism disorder NOS, Unspecified disorder of thyroid, Dizziness, Giddiness, Hyperlipidemia, Hypokalemia, Pure hypercholesterolemia, Thyrotoxicosis, Acquired hypothyroidism, Urinary tract infection, Drug allergy (Allergy to Amoxicillin), Drug allergy (Allergy to Sulfa) and Drug allergy (Allergy to Penicillin.). Concomitant products included DOCOSANOL (ABREVA), ANASTROZOLE, ATORVASTATIN CALCIUM, CALCIUM CARBONATE, COLECALCIFEROL (CALTRATE +VIT.D), MECLIZINE HCL, PROCHLORPERAZINE MALEATE, ZOLEDRONIC ACID MONOHYDRATE (ZOMETA) and LEVOTHYROXINE SODIUM (SYNTHYROID) for an unknown indication. In February 2021, the patient started PALBOCICLIB (IBRANCE) (unknown route) 125 milligram. On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced LOSS OF CONSCIOUSNESS (Passed out 3 times after Moderna vaccine) (seriousness criterion medically significant), ALOPECIA (hair thinning), DRY SKIN (dry skin and nose), NASAL DRYNESS (dry skin and nose) and MUSCLE SPASMS (muscle spasm in back). At the time of the report, LOSS OF CONSCIOUSNESS (Passed out 3 times after Moderna vaccine), ALOPECIA (hair thinning), DRY SKIN (dry skin and nose), NASAL DRYNESS (dry skin and nose) and MUSCLE SPASMS (muscle spasm in back) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. The patient reported that the co-suspect drug Ibrance (palbociclib) was taken once daily for 21 days. The patient reported</p> |

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that she went to ER (emergency room) for "passing out". No treatment information was provided. Very limited information regarding these events has been provided at this time. The patient's medical history and con meds are confounders.; Sender's Comments: Very limited information regarding these events has been provided at this time. The patient's medical history and con meds are confounders.

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| 1299288 | 5/8/2021 | TX | 63 | M | 4/14/2021 | 4/15/2021 | <p>passed out; no energy; Tired/exhausted; Blurred vision; This is a spontaneous report from a contactable consumer (patient). A 63-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), dose 2 via an unspecified route of administration, administered in Arm Right on 14Apr2021 09:00 (Lot Number: RW0150) as SINGLE DOSE for COVID-19 immunization. The patient previously took BNT162B2 (lot number: EN6207) dose 1 in the right arm on 24Mar2021 for COVID-19 immunization. Medical history included ongoing hormones are low. Concomitant medications included levothyroxine sodium (SYNTHROID) taken for hormone from an unspecified start date and ongoing; hydrocortisone taken for hormone from an unspecified start date and ongoing. The patient took the second dose of the COVID-19 vaccine, the next day he was tired on 15Apr2021. The patient had never been tired in his life like that. The patient was completely passed out. His wife wanted to call an ambulance and the caller told her no ambulance please. He knew the tiredness would eventually go away. The patient had no energy, zero, for 4 days or so. He has blurred vision for some reason on 15Apr2021. He thinks that the vaccine was no good. The patient has never had blurred vision before that that he is still experiencing some blurred vision. The blurred vision is what concerns him. His vision is not right and his side effects were severe. The tired disappeared, but the blurred vision is still there at time of call on 23Apr2021. The patient was wearing his reading glasses but that something has happened with his vision. He had 20/20 vision and now something is not right. The patient was exhausted, passing out, and not polite. The patient has to go to the doctor for the doctor to check his eyes. The outcome of tired was recovering. The outcome of the event blurred vision was not recovered and the outcome of the rest of the events was unknown.</p> |

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| 1299172 | 5/8/2021 | MN | 16 | M | 4/23/2021 | 4/23/2021 | seizure; passed out; light headed; fell out of chair and hit floor; making a gurgling/growling sound; his right arm was contracted and tight; his right arm was contracted and tight; This is a spontaneous report from a contactable consumer, the parent. A 16-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot: ER8736), via an unspecified route of administration in the left arm on 23Apr2021 at 09:30 (at the age of 16-years-old) as a single dose for COVID-19 immunization. Medical history included Ehlers-Danlos syndrome. The patient had no known allergies. The patient was not diagnosed with COVID-19 prior to the vaccination. Concomitant medications were none. The patient did not receive any other vaccinations within 4 weeks of the vaccine. On 23Apr2021 at 09:45 (reported as 13 minutes after the vaccine), the patient said he was lightheaded and then fell out of the chair and hit the floor. He started making a gurgling/growling sound. After the nurses flipped him over, they noted that his right arm was contracted and tight. They were unable to determine if he had passed out or had a seizure. He had no seizure history. He regained consciousness after about 45 seconds to a minute. The patient was not treated for the events. Since the vaccination, the patient was not tested for COVID-19. The clinical outcome of passed out was resolved on 23Apr2021, while of seizure, lightheaded, fell out of chair and hit floor, making a gurgling/growling sound, his right arm was contracted and tight was resolving. |

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| 1299147 | 5/8/2021 | IL | 21 | F | 4/21/2021 | 4/21/2021 | I fainted; This is a spontaneous report from a non-contactable consumer (patient). A 21-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported) via an unspecified route of administration, administered in left arm on 21Apr2021 12:45 as a single dose for COVID-19 immunisation. Medical history included allergies to Penicillin. The patient was not pregnant at the time of vaccination. The patient has not had COVID prior to vaccination. Concomitant medication included etonogestrel (NEXPLANON). The patient has not had any other vaccine in four weeks. The patient fainted on 21Apr2021 17:00. No treatment was given in response to the event. The outcome of the event was recovering. The patient was not tested for COVID post vaccination. No follow-up attempts are possible; information about lot/batch number cannot be obtained. |
| 1299145 | 5/8/2021 | TX | 30 | M | 3/23/2021 | 4/5/2021 | Arrhythmia; Syncope event; Supraventricular tachycardia (SVT); Heart palpitations; This is a spontaneous report from a contactable consumer (patient). A 30-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot number was not reported), via an unspecified route of administration, administered in left arm on 23Mar2021 13:00 as single dose for Covid-19 immunization. Medical history included cervical spondylosis from an unknown date and unknown if ongoing. The patient has no history of COVID prior vaccination. The patient was not COVID tested post vaccination. There were no concomitant medications. On 05Apr2021, the patient experienced Supraventricular tachycardia (SVT), arrhythmia resulting in syncope event, and heart palpitations following. The event resulted in a doctor or healthcare professional office/clinic visit, emergency room/department or urgent care, and has caused hospitalization for one day. It was unknown if a treatment was received for the events. The patient was recovering from the events. Information about lot/batch number has been requested. |

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| 1299128 | 5/8/2021 | MA | | F | 4/21/2021 | 4/22/2021 | fainted twice shortly after waking up/diagnosis was vasovagal syncope; fainted twice shortly after waking up/diagnosis was vasovagal syncope; This is a spontaneous report from a contactable consumer. A 35-year-old female patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), via an unspecified route of administration on 21Apr2021 (batch/lot number and expiration date were unknown) as a single dose for COVID-19 immunization. The patient previously received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date were unknown) on 31Mar2021 for COVID-19 immunization. Relevant medical history included a history of fainting on an unknown date in the past. It was unknown if the patient had known allergies. The patient's concomitant medications were not reported. The patient was not pregnant at the time of vaccination. The patient had no other vaccine in four weeks. The patient had no COVID-19 prior vaccination. It was unknown if the patient was tested for COVID-19 post vaccination. The morning after receiving the second vaccine dose, on 22Apr2021, the patient fainted twice shortly after waking up. The patient went to the emergency room (ER), and the diagnosis was vasovagal syncope. Vital signs were normal on an unspecified date. The adverse event (AE) resulted in an emergency room/department or urgent care. The patient did not receive any treatment for the AE. The patient recovered from the event on an unspecified date in 2021. Information on the batch/lot number has been requested. |

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| 1299124 | 5/8/2021 | NC | 45 | F | 4/9/2021 | 4/10/2021 | Severe allergic reaction; Fainting; Hives; Itching; Burning; Shortage of breath; This is a spontaneous report from a contactable consumer (patient). A 45-year-old non-pregnant female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number was not reported), via an unspecified route of administration, administered in Arm Left on 09Apr2021 08:45 as single dose for COVID-19 immunization in an hospital. Medical history included known allergy from an unknown date. There were no concomitant medications. No other vaccines taken in four weeks. No COVID-19 prior to vaccination and has not been tested for COVID-19 post vaccination. On 10Apr2021 13:00, the patient experienced severe allergic reaction - hives, itching, burning, shortage of breath, fainting. She was unable to stand or sit, and had to call ambulance and go to emergency. The events resulted in emergency and physician's office visit and required hospitalization. The patient was given a steroid and unspecified allergy medications as treatment. The outcome of the events was reported as recovered. Information on the lot/batch number has been requested. |

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| 1299089 | 5/8/2021 | NJ | | F | | 4/8/2021 | I then passed out and ended up on the floor; got sick in the stomach; This is a spontaneous report from a contactable consumer (patient). An 86-year-old non-pregnant female patient received bnt162b2 (Pfizer Covid vaccine), dose 1 on an unspecified date and dose 2 administered in left arm on 20Apr2021 00:15 (Lot Number: 101 #EP7534); both via an unspecified route of administration, as single dose for COVID-19 immunisation. Medical history included post phlebitic syndrome, macular degeneration and arthritis from an unknown date and unknown if ongoing. Concomitant medications included pravastatin taken for an unspecified indication, start and stop date were not reported; gabapentin taken for an unspecified indication, start and stop date were not reported; levothyroxine sodium (LEVOTHYROXIN) taken for an unspecified indication, start and stop date were not reported. The patient has not received other vaccine in four weeks. The patient had known allergies to Sulfer Plus (also reported as Sulfer). On 08Apr2021 10:00, the patient suddenly got sick in the stomach and thought was going to throw up. She then passed out and ended up on the floor. She was only out a second and woke up when she hit the floor. Outcome of the events was recovering. No treatment given for AEs. The patient was not diagnosed of Covid prior vaccination and has not been tested for Covid post vaccination. Information on the lot/batch number of first dose has been requested. |

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| 1299087 | 5/8/2021 | KY | 34 | F | 4/15/2021 | 4/15/2021 | After 15 minutes of sitting I passed out; slight seizure; headache; diarrhea; severe lethargy; arm soreness; This is a spontaneous report from a contactable consumer. A 34-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot Number: EW0164), via an unspecified route of administration, administered in Arm Right, at the age of 34 years, on 15Apr2021 12:45 at a SINGLE DOSE for covid-19 immunisation. Medical history included basedow's disease, gastroesophageal reflux disease and allergy to metals from an unknown date and unknown if ongoing. Concomitant medications included methimazole (METHIMAZOLE) taken for an unspecified indication, start and stop date were not reported. The patient previously took hydrocodone and experienced drug hypersensitivity and gluten and experienced food allergy. The patient stated, "After 15 minutes of sitting I passed out and had a slight seizure, then passed out and seized a second time. I had headache and diarrhea for two days following with severe lethargy and arm soreness" on 15Apr2021 01:00 PM. The patient underwent lab tests and procedures which included sars-cov-2 test: negative on 19Apr2021. No treatment was received for the events. The outcome of the events was recovered on an unspecified date. |

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| 1299082 | 5/8/2021 | FL | 56 | F | 4/20/2021 | 4/21/2021 | faint; I start to see blurry; I start to sweat; nauseous; blood pressure was dropping; headache; fever; chills; joint pain; This is a spontaneous report from a contactable other healthcare professional. A 56-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in Arm Left on 20Apr2021 (Batch/Lot number was not reported) as a single dose (at the age of 56 years) for covid-19 immunization. The patient's medical history was not reported. Concomitant medications included curcuma longa (TURMERIC [CURCUMA LONGA]); fish oil (OMEGA 3 [FISH OIL]); zinc (ZINC); vitamin d [vitamin d nos] (VITAMIN D [VITAMIN D NOS]). The patient received the first dose of COMIRNATY on 30Mar2021, 11:00 in the left arm at the age of 56-years for covid-19 immunization. On 21Apr2021 at 19:00, when the patient stood up for 10 minutes she started to see blurry, start to sweat, felt nauseous and felt like going to faint, she had to sit or lie down immediately so she don't fall. Patient sweat cold as if her blood pressure was dropping, this was happening to her on the second day after the second dose, also headache, a little fever, chills and a little nausea, on the third day (at the time of the report) she got up and stood up for 10 minutes again the same thing happened to me, although I no longer have fever or joint pain only a slight headache. The outcome of the events was not recovered. Information on the lot/batch number has been requested.; Sender's Comments: Based on data given and temporal association, the event syncope is assessed as possibly related to BNT162B2. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate. |

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| 1298896 | 5/8/2021 | MA | | U | 4/30/2021 | 4/30/2021 | passed out; Based on the current case data, this case has been classified as invalid. This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of LOSS OF CONSCIOUSNESS (passed out) in a patient of an unknown age and gender who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No medical history was provided by the reporter. On 30-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 30-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (passed out) (seriousness criterion medically significant). At the time of the report, LOSS OF CONSCIOUSNESS (passed out) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. |

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| 1298892 | 5/8/2021 | TX | | F | 4/10/2021 | | <p>She fainted, felt too much weakness; Stomach cramps; Diarrhea; Migraine pain; out of breath; cold sore; whenever close eye feel like falling down; admitted to ER because of dehydrated; body ache and pain all over the body; injection site in the left arm had big ball, big rash almost tennis ball size; pain at the injection site for a week; fever; knee got too weak; vomiting; nausea; Muscle pain; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (She fainted, felt too much weakness) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 039A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 10-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced LOSS OF CONSCIOUSNESS (She fainted, felt too much weakness) (seriousness criterion medically significant), ABDOMINAL PAIN UPPER (Stomach cramps), DIARRHOEA (Diarrhea), MIGRAINE (Migraine pain), DYSPNOEA (out of breath), ORAL HERPES (cold sore), DIZZINESS (whenever close eye feel like falling down), DEHYDRATION (admitted to ER because of dehydrated), PAIN (body ache and pain all over the body), VACCINATION SITE RASH (injection site in the left arm had big ball, big rash almost tennis ball size), VACCINATION SITE PAIN (pain at the injection site for a week), PYREXIA (fever), ARTHRALGIA (knee got too weak), VOMITING (vomiting), NAUSEA (nausea) and MYALGIA (Muscle pain). At the time of the report, LOSS OF CONSCIOUSNESS (She fainted, felt too much weakness), ABDOMINAL PAIN UPPER (Stomach cramps), DIARRHOEA (Diarrhea), MIGRAINE (Migraine pain), DYSPNOEA (out of breath), ORAL HERPES (cold sore), DIZZINESS (whenever close eye feel like falling down), DEHYDRATION (admitted to ER because of dehydrated), PAIN (body ache and pain all over the body), VACCINATION SITE RASH (injection site in the left arm had big ball, big rash almost tennis ball size), VACCINATION SITE PAIN (pain at the injection site for a week), PYREXIA (fever), ARTHRALGIA (knee got too weak), VOMITING (vomiting), NAUSEA (nausea) and MYALGIA (Muscle pain) outcome was unknown. The</p> |

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action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Concomitant product use was not provided by the reporter. The patient stated, After getting dose, she had all kind of adverse events, including stomach cramp, diarrhea, nausea, vomiting, dizziness, migraine pain , pain at the injection site for the week, out of breath, fever, cold sore, whenever she closed her eyes, she felt like falling down. She had to go to emergency department because of she was too much dehydrated, they had to give nausea medication and migraine pain medication through IV, over. She fainted, felt too much weakness, knee get too weak, when she massaged her left arm after 2 days, there was big ball (inflamed), when she message there was huge rash size of tennis ball, body ache, pain all over muscle and body. She thought she will gonna dye but 2 days later, she was okay. Treatment for the event included nausea and migraine pain medication intravenously. Company Comment - Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

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| 1298888 | 5/8/2021 | GA | 53 | F | 3/31/2021 | 4/1/2021 | <p>Feel achy; Have headache; Really really tired; Sweating; Got dizzy; Passed out; Fever in middle of night; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out) in a 53-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 048821A and 047821A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 31-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 28-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. In April 2021, the patient experienced LOSS OF CONSCIOUSNESS (Passed out) (seriousness criterion medically significant), DIZZINESS (Got dizzy) and PYREXIA (Fever in middle of night). On 28-Apr-2021, the patient experienced HYPERHIDROSIS (Sweating) and FATIGUE (Really really tired). On 29-Apr-2021, the patient experienced PAIN (Feel achy) and HEADACHE (Have headache). On 29-Apr-2021, PYREXIA (Fever in middle of night) had resolved. At the time of the report, LOSS OF CONSCIOUSNESS (Passed out), HYPERHIDROSIS (Sweating), DIZZINESS (Got dizzy), PAIN (Feel achy), HEADACHE (Have headache) and FATIGUE (Really really tired) outcome was unknown. No concomitant medications were reported. Treatment information was not provided. The patient did not experience any side effects after first dose. Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded.</p> |

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| 1298854 | 5/8/2021 | NM | 50 | F | 3/1/2021 | | <p>PRESYNCOPOAL SYMPTOMS/ALMOST FAINTED; LEFT ARM RADIANT PAIN; HEART PALPITATIONS; ABDOMINAL PAIN; SEVERE ENOUGH THAT SHE COULD NOT EAT; BURNING SENSATION OF STOMACH; TENDER/SORE SUBMANDIBULAR LYMPH NODE; LEFT JAW SWOLLEN; INFLAMMATION ON LEFT JAW; CHEST PAIN; TINGLING LEFT ARM; NUMBING OF LEFT ARM; DIZZINESS; LEFT ARM TENDERNESS AT INJECTION SITE; NAUSEA; HEADACHE; NECK LEFT LYMPH NODE INFLAMED;</p> <p>This spontaneous report received from a patient concerned a 50 year old female. The patient's height, and weight were not reported. The patient's past medical history included brain injury, and concurrent conditions included hypothyroidism, asthma, food allergies, latex allergy, nsaid (ibuprofen and aspirin) allergy, erythromycin allergy, betadine allergy, ct scan iodine allergy, dizziness, nausea, intermittent headache, and sulfa allergy. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported and batch number: 1805018 expiry: 25-MAY-2021) dose was not reported, administered on 24-MAR-2021 for prophylactic vaccination. Concomitant medications included fluticasone propionate for asthma, midodrine for brain injury, and levothyroxine for hypothyroidism. On MAR-2021, the subject experienced neck left lymph node inflamed. On 24-MAR-2021, the subject experienced dizziness. On 24-MAR-2021, the subject experienced left arm tenderness at injection site. On 24-MAR-2021, the subject experienced nausea. On 24-MAR-2021, the subject experienced headache. On 25-MAR-2021, the subject experienced numbing of left arm. On 25-MAR-2021 01:30, the subject experienced chest pain. On 25-MAR-2021 01:30, the subject experienced tingling left arm. On 31-MAR-2021, the subject experienced tender/sore submandibular lymph node. On 31-MAR-2021, the subject experienced left jaw swollen. On 31-MAR-2021, the subject experienced inflammation on left jaw. On 07-APR-2021, the subject experienced abdominal pain. On 07-APR-2021, the subject experienced severe enough that she could not eat. On 07-APR-2021, the subject experienced burning sensation of stomach. Laboratory data included: CT scan (NR: not provided) came out clear. On 13-APR-2021, Laboratory data included: Endoscopy (NR: not provided) came out</p> |

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clear. On 26-APR-2021, the subject experienced presyncopal symptoms/almost fainted. On 26-APR-2021, the subject experienced left arm radiant pain. On 26-APR-2021, the subject experienced heart palpitations. Laboratory data included: Diagnostic ultrasound (NR: not provided) came out clear. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from chest pain, and tingling left arm on 25-MAR-2021, recovered with sequelae from numbing of left arm on 25-MAR-2021, had not recovered from dizziness, nausea, headache, and left arm tenderness at injection site, and the outcome of tender/sore submandibular lymph node, left jaw swollen, abdominal pain, burning sensation of stomach, presyncopal symptoms/almost fainted, left arm radiant pain, heart palpitations, severe enough that she could not eat, inflammation on left jaw and neck left lymph node inflamed was not reported. This report was non-serious.

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| 1299340 | 5/8/2021 | MD | | F | 4/8/2021 | 4/16/2021 | This is a spontaneous report from a contactable other hcp (registered nurse). A 30-years-old adult female patient of received second dose of bnt162b2 (BNT162B2, solution for injection, Lot Number and expiry date was not reported) via an unspecified route of administration on 08Apr2021 as single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. On 16Apr2021, the patient experinced fainting and she lost consciousness and abdominal pain. Event Verbatim included, She had a fainting and she lost consciousness as one of the staff reporter was asking her question that fainting event occurred on Friday April 16th and so reporter was asking her if she has Vaccinated and she has received her second Pfizer vaccination on prior Thursday which was on April 8th so it was of Pfizer. reporter wish if had more information to provide you. She was taken by ambulance and reporter found out about her six hours later occurred at 9hr in the morning and reporter found out about that by clinical manager that she is in surgery for two hours, So reprter found out that she has an emergency surgery. Reporter was told an identifiable drug identifiable patient and identifiable reaction, So unfortunately, They would not tell me what precipitated the emergency surgery. So reporter know that it's not a lot information but reporter wanted to report it with all the information. Reporter said that morning was that she fainted had a lost consciousness and she said that she has had prior episodes of something that as prior has affected, may be related to food although they tested her and could not figured out what food it was. She was complaining of severe abdominal pain and when EMT scan was done, she said she did want to go to the hospital and like, reporter said all reporter knew 6hrs later that the clinical manager said that she has been in surgery for two hours and that did occur. That reporter do not know. The outcome of the events was unknown. Follow up attempts needed. Further information is expected.; Sender's Comments: Based on the current limited available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events cannot be totally excluded/assessed. The case will be reassessed if additional information becomes available. The impact of |

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this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

I got super nauseous.; I really wasn't feeling well; Then I got super hot and sweaty; Then I got super hot and sweaty; I passed out.; I had a fever of up to 103.5; This is a spontaneous report from a contactable consumer (patient). A 23-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), via an unspecified route of administration, administered in right arm on 21Apr2021 08:45 (Batch/Lot number was not reported) (at the age of 23 years old) as single dose for COVID-19 immunization. The patient medical history was not reported. The patient was not pregnant at the time of vaccination. Concomitant medication included ibuprofen. The patient previously took sepra and experienced allergies (known allergies); and first dose of BNT162B2 on 31Mar2021 08:45 at right arm for COVID-19 immunization. No other vaccine in four weeks. On 22Apr2021, the patient had a fever of up to 103.5 and was down to around 102 by the time of the incident (around 4:00). The patient woke up and was standing for about 3 minutes to refill water when she got super nauseous. She was making her way to the bathroom to throw up, and the next thing she knew she was on the floor. The patient was not sure how long she was passed out for though she had no reason to believe it was long. She tried to sit up, but she really wasn't feeling well, so she laid back down and closed her eyes for a bit. Then she got super hot and sweaty. Once that passed (maybe a few more minutes), she was able to check her temperature and she was down to around 101 and was able to get back to bed. No treatment for the events. No COVID prior vaccination. The patient had not been COVID tested post vaccination. The outcome of the events was recovered in Apr2021. Information about Batch/Lot number has been requested.

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| 1299086 | 5/8/2021 | PA | 19 | F | 4/20/2021 | 4/20/2021 | nausea; passed out; seizure; enlarged heart; hurt knee; sore mouth; This is a spontaneous report from a contactable other HCP (patient). A 19-year-old female non-pregnant patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EP7534) via an unspecified route of administration, in the left arm on 20Apr2021 at 11:00 (at the age of 19-years-old) as a single dose for COVID-19 immunisation. Medical history was none. The patient's concomitant medications were not reported. The patient has no history of COVID-19 prior to vaccination. The patient had received other vaccines within 4 weeks prior to the COVID-19 vaccine: 2nd dose of Human papilloma virus (HPV) vaccine on 06Apr2021 in the right arm. On 20Apr2021 22:30, the patient experienced passed out, seizure, hurt knee, sore mouth, enlarged heart, and nausea. The patient reported, "I was fine all day until around 10:30 pm I went into my mothers room and she was asking me how my arm feels I told her it was fine and right after saying that she said I passed out in front of her and then I began to have a seizure for about 50 seconds and then I woke up. After waking up from the event I had a hurt knee and sore mouth as well as an enlarged heart. I have no history of seizures in the past so it was definitely scary." The patient underwent lab tests and procedures which included SARS-COV-2 test: negative on 20Apr2021. Therapeutic measures taken included anti seizure meds, fentanyl, and paracetamol (TYLENOL). The patient recovered with sequelae from the events, passed out, seizure, hurt knee, sore mouth, and enlarged heart. Outcome of nausea was unknown.; Sender's Comments: A contributory role of BNT162B2 to the reported events cannot be fully excluded based on close temporal relationship and lack of alternate explanation at this time. However, the information provided is very limited and does not allow for a complete medical assessment. Case will be reassessed if additional information is received. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and |

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| | | | | | | | Investigators, as appropriate. |
| 1300324 | 5/8/2021 | NY | 17 | F | 5/6/2021 | 5/6/2021 | PATIENT HAD A SYNCOPE EPISODE AROUND 5- 10 MINUTES AFTER GETTING THE INJECTION |
| 1299279 | 5/8/2021 | OR | 44 | F | 4/5/2021 | 4/5/2021 | almost passed out; Dizzy; heart started racing; Dry mouth; metal taste; hard to swallow; itchy on arm it is little bit blotchy; itchy on arm it is little bit blotchy; Migraine; This is a spontaneous report from a contactable consumer. A 44-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EW0180), dose 1 via an unspecified route of administration, administered in left arm on 05Apr2021 as single dose for covid-19 immunisation. The patient medical history was not reported. The patient had unspecified concomitant medications; unspecified allergy medicine and unspecified vitamins. On 05Apr2021, the patient experienced the following events: almost passed out, dizzy, heart started racing, dry mouth, metal taste, hard to swallow, itchy on arm it is little bit blotchy, migraine. Details were as follows: patient had a reaction after the vaccination. She got really dizzy, almost passed out. Then her heart started racing. It took about 10 minutes to go normal and then she got like a super dry mouth and a metal taste after that, elaborated as like she had penny or something in her mouth like metal. After that, it was little more hard to swallow and just started to get itchy on arm, it is little bit blotchy. Therapeutic measures were taken as a result of migraine, and included treatment with sumatriptan (MANUFACTURER UNKNOWN), at 100 mg (take half every time). The outcome of events, almost passed out, dizzy, heart started racing, dry mouth, metal taste, hard to swallow, itchy on arm it is little bit blotchy, migraine was unknown. |
| 1300395 | 5/8/2021 | MI | 16 | F | 5/7/2021 | 5/7/2021 | Patient received Pfizer vaccination at 04:55 pm. Her father accompanied her. A few minutes after receiving the vaccination, she passed out. Her father shook her arm and she became cognizant again. She did not remember passing out and has never passed out in the past. I monitored her for 30 minutes and gave her bottled water to stay hydrated. After 30 minutes she was feeling well and I observed her as she stood up. She had no further problems. |

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| 1300281 | 5/8/2021 | AZ | 22 | M | 5/8/2021 | 5/8/2021 | Pt received Johnson and Johnson vaccine at about 145 pm. About 10 - 15 minutes later the pt was feeling light headed, nauseous, sweaty, and felt like he was going to faint. I attended to the patient, laid him on the ground bein case he fainted (which he did not), put his feet up, and asked him how he was feeling. The pt stated he felt better after laying down for a couple minutes and sat back up in his chair. I gave the pt the pt water and Gatorade and told the pt he would need to hang out for about 15 minutes longer. Pt stated he felt fine and 100% and requested to leave. |
| 1300235 | 5/8/2021 | NY | 16 | M | 5/4/2021 | 5/5/2021 | Child woke up at 3 am with severe nausea. Within minutes he complained about not being able to breathe. His lips turned blue and he was about to pass out. As I was able to keep him awake, I am not sure whether he would have had a febrile seizure (it very much looked like it) or just fainted. The fever spike was too fast, and his body couldn't handle it. His extreme nausea persisted for four hours (but he didn't vomit). He was completely debilitated. Fever spiked to 103 but stabilized at 102 for the following 24 hrs. |
| 1300200 | 5/8/2021 | CT | 21 | F | 5/7/2021 | 5/7/2021 | Patient fainted and hit her head on the floor. Once she came to she stated that she does faint sometimes after a vaccine. We called 911 and the ambulance responded and transported her to the hospital. I spoke with patient later in the day and she stated that she was feeling fine. |
| 1300143 | 5/8/2021 | | 43 | M | 5/8/2021 | 5/8/2021 | Syncope post vaccine with fall and head injury. Transported to trauma hosp by ambulance |
| 1300140 | 5/8/2021 | RI | 18 | M | 5/8/2021 | 5/8/2021 | Shortly after vaccine patient fainted. Came to within minutes, light headed. Rescue came, low BP. Took patient to hospital per patient request |

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| 1300120 | 5/8/2021 | NY | 37 | M | 5/8/2021 | 5/8/2021 | Pt fainted right after sitting down after the vaccine was administered. I called his name and he responded and slowly sat up. He said he was feeling better, so I helped him into the chair. I sat with him for about 15 minutes and he was alert and seemed completely fine. I asked if he had ever had a problem after a vaccine, and he said that he fainted once after a vaccine more than 20 years ago. (He claimed on question 4 of the questionnaire that he had never fainted after a vaccine.) I had him call for a ride home and for someone to pick up his car. He waited another 45 minutes and left. I checked on him frequently throughout the hour he was here and he reported he was fine each time. |
| 1300084 | 5/8/2021 | IL | 28 | M | 5/8/2021 | 5/8/2021 | 28 y/o male experienced a syncopal episode approximately 10 min following janssen vaccine left deltoid. He suffered an abrasion to outer left patella. He struck to left side of his head on the floor. No signs of abrasion or swelling that area. approximately 3 minutes after syncope, he vomited. x3 h= His pupils |
| 1299976 | 5/8/2021 | FL | 27 | M | 5/8/2021 | 5/8/2021 | PATIENT FAINTED 10 MINUTES AFTER ADMINISTRATION OF COVID VACCINE. CALLED 911. EMS CAME TO PHARMACY AND EVALUATED PATIENT. PATIENT WAS NOT BROUGHT TO HOSPITAL AT THIS TIME. |
| 1299962 | 5/8/2021 | WA | 24 | M | 4/30/2021 | 4/30/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: PATIENT EXPERIENCED SYNCOPE (FAINTING) BUT REGAINED CONSCIOUSNESS WITHIN A FEW SECONDS. HE WAS CONFIRMED THAT HE IS GOOD TO GO HOME BY HIMSELF. |
| 1299921 | 5/8/2021 | IL | 16 | M | 5/8/2021 | 5/8/2021 | Patient fainted at front of store approximately 10 minutes after vaccine administration. |
| 1299920 | 5/8/2021 | NH | 25 | M | 5/8/2021 | 5/8/2021 | pt was seated and fainted approx 5 mins after vaccine, did hit head on ground. Pt regained consciousness right after. Gave water and a banana and pt felt fine 10-15 minutes after. did report headache. advised to have md check him out if headache does not lessen |
| 1299881 | 5/8/2021 | MI | 26 | M | 5/8/2021 | 5/8/2021 | Light headed , he passed out and fall on the floor |

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| 1299512 | 5/8/2021 | PA | 49 | F | 5/7/2021 | 5/7/2021 | Systemic: Dizziness / Lightheadness-Medium, Additional Details: developed syncope, fell over in store |
| 1300419 | 5/8/2021 | CA | 64 | F | 12/23/2020 | 12/23/2020 | This is my 7th report to VAERS and my number is 908013. I developed burning and numbness in my face and tongue as well as presyncope and high bp spike of 180/126, 30 minutes after receiving the Pfizer covid vaccine. I became severely ill after and have had persistent severe paresthesias in my face and scalp, tongue, limbs and tight constricting band around chest as well as fatigue, tremors, fasciculations, internal vibrations, dizziness, blurred vision and headaches for 19 weeks. I have seen many physicians and have been very ill. My case was presented to the CDC grand rounds and I have been evaluated by neurologists. I am on many meds and my severe agonizing paresthesia pain is better controlled now. I have been severely debilitated now for 19 weeks. |
| 1299844 | 5/8/2021 | MA | 17 | F | 4/25/2021 | 4/25/2021 | Patient had syncope event following first shot. Father was in room with pharmacist. She also stated she had no eaten anything prior. After event, she claimed this had happened prior BUT SHE DID NOT make aware that this previously occurred on form. |
| 1299511 | 5/8/2021 | OR | 16 | F | 5/7/2021 | 5/7/2021 | Systemic: Fainting / Unresponsive-Mild |
| 1299531 | 5/8/2021 | PA | 24 | M | 5/7/2021 | 5/7/2021 | Systemic: Fainting / Unresponsive-Severe, Additional Details: Patient stood from seat during his 15 minute waiting period. Syncope occurred within 5 minutes. Patient fell face first on to floor and hit shelves with left arm. Loss of consciousness for approximately 2 minutes. Lost both 2 front teeth. Bleeding from mouth and left arm laceration. Patient was escorted Hospital via ambulance upon their arrival. Patient did not recall passing out. |
| 1299538 | 5/8/2021 | IN | 35 | M | 5/7/2021 | 5/7/2021 | Systemic: Fainting / Unresponsive-Medium, Additional Details: pt has a history of fainting with needles. We do not think it was the vaccine but the needle. We did call an ambulance to check him out. |

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| 1299540 | 5/8/2021 | VA | 57 | M | 5/7/2021 | 5/7/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Additional Details: 3 minutes post vaccination patient was pale, experiencing diaphoresis, felt funny. Immediately he drank apple juice and right after still felt like he was going to faint. As he was sitting upright in chair talking his eyes rolled back in his head and he became unresponsive. I had him lie down and propped up his feet. Called 911 and took his blood pressure. He regained consciousness but was still not coherent. He attempted to sit in chair again and immediately felt like he was going to pass out |
| 1299543 | 5/8/2021 | MO | 36 | M | 5/7/2021 | 5/7/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Additional Details: Patient warned pharmacist he passes out often after vaccines or blood draws. Within 1 minute after vaccine, patient started to sweat and lean forward off of bench he was sitting on. Pharmacist helped patient sit back at first but then decided to lay the patient down on the patient after it was clear patient was about to faint. Patient fainted for about 10-20 seconds then abruptly opened eyes and quickly acknowledged that he had fainting and sat up. Patient was given water and left in 40 minutes |
| 1299727 | 5/8/2021 | OH | 16 | F | 5/5/2021 | 5/6/2021 | 18 hours after administration, vasovagal syncope and low blood pressure for 11 hours after onset; patient fainted and could not sit up or stand -- blood pressure would drop; symptoms persisted for 11 hours |
| 1299544 | 5/8/2021 | MN | 32 | M | 5/7/2021 | 5/7/2021 | Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Exhaustion / Lethargy-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Additional Details: Shortly after vaccination, the patient became lethargic and slow to respond. Immunizing technician immediately called the RPh over to assess the patient. RPh instructed technician to grab blood pressure (BP) cuff and bottled water. BP did not register on cuff, the patient's pulse was 54. After a brief unresponsive episode, the patient became responsive & drank water. Then became sweaty and unresponsive 2 more times. RPh monitored for 30 minutes and will check in on 5/8/2021. |

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| 1299429 | 5/8/2021 | FL | 53 | M | 5/5/2021 | 5/5/2021 | Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Severe, Systemic: Seizure-Severe, Systemic: Shakiness-Severe, Additional Details: He came with his caretaker (sister) and was told side effects after vaccine administration. I also advised to remain seated for 15 minutes. The patient is special needs and got up anyways. I had pharmacy door open to watch patient while sister was in front of him watching him for reactions. I saw him through door standing against the wall. I ran to help him sit back down and he collapsed and hit his head on the floor . Sister said he has seizures. Called 911 |
| 1299709 | 5/8/2021 | FL | 35 | F | 5/8/2021 | 5/8/2021 | Patient fainted about 5 minutes after administration while being observed. Came to immediately afterwards. |
| 1299715 | 5/8/2021 | FL | 58 | F | 5/8/2021 | 5/8/2021 | pt fainted , heavy breathing , semi unresponsive .. Epi pen administered EMS called . Pt came to shortly after epi pen administration .. She told us after vaccine administration she has experienced Syncope in the past post vaccine admin |
| 1300488 | 5/8/2021 | CA | 23 | M | 5/8/2021 | 5/8/2021 | Patient had the vaccine and was doing well for 13 minutes then became nauseous and had feelings of throwing up. patient then fainted briefly but regained consciousness after 30 seconds. Was laying down on floor for 10 mins and was clammy, sweating and low blood pressure 116/68 but high pulse 90. Patient states was very anxious after with frequent respirations. Patient then was helped up to the chair and sat for 1 hour with blood pressure taken every 15 minutes. Blood pressure was taken before leaving 128/71 before leaving attended by caregiver. Patient states didn't eat and was working outside for 2 hours before getting vaccine. Patient was advised to seek medical attention if condition worsened and was amendable to that suggestion. |

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| 1299763 | 5/8/2021 | PA | 18 | F | 5/8/2021 | 5/8/2021 | Patient was near syncope. After receiving the vaccine about 2 minutes she started getting light headed. Patient was given water and animal crackers to get. She was feeling a little better but when she turned her head she still felt lightheaded. I had her eat and drink some more water. I asked how she was feeling. She stated that she was feeling better so i had her sit the rest of the way up with her feet hanging over the bed. I asked how she was feeling. She stated that she was feeling good. I then had her stand up with me standing in front of her and asked how she was feeling. She stated that she was feeling light headed in the middle of her forehead. I had her sit back down and gave her an ice pack to put on her neck. I then asked how she was feeling and she stated that she was feeling better and while she had the ice pack on her forehead she kept eating and drinking. I then had her stand up and she stated that she was better. i took her vitals at 11:24 am heart rate 75, o2 99 and BP 115/81, again at 11:30 am heart rate 79, o2 97 and BP 117/82. I released her to go home with her mom and dad at 11:41. |
| 1295066 | 5/7/2021 | CA | 20 | F | 5/6/2021 | 5/6/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Additional Details: patient fainted and fell to the floor and hit her head on the floor. She was with her boyfriend who was able to catch her and prevent a more severe fall. I went to the outside of the vaccination area and try to hold her head down and support it so she would not hit her head she came to within a minute and dioriented and confused. she remembered that she was in target and that she received her covid 19 moderna vaccine approximately 5 min before incident |
| 1295080 | 5/7/2021 | WV | 16 | F | 5/5/2021 | 5/5/2021 | Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Exhaustion / Lethargy-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Nausea-Mild, Systemic: Seizure-Mild, Additional Details: Parents were with patient. says it happens every time she gets shots or blood work. possible NES and/or hypotension. says its happened in docs office before and they're testing her for pots and her sister has non epileptic seizures. She was fine after about 15 minutes. gave her a cold packet to put on the back of her neck and just monitored her for further symptoms. |

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| 1295086 | 5/7/2021 | NY | 42 | F | 5/6/2021 | 5/6/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Hypotension-Mild, Additional Details: pt had syncope event. pt did not pass out, but almost did. blood pressure was taken and bp was low. heart rate 84. pt recovered within 5 minutes and drank gatorade |
| 1295107 | 5/7/2021 | CA | 37 | F | 5/6/2021 | 5/6/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Weakness-Mild, Additional Details: patient hit her head against the wall upon fainting, complained of pain on her head |
| 1295120 | 5/7/2021 | CA | 25 | F | 5/6/2021 | 5/6/2021 | Systemic: syncope, brady cardia, hypotension, feeling faint-Severe, Systemic: Hypotension-Severe |
| 1295127 | 5/7/2021 | PA | 30 | M | 5/6/2021 | 5/6/2021 | Systemic: Confusion-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Severe |
| 1295218 | 5/7/2021 | IN | 33 | F | 5/5/2021 | 5/6/2021 | I had chills and High fever. When I tried to get out of bed I fainted and was completely pale and weak for an hour. |
| 1295141 | 5/7/2021 | IL | 44 | M | 5/6/2021 | 5/6/2021 | Site: Pain at Injection Site-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Headache-Mild, Systemic: Tingling (specify: facial area, extremities)-Mild, Systemic: Tinnitus-Mild, Systemic: Visual Changes/Disturbances-Mild, Additional Details: Within a few minutes, pt began to sweat/feel light headed/dizzy/ringing in the ears. Pt stated he felt like he was going to pass out. Pt reported no symptoms related to anaphylaxis. Pt did not lose consciousness and symptoms started improving within 10 minutes. Pt then noticed blurry vision which resolved. Pt's BP was checked: 120/90, pulse WNL. Pt. was feeling fine but per PCP guidance, went to ER for a follow up when I followed up via phone. Reported no further issues after leaving pharmacy |

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| 1295162 | 5/7/2021 | CA | 53 | M | 5/6/2021 | 5/6/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Hypotension-Medium, Additional Details: BP 117/74 HR 62, second reading 122/111 HR 64, 3rd reading 142/81 HR 63. Patient was loss consciousness within 3 minutes of vaccine. I called the paramedics but he regained consciousness after 1 minute so we cancelled the call. He continued to complain of feeling dizzy so I had him stay for an additional 15 minutes. He has history of fainting with IVs/blood draws. |
| 1295047 | 5/7/2021 | PA | 28 | F | 5/6/2021 | 5/6/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Mild |
| 1294581 | 5/7/2021 | CA | 46 | F | 4/20/2021 | 4/20/2021 | Vasovagal Syncope starting five minutes after injection lasting about 20 minutes. BP fluctuated. Heart rate and O2 were normal. Monitored for approximately 30 minutes and then released. Abdominal pain started 3 hours after vaccination. Pain worsened and became severe over several hours, peaking with other flu-like symptoms and decreased over the next several days as other symptoms decreased. Pain was worse on left side about half way up rib cage and lasted for 5 days. Abdominal pain was worse and sharpened when twisting, rolling or bending torso. I can still feel a pulling sensation under ribs on left side off and on. Also starting about 15 hours after vaccination I had brownish colored urine that lasted about 36 hours. Saw FNP 10 days after vaccination. CBC, liver & kidney function blood work & urine dip stick tests all normal. They could not feel any enlargement on physical examination, but suspect spleen issue |
| 1295259 | 5/7/2021 | CA | 46 | F | 4/15/2021 | 4/17/2021 | I had a blackout. Fainted with no previous signs of me feeling dizzy. Fell on the cement with my face and head. Was confused for weeks after and bad headaches. Blackout and concussion plus some injuries from the fall. |
| 1295139 | 5/7/2021 | PA | 60 | M | 5/4/2021 | 5/5/2021 | Morning after the 2nd vaccine, I felt nauseous after eating breakfast, went to the kitchen sink to puke, passed out, and woke up on the floor in a puddle of vomit and with 2 broken teeth. |

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| 1295046 | 5/7/2021 | FL | 49 | M | 5/2/2021 | 5/2/2021 | Client verbalized feeling light headed after receiving the vaccine. Client stated, "I passed out, but this is normal for me after receiving any shots or seeing blood." Client refused medical evaluation from Fire Rescue. Client was educated on the importance of a full evaluation by rescue. Client exit location at 12:20pm. |
| 1294851 | 5/7/2021 | TX | 23 | M | 5/4/2021 | 5/4/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient slumped on chair at observation area within 5 minutes of vaccination but quickly regained consciousness when rph attempted to assist patient. Patient did not hit the ground and was unconscious for less than 30 seconds. patient urinated on self. blood pressure reading was 107/75mmhg and temperature was 97. Patient was monitored for more than 30 minutes afterward and left with a family member. |

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| 1294837 | 5/7/2021 | MA | 59 | F | 2/24/2021 | 3/24/2021 | In and out of consciousness; feeling faint, fainted briefly/Passed out multiple times; Couldn't stand up; Flu-like symptoms; Fever with a temperature of 103 degrees; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (In and out of consciousness) and SYNCOPE (feeling faint, fainted briefly/Passed out multiple times) in a 59-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 010N120A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No reported medical history. Concomitant products included AMITRIPTYLINE for an unknown indication. On 24-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 24-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 24-Mar-2021, the patient experienced LOSS OF CONSCIOUSNESS (In and out of consciousness) (seriousness criteria hospitalization and medically significant), SYNCOPE (feeling faint, fainted briefly/Passed out multiple times) (seriousness criteria hospitalization and medically significant), DYSSTASIA (Couldn't stand up) and INFLUENZA LIKE ILLNESS (Flu-like symptoms). 24-Mar-2021, the patient experienced PYREXIA (Fever with a temperature of 103 degrees). At the time of the report, LOSS OF CONSCIOUSNESS (In and out of consciousness), SYNCOPE (feeling faint, fainted briefly/Passed out multiple times), DYSSTASIA (Couldn't stand up), INFLUENZA LIKE ILLNESS (Flu-like symptoms) and PYREXIA (Fever with a temperature of 103 degrees) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 24-Mar-2021, Body temperature: 103 High. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Patient received treatment medication included Tylenol, to alleviate the symptoms. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a |

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causal relationship cannot be excluded.

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| 1294829 | 5/7/2021 | OH | 40 | F | 1/4/2021 | 1/5/2021 | <p>Passed out; Right arm became norm down to her fingers; No longer move right arm from elbow down to fingers / lost functioning completely in the entire right arm; Terrible pain in the entire right arm; Heart rate dropped; Vomited; This spontaneous case was reported by an other health care professional (subsequently medically confirmed) and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out) in a 40-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 039K20A and 031L20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No medical history was reported. Concomitant products included LEVOCETIRIZINE DIHYDROCHLORIDE (XYZAL) for an unknown indication. On 04-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 06-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 05-Jan-2021, the patient experienced LOSS OF CONSCIOUSNESS (Passed out) (seriousness criterion medically significant), HYPOAESTHESIA (Right arm became norm down to her fingers), HYPOKINESIA (No longer move right arm from elbow down to fingers / lost functioning completely in the entire right arm), PAIN IN EXTREMITY (Terrible pain in the entire right arm), HEART RATE DECREASED (Heart rate dropped) and VOMITING (Vomited). At the time of the report, LOSS OF CONSCIOUSNESS (Passed out), HYPOAESTHESIA (Right arm became norm down to her fingers), HYPOKINESIA (No longer move right arm from elbow down to fingers / lost functioning completely in the entire right arm), PAIN IN EXTREMITY (Terrible pain in the entire right arm), HEART RATE DECREASED (Heart rate dropped) and VOMITING (Vomited) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Electromyogram: unknown (Inconclusive) result unknown. On an unknown date, Heart rate: low (Low) Drop in heart rate was reported. On an unknown date, Spinal X-ray: normal (normal) Reported to be normal. mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) dosing remained unchanged. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Treatment</p> |

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| 1294778 | 5/7/2021 | | 24 | M | 5/6/2021 | 5/7/2021 | patient fainted |
| 1294728 | 5/7/2021 | CO | 67 | F | 4/19/2021 | 4/20/2021 | fainting; Severe head, neck and back pain; Severe head, neck and back pain; Severe head, neck and back pain; nausea; vomiting; This is a spontaneous report from a contactable consumer, the patient. This 67-year-old non-pregnant female patient reported that she received the second dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Lot Number: ER8737) via an unspecified route in the right arm on 19Apr2021 at 14:45 (at the age of 67-years-old) as a single dose for COVID-19 immunization. Medical history included chronic severe tension headaches and allergies to some antibiotics (unspecified products). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient did not have COVID prior to vaccination. Concomitant medications included unspecified supplements and herbals. The patient previously received first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Lot Number: EP7534) on 27Mar2021 at 14:45 in the right arm as a single dose for COVID-19 immunization. On 20Apr2021 at 02:30, the patient experienced severe head, neck and back pain, combined with nausea, vomiting and fainting. There was no treatment received for severe head, neck and back pain, combined with nausea, vomiting and fainting. The clinical outcomes of severe head, neck and back pain, nausea, vomiting and fainting was recovering. The patient was not tested for COVID post vaccination. |

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| 1294691 | 5/7/2021 | TX | 29 | M | 4/20/2021 | 4/21/2021 | fainted; aches; headache; fever; nauseous; excessively sweating; heartrate was elevated to about 90 bpm vs resting heartrate of 60 and remained elevated for the next 12 hours; This is a spontaneous report from a contactable consumer reporting for himself. A 29-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE) (lot number ER8735/expiration date: not provided), via an unspecified route of administration, on 20Apr2021 at 08:30 (at the age of 29 years old) as a single dose in the left arm for COVID-19 IMMUNIZATION. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE) (lot number /expiration date: not provided), via an unspecified route of administration, on 04Jan2021 at 12:00 (at the age of 29 years old) as a single dose in the left arm for COVID-19 IMMUNIZATION. Relevant medical history included was not provided. The patient did not have any known allergies to medications, food, or other products. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medication included melatonin, fish oil, calcium. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 21Apr2021 at 02:00, the patient fainted, experienced aches, headache, fever, nauseous, excessively sweating, and heartrate was elevated to about 90 bpm vs resting heartrate of 60 and remained elevated for the next 12 hours. The patient went to the emergency room due to the events and received treatment for these events which included fluids. The clinical course was as follows: after experiencing expected side effects (aches, headache, fever), the patient got up to use the restroom in the middle of the night. About 1-2 minutes after getting up, he fainted. The patient awoke shortly after on the floor and felt nauseous and was excessively sweating. His heartrate was elevated to about 90 bpm vs resting heartrate of 60 and remained elevated for the next 12 hours. The outcome of the events was recovering. Since the vaccination, the patient had been tested for COVID-19 (saliva test) on 20Apr2021, and the result was negative. |

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| 1294558 | 5/7/2021 | | 29 | F | 5/5/2021 | 5/6/2021 | 29-year-old female brought to the emergency room by EMS after syncopal episode at sick all this morning. Patient states that she receive the Johnson and Johnson coronavirus vaccine yesterday at approximately 1500. Throughout the evening and overnight she developed the expected side effects of myalgias, mild headache and fatigue. She states because she was not feeling well this morning she was instructed to give us a call. She is sick, she was sitting in a chair and when she was called to code forward she stood up, developed tunneling of her vision with spots in front of her eyes, felt dizzy and then passed out. When she woke up the dizziness had resolved. She states that she feels dizzy intermittently at base! |
| 1294547 | 5/7/2021 | FL | 37 | M | 4/24/2021 | 4/25/2021 | Extreme Fatigue that led to multiple syncope. A police officer thought I had a heart attack and thus I ended up in the hospital. I did not have a heart attack but seemed to have fainted while walking or realizing it. |
| 1294541 | 5/7/2021 | IL | 24 | M | 5/4/2021 | 5/5/2021 | Unexpected loss of consciousness day after vaccination, emailed my doctor and they said it was most likely vasovagal syncope from anxiety. Resolved within minutes with no lasting effects. |
| 1295404 | 5/7/2021 | CA | 24 | F | 5/6/2021 | 5/6/2021 | DIZZY, TINNITIS, SYNCOPE, EMESIS, SEEN BY PARAMEDICS, PROVIDED GATORADE AND SNACK, SYMPTOMS IMPROVED, REFUSED TRANSPORT, AMA SIGNED. |
| 1295279 | 5/7/2021 | | 16 | F | 5/4/2021 | 5/5/2021 | My daughter reported general achiness the night of the vaccine (May 4) and went to bed. The next morning (May 5) she passed out standing up from the toilet (about 5 minutes after getting out of bed). |

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| 1294709 | 5/7/2021 | AR | 47 | M | 3/16/2021 | 3/16/2021 | Guillain Barre syndrome; Doesn't feel from his waist down on left side; Doesn't feel from his waist down on right side; Weakness on right side; Weakness on left side; Passed out; High blood pressure; Lost hearing on right side; Headache; Fever; Pain in back; Pain in neck that went up to his head; This is a spontaneous report from a contactable consumer. A 47-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) via an unspecified route of administration on 16Mar2021 at 15:00 or 15:10 (at the age of 47-years-old) as a single dose in the right arm for COVID-19 immunization. Medical history was reported as none. It was reported that the patient had no pre-existing conditions and was "100% healthy and normally ran every day for 2-3 miles." Concomitant medications were reported as none. The patient did not receive any other vaccines within 4 weeks prior to the COVID-19 vaccination. The patient did not have a history of adverse events that followed prior vaccinations. The patient previously received the flu shot in Sep2020 (at the age of 47-years-old) for immunization and experienced no side effects. It was reported that the patient received a flu shot every year and experienced no side effects. On 16Mar2021 the patient experienced fever, pain in back and pain in neck that went up to his head; on 17Mar2021 the patient experienced headache; on 18Mar2021 the patient experienced does not feel from his waist down on left side, does not feel from his waist down on right side, weakness on right side, weakness on left side, passed out and on unspecified dates the patient experienced Guillain Barre syndrome, lost hearing on right side and high blood pressure. The events does not feel from his waist down on left side, does not feel from his waist down on right side, weakness on right side, weakness of left side and passed out (911 was called) required an emergency room visit; does not feel from his waist down on left side, does not feel from his waist down on right side, weakness on right side, weakness on left side and Guillain Barre syndrome also required a physician office visit. The patient was hospitalized for the events passed out, does not feel from his waist down on left side, does not feel from his waist down on right side, Guillain Barre syndrome, weakness of right side and weakness of left side from 18Mar2021 to 08Apr2021 (also reported as "for 22 days"). The reporter (friend of |

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the patient) called to file a report for his friend, who did not speak any English. The reporter wanted to make Pfizer aware of the adverse event that the patient experienced. The reporter stated that the hospital staff stated that they reported the patient's adverse event to Pfizer, the local health department and the CDC, but the patient's family and friends were not sure if the report was filed, thus the reporter was calling. The clinical course was reported as follows: "6-7 hours after getting home from getting the vaccine on 16Mar2021, the patient started to feel fever, pain in his back, and pain in his neck that went up to his head. The hospital had given the patient Tylenol and the hospital staff informed the patient that if he felt a fever or pain after the COVID-19 vaccine, he should take the Tylenol. The hospital staff also informed the patient that if his symptoms got worse to call 911 and go to the emergency room. The patient took the Tylenol and his fever came down a bit and the patient went to sleep. On the next day, 17Mar2021, the patient's neck pain started going up more like a headache. On the morning of Thursday, 18Mar2021, the patient got weak. The patient could barely move his hand or neck or leg. After the weakness began, "it was like 1-2-3" and the patient was passed out. After the patient passed out, 911 was called and when emergency personnel arrived, the emergency personnel thought that the patient had had a stroke. When the patient woke up on 18Mar2021, the patient was unable to feel from the waist to all the way down. The medical staff at the hospital did a lot of testing on the patient, MRIs and all that stuff, and all of the test results were coming back negative. The medical staff took some fluid from the patient's back after the patient was in the hospital for 2-3 days. The results came back negative until 2 weeks later when the patient's friends and family were informed that the patient had Guillain-Barre Syndrome. The patient's left side got a little improvement with medicine, but the patient's right side did not get any improvement." The patient's fever was treated for the first few days while hospitalized, the patient no longer had a fever. The patient was also treated for high blood pressure for the first few days that he was hospitalized. The reporter was informed of the patient's hearing loss "after the patient started speaking good, about 3-4 days after the patient had the first dose of the COVID-19 vaccine on 16Mar2021. The patient was

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| | | | | | <p>losing hearing before that, but the patient was not able to talk to the caller or family a lot." (as reported). The reporter did not provide details on medications administered during the patient's hospital stay. The reporter stated that the patient was just discharged from the hospital and sent home. The reported believed that the patient needed more care and more medicine and that he was not finished with treatment. The reporter stated that the patient should have been back to normal health before having been discharged from the hospital. He did not know why the patient was discharged. The reporter stated that the patient was sent home without any medicine and was still experiencing daily headaches. The patient took Advil Migraine for his headaches which did not work, or only worked for 10 minutes and then the pain would come back. The hospital referred the patient to a different facility. The reporter stated that the patient could not get an appointment with this facility for up to 2 months from now. The patient could not wait 2 months for relief. He could not be like that with a headache and no feeling on his right side for 2 months. According to a different doctor the patient needed "more IVIG, immunoglobulin and needed to get attention from a neurologist to watch him until he got better." The patient had an appointment scheduled with a neurologist for Monday 26Apr2021 at 08:00. The clinical outcome of the event fever was recovered/resolved on an unspecified date; does not feel from his waist down on left side and weakness on left side were recovering/resolving; does not feel from his waist down on right side, weakness on right side, lost hearing on right side, pain in back, pain in neck that went up to his head and headache were not recovered/not resolved and passed out, Guillain Barre syndrome and high blood pressure were unknown. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up</p> | | |
| 1296539 | 5/7/2021 | CA | 27 | M | 5/7/2021 | <p>FELT FAINT, DIAPHORETIC, PALE, SYNCOPE FOR 15 SEC, WOKE UP, PROVIDED DRINK AND SNACK, SYMPTOMS RESOLVED, REFUSED TRANSPORT.</p> | |
| 1295220 | 5/7/2021 | MN | 85 | F | 3/19/2021 | 4/14/2021 | <p>Patient presented to the ED on 3/18/21 with syncope. Patient presented to the ED and was subsequently hospitalized on 4/14/21 with sinus pause, syncope.</p> |

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| 1295509 | 5/7/2021 | TX | 16 | F | 4/10/2021 | 4/14/2021 | My 16-year-old daughter, very healthy without any health conditions, got her first dose of the Pfizer vaccine on Saturday evening, April 10th, at around 5pm. On Wednesday, she started complaining of shortness of breath, chest pains, which she described as a feeling of someone stubbing her heart. By Thursday, she began blacking out repeatedly throughout the day, each blackout lasting about a minute. These progressed and whenever she blacked out, she would not remember what happened. At first, she and I brushed it off as maybe lack of calcium since she rarely drinks milk. But as they intensified, I began to become more concerned. I told her I cannot leave her by herself in the house as I prepared to go pick up her young siblings from school then schedule an appointment with her doctor. On our way back home, she blacked out again, however, it was for more than a minute. Straight away, I drove to the ER close by. The doctor came back to inform me that her heartbeat was irregular and concerning based on her age. In that same moment, she began complaining of excessive pain like someone punching her heart out, and then she passed out again. Still with my two other children, the whole ordeal began to frighten them and illicit some heavy tears. Being that this ER was general admission, the doctors insisted they call in the paramedics to transport her to another ER for children. However, after being transported to the other ER, her condition began to intensify rather quickly and the pediatric doctor at the second ER informed us we would have to be transferred to Childrens intensive care unit where the cardiologists could check her heart, find the ultimate cause, and monitor her closely. In that moment, as a mother, I was speechless and extremely terrified. Seeing my daughter being transferred from ER to ER, made it even tougher on me so much that I could no longer hold myself together. Here she was in terrible pain and being moved around with no clear diagnosis and treatment. From there on, we spent a couple days in the Cardiac ICU waiting and praying with friends for answers and the best treatment she could get to ease the pain. By about the third day of being in the ICU, the cardiologists informed me, she had Acute Myocarditis. This was so shocking in a sense that both sides of the family have no history of heart issues. Secondly, she is a very healthy child. |

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| 1298008 | 5/7/2021 | AZ | 24 | F | 5/7/2021 | 5/7/2021 | patient fainted as soon as I administered the vaccine to her. she did not fall because she was leaning against her friend. I offered to put her on the floor but she declined. she put her head between her knees and got her consciousness right back. EMT was called but pt told her she was fine and no assessment was done. |
| 1297599 | 5/7/2021 | OR | 16 | F | 5/7/2021 | 5/7/2021 | 16yoF was accompanied with an adult who was present for the vaccination. The COVID-19 Vaccine Pfizer-BioNTech 0.3mL administered IM in right deltoid while patient was sitting. Patient remained sitting for 10 minutes after administered dose. Patient reported feeling well after the injection. Patient stood up while we continued to talk, after 2 more minutes passed out while standing. Suddenly, patient began to go limp and her eyes crossed and rolled back. Patient fell backwards into the privacy curtain and into aisle 13 of the store. Patient's head bounced off the floor. Immunizer knelt next to patient. Patient was unresponsive until immunizer placed cold hand on back of neck and front of chest to check if she was breathing, immunizer calmly guided patient to breath, slow deep breaths into the belly and patient's eyes fluttered open. She said her head hurt really bad. Immunizer offered to the accompanying adult to call EMS because patient should be evaluated after hitting her head so hard. The accompanying adult denied EMS, then stating that patient had previously fainted while walking and said that she would be fine. Immunizer advised patient to remain laying down while immunizer got some ice. Ice was then placed on the back of the head. Patient slowly stood up after laying for 10 minutes and was walked over to a sitting area to put feet up and continue with ice for another 5 minutes before the accomanying adult wanted to leave. |
| 1297542 | 5/7/2021 | OH | 61 | F | 3/15/2021 | 4/11/2021 | Fainted irregular heartbeat very high blood pressure constant serious heart burn |

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| 1297330 | 5/7/2021 | MO | 16 | M | 5/7/2021 | 5/7/2021 | Patient had no issues with 1st shot. After 5 minutes of injection pt fainted. He revived right away but pupils were dilated and he had trouble staying conscious. After a few more minutes pupils were normal but he was pale and sweaty. He drank some water and felt better. EMS were called and said he was ok. All happened within 30 minutes. |
| 1296970 | 5/7/2021 | GA | 42 | F | 4/15/2021 | 5/1/2021 | Passed out on May 1 2021 admitted into hospital with saddle bag pe and dvt |
| 1296554 | 5/7/2021 | IL | 30 | M | 5/7/2021 | 5/7/2021 | Pt had near syncopal episode following vaccine. Pt states "he has fainted around needles in the past" Vitals taken, hypotensive, reassessed pt after 5 minutes to find vitals WNL. Refused transport to hospital |
| 1296509 | 5/7/2021 | ME | 17 | M | 5/7/2021 | 5/7/2021 | Patient describes his experience as a "loss of vision" shortly followed by "blinking out" and dropping his phone. Patients in the observation area noticed him fainting and called pharmacy staff over to the location. Patient experienced no issues breathing nor experienced any swelling. Patient describes quickly feeling better, though pulse showed 60 BPM once EMS arrived. |
| 1296455 | 5/7/2021 | MI | 22 | F | 5/7/2021 | 5/7/2021 | Patient got warm was sweating fainted temporarily lost eyesight |
| 1296404 | 5/7/2021 | NY | 23 | M | 5/7/2021 | 5/7/2021 | The patient after receiving his vaccine, was recommended to take a seat for 15 minutes to observe for any adverse reactions. Very shortly after the shot, he walked up to the counsel window to ask for a bottled water because he was starting to feel faint. As I was trying to suggest he immediately take a seat, he fainted and fell forward into the immunization booth which absorbed most of his fall as he went to the ground and landed almost sitting cross legged. Immediately myself and pharmacy staff laid him flat onto his back and raised his legs above his head where he regained consciousness immediately and stayed laying down for a period of time to make sure he was feeling okay. After a few minutes we gave him a bottled water and had him sit down for 15 more minutes where he claimed he was feeling much better. |

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| 1296340 | 5/7/2021 | UT | 16 | M | 5/7/2021 | 5/7/2021 | syncope - pallor, nausea, sweating, Had pt sit on floor and remove mask, gave water & stay for 30 min. Checked BP wnl before he left, with someone else driving. |
| 1296184 | 5/7/2021 | MI | 45 | M | 5/6/2021 | 5/6/2021 | Before receiving the vaccination the patient mentioned he had a fear of needles. Patient was asked if he ever fainted after getting a vaccination or injection and patient reported no. The vaccine was administered to the patient and patient appeared to be fine for the next few minutes after getting vaccinated. Patient was told he could take a seat in the waiting area and wait until his 15-minutes were up and he could go. Patient was seated in the waiting area for about a minute but then got up to walk down one of the isles. When walking down the isle patient fainted and collapsed. This occurred approximately 10 minutes or so after he received the vaccine. Patient was helped to a chair and once seated appeared to shake/convulse (almost like a seizure) for approximately 5-10 seconds before snapping out of it and regaining consciousness. Afterwards he was alert and talking but didn't remember fainting. 911 was called and he was checked out by paramedics. After observing him for 15 minutes or so and determining his heartrate and blood pressure were normal and he appeared to be ok, the paramedics told him they can take him to the hospital to be evaluated further, or he was free to leave on his own without going to the hospital. The patient said he felt fine and declined being taken to the hospital. After another 10-15 minutes the patient left under his own power. Patient mentioned he would possibly be calling his physician and alerting them to the episode. |
| 1295723 | 5/7/2021 | FL | 77 | F | 3/23/2021 | 5/6/2021 | 5/6/21 Presented to ED by EMS with SOB and CP, near syncope, N&V |

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| 1296958 | 5/7/2021 | CA | 37 | F | 5/7/2021 | 5/7/2021 | Patient started with dizziness and fainted/fell to the ground, patient was warm and sweating, BP, temp and glucose levels was taken, patient sat up on the ground and ice pack was applied to her neck, pt got back up and sat on the chair and symptoms started getting worst, patient started sweating more and was not responding to questions being asked, finally patient was able to respond and wanted us to call 911. EMT came and continued monitoring patient and they said her tests came back normal so she felt comfortable to go home. |
| 1296138 | 5/7/2021 | CA | 16 | M | 5/6/2021 | 5/6/2021 | Syncope, dizziness, pallor, hungry, no breakfast. Stable and released with mother after significant improvement. |
| 1295672 | 5/7/2021 | CO | 28 | M | 5/6/2021 | 5/6/2021 | Patient experienced vasovagal syncope approximately 5 minutes following vaccination. Patient regained consciousness but was standing at time of incident and has a cut above eye after falling. He was taken by EMS to attend to the cut. |
| 1295710 | 5/7/2021 | TN | 65 | F | 4/7/2021 | 4/26/2021 | Do not know that this is a reaction to the Vaccination but, approximately 2 weeks after the second dose of the Pfizer vaccine, I was admitted to the hospital with Bilateral and saddle pulmonary embolism with acute cor pulmonale, repeated syncope, elevated troponin and BNP and RV strain by CT as well as EKG. 1. Ultrasound-guided right common femoral venous access. 2. Pulmonary angiogram. 3. Pulmonary artery pressure measurement. 4. Bilateral selective pulmonary angiogram. 5. Flowtreiver thrombectomy of bilateral pulmonary arteries with extraction of large thrombus burden. |
| 1295651 | 5/7/2021 | NC | 45 | F | 5/6/2021 | 5/6/2021 | Patient had syncope at work with periorbital swelling and closure of airway with swelling of the mouth. patient was given subq epi pen, solumedrol, and bendryl via EMS prior to ER arrival. 21:45pm on 05/06/2021 |
| 1295876 | 5/7/2021 | | 20 | M | 5/5/2021 | 5/5/2021 | Patient displayed syncope and observed contracting arms (those who witness expressed seizure like activity lasting less than one minute). Patient was pale and diaphoretic with a glazed over look. Vitals were taken and patient was transported to hospital for evaluation. |
| 1295897 | 5/7/2021 | AL | 18 | M | 5/7/2021 | 5/7/2021 | Patient passed out immediately after I gave him the shot |

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| 1295921 | 5/7/2021 | AR | 54 | F | 5/7/2021 | 5/7/2021 | Patient felt really hot. stood up and fainted. fell to the floor hitting her face. ended up with blood in the mouth and nose. Went with EMS |
| 1295946 | 5/7/2021 | | 19 | F | 5/5/2021 | 5/5/2021 | Patient stated feeling dizzy after receiving the vaccine and fainted immediately afterward. Patient fell slowly from sitting position to the floor; hit her head on the left side of forehead leaving redness at the site. Patient reported blurry vision, pressure on ears, and nausea that went away after a few minutes. Patient fainted three (3) times. Patient was pale and had diaphoretic skin. Approximately 30 minutes post, patient stated feeling better and symptoms went away. |
| 1295982 | 5/7/2021 | TX | 37 | M | 5/7/2021 | 5/7/2021 | FAINTING, SWEATING, EYES ROLLED BACK, ARMS AND LEGS JERKED. ABOUT 5 MINUTES OF SYMPTOMS, THEN RESTED FOR 30 MINUTES BEFORE LEAVING. |
| 1296130 | 5/7/2021 | IL | 45 | F | 5/6/2021 | 5/7/2021 | At 8:00am on 5/7/2021, I was using the toilet. I began to feel nauseated and sweaty, and then I passed out. I don't know how long I was out, but I was extremely exhausted and cold after the event. |
| 1295681 | 5/7/2021 | CO | 19 | M | 5/6/2021 | 5/6/2021 | Patient experienced vasovagal syncope approximately 5 minutes after vaccination. Patient regained consciousness shortly after. He was monitored by EMS in the pharmacy and left shortly after and was feeling fine. The patient's mother spoke with us a few hours later when she was separately at the pharmacy and stated he was feeling fine and had no further issues. |

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| 1291869 | 5/6/2021 | FL | 75 | F | 4/6/2021 | 4/28/2021 | FEELING LIGHTEADED WHEN SHE STANDS. REPORTS NEAR SYNCOPE UPON STANDING AND GUIDED HERSELF DOWN WHILE HOLDING A PLATE THAT DID NOT BREAK. REPORTS SLIGHT RIGHT SIDED HEADACHE DESCRIBED AS ELECTRICTY ONLY. NO CONFUSION. NO SPEECH CHANGES. WAS READING WSJ OUTLOUD TO DETERMINE. I ADVISED HER TO GO TO THE NEAREST EMERGENCY ROOM FOR EVALUATION AS I COULD NOT ATTRIBUTE HER SYMPTOMS TO VACCINE ADR. RESTING IN BED TO HELP ALEVATE SYMPTOMS. NO MEDICATIONS. 5/2-Called the home and there was no answer, 2nd attempt. Message was left to call the Covid hotline for further follow up. |
| 1291876 | 5/6/2021 | NJ | 29 | F | 5/5/2021 | 5/5/2021 | Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Mild, Systemic: Headache-Mild, Systemic: Weakness-Mild, Additional Details: approx 10 minutes after the vaccine pt felt light headed then fainted. she was unresponsive at first then she woke up. i gave the patient orange juice and used checked her bp. her blood pressure came back 115/75 i asked if the pt has taking any meds and pt said no. when pt fainted she fell on the floor scratcing her forehead and upper lip. no other problems |
| 1291919 | 5/6/2021 | NJ | 24 | M | 5/5/2021 | 5/5/2021 | Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Shakiness-Mild, Systemic: Tinnitus-Mild, Systemic: Visual Changes/Disturbances-Mild |
| 1291878 | 5/6/2021 | NJ | 24 | M | 5/5/2021 | 5/5/2021 | Site: Pain at Injection Site-Mild, Systemic: Fainting / Unresponsive-Mild |
| 1291908 | 5/6/2021 | OR | 24 | M | 5/5/2021 | 5/5/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Shakiness-Mild, Systemic: Weakness-Mild, Additional Details: Patient experienced symptoms for few minutes and was resolved within 20 minutes of injection |

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| 1291912 | 5/6/2021 | NJ | 24 | M | 5/5/2021 | 5/5/2021 | Systemic: Bell's Palsy-Mild, Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: OTHER-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Shakiness-Mild, Systemic: Tinnitus-Mild, Systemic: Weakness-Mild |
| 1291915 | 5/6/2021 | IL | 31 | M | 5/5/2021 | 5/5/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Nausea-Mild, Systemic: Vomiting-Mild |
| 1291929 | 5/6/2021 | TX | 44 | M | 5/5/2021 | 5/5/2021 | Systemic: Confusion-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Additional Details: Patient fainted after receiving covid vaccine (Janssen). He was sitting for the required 15 mintute interval and collapsed from his seat after about 5 to 7 mintutes. I quickly help position pt. against the wall. He was disoriented and slightly confused. He was conscious and alert but dazed. I immediately had by technician call 911 and the paramdeics attended to pt. After doing thorough evaluation of symtoms, pt. declined further treatment. His friend picked him up |
| 1291942 | 5/6/2021 | CA | 29 | F | 5/4/2021 | 5/4/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: The patient just fainted after recieving covid shot briefly. She stated that she usually faints after receiving shots or needles. |
| 1291956 | 5/6/2021 | IL | 28 | F | 5/5/2021 | 5/5/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Severe, Additional Details: Patient was unresponsive for 30 seconds and recovered quickly - orange juice was given. |
| 1292150 | 5/6/2021 | | 76 | F | 4/5/2021 | 4/14/2021 | On 5/6, the patient reports she was hospitalized on 4/14 after experiencing myocardial infarction, syncope, and fall resulting in the patient hitting her head |

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| 1291981 | 5/6/2021 | NH | 19 | F | 5/5/2021 | 5/5/2021 | PATIENT IMMEDIATELY FELT DIZZY AND PASSED OUT A FEW SECONDS LATER. THE VACCINATOR WAS NOT ABLE TO CATCH HER FALL AND SHE FELL OUT OF THE CHAIR AND HIT HER FOREHEAD. PT WAS IN AND OUT OF CONSCIOUSNESS Q5 MIN, UNRESPONSIVE TO PAINFUL STIMULI, AND MUCOUS MEMBRANES WERE BLUE FOR 30 SECONDS BEFORE JERKING AWAKE AND COLOR RETURNED TO NORMAL. SHE DENIES NECK PAIN, HEADACHE, AND SPINE INTACT. SHE REPORTED DIZZINESS, BLURRED VISION, AND RINGING IN THE EARS FOR Q15 MINUTES UNTIL RESIDED. PT PRESENTED WITH DIAPHORESIS UNTIL HER REPORTED SYMPTOMS RESIDED. VITALS, CLEAR LUNG SOUNDS, AND GLUCOMETER WERE DONE. MEDICS GAVE ORAL GLUCOSE. VITALS MONITORED UNTIL STABLE. PATIENT STAYED WITH FIRE Q1H AND SIGNED AMA WITH FIRE TO GO HOME. SCHOOL SECURITY WALKED HER HOME. |
| 1292115 | 5/6/2021 | VA | 61 | F | 5/5/2021 | 5/5/2021 | About 10 hours after receiving the vaccine I became nauseous and weak. I sat down on a kitchen chair and then passed out, falling to my right onto the floor. |
| 1291867 | 5/6/2021 | PA | 27 | M | 5/5/2021 | 5/5/2021 | Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadedness-Medium, Systemic: Fainting / Unresponsive-Medium, Additional Details: Patient received vaccine, sat in observation chair for about 3 min speaking on his phone, patient leans forward and passes out, falling out of the chair and hitting the floor. The patient was unconscious for about 10-15secs. Pharmacist administering vaccine, immediately went to his aid and had his sit. I was called over and offered medical care, which he declined. Patient was given water and an ice pack for the abrasions received. |
| 1291482 | 5/6/2021 | | 24 | F | 5/5/2021 | 5/5/2021 | Patient received vaccine today at 1500. Immediately after patient felt lightheaded, and was told by staff at vaccine sight she was pale. At home pt reports fever, syncope episode x 2 without hitting head, headache, N/V and chills. |

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| 1291988 | 5/6/2021 | AZ | 28 | F | 5/5/2021 | 5/5/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Numbness (specify: facial area, extremities)-Mild, Additional Details: pt reported feeling faint 2 minutes after vaccination, pt became dizzy, lightheaded, and fainted. pt did not fall or injur themselves, technician observer and pharmacist were in view of the patient during the event. we layed the patient down on the floor and put her feet up and checked her blood pressure (100/70, low per pt hx). pt recovered after 3-4 minutes, but layed on the floor for an additional 15. pt then sat in a chair and fully recovered and sat for 15 minutes. no injuries reported |
| 1291805 | 5/6/2021 | PA | 29 | M | 5/5/2021 | 5/5/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Medium, Systemic: Numbness (specify: facial area, extremities)-Medium, Systemic: Tingling (specify: facial area, extremities)-Medium, Additional Details: NAUSEOUS BUT NO VOMITING |
| 1291976 | 5/6/2021 | CA | 87 | F | 5/5/2021 | 5/5/2021 | Systemic: Chills-Mild, Systemic: Confusion-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Severe, Systemic: Hypotension-Severe, Systemic: Nausea-Medium, Systemic: Tingling (specify: facial area, extremities)-Medium, Systemic: Visual Changes/Disturbances-Severe, Systemic: Vomiting-Mild, Systemic: Weakness-Severe, Additional Details: shot 4:23pm, pt complained of seeing stars, being nousous, weak, was going in and out of concsciousness for 30 -45 seconds. Had patient elevate legs a while seated and took bp at 4:30pm was 115/36 pulse 52. pt tried to vomit but nothing came up. Took 2nd bp at 4:44pm 137/91 pulse 75. Moved patient inside pharmacy had her lay down flat with legs elevated for 8 minutes. complained of tingliness in both arms up to elbows. 3rd bp at 4:50pm was 127/80 pulse 65, 4th bp 125/82 pulse 77, left at 5pm |
| 1292160 | 5/6/2021 | | 60 | F | 2/23/2021 | 3/6/2021 | Patient presented to the ED on 3/6/21. Patient presented to the ED on 3/9/21 and was subsequently hospitalized for 5 days. Prinicipal problem was syncope and collapse. He was diagnosed with elevated brain natriuretic peptide and pleural effusion. These visits are within 6 weeks of receiving COVID vaccination. |

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| 1291457 | 5/6/2021 | CA | 27 | F | 4/9/2021 | 4/9/2021 | AFTER VACCINATION, PATIENT HAD A BLACK OUT/FAINTING SPELL DURING HER 15 MINUTES OBSERVATION AT THE PHARMACY. PATIENT STATED SHE FELL DOWN AND BUMP THE BACK OF HER HEAD. PATIENT ABLE TO GAIN CONCIUSNESS AND DENIED EMERGENCY HELP. PATIENT SAT AT THE PHARMACY WAITING AREA FOR APPROXIMATELY 45 MINUTES BEFORE SOMEONE PICKS HER UP. |

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| 1291567 | 5/6/2021 | AR | 87 | F | 1/22/2021 | 1/22/2021 | patient was unconscious; patient was unconscious; UTI; Bedridden; Patient began to vomit; This case was received via FDA VAERS (Reference number: 0967119) on 27-Apr-2021 and was forwarded to Moderna on 27-Apr-2021. This regulatory authority case was reported by an other health care professional (subsequently medically confirmed) and describes the occurrence of LOSS OF CONSCIOUSNESS (patient was unconscious) and SYNCOPE (patient was unconscious) in an 87-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 029L20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Penicillin allergy, Syncope (granddaughter states patient has episodes of syncope) and Wheelchair user. On 22-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 22-Jan-2021, the patient experienced LOSS OF CONSCIOUSNESS (patient was unconscious) (seriousness criterion medically significant) and SYNCOPE (patient was unconscious) (seriousness criterion medically significant). 22-Jan-2021, the patient experienced URINARY TRACT INFECTION (UTI), BEDRIDDEN (Bedridden) and VOMITING (Patient began to vomit). At the time of the report, LOSS OF CONSCIOUSNESS (patient was unconscious) and SYNCOPE (patient was unconscious) had resolved and URINARY TRACT INFECTION (UTI), BEDRIDDEN (Bedridden) and VOMITING (Patient began to vomit) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. After administration, the patient remained in waiting area for the recommended 15 minutes observation time. Approximately 20 minutes after vaccination, patient was unconscious and appeared not to be breathing, but pulse was palpable. Pharmacist administered 1 dose of 0.3mg epinephrine via epi-pen into patient's left thigh. The patient quickly regained consciousness, spoke to family, said she did not feel well. Emergency medical services (ems) arrived. The patient began to vomit, was placed on stretcher and left with ems. A few hours later the granddaughter reported |

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that the patient had a urinary tract infection (UTI) and physical exam by emergency room (ER) attributed her experience to untreated infection.; Sender's Comments: Based on the information provided which includes a strong temporal association between the use of mRNA-1273 vaccine and onset of the reported events, a causal relationship cannot be excluded. Vomiting is consistent with event safety profile.

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| 1291608 | 5/6/2021 | CA | 24 | F | 4/17/2021 | 4/17/2021 | face feels like it's tightening; painful menstrual period; Pale as a ghost; severe non-stop diarrhea since the day she got her vaccine; little stomach bug; Cannot keep eyes open at work; diarrhea has been all kinds of colors(now orange)/black when she was taking Pepto-Bismol; Fainted; Anxiety high; general health bad; Nausea; consistent low grade fever (100F to 100.4F); This spontaneous case was reported by a non-health professional (subsequently medically confirmed) and describes the occurrence of SYNCOPE (Fainted) in a 24-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 17-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 17-Apr-2021, the patient experienced SYNCOPE (Fainted), ANXIETY (Anxiety high), GENERAL PHYSICAL HEALTH DETERIORATION (general health bad), NAUSEA (Nausea) and PYREXIA (consistent low grade fever (100F to 100.4F)). On 18-Apr-2021, the patient experienced FAECES DISCOLOURED (diarrhea has been all kinds of colors(now orange)/black when she was taking Pepto-Bismol). On 19-Apr-2021, the patient experienced SOMNOLENCE (Cannot keep eyes open at work). On 20-Apr-2021, the patient experienced DIARRHOEA (severe non-stop diarrhea since the day she got her vaccine) and FOREIGN BODY IN GASTROINTESTINAL TRACT (little stomach bug). On 28-Apr-2021, the patient experienced SKIN TIGHTNESS (face feels like it's tightening), DYSMENORRHOEA (painful menstrual period) and PALLOR (Pale as a ghost). At the time of the report, SYNCOPE (Fainted) had resolved, SOMNOLENCE (Cannot keep eyes open at work), SKIN TIGHTNESS (face feels like it's tightening), ANXIETY (Anxiety high), GENERAL PHYSICAL HEALTH DETERIORATION (general health bad), FAECES DISCOLOURED (diarrhea has been all kinds of colors(now orange)/black when she was taking Pepto-Bismol), FOREIGN BODY IN GASTROINTESTINAL TRACT (little stomach bug), DYSMENORRHOEA (painful menstrual period), PALLOR (Pale as a ghost), NAUSEA (Nausea) and PYREXIA (consistent low grade fever (100F to 100.4F)) outcome was unknown and |

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DIARRHOEA (severe non-stop diarrhea since the day she got her vaccine) had not resolved. Not Provided
The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No concomitant medications were reported. Treatment medications include Pepto-Bismol (bismuth subsalicylate) for diarrhea for 1.5 days (unknown dose/frequency). Patient waited out 20 minutes post-vaccination and then went to the bathroom. When she came out of bathroom she fainted, paramedics were summoned. Mother took patient to Emergency Room(ER) 20 April 2021, after taking her first to urgent care (who directed mother to take patient to the ER), ER sent her home saying it was just a little stomach bug, but no one else in the family got this "bug". Patient's last test for Covid-19 was on Monday (26-Apr-2021) and results came back negative on 28-Apr-2021. Company comment: The event of faeces discolored is assessed as unlikely due to mRNA-1273 administration but due ingesting Pepto-Bismol. Based on the current available information and temporal association between the use of the product and the start date of the other events, a causal relationship cannot be excluded. Pyrexia and nausea are consistent with the product established safety profile.; Sender's Comments: The event of faeces discolored is assessed as unlikely due to mRNA-1273 administration but due ingesting Pepto-Bismol. Based on the current available information and temporal association between the use of the product and the start date of the other events, a causal relationship cannot be excluded. Pyrexia and nausea are consistent with the product established safety profile.

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| 1291612 | 5/6/2021 | OH | 38 | M | 4/26/2021 | 4/26/2021 | thinks it was a potential seizure; vasovagal effect from the needle; Patient fell off the bench onto the floor and became rigid and stiff and exhibited some rigid movement; Patient fell off the bench onto the floor and became rigid and stiff and exhibited some rigid movement; This spontaneous case was reported by a pharmacist (subsequently medically confirmed) and describes the occurrence of SEIZURE (thinks it was a potential seizure) and PRESYNCOPE (vasovagal effect from the needle) in a 38-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 007C21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 26-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 26-Apr-2021, the patient experienced SEIZURE (thinks it was a potential seizure) (seriousness criterion medically significant), PRESYNCOPE (vasovagal effect from the needle) (seriousness criterion medically significant), MUSCULOSKELETAL STIFFNESS (Patient fell off the bench onto the floor and became rigid and stiff and exhibited some rigid movement) and FALL (Patient fell off the bench onto the floor and became rigid and stiff and exhibited some rigid movement). At the time of the report, SEIZURE (thinks it was a potential seizure), PRESYNCOPE (vasovagal effect from the needle), MUSCULOSKELETAL STIFFNESS (Patient fell off the bench onto the floor and became rigid and stiff and exhibited some rigid movement) and FALL (Patient fell off the bench onto the floor and became rigid and stiff and exhibited some rigid movement) was resolving. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant medications taken by the patient were not provided. The reporter reported that patient never had any allergic reactions to vaccines or medications before and had no past medical histories for vasovagal reactions. After receiving the vaccine, the patient waited in the pharmacy for 15 minutes - 20 minutes. The patient fell off the bench onto the floor and became rigid and stiff and exhibited some rigid movement. The patient was out of it for 15-30 seconds. |

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The reporter stated that she called 911. The patient came to, his eyes were huge, but he was aware to self and surroundings. The emergency team came, took the patient's vitals which were stable and stated the patient likely experienced a vasovagal effect from the needle. However, the reporter thinks it was a potential seizure; more than a vasovagal response. Emergency team offered no treatment. The emergency team had encouraged the patient to follow up with a doctor but the patient did not want to make a big scene. Emergency team offered no treatment for the patient. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

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| 1291607 | 5/6/2021 | GA | 71 | F | 3/17/2021 | 4/14/2021 | Passed out in bathroom; Sweating; Fever; Headache; Nausea; Chills; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out in bathroom) in a 71-year-old female patient who received (batch nos. 031B21A and 023M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Blood pressure. Concomitant products included METFORMIN for an unknown indication. On 17-Mar-2021, the patient received first dose of mRNA-1273 (Intramuscular) 1 dosage form. On 14-Apr-2021 at 9:30 AM, received second dose of mRNA-1273 (Intramuscular) dosage was changed to 1 dosage form. On 14-Apr-2021 at 10:30 PM, the patient experienced HYPERHIDROSIS (Sweating), PYREXIA (Fever), HEADACHE (Headache), NAUSEA (Nausea) and CHILLS (Chills). On 15-Apr-2021 at 2:00 AM, the patient experienced LOSS OF CONSCIOUSNESS (Passed out in bathroom) (seriousness criteria medically significant). At the time of the report, LOSS OF CONSCIOUSNESS (Passed out in bathroom), HYPERHIDROSIS (Sweating), PYREXIA (Fever), HEADACHE (Headache), NAUSEA (Nausea) and CHILLS (Chills) outcome was unknown. Concomitant medications included blood pressure medications. The patient took Tylenol medication for the treatment. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events 13 hours after the second vaccination, a causal relationship cannot be excluded. Further information has been requested |
| 1291641 | 5/6/2021 | CA | 23 | M | 5/4/2021 | 5/4/2021 | Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Hypotension-Medium, Systemic: Weakness-Mild |
| 1291865 | 5/6/2021 | NJ | 17 | M | 5/5/2021 | 5/5/2021 | Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Severe, Systemic: Hyperventilation-Mild. |

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| 1291815 | 5/6/2021 | MO | 36 | M | 5/5/2021 | 5/5/2021 | Systemic: Chills-Medium, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Nausea-Severe, Systemic: Vomiting-Severe, Additional Details: patient was sitting in chair waiting for 15 min time period and fainted. when patient fell he hit his head on the ground causing a cut. patient was attended to by clinic staff and eventually emt |
| 1291819 | 5/6/2021 | CA | 52 | F | 4/30/2021 | 5/1/2021 | Site: Pain at Injection Site-Medium, Systemic: Abdominal Pain-Medium, Systemic: Body Aches Generalized-Medium, Systemic: Fainting / Unresponsive-Mild, Additional Details: constant pain down spine (midback to lower back). |
| 1291833 | 5/6/2021 | AZ | 23 | F | 5/5/2021 | 5/5/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Nausea-Medium, Systemic: Shakiness-Medium, Systemic: Tachycardia-Medium, Additional Details: pt felt lightheaded and dizzy, was unable to stand without passing out or some weakness. ems came and gave her an IV. she went to the emergency room. |

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| 1291852 | 5/6/2021 | NJ | 35 | F | 2/4/2021 | 2/16/2021 | Effects of vaccine were all normal during the first few days and through the first week. Had a bit of heart palpitations and fever after dose #2 - but it subsided by day 2 and i was back to normal mostly, no real issues. A week later i experienced an episode of almost-syncope in which i start falling forward in my seat and almost hit the wall in front of me and couldn't hold my head up. This has NEVER happened to me before. I did have a panic attack AFTER this because of how scared i had become of that feeling, but i recognize that and know the difference. After that i continued to experience bouts of dizziness and disequilibrium. I have almost fallen reaching for things, opening my car door, walking, etc. Several weeks later i experienced another flare up of the syncope feeling while at work where i almost fainted again and was able to regain composure and the disequilibrium sensation lasted for several days to which i sought medical help. I have been visiting a chiropractor and a physical therapist for over a month now with minor improvement. I still experience unexplained episodes that prevent me from being able to work properly or leave my home as it would be unsafe to drive or be out in case i need medical assistance. I have never experienced ANYTHING like this until i was vaccinated and three months later it is still affecting my quality of life. |
| 1291856 | 5/6/2021 | NJ | 17 | M | 5/5/2021 | 5/5/2021 | Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Hyperventilation-Medium, Systemic: Visual Changes/Disturbances-Medium |
| 1291859 | 5/6/2021 | NJ | 17 | M | 5/5/2021 | 5/5/2021 | Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Hyperventilation-Medium, Systemic: Visual Changes/Disturbances-Medium. |

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| 1291615 | 5/6/2021 | NJ | 51 | M | 4/26/2021 | 4/26/2021 | no appetite; cough; feels sick; exhausted; passed out; This spontaneous case was reported by a consumer and describes the occurrence of PRESYNCOPE (passed out) in a 51-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 045B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 26-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 26-Apr-2021, the patient experienced PRESYNCOPE (passed out) (seriousness criterion medically significant). On an unknown date, the patient experienced DECREASED APPETITE (no appetite), COUGH (cough), MALAISE (feels sick) and FATIGUE (exhausted). At the time of the report, PRESYNCOPE (passed out), DECREASED APPETITE (no appetite), COUGH (cough), MALAISE (feels sick) and FATIGUE (exhausted) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Treatment medication includes naproxen. Patient received the first dose of the Moderna Covid 19 vaccine (Lot:045B21A, expiration:Unknown) on 26APR2021 at a pharmacy. After the administration of the vaccine, patient passed out at a pharmacy and he had to wait there for 45 minutes. Since the administration of the vaccine patient has been exhausted, has no appetite, cough, and overall, just feels sick. Patient took Aleve to help alleviate his symptoms. |
| 1293834 | 5/6/2021 | PA | 46 | M | 5/6/2021 | 5/6/2021 | pt was hot and lightheaded while sitting then fainted in his chair pt reawoke after maybe 2 minutes and then was helped to floor 911 was called and ambulance crew checked pt over he refused to go to hospital after they checked him out and said that he looked fine he sat for maybe 5 more minutes then walked out of pharmacy |
| 1293097 | 5/6/2021 | NJ | 30 | M | 5/5/2021 | 5/5/2021 | Site: Pain at Injection Site-Mild, Systemic: Allergic: Difficulty Breathing-Medium, Systemic: Confusion-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Exhaustion / Lethargy-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Shakiness-Severe, Systemic: Weakness-Severe |

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| 1293209 | 5/6/2021 | NJ | 55 | F | 4/20/2021 | 4/27/2021 | Passed out on the road while on a walk with friends . Unable to standup w balance and weakness. Went to ER and was a TIA code. Full work up MRI, TC scan, chest X-ray, blood work, heart monitor COVID test. All were negative. Symptoms seem to have worsen (tired, weak, no appetite, diarrhea, confusion while talking). My fall was on my left side never hit my head and my hands have no cuts, that would show I braced my fall. |
| 1293393 | 5/6/2021 | | 17 | M | 5/6/2021 | 5/6/2021 | SYNCOPE, NAUSEA. Evaluated by EMS-Cleared |
| 1293417 | 5/6/2021 | | 40 | M | 5/6/2021 | 5/6/2021 | SYNCOPE. Evaluated by EMS-Cleared |
| 1293443 | 5/6/2021 | VA | 17 | M | 5/6/2021 | 5/6/2021 | 15:30 Client got Pfizer #2 1535 Client had full lost of consciousness (Syncope) in route to Observation due Vasovagal Client observed by Safety Officers and symptoms resolved Client able to leave with mom |
| 1293553 | 5/6/2021 | | 23 | M | 5/6/2021 | 5/6/2021 | patient fainted, had him sit down, drink water and a piece of candy. pt reported feeling much better |
| 1293034 | 5/6/2021 | MA | 54 | F | 5/4/2021 | 5/4/2021 | Systemic: Fainting / Unresponsive-Mild |
| 1293674 | 5/6/2021 | WA | 16 | M | 5/5/2021 | 5/5/2021 | Patient who has a history of fainting came in for a Covid-19 vaccine. Patient fainted right after getting the shot. Medics were called. Patient is okay after a few minutes of rest. Patient's father brought him home |
| 1294127 | 5/6/2021 | NY | 29 | M | 5/6/2021 | 5/6/2021 | Patient fainted for 1 to 2mins after receiving the vaccination. This happened 5 to 6 mins after the injection. The patient was sitting down, so I approached to see if it was an allergic reaction or not. I checked for breathing and had another patient call 911. Patient woke back up while we had the 911 operator on the phone. He asked for some water and he felt light headed. |
| 1293836 | 5/6/2021 | IL | 17 | F | 5/6/2021 | 5/6/2021 | Pre-syncope while at restraint approximately 45 minutes after vaccine. She slumped to the ground and lost muscle tone before being caught by her grandparents. |
| 1293847 | 5/6/2021 | CA | 27 | M | 5/6/2021 | 5/6/2021 | DIZZY, SYNCOPE, DIAPHORETIC, PALE, BS: 62, ATE SMALL MEAL EARLY AM, SEEN BY PARAMEDICS, VSS, PROVIDED GATORADE AND FOOD, SX IMPROVED, REFUSED TRANSPORT, AMA SIGNED. |

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| 1293902 | 5/6/2021 | CA | 63 | M | 3/16/2021 | 3/16/2021 | Within a minute I had a hot flash that started in my calf and went through my body. In less than a minute I was lightheaded and almost passed out (or fell asleep). I beeped my horn and the nurse came right over. They took my blood pressure and it was 150 over 120. (I've never had high blood pressure before. The second reading was 140 over 110. In about 5 minutes my BP was normal 120 over 80. |
| 1294106 | 5/6/2021 | OH | 24 | F | 5/6/2021 | 5/6/2021 | In reviewing patient information, she marked she has fainted in the past from vaccines. She clarified during the pre-examination that she fainted after getting a flu shot 2 years ago. She said she has not gotten a flu shot since and she had not had one prior to that since childhood. She said he thinks she fainted because she did not wait to be monitored after her shot and left immediately. She was informed that she should wait 30 minutes after her COVID vaccine to have proper monitoring. Patient received shot at 5pm, sat out in the waiting area outside pharmacy. Pharmacist checked on patient at 5:09pm and she was slumped over against the body of her friend. Pharmacist asked if she was okay and friend said she is beginning to faint. Friend was advised to lay friend on the ground, legs elevated, and a cold compress pack was giving to apply to patient's neck and face. At 5:14pm, patient was awake and alert. She remained seated on the ground for the remainder of her 30 minutes of monitoring. Patient left alert and well. |
| 1294148 | 5/6/2021 | IN | 44 | F | 4/1/2021 | 4/11/2021 | Pt received vaccine 4/1/2021, started to feel ill 4/11/2021 thought it was allergies. Continued to current date 5/6/2021. Had 3 different occurrences where she passed out. Dates were 4/30/2021, 5/5/2021, and today 5/6/2021 which lead to current admission. Came to ER found to have saddle PE from CTA scan. Went to Cath Lab and had INARI procedur to remove clot. Sent to ICU afterwards, was found to have DVT in left leg from ultrasound, started on argatroban. Currently is still in ICU, was admitted to ICU from cath lab today. |
| 1292166 | 5/6/2021 | OH | 24 | F | 5/5/2021 | 5/5/2021 | Syncope for less than one minute and quickly regained consciousness. |

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| 1291946 | 5/6/2021 | PA | 61 | M | 5/6/2021 | 5/6/2021 | Patient received first Pfizer COVID-19 vaccine. About 10 minutes after vaccine was given, patient passed out. He was diaphoretic and unconscious. At one point, he respiration rate stopped, patient had very diminished, weak carotid pulse. Epi was about to be given and patient started spontaneously breathing. Patient did not fall. Patient became conscious a few minutes later. He said he felt lightheaded and dizzy then he was out. Patient's wife said he has no allergies and not diabetic. He ate breakfast this morning. Medical response was called to bedside. Vitals were taken. Medical response transported patient to ER. As patient was getting transported, he started to go in and out of consciousness again. Patient in ER at this time. |
| 1293627 | 5/6/2021 | TN | 16 | F | 5/3/2021 | 5/4/2021 | At approximately 9 AM on the morning after receiving the second dose, the patient became dizzy at school. As she was walking to the teacher's desk, she lost consciousness and fainted, hitting her head on a desk, scraping her neck on a desk, and suffering several other minor injuries from the fall. She was immediately seen by school nurse and released to my care for the rest of the day. She rested at home and then was seen in at Walk-In Clinic to be evaluated for a concussion. On Day 2 after receiving the vaccine, the patient reported a sore throat, but no other symptoms. She was seen on the third day post-vaccine by our pediatrician's office for possible strep. She tested negative for strep and a concussion from her fainting episode was confirmed due to the lingering headache. |
| 1292542 | 5/6/2021 | WI | 27 | M | 5/5/2021 | 5/5/2021 | Patient received vaccination. While he was sitting for 15 minute post-observation he notified us that he was feeling dizzy. He also became pale and started sweating. We had patient put his head between his knees, gave him some water, and a cool, moist towel. After a few minutes patient felt much better and got his color back. He never fainted or lost consciousness. |
| 1292993 | 5/6/2021 | WA | 31 | M | 5/6/2021 | 5/6/2021 | After about 10 minutes post-injection, patient started to get really dizzy. He was helped from chair to the floor. He never fully passed out but said he has gotten dizzy after traumatic events in the past. The paramedic was already onsite and monitored him for next 15 minutes until he felt better and was stable. He left feeling fine. |

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| 1292217 | 5/6/2021 | ME | 25 | M | 5/6/2021 | 5/6/2021 | Patient fainted 2 minutes after getting vaccination |
| 1292637 | 5/6/2021 | VT | 31 | F | 5/6/2021 | 5/6/2021 | Pt received vaccine and roughly 5 mins post vaccination pt became delirious and then fainted. Pt was put supine on ground to prevent falling. 911 was dialed. Pt came to roughly 30 seconds after fainting. Paramedics came and treated the pt 10 mins after episode. |
| 1294164 | 5/6/2021 | TX | 27 | F | 5/6/2021 | 5/6/2021 | Immediate reaction included cold sweats, nausea, feeling of fainting |
| 1292668 | 5/6/2021 | MO | 33 | F | 5/6/2021 | 5/6/2021 | patient received Janssen covid 19 vaccine. she informed me before she received it that she gets dizzy with needles and has fainted in the past with drawing blood. I gave the vaccine and pt said she was okay. a couple minutes later she said she was feeling very warm and asked for something to fan herself with. I asked another pharmacist to get her a cold compress. When she came back with it and went to give it to the patient she fainted and slumped in her chair; she did not fall out of the chair. she was unconscious for less than 30 seconds and lost bladder control. I continued to rub her wrists and neck with the cold paper towel and she regained consciousness and said she was okay. we observed her for at least 20 minutes more and then she left. she said she did not require any further medical attention. |
| 1292174 | 5/6/2021 | NH | 34 | F | 5/5/2021 | 5/6/2021 | Dizzy, vertigo, fainting |
| 1292720 | 5/6/2021 | OH | 53 | F | 1/20/2021 | 4/2/2021 | 4/2/21 woke up with whole left side without feeling/weakness, to ER, stroke ruled out, sent home, progressively got weaker. Blood pressure and pulse remaining low around 114/58 and 48 despite no longer taking BP meds. Passed out 2am 4/4/21, 911 to hospital. Continued to decline, sent to acute rehab 4/7-4/10. d/c'd home currently wearing heart monitor for 30days, follow up with neuro tomorrow 5/7, f/u with cardio 5/14. Therapy twice a week. |
| 1292881 | 5/6/2021 | MA | 16 | F | 5/6/2021 | 5/6/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Vomiting-Mild |

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| 1292927 | 5/6/2021 | TX | 22 | F | 5/6/2021 | 5/6/2021 | pt was given the Janssen vaccine at 12:05pm and pt had little bit of anxiety and was also having menstrual cycle. pt felt light headed 3 minutes after the shot and continued to have it for 20 minutes. Pharmacist offered to call 911 and pt denied it as pt have had panic attacks before. Pt was given ammonia inhalant once to breath in as she felt like fainting. Pt also developed chills. Pt was back to normal except menstrual cramping and had a friend come pick her up. Pt was advised to go to talk to her doctor and get medically checked out and go to ER/call 911 if any of the symptoms comes back. |
| 1292929 | 5/6/2021 | IL | 16 | F | 5/5/2021 | 5/5/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: mom said she passes out after shots, fainted less than 1 min, had her lay down with feet up for 15 min, then sit up for 15min before leaving, |
| 1292930 | 5/6/2021 | WA | 19 | F | 5/6/2021 | 5/6/2021 | After about 6 minutes post-injection, she started feeling really dizzy and briefly passed out. After a couple minutes she was responsive, but still really weak and tired and said she had blurry vision. We called 911 and they came in and monitored blood pressure and heart rate, which was really low when they started, but did come back up into normal range and patient was feeling much better after about 15 minutes, but still tired. |
| 1292949 | 5/6/2021 | CA | 34 | M | 4/26/2021 | 4/26/2021 | CUSTOMER REPORTED FEELING LIGHTHEADED/DIZZY ABOUT 2 MIN AFTER INJECTION. HE SAT DOWN AND PUT HIS HEAD DOWN ON TABLE AND PASSED OUT FOR ABOUT 5 SECONDS, WOKE UP THEN PUT HEAD DOWN AGAIN AND PASSED OUT AGAIN FOR 5 SECONDS THEN WOKE UP AND SAID HE WAS FEELING NAUSEOUS THEN WE CALLED 911 . HE LAID ON FLOOR AND RAISED HIS LEGS AND HE WAS OK AFTER AND HE DID NOT WANT TO GO TO THE HOSPITAL |

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| 1292972 | 5/6/2021 | CA | 17 | F | 5/6/2021 | 5/6/2021 | Client received her second dose of the Pfizer COVID-19 vaccine (Lot #EW0179 Exp. 8/2021) at 10:03 AM. EMT saw client stand in observation area. Client appeared "unsteady on her feet". EMT rushed to patient and guided her slowly to the ground while protecting her head. Patient then fainted. EMTs assisted patient to gravity bed where patient regained consciousness. Patient was alert and oriented to person, place, time, and event (AAO x 4) immediately following the incident. Client's vitals were assessed every 5 minutes. They were recorded as follows 10:19- Blood Pressure (BP) 100/74, Heart Rate (HR) 86, Oxygen Saturation (SPO2) 99%, and Respiratory Rate (RR) 18; 10:24- BP 100/72, HR 81, SPO2 99% RR 18; 10:29- BP 100/76, HR 82, SPO2 99% RR 16; 10:34- BP 102/74, HR 84, SPO2 99% RR 18; 10:39- BP 100/72, HR 82, SPO2 99% RR 18; 10:44- BP 110/76, HR 86, SPO2 99% RR 18. Client was given a bottle of water and instructed to remain in a semi-fowler's (45 degree) position until vitals stabilized. Patient remained on vaccination site for 30 minutes following the episode of fainting. EMT obtained orthostatic vital signs (vital trend from lying down, to sitting, to standing). Patient was negative for orthostatic hypotension. Symptoms resolved as indicated above in vital signs. Patient stated she was "feeling better" and declined EMS transport. Patient and father were educated by RN on home care (rest and fluids) and to seek emergency medical attention if symptoms persisted or worsened. Patient left the vaccination site at 10:45 with father and sister with steady gait and in no change in status. |
| 1292852 | 5/6/2021 | NC | 79 | M | 2/9/2021 | 2/16/2021 | 23 Feb 2021: event: fainting spell, nausea, no prior warning 26 Feb 2021: doctor visit, fitted with heart monitor 1 March 2021: Doctor visit, readout of heart monitor showed no anomaly. 16 Mar 2021: event: fainting spell, nausea, no prior warning 30 Mar 2021: event: passed out in shower, EMT called, rushed to Medical Center, admitted to ICU 31 Mar 2021: treatment: pacemaker installed circa 1000 AM, 2 Apr 2021: released from Hospital xxx |

| <i>VAERS_ID</i> | <i>RECVDATE</i> | <i>STATE</i> | <i>AGE_YRS</i> | <i>SEX</i> | <i>VAX_DATE</i> | <i>ONSET_DATE</i> | <i>SYMPTOM_TEXT</i> |
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| 1292984 | 5/6/2021 | NC | 17 | M | 5/5/2021 | 5/5/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Nausea-Medium, Systemic: Seizure-Severe, Systemic: Vomiting-Medium, Additional Details: Patient began to seize/faint in chair within 5 minutes post-vaccination. Paramedics were called as I stabilized patient on floor. Consciousness regained within 60 seconds, patient confused/unaware of what had occurred. Patient flush, lightheaded, vomiting. Paramedics arrived and confirmed patient was stable and safe to leave scene without further intervention. |
| 1288905 | 5/5/2021 | NY | 20 | M | 5/4/2021 | 5/4/2021 | Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Mild, Systemic: Fainting / Unresponsive-Mild |

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1288441 | 5/5/2021 | FL | 81 | F | 1/12/2021 | 1/15/2021 | shortness of breath; congestive heart failure; fainting; dizziness; This is a spontaneous report from a contactable consumer. An 81-year-old female patient (consumer's wife) received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number:EJ1289), dose 1 via an unspecified route of administration on 12Jan2021 as SINGLE DOSE (at the age of 81 years-old) for covid-19 immunisation. The patient's medical history was not reported. Concomitant medication included metoprolol taken for congestive heart failure from Jan2021 to 2021 and unspecified medication. The patient experienced shortness of breath, congestive heart failure, fainting and dizziness on 15Jan2021. The patient was hospitalized for shortness of breath from 15Jan2021 to Jan2021. On 15Jan2021, she had such trouble breathing that he had to take her to urgent Care. Urgent care diagnosed it as congestive heart failure with enlarged heart and fluid in her lungs because of her heart being enlarged. She had not had any previous heart problems. Then states there may have been some earlier but it did not rise to the level of being noticed. The urgent care said she should be admitted to the hospital and to go the emergency room. Urgent Care told the consumer that they thought it was important to admit her as soon as possible. The patient was hospitalized for congestive heart failure from Jan2021 to Jan2021 for 5 or 6 days. The patient underwent lab tests and procedures which included computerised tomogram: unknown result in 2021, computerised tomogram: images of the heart: unknown result in 2021, transesophageal echocardiogram: unknown result in 2021, echocardiogram: unknown result in 2021, magnetic resonance imaging brain scan: no activity in 2021, sars-cov-2 test: negative in Feb2021 and x-ray: unknown result in 2021. Therapeutic measures taken as a result of congestive heart failure included metoprolol from Jan2021 to 2021 and furosemide (LASIX) to get the fluid out and once the fluid was out they did a transesophageal echocardiography (TEE). The patient was told to follow up with the cardiologist and the regular general practitioner (GP) and things seemed to be going ok. They advised her to get the second COVID shot and she got it. The second dose of COVID Vaccine was on 02Feb2021, Lot: EM9810, NDC and Expiration unknown. The events shortness of |

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| 1288522 | 5/5/2021 | | | M | | | breath, congestive heart failure required an emergency room visit. The clinical outcome of the events shortness of breath, congestive heart failure, fainting and dizziness was unknown. PASSED OUT 11 HOURS FROM THE TIME OF VACCINATION; This spontaneous report received from a patient concerned a 27 year old male with unknown race and ethnicity. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, 1 total, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date patient passed out 11 hours from the time of vaccination. Patient had slept two hours with his head elevated. Near the end of his pee he passed out in the bathroom. He had another person with him, helping him stay hydrated. Temperature was staying below 100. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of passed out 11 hours from the time of vaccination was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210502538-covid-19 vaccine ad26.cov2.s-Passed out 11 hours from the time of vaccination . This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s). |
| 1288863 | 5/5/2021 | NC | 24 | M | 5/4/2021 | 5/4/2021 | vasovagal syncope after injection. paramedics and md checked out, patient went home with doctor |
| 1288865 | 5/5/2021 | CA | 17 | F | 5/4/2021 | 5/4/2021 | Systemic: Fainting / Unresponsive-Mild |
| 1288866 | 5/5/2021 | MA | 20 | F | 5/4/2021 | 5/4/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium |

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1288886 | 5/5/2021 | FL | 37 | M | 5/4/2021 | 5/4/2021 | Systemic: Allergic: Difficulty Breathing-Mild, Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Severe, Systemic: Exhaustion / Lethargy-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Mild, Systemic: Headache-Mild, Systemic: Seizure-Mild, Systemic: Shakiness-Medium, Additional Details: About 5 minutes after the shot, the patient lost conciousness, fell face forward on the ground. Face appeared grey, was unresponsive, but was making grunting sounds. His body appeared to be shaking lightly, possible seizure, was not responsive. Oral benadryl was not possible at this point. Turned patient on back/side in order to adminster the epipen. Patient quickly became alert and responded. No injection site reaction. Paramedics arrived shortly to check vitals and transfer him |
| 1288887 | 5/5/2021 | CA | 22 | M | 5/4/2021 | 5/4/2021 | Systemic: Fainting / Unresponsive-Severe, Additional Details: patient fell as he passed out called 911 paramedics checked out patient |
| 1288889 | 5/5/2021 | ID | 21 | F | 5/4/2021 | 5/4/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Hypotension-Severe, Additional Details: light headed started to fall sweating called 911 paramedics took to hospital as blood pressure too long could not leave her |
| 1288924 | 5/5/2021 | OH | 22 | M | 5/4/2021 | 5/4/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Additional Details: Patient fainted after receiving Johnson and Johnson covid vaccine. He asked for water, I told him to put his head inbetween his legs which he did and then he fainted and fell out of his chair onto the ground. He came to after about 15 seconds. Blood pressure 120/75 pulse 55. Had him stay for 30 minutes after. Followed up tonight he said feeling fine. |
| 1288896 | 5/5/2021 | CA | 29 | M | 5/4/2021 | 5/4/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Additional Details: PATIENT FAINTED AFTER RECEIVING VACCINE AND INJURED THEIR CHIN, PATIENT WAS SITTING DOWN AND WAS ABLE TO FEEL BETTER AFTER GIVEN WATER AND REST ON BENCH |

| <i>VAERS_ID</i> | <i>RECVDATE</i> | <i>STATE</i> | <i>AGE_YRS</i> | <i>SEX</i> | <i>VAX_DATE</i> | <i>ONSET_DATE</i> | <i>SYMPTOM_TEXT</i> |
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| 1288921 | 5/5/2021 | OH | 22 | M | 5/4/2021 | 5/4/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Additional Details: Patient asked for water, I told him to put his head down in between his knees and asked my tech to get him water. Patient fainted and fell out of the chair onto the floor. Unresponsive for about 15 seconds, felt pulse. Blood pressure was 120/75, pulse 55. Had him lay with feet propped on chair until he was feeling normal and then had him sit, drink water, and stay 30 minutes. Said he felt fine after, called to check in on him tonight at closing and he said feeling fine. |

| <u>VAERS_ID</u> | <u>RECVDATE</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1288436 | 5/5/2021 | TX | 57 | M | 3/15/2021 | 3/15/2021 | Approximately 3 hours after injection, I became very dizzy, lightheaded, and passed out for a few minutes.I experienced vertigo for 24 hours, and was unable to sleep for longer than an hour at a time; Approximately 3 hours after injection, I became very dizzy, lightheaded, and passed out for a few minutes.I experienced vertigo for 24 hours, and was unable to sleep for longer than an hour at a time; Approximately 3 hours after injection, I became very dizzy, lightheaded, and passed out for a few minutes.I experienced vertigo for 24 hours, and was unable to sleep for longer than an hour at a time; Was unable to sleep for longer than an hour at a time for 5 days; This is a spontaneous report from a contactable consumer (patient). A 57-year-old male patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration administered in left arm at school or student health clinic on 15Mar2021 16:45 (at the age of 57-year-old) as SINGLE DOSE for COVID-19 immunisation. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination and has not been tested for COVID-19 since the vaccination. The patient had no medical history. The patient had no allergies to medication, food, or products. Concomitant medications included finasteride and morniflumate (FLOMAX [MORNIFLUMATE]). On 15Mar2021 at 19:15, approximately 3 hours after injection, the patient became very dizzy, lightheaded, and passed out for a few minutes. The patient also experienced vertigo for 24 hours, and was unable to sleep for longer than an hour at a time. There was no treatment for the events. On an unspecified date, the patient recovered from all events. Information about batch/lot number has been requested. |

| <u>VAERS_ID</u> | <u>RECVDATE</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1288280 | 5/5/2021 | | | F | | | he passed out/fell out during court; covid-19; diarrhea; This is a spontaneous report received from a contactable consumer. A 61-year-old female consumer (patient) reported for herself that she received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; Lot number: unknown) via an unspecified route at a single dose for COVID-19 immunization. The patient had a history of shortness of breath often, had fatigue, muscle and body ache and headache, loss of taste and smell not that one. People had told her that so many people have died from it from blot clots. She also had a history of irritated bowel syndrome and had these side effects because she went through it anyways. She had a history of anxiety but had not had an attack in a long time. The patients niece broke out in hives (she did not know which vaccine). She had been high step and said that she was a hand washer at a restaurant and once she was done and got home and it started piling up at the end of the day when she layed down. She had heard that people were having heart attacks so must take a baby aspirin. The patients concomitant medications were not reported. After receiving the vaccine she passed out/fell out during court. Some people told her that some costumers died of covid 19 infection. On an unknown date she had covid-19 (she and her husband had covid and both got vaccinated with both shots) and had diarrhea for a month and got over. Someone had told her that they would chip her. The outcome of events was unknown for passed out and Covid-19 and recovered on unspecified date for diarrhea. Information about the Lot/batch number has been requested. |
| 1288890 | 5/5/2021 | CA | 25 | M | 5/4/2021 | 5/4/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Mild, Systemic: Hypotension-Mild, Additional Details: Pt fainted about 2 minutes after getting their COVID vaccine. We had him sit with his feet up. We checked blood pressure about 5 minutes after and found he was hypotensive (109/71). Called the ambulance was was released by them. |

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1288173 | 5/5/2021 | NJ | 55 | F | 2/4/2021 | 2/4/2021 | chills; joint pain/Joint achiness/she fell off of her roof; hives/she broke out in hives; severely itchy; This is a spontaneous report from a contactable consumer reported that a 55-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number: EL3249) intramuscularly in left shoulder as single dose on 04Feb2021 at 12 for COVID-19 vaccination. Medical history reported was ongoing asthma diagnosed at about age 21. Stated that it is under control and she gets her allergy shots. She stated that it was environmental, ongoing bee allergy and severe allergy. She carries an epipen. Concomitant medications were not reported. Caller received the first shot of the Pfizer covid vaccine yesterday at 12 and after staying for 45 mins did not experience any issue. Later on, she started developing hives all over her body (itchy palms, neck, scalp, stomach) which she took 2 Benadryl for. Her hives have gotten 90% better, but she was experiencing some chills and joint pain. Caller was a consumer that was calling about the Covid-19 Vaccine and reported that she went yesterday, 04Feb2021, for her first shot at 12:00 and stayed there for 45 minutes because she was allergic to certain things. She said that she had no issues when she left at 12:45. Caller said that at about 16:45, she started to get severely itchy, and she broke out in hives. Caller said that it was on her scalp, her lips, her neck, her stomach, her arms, the palms of her hands, and the pads of her feet. The caller stated that there was nothing on her legs. She said that she woke up with more symptoms today 05Feb2021, and said that she woke up with chills and like every joint in her body feels like she fell off of her roof. Caller said that she took 2 Benadryl, and the hives are better. She stated that it totally knocked her out and she passed out on the sofa. Caller stated that the hives and the itching are about 90 percent better. Caller estimated her weight at about 160lbs. Caller stated that she took Tylenol for the chills and stated that it did not help the achiness in her joints at all. Caller stated that her chills and her joint achiness are the same. She said that she is allergic to Tetracycline, Penicillin, and sulfa drugs. Caller does not have the NDC, Lot, or expiration date for the medications. She stated that it was a long time ago. She has not followed up with her physician. They told her at the facility that for a reaction she needed to call Pfizer. |

VAERS_ID RECVDATE STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

Caller stated that she has a EpiPen, nebulizer and a rescue inhaler at home with her if needed. There was no previous immunization with the Pfizer vaccine considered as suspect. Prior Vaccinations was reported as non (within 4 weeks). Just takes her allergy shots, but that was 3 weeks prior, and it was cleared with the physician. Outcome of the events hives/she broke out in hives and severely itchy was recovering, chills and joint pain/Joint achiness/she fell off of her roof was not recovered. Follow-up attempts are completed. No further information is expected.

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1288056 | 5/5/2021 | OR | 61 | F | 4/28/2021 | 4/28/2021 | I had the second Moderna shot that afternoon, scheduled for 4:15pm but it was about 4:30pm when I got it. I moved around as instructed by my doc, and after 15 minutes went back to my car. I noticed after another several minutes that my pulse was still elevated so opted to go back in and talk to a health care professional. Pulse was 120. Paramedic wanted me to lie down in waiting area but I didn't want to be in such a potentially germ environment, and the guy next to me who had fainted earlier was just getting up himself. She walked me back to my car, where I agreed to wait, listen to a stress relief hypnosis audio and see if my pulse rate would calm down. She came back out w/ a BP cuff and said my blood pressure was 210 over 130 (or some number over 100; I don't recall which) and she said I needed to get in an ambulance right away and go to the hospital. I said I would make my own decisions about my body and I wanted to try a couple of other things first, promised not to leave, contacted my doctor, naturopath. (Note: I did not have any other worrisome symptoms -- blurred vision, dizziness, etc. My head was a little buzzy, but whether out of fear or in reaction to the shot I didn't know. I was a little flushed). He asked me a bunch of questions, said my body hadn't had time to mount an immune response to the vaccine and that I had likely had a histamine reaction to a preservative in the vaccine (or similar), which a couple of his other patients had experienced. He asked if I'd been drinking fluids (yes, plenty), had eaten recently (no, so he suggested I have some food; I had some nuts, a little cheese and some Cheez-Its so had that), asked if I had an antihistamine around -- I did, but I don't do well with Benadryl and didn't have Claritin, but after looking through my bag found some Allervive, an herbal product he compounds. He said, "That's perfect." I took two of the three capsules and hung up. Staff were checking up on me in my car every ten minutes or so, by the way, very kind and professional as I had been quite upset at the whole "get in an ambulance" scenario. He thought some of my reaction was probably also stress-related, and I noticed before the shot that I was teary, not from anxiety but the kind you get when you feel relief after a long ordeal. I didn't feel anxiety, really, until the first blood pressure measurement. He also let me know that if the bottom number didn't drop below 100 they couldn't let me go. |

VAERS_ID RECVD STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1288974 | 5/5/2021 | FL | 81 | M | 4/9/2021 | 4/16/2021 | After eating, drinking some more water and taking the Allervive my BP was down to 138 over 75 in just a few minutes. I agreed to stick around and make sure it stuck. We re-tested again about 15 minutes later, perhaps longer, and it was the same. I had been a little flushed but that had gone away too. I left and went for a light walk and eventually drove home without incident. I had symptoms after the shot that could have been related to my body fighting off the allergic reaction or to the vaccine itself, but they were pretty mild (fatigue later that night; occasional heart rate elevation sometimes after eating or with very mild exertion -- not unusual for me if I'm "fighting off" something; sore, itchy, red blotch sized between a quarter and a half dollar at vaccination site -- it is still a little tender today and appears a bit bruised; a bit sinus headache-y for three days, especially when I bent down to tie my shoes or something like that - also not that unusual as I often seem to "cleanse" through my sinuses when I have a bug or am fighting something off). In hindsight, I think the symptoms I had after the first shot, which lasted about 9 hours, may have been fighting off the allergic reaction and not a reaction to the virus vaccine itself. |
| 1288937 | 5/5/2021 | IL | 20 | M | 5/4/2021 | 5/4/2021 | 1 WEEK AFTER VACCINATION- EXPERIENCED HEAD ACHES , SORE THROAT AND EAR ACHES. AROUND 2 WEEKS- PATIENT. FELT DIZZY AND PASSED OUT. STILL HAS SOME BRUISING IN THE ARM NEAR BICEPS. Systemic: Fainting / Unresponsive-Severe, Systemic: Very pale upon awakening, sweaty, feeling "hot"-Severe |

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| 1288101 | 5/5/2021 | FL | 86 | M | 1/20/2021 | 2/18/2021 | Sharp pain in heart/feels like scar tissue around heart; hurting in his chest, boom in chest; He felt severe pain from the pacemaker jolt on his heart/pacemakers is giving him violent reactions; Almost passed out; blood pressure has been erratic; severe swelling at injection site/swelling right arm; a lot of pain at the injection site/swelling and pain in his right arm; This spontaneous case was reported by a consumer and describes the occurrence of ANGINA PECTORIS (Sharp pain in heart/feels like scar tissue around heart) in an 86-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 039K20A and 031M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Atrial fibrillation and Pacemaker insertion (cardiac) (He has a pacemaker for 10 years, implanted on 2007. He had the battery replaced in his pacemaker on 01/Dec/2018). Concurrent medical conditions included Post-traumatic stress disorder and Plantar fasciitis. Concomitant products included ASPIRIN [ACETYLSALICYLIC ACID] for an unknown indication. On 20-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 17-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 18-Feb-2021, the patient experienced PRESYNCOPE (Almost passed out), BLOOD PRESSURE FLUCTUATION (blood pressure has been erratic), VACCINATION SITE SWELLING (severe swelling at injection site/swelling right arm) and VACCINATION SITE PAIN (a lot of pain at the injection site/swelling and pain in his right arm). On 27-Apr-2021, the patient experienced ANGINA PECTORIS (Sharp pain in heart/feels like scar tissue around heart) (seriousness criteria hospitalization and medically significant) and CARDIAC COMPLICATION ASSOCIATED WITH DEVICE (He felt severe pain from the pacemaker jolt on his heart/pacemakers is giving him violent reactions). On an unknown date, the patient experienced CHEST PAIN (hurting in his chest, boom in chest). At the time of the report, ANGINA PECTORIS (Sharp pain in heart/feels like scar tissue around heart), CARDIAC COMPLICATION ASSOCIATED WITH DEVICE (He felt severe pain from the pacemaker jolt on his |

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heart/pacemakers is giving him violent reactions), CHEST PAIN (hurting in his chest, boom in chest), BLOOD PRESSURE FLUCTUATION (blood pressure has been erratic), VACCINATION SITE SWELLING (severe swelling at injection site/swelling right arm) and VACCINATION SITE PAIN (a lot of pain at the injection site/swelling and pain in his right arm) outcome was unknown and PRESYNCOPE (Almost passed out) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In February 2021, Oxygen saturation: 63 percent (Low) low. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Further information has been requested. Concomitant medication used by patient includes Aspirin 325 mg. No treatment medication information provided. This case was linked (Patient Link). Most recent FOLLOW-UP information incorporated above includes: On 27-Apr-2021: Angina pectoris was added as event. Start date of other events are updated.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Further information has been requested.

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| 1288109 | 5/5/2021 | TX | 65 | F | 3/4/2021 | 4/19/2021 | <p>passed out; can't walk very well without assistance; Sleepy; Very weak; headache; In appropriate doses interval, more than 35 days; This spontaneous case was reported by a non-health professional (subsequently medically confirmed) and describes the occurrence of LOSS OF CONSCIOUSNESS (passed out) in a 65-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 013M20A and 013M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Asthma (Taking asthma medication as concomitant). On 04-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 19-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 19-Apr-2021, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (In appropriate doses interval, more than 35 days). On 20-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (passed out) (seriousness criterion medically significant), GAIT DISTURBANCE (can't walk very well without assistance), SOMNOLENCE (Sleepy), ASTHENIA (Very weak) and HEADACHE (headache). At the time of the report, LOSS OF CONSCIOUSNESS (passed out), GAIT DISTURBANCE (can't walk very well without assistance), SOMNOLENCE (Sleepy), ASTHENIA (Very weak) and HEADACHE (headache) outcome was unknown and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (In appropriate doses interval, more than 35 days) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 23-Apr-2021, Computerised tomogram: (Negative) negative. On 23-Apr-2021, X-ray: (Negative) negative. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. The patient's heart was checked but no abnormal results. Company comment: This report refers to a case of Inappropriate schedule of vaccine administered for mRNA-1273, lot # 013M20A with associated AEs(loss of consciousness, gait disturbance, somnolence, asthenia and headache). Based on the current available information and temporal association</p> |

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1288110 5/5/2021 PA

22 M

3/31/2021

between the use of the product and the start date of the events, a causal relationship cannot be excluded.;
 Sender's Comments: This report refers to a case of Inappropriate schedule of vaccine administered for mRNA-1273, lot # 013M20A with associated AEs(loss of consciousness, gait disturbance, somnolence, asthenia and headache). Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

fainted twice; hypotensive; head injury; This spontaneous case was reported by a consumer and describes the occurrence of SYNCOPE (fainted twice) in a 22-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Autism. On 31-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced SYNCOPE (fainted twice) (seriousness criterion medically significant), HYPOTENSION (hypotensive) and HEAD INJURY (head injury). At the time of the report, SYNCOPE (fainted twice), HYPOTENSION (hypotensive) and HEAD INJURY (head injury) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown Route) was unknown. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. However, Further information has been requested.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. However, Further information has been requested.

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| 1288366 | 5/5/2021 | ME | 34 | F | 4/9/2021 | 4/9/2021 | <p>unusual and pronounced panic attacks and depression; unusual and pronounced panic attacks and depression; fatigue; fever; sweats; pain in my arm and neck; pain in my arm and neck; swollen lymph nodes; I nearly passed out from an anxiety attack; I nearly passed out from an anxiety attack; This is a spontaneous report from a contactable consumer reporting for herself. A 34-year-old female consumer reported that she received the first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration in arm left on 09Apr2021 01:15PM (at the age of 34-year-old) for COVID-19 immunisation. Relevant medical history included COVID prior vaccination. Past drug history included known allergy to cefaclor (CECLOR) and morphine. Concomitant medications were not reported. The patient nearly passed out from an anxiety attack 15 minutes after the vaccine was administered, on 09Apr2021 01:30PM: this had never happened before. For a week after, she experienced fatigue, fever, sweats, pain in arm and neck, and swollen lymph nodes. She had also experienced unusual and pronounced panic attacks and depression since receiving the vaccine and would be seeking medical attention for those issues. Events resulted in physician or other healthcare professional office/clinic visit. No treatment was received. The patient had not tested for COVID post vaccination. Outcome of the events was unknown. Information on the lot/batch number has been requested.</p> |

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| 1288145 | 5/5/2021 | MO | 67 | M | 1/23/2021 | 1/23/2021 | soreness at injection site; Light headed/dizzy; Felt very anxious and tense; Tense; Heart racing; This is a spontaneous report received from a contactable consumer (reporting on himself). A 67-years-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Formulation: Solution for injection, Lot Number: EK9231; Expiration Date was not reported), via intramuscular route of administration in Arm Right on 23Jan2021 12:00 as single dose for COVID-19 immunization. Medical history included prostatomegaly, drug hypersensitivity both from an unknown date and unknown if ongoing. Concomitant medication(s) included finasteride (FINAS-TERIDE); ergocalciferol (VITAMIN D [ERGOCALCIFEROL]) both taken for an unspecified indication, start and stop date were not reported. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, patient was not diagnosed with COVID-19 Since the vaccination, the patient has not been tested for COVID-19. On 23Jan2021 12:30, he received his first dose of the Pfizer COVID vaccine. Patient states he felt fine at the clinic after 15 mins and then after he left he felt lightheaded and dizzy and this continued on. Patient says his reaction was about 20 plus minutes after his injection, which he was fine when he got the injection, he became lightheaded and that has kind of continued on. He says it was pretty bad on the first day, then the second day it went away. He says a couple days later it came back, with his heart kind of racing, and he was still experiencing that though it was getting better. This was not something he had be-fore and he feels anxious and body is tight with dizziness. He says he experiences it periodically, and today it was not bad, but yesterday it came back again. He says he was concerned about that, but he hasn't passed out or anything. He says he went to the doctor and had an EKG and blood work done, which were all ok. He says it has been off and on, and he was kind of very anxious and tense as well, his insides are tight and jittery, sort of. He says he didn't see that listed as a common side effect. He says he had soreness at injection site, that went away, and he had no fever or any-thing, just the lightheadedness. He says he wants to see about the lightheadedness, if it had been reported by others, since he didn't notice it as a common reaction, to see what is |

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going on there, since it has been over a week and it hasn't totally gone away, so he is concerned about having his second dose. Am doing better now. Went to the doctor for tests on 27Jan2021 (Wednesday). Test results were okay. Patient states these are not some of the common side effects he has seen or read about. He would like to know when will his symptoms go away. Patient would like to know if he should receive the second dose that was scheduled in less than two weeks. Patient states he called his doctor had an EKG and blood work done and his tests were negative. The outcome for soreness at injection site was recovered on an unspecified date and for rest events was recovering.

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| 1288414 | 5/5/2021 | PA | | M | 4/9/2021 | 4/11/2021 | <p>bilateral pulmonary embolism; right DVT; sinus tachycardia; Afib with RVR.; This is a spontaneous report from a contactable physician. This report was received via a sales representative. A 68-year-old male patient received BNT162B2 (Pfizer COVID vaccine), dose 2 via an unspecified route of administration on 09Apr2021 (Batch/Lot Number: Unknown) as single dose for Covid-19 immunisation. Medical history included hypertension, gastroesophageal reflux disease (GERD), and deep vein thrombosis (DVT) original diagnosis from Jan2018. The patient previously received the first dose of BNT162B2 on 19Mar2021 for Covid-19 immunisation. The physician reported the patient had bilateral pulmonary embolism and a right DVT on 11Apr2021. The patient went to the ER on 11Apr2021. She confirms the pulmonary embolisms and the DVT were diagnosed 11Apr2021 when the patient went to the ER. She has more of the patient's story, caller does not think this would be linked to the vaccine but that is for someone else to decide she is reporting. The day of the event the patient's heart was racing, he passed out and went to the ER, he had sinus tachycardia and Afib with RVR (date/s unspecified). His heart rate was up to 140s and 150s. The patient has history of hypertension, GERD, and previous DVT, the original DVT that patient had was diagnosed in Jan2018 and he was placed on Xarelto at that time and he was on Xarelto until Jun2019. He has not been on anything for this since that time, until this episode. Caller says reporter did not provide any specific treatment information that the patient has received for the event she is reporting. Reporter provided the patient went to the emergency room, he did not say if the patient was admitted or had hospitalization. The outcome of events was unknown. Information about the Lot/batch number has been requested.; Sender's Comments: Drug causality would seem unlikely for BNT162B2. The reported events may be regarded as natural progression of patient's pre-existing conditions. The impact of this report on the benefit/risk profile of the Pfizer drug is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Committees and Investigators, as appropriate.</p> |

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| 1288299 | 5/5/2021 | FL | 67 | M | 2/15/2021 | 2/1/2021 | <p>he had a very lightheaded episode that was much more vertigo-like where things were spinning; I had almost a very light headache where I almost fainted; he had a very lightheaded episode that was much more vertigo-like where things were spinning; he had a very lightheaded episode that was much more vertigo-like where things were spinning; This is a spontaneous report from a contactable consumer. This 67-year-old male consumer reported that: Patient characteristics - Weight (kg): 95.25 Height (cm): 183 Sex: MALE</p> <p>Reaction(s)/Event(s) Reaction/event as reported by primary source- Very, very lightheaded episode where he almost passed out Term highlighted by the reporter: YES Date of start of reaction/event: Feb2021 Outcome of reaction/event at the time of last observation: UNKNOWN Reaction(s)/Event(s) Reaction/event as reported by primary source: Very lightheaded episode that was much more vertigo-like where things were spinning Outcome of reaction/event at the time of last observation: RECOVERING/RESOLVING Results of tests and procedures for investigation of the patient Date: Feb2021 Test: EKGs Result: Normal More information available: NO Results of tests and procedures for investigation of the patient Date: Feb2021 Test: MRIs of his head Result: Normal More information available: NO Results of tests and procedures for investigation of the patient Date: Feb2021 Test: echocardiograms of his heart Result: Normal More information available: NO Results of tests and procedures for investigation of the patient Date: 17Mar2021 Test: VNG test- Videonystagmography Result - Unknown, not resulted yet More information available: NO Results of tests and procedures for investigation of the patient Date: 10Mar2021 Test: Nuclear stress test Result: Normal More information available: NO Results of tests and procedures for investigation of the patient Date: 10Mar2021 Test: Exercise stress test Result: Normal More information available: NO Results of tests and procedures for investigation of the patient Date: Feb2021 Test: Blood work Result: Normal More information available: NO Drug(s) Information Characterization of drug role: (SUSPECT) Proprietary medicinal product name: Pfizer-BioNTech COVID-19 Vaccine Batch/lot number: EL9263 Dosage text: Unknown strength/volume/dose injection to left arm shoulder</p> |

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before 12:00 Pharmaceutical form (Dosage form):
Injection Indication for use in the case: Vaccination)
Date of start of drug: (26Jan2021 Date of last
administration: 15Feb2021 Drug(s) Information
Characterization of drug role - CONCOMITANT
Proprietary medicinal product name: Amlodipine Dosage
text: 5mg taken daily Indication for use in the case:
Blood pressure Drug(s) Information Characterization of
drug role: CONCOMITANT Proprietary medicinal
product name: Esomeprazole Dosage text: 40mg taken
daily Drug(s) Information Characterization of drug role:
CONCOMITANT Proprietary medicinal product name:
Centrum Silver for people over 50 years Dosage text:
Once daily Narrative case summary and further
information Submitted by Call Centre 1 Ref: #; ININ:#
Selected Report Type: Initial Is report related to a study
or programme? No Is the patient also the reporter? Yes
Reporter type: Consumer or other non health
professional Specify Consumer or other non health
professional: Patient Dates for Very, very lightheaded
episode where he almost passed out: (From: Feb2021
To: Unknown) Dates when patient was in hospital for
Very, very lightheaded episode where he almost passed
out: Feb2021 to Feb2021 Dates for Very lightheaded
episode that was much more vertigo-like where things
were spinning: (From: Feb2021 To: Ongoing) Is Pfizer-
BioNTech COVID-19 Vaccine a Pfizer product? Yes
Pfizer-BioNTech COVID-19 Vaccine manufacturer: Pfizer-
BioNTech Dates for Pfizer-BioNTech COVID-19 Vaccine:
(Start: 26Jan2021 Stop: 15Feb2021) NDC number of
Pfizer-BioNTech COVID-19 Vaccine: Unknown Expiry
Date of Pfizer-BioNTech COVID-19 Vaccine: Unknown
Pfizer-BioNTech COVID-19 Vaccine: Dosage previously
discontinued/treatment completed Other Products: Yes
Dates for Concomitant Products Amlodipine: (Start:
Unspecified Stop: Ongoing) Additional Information for
Concomitant Products Amlodipine: Taken for years.
Dates for Concomitant Products Esomeprazole: (Start:
Unknown Stop: Ongoing) Additional Information for
Concomitant Products Esomeprazole: Taken for years.
Why was the patient taking Concomitant Products
Esomeprazole (Verbatim): Acid reflux Dates for
Concomitant Products Centrum Silver for people over 50
years: (Start: Unknown Stop: Ongoing) Additional
Information for Concomitant Products Centrum Silver for

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people over 50 years: Taken for years. Why was the patient taking Concomitant Products Centrum Silver for people over 50 years (Verbatim): Multivitamin Patient History: No Investigation Assessment: Yes Additional Context: This consumer is the patient who has been administered both first and second doses of Pfizer-BioNTech COVID-19 Vaccines. About 8-11 days after first dose of Pfizer-BioNTech COVID-19 Vaccine he had a very, very lightheaded episode where he almost passed out. About 8-11 days after second dose of Pfizer-BioNTech COVID-19 Vaccine he had a very lightheaded episode that was much more vertigo-like where things were spinning. He clarified he thinks one event was like 8 days and the other was like 10 days after the vaccine doses were administered, but is not sure, so left it as about 8-11 days. Consumer is not sure if the events are Pfizer-BioNTech COVID-19 Vaccine related, but they never happened to him before those doses were administered. He does not know if this is vaccine related or just coincidence that they popped up at the same time as the vaccine doses. He does not know if events could be age related, the medical community can't figure it out so he is trying to get information on if events could be related to the vaccines. Patient: Age at onset: Over the age of 65 years. Reporter: Address: Unknown. Primary: Further address details/Email: Unknown. Very, very lightheaded episode where he almost passed out: Onset about 8-11 days after first dose was administered, maybe 09Feb2021 or 10Feb2021. He went to the emergency room on the date of event onset and was admitted to hospital from about 13:00 that day, overnight and discharged about 17:00-18:00 the following day. While in hospital he had EKGs of his head-verified this information with caller repeatedly; MRIs of his head; CTs of his head; and echocardiograms of his heart. All of those tests came back ok, nothing abnormal on results. They recommended he have a stress test done which was not performed until after the second reported event following second dose of Pfizer-BioNTech COVID-19 Vaccine. Very lightheaded episode that was much more vertigo-like where things were spinning: Onset was about 8-11 days after second dose of Pfizer-BioNTech COVID-19 Vaccine was administered. He has never had vertigo in his life before event. He went back to the emergency room on date of onset of this event, but was not admitted

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to the hospital at that time; was only in the emergency room about 5-6 hours. While in the emergency room he had CT scans of his head, MRIs of his head and EKGs and everything looks good, nothing abnormal on results. Outcome: He still has ongoing very lightheaded episodes for a good part of the day. Those episodes usually last about 30 minutes and occur multiple times daily but are not really severe like the 2 initial events were following the first dose and then the second dose. Pfizer-BioNTech COVID-19 Vaccine: First dose: 26Jan2021 Lot: EL9263 NDC/Expiry: Unknown, this is not on CDC vaccine record card. Dose: Unknown strength/volume/dose injection to left arm shoulder before 12:00 Second dose: 15Feb2021 Lot: EL9267 NDC/Expiry: Unknown, this is not on CDC vaccine record card. Dose: Unknown strength/volume/dose injection to left arm shoulder before 12:00 - verified with reporter that details were same for both first and second doses. This completed his prescribed therapy. Regarding concomitant products and other medical conditions caller reported he really had no issues going on prior to onset of these events. Regarding other testing/investigations done relative to these events: He had a nuclear stress test and exercise stress test, both performed on 10Mar2021 he believes and results of those tests were they both came back good, family doctor emailed him the results which were normal. He has gone to the ENT-ear, nose and throat doctor where he had a balance test done which he referred to also as a VNG test-Videonystagmography done on 17Mar2021. He will get results of balance test on Wednesday, 24Mar2021. He had blood work done the first time he was in the emergency room when he was admitted to the hospital in Feb2021; they took his blood 3-4 times while he was there overnight and blood work results all came back normal. He is not sure what they were testing for, but thinks they were looking for stroke type things because event almost made him pass out. They did not draw more blood the second emergency room visit. Follow-up (23Mar2021): This is a follow-up spontaneous report from a contactable consumer. This consumer reported that: Reaction(s)/Event(s) MedDRA version for reaction/event term LLT - N/A Reaction/event in MedDRA terminology (LLT) - Medical Information Potential AE Drug(s) Information Characterization of drug Role: 1 (SUSPECT) Proprietary medicinal product

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name : PFIZER-BIONTECH COVID-19 VACCINE
Active Substance Information :Active Drug substance
names PFIZER-BIONTECH COVID-19 VACCINE
Narrative case summary and further information:
Originating AE Request: REQ-# Attachments: 1 Contact
HCP: N/A Patient Age: 67 Reporter Subtype: Patient
PQC Present: No AE Present: Yes PQC Details:
Request Name: REQ-# Product:PFIZER-BIONTECH
COVID-19 VACCINE Question: AUTO-CALLBACK
REQUEST 23Mar2021 10:06AM Caller received both
doses of the Pfizer-BioNtech Covid-19 vaccine (1st dose
26Jan2021, 2nd dose 15Feb2021). About ten days after
the first dose he had a very lightheaded episode and he
almostfainted, he went to ER and had an MRI of his
head, a CT scan, a CT scan with contrast and also an
echocardiogram, they were relating this to a strokelike
symptom however the results were normal, also his blood
test results were fine. He went to his HCP and he was
schedules to get a nuclear stress test and an exercise
stress test, his results came back normal; before this
tests he received the second dose on 15Feb2021 and 10
days later he had again a very bad episode in his house
he had a lot of vertigo, he felt the walls were moving so
he went back to ER and had another EKG and CT scan,
his heart was ok, so they suspected it was vertigo. He
has daily episodes that las a few minutes were he feels
lightheaded. He went to an otolaryngologist ("ear and
nose doctor") to see if this was vertigo and had a balance
test done. Caller states he had never this symptoms
before, his vaccination card has the lot number for both
doses, he hasn't changed his medications or habits and
it's odd that this happened 9-10 days after both doses of
the vaccine. He would like to know if this has been
reported before as a side effect related to the vaccine.
Caller states that he already called Safety twice, report #.
Potential duplicate E-transmitting to DSU.
Response:Spoke from attached documents. Referred
caller to his HCP. Request Name: REQ-#
Product:PFIZER-BIONTECH COVID-19 VACCINE
Question: Caller received both doses of the Pfizer-
BioNtech Covid-19 vaccine (1st dose 26Jan2021, 2nd
dose 15Feb2021). About ten days after the first dose he
had a very lightheaded episode and he almost fainted, he
went to ER and had an MRI of his head, a CT scan, a CT
scan with contrast and also an echocardiogram, they

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were relating this to a strokelike symptom however the results were normal, also his blood test results were fine. He went to his HCP and he was scheduled to get a nuclear stress test and an exercise stress test, his results came back normal; before this tests he received the second dose on 15Feb2021 and 10 days later he had again a very bad episode in his house he had a lot of vertigo, he felt the walls were moving so he went back to ER and had another EKG and CT scan, his heart was ok, so they suspected it was vertigo. He has daily episodes that last a few minutes where he feels lightheaded. He went to an otolaryngologist ("ear and nose doctor") to see if this was vertigo and had a balance test done. Caller states he had never this symptoms before, his vaccination card has the lot number for both doses, he hasn't changed his medications or habits and it's odd that this happened 9-10 days after both doses of the vaccine. He wanted to know if his information will help somebody else who may experience the same symptoms, and is his information could be useful for Pfizer. Follow-up (23Mar2021): This is a follow-up spontaneous report from a contactable consumer. This consumer reported that: Patient Details Sex - Male Height - 183 cm Or 6 feet Weight -95.25 kg Or 210 pounds Is the patient also the reporter? Yes Age - 67 Years Reporter Details Reporter type: Consumer or other non health professional Primary / Prescribing Healthcare Professional Info (the) Event Details I have been having some strange things; it's symptom like I never had before I had almost a very light headache where I almost fainted It might be stroke like symptom I continued to have some light headed symptoms but nothing real bad; continued to have symptoms which was not normal for me I had another episode; this was much more vertigo like or the room is spinning and the walk and things are moving Products Suspect products: Covid Vaccine Is this a Pfizer product? Yes NDC number: Unknown UPC number: Unknown Lot Number: EL9267 Expiry date: Unknown History Concomitant Products Other Products Yes Omeprazole Indication - Acid reflux Multivitamin Amlodipine Dosage 5 MG Indication Blood pressure Additional Context: Consumer stated, "I have been having some symptoms but I did call into one of your number yesterday and they told me call back and try to get into you but they did gave me some case number in case help you, they did an

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open internet case# and I will give you that number if you like it. It's # (Hence follow-up was checked). Well I have been having some strange things that I don't know if its Covid shot related but it's symptom like I never had before. After I had received the first shot, I had almost a very light headache where I almost fainted. We went to ER, they were sort of testing, it might be stroke like symptom and they did a MRI of my brain and they did CT scan of my brain and CT scan contrast. They did micro cardiogram, some EKGs and work. All of those come back normal. So I spent the night in hospital, they sent me the next day. I continued to have some light headed symptoms but nothing real bad but continued to have symptoms which was not normal for me. After I had my shot about 10 days after the second shot, I had another episode. This was much more vertigo like or the room is spinning and the walk and things are moving. I did go back to ER again just in case there was something going on. They tested again another CT scan and EKG and everything looked normal and they said it sounded like a vertigo related. I told him I had shot about 10 days after each shot, the symptoms hit me. Because of the first episode my family doctor ordered some other testing done, and they did stress test of my heart, a nuclear stress test and an exercise stress test of my heart and both came back normal. But I am continuing to have the light headed, the episodes just about daily. Sometimes they last for 30 minutes or more, multiple times a day. Sometimes I have a good day but I have those light headed episodes and I never had it before I got the shot. I am also going ENT- ear, nose and throat doctor to check on vertigo stuff and they did some testing last week and I am supposed to get the result tomorrow on what they found about vertigo test but I never had vertigo or light headed or anything before the shot. So I don't know if anybody else is reporting this but I had 2 sorts of severe episodes both of them 10ish days after each shot and I am continuing to have light headed episodes but not severe as those 2 but I had light headed dizzy episodes daily, since the Covid vaccine. I want to report it, so you guys have a report file and other people reporting it. I guess I sort of want to know if you guys were having any other report or something like this. So that I know it might be related to the shot. I am still working with my ENT and I tried to figure out if it's vertigo.

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If it's not vertigo then they have really run all sorts of test and if it's not vertigo we don't know if Covid shot triggered the vertigo or not. Let me know, we don't know. So they have ran 30,000 dollar test on me and so far all my tests are coming back normal." Consumer was informed about the role of Pfizer Drug Safety and Pfizer Medical Information. Consumer was provided with the contact# for Pfizer Medical Information as # and requested to dial the Option 3 and informed about timings as Monday to Sunday from 8 am to 8 pm EST. Consumer stated, "I already did, and that's what I just dialed. I just dialed that number and option no. 3, I just dialed. That's the no. I dialed that's #and pressed option number 3. Can you forward this call to that department?" Call could not be transferred because of some technical issue. When probed for exact date of AE, "Consumer stated, hang up one second. Let me pull my card out. I think it's all I that other file that I gave but I'll give it you again. I received my first shot on January 27 of this year and I had the first episode February 10th, then I received my second shot on February 25th of this year and I believe it was march 4th, I think when I had those episodes. Those are the 2 episodes. I had smaller episodes daily but they were two bad episodes." When probed for Physician's details, Consumer stated, "It was distributed from a count location." When probed for LOT#, Consumer stated, "Hang up one second. I haven't told you one thing, my second shot was February 15 not 25. I was looking at my visa card. My first shot was EL9263 and my second shot was EL9267." Expiration date of vaccine: Consumer stated, "I doesn't have that." Dose of vaccine: Consumer stated, "It did not write that on card." When probed for anatomical site of vaccine administration, Consumer stated, "Left arm shoulder." Lab Test: Consumer stated, "Every year I go and get my yearly test in which they had my blood work and my glucose levels are always good, cholesterol level as always good. All my other tests come back as normal." (Further not clarified hence not captured in tab) Treatment: Consumer stated, "The hospital was, the emergency room gave me something for dizziness that I am no longer taking. They gave me something for dizziness when I was there but I am no longer taking it. So I am really taking nothing. This time I am working with ENT i.e. ear, nose and throat doctor, they are doing vertigo type testing but they got nothing,

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the results are supposed to be back tomorrow. I don't know what test they are going to show, if they do show vertigo there will be some treatments to help me. But we don't know what brought these episodes on, other than timing wise it was during the Covid shot. And I never had anything like that and I am not blaming it on the Covid shot. That was the only thing changed in my lifestyle. There might be a possibility, because that's the only thing changed, my medication has not changed, diet doesn't changed. Nothing is changed other than I got Covid." Consumer stated, "Can you give me report#." Reportum# was provided as # #Is there a product complaint to report?No Is there a medical information request?Yes Please describe the medical information request Consumer stated, "I have been having some symptoms but I did call into one of your number yesterday and they told me call back and try to get into you but they did gave me some case number in case help you, they did an open internet case# and I will give you that number if you like it. It's 4NW3L5MR (Hence follow-up was checked). Well I have been having some strange things that I don't know if its Covid shot related but it's symptom like I never had before. After I had received the first shot, I had almost a very light headed where I almost fainted. We went to ER, they were sort of testing, it might be stroke like symptom and they did a MRI of my brain and they did CT scan of my brain and CT scan contrast. They did micro cardiogram, some EKGs and work. All of those come back normal. So I spent the night in hospital, they sent me the next day. I continued to have some light headed symptoms but nothing real bad but continued to have symptoms which was not normal for me. After I had my shot about 10 days after the second shot, I had another episode. This was much more vertigo like or the room is spinning and the walk and things are moving. I did go back to ER again just in case there was something going on. They tested again another CT scan and EKG and everything looked normal and they said it sounded like a vertigo related." Consumer was informed about the role of Pfizer Drug Safety and Pfizer Medical Information. Consumer was provided with the contact# for Pfizer Medical Information as #and requested to dial the Option 3 and informed about timings as Monday to Sunday from 8 am to 8 pm EST. Consumer stated, "I already did, and that's what I just dialed. I just dialed that number and

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| 1288057 | 5/5/2021 | CA | 26 | F | 5/3/2021 | 5/3/2021 | <p>option no. 3, I just dialed. That's the no. I dialed that's # and pressed option number 3. Can you forward this call to that department?" Call could not be transferred because of some technical issue.</p> <p>Around 4 pm I had flu like symptoms. Headache, back pain, fatigue, chills, sweats. Around 5:30 I started feeling light-headed. I got out of bed and fainted on the floor. Laid there for a few moments. Got water. Laid back into bed and my body completely locked up. It felt like there were pins and needles coursing through my entire body. I couldn't bend or move my legs. My wrists were bent down and my fingers all locked together. I could not move them at all. I was screaming out in pain. It was the worst pain I've ever felt. My roommate called 911. Paramedics arrived and took my temperature and blood pressure. They tried calming me down. eventually I did. And my fingers and legs unlocked but I continued having a severe headache, back pain, muscle aches and nausea. I woke up every hour of the night and threw up several times. It's been 24 hours after the shot and I am still having headaches fatigue and muscle spasms.</p> |

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| 1288374 | 5/5/2021 | NJ | 33 | F | 4/7/2021 | 4/14/2021 | <p>Presyncope severe disequilibrium; Presyncope severe disequilibrium; vertigo; nausea; migraine (head and ear pressure); migraine (head and ear pressure); migraine (head and ear pressure); tinnitus; tremors; Vestibular disturbances; This is a spontaneous report from a non-contactable Nurse (patient). A 33-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at left arm on 07Apr2021 10:00 AM at single dose for COVID-19 immunisation in Pharmacy or Drug Store. Medical history was none. If No other vaccine in four weeks. No Known allergies. No other medications in two weeks. Patient was not pregnant. Patient experienced Presyncope severe disequilibrium, vertigo, nausea, migraine (head and ear pressure), tinnitus, tremors. Vestibular disturbances lasting for Weeks. Adverse event start date was 14Apr2021 03:15 PM. event resulted in doctor or other healthcare professional office/clinic visit, disability or permanent damage. No covid prior vaccination. no covid tested post vaccination. Treatment received for the events with Steroids, Xanax, Benadryl, ibuprofen. Patient was recovering from the events. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of Presyncope severe disequilibrium, vertigo, nausea, migraine (head and ear pressure), tinnitus, tremors and Vestibular disturbances due to temporal relationship. However, the reported events may possibly represent intercurrent medical conditions in this patient. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including head CT/MRI, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p> |

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| 1288386 | 5/5/2021 | MN | 52 | F | 4/8/2021 | 4/8/2021 | <p>allergic reaction; wasn't able to lift her hands; blood pressure was very low at about 80/59; tired; light headedness; Didn't feel very comfortable; weak in the legs; She was warm or cold, hot then suddenly cold; chills; fogginess; fainting reaction 15 minutes after getting the shot; palpitations for an hour; numbness in her lower jaw/bottom jaw was half numb; weakness on her bottom lip which was difficult to move, causing her to have difficulty in talking; weakness on her bottom lip which was difficult to move, causing her to have difficulty in talking; inner side of her leg, calf, and thigh was feeling hot; kind of a tightness in her chest/Every next breath was getting weaker and they disappeared after an hour. She felt like someone was holding her chest, do not let her to deep breath; This is a spontaneous report from a contactable consumer (patient) via a Pfizer-sponsored program. A 52-year-old female patient received BNT162B2, dose 1 via an unspecified route of administration, administered in left arm on 08Apr2021 08:30 (Batch/Lot Number: ER8729; Expiration Date: 31Jul2021) (at the age of 52-years-old) as single dose for COVID-19 immunisation. She reported says she was getting it because people who were vaccinated are being less cautious and putting her at risk for COVID. The vaccination facility was organized through a pharmacy was not administered in a military facility. Medical history included measles on an unknown date (she was sick only once with measles). The patient reported no family medical history but the only thing to put about her probably was that she has maybe rare in a good way immune system. She thought children infections that kids usually get, some of them are very contagious, she was sick only once with measles. She says she has never had chicken pox, she was not vaccinated for chicken pox, she was in contact with multiple people with chicken pox, has antibodies with chicken pox but she never had symptoms, she was never sick. She said she was never sick with any children's infection, she usually did not get sick at all, no flu, no cold things, never. She was not sure if it was measles or if it was rubella as she was translating from another language. There were no concomitant medications. The patient previously took lidocaine and experienced allergy with symptoms of cold sweat and palpitations. She says this allergy started a very long time ago. She said it was affecting only dental procedures and that they know</p> |

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about so they just don't use it on her. She says they consider it not be the lidocaine but due to the ephedrine inside of the lidocaine. She lists her symptoms as cold sweats and palpitation, no pain. She reported they thought the reaction was just too strong, she had 2 episode in 2 different offices, they don't use it on her. The patient had no prior vaccinations within four weeks. The patient declined being sick at the time of vaccination. On 08Apr2021, the patient experienced fainting reaction 15 minutes after getting the shot , palpitations for an hour, numbness in her lower jaw/bottom jaw was half numb, weakness on her bottom lip which was difficult to move, causing her to have difficulty in talking, inner side of her leg, calf, and thigh was feeling hot; kind of a tightness in her chest/every next breath was getting weaker and they disappeared after an hour. she felt like someone was holding her chest, do not let her to deep breath, not destructions with breathing, tired, lightheadedness, didn't feel very comfortable, weak in the legs, she was warm or cold, hot then suddenly cold, chills, and fogginess. On 14Apr2021, the patient experienced blood pressure was very low at about 80/59, wasn't able to lift her hands, weak again and dizziness. The patient's second dose was supposed to be next Friday but her healthcare provider thought it was an allergic reaction (unspecified date) and advised her to not get the second dose. The patient wanted to know what would Pfizer advise. The patient did not know if it was because of COVID but thought those were the effects of any kind of vaccines. The patient clarified her jaw was only half numb. She reported the events started after 15 minutes, the jaw was later, palpitations started after she broke the pattern of her thinking, that wasn't right. She said we had the list but it was missing that it started with one symptom and was replaced by another symptom. She said the only 2 that were together was the jaw part and the palpitations. She says the jaw part was a very short period of time, she felt it and thought what was this, she did not know how long it was, maybe one minute, less than one minute. She reported her palpitations were periodical palpitations, every next breath was getting weaker and they disappeared after an hour. The patient also reported her legs part was after the palpitations were gone. She had talked to multiple nurses and she realized from telling the story 5 times that the symptoms started from

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up to the bottom; the reaction was from her head to her legs. She reported that she doesn't feel very comfortable, she doesn't know what will happen to her, no one knows. She says all symptoms were on the same day, she was able to move and felt comfortable to move after an hour and a half. She says she started to move after symptoms in the legs started to disappear, she was not able to take deep breath but she was able to breathe without destructions. She says she felt like someone was holding her chest, do not let her to deep breath, not destructions with breathing. She tries to explain the temperature situation, saying the feeling during this time was warm or cold, hot then suddenly cold, that there was no one explaining what happened with her. She says she she remembers noticing that suddenly she had chills. cold, she was talking to someone and she felt cold, she can't exactly say what. She says this probably lasted half a day, maybe 12 hours: She says she was very dizzy on that day, suddenly, and at night she measure her pressure to see what is going on. She says she she has been known for low blood pressure earlier in her life. She says 110/70 was her normal and she had around 80 something, 86/59, something like that, she hasn't had such a low blood pressure in 30 years, maybe since her pregnancy. She stated that she has recovered completely from everything. She says she is not sure if its coming back, she did not expect to have low blood pressure, but right now she is totally fine, a normal person. The patient confirmed her blood pressure was, she thought 86/59 on 14Apr2021. She said she took her blood pressure 2 times, a couple times, the first time was even lower on 14Apr2021. She says on the actual 08Apr2021 she took her blood pressure and it was 120 over something, a little bit higher than it usually would have been. She said she was usually running towards the lower acceptable range, 110 to 70, 110 to 75, something like at doesn't get more than 113. The events did not require a visit to emergency room nor a visit to physician's office. The patient wanted to know if these side effects were known to Pfizer and what happens to those side effects. She asked do they have information on if they increase with the second vaccine. The outcome of the events fainting reaction 15 minutes after getting the shot, palpitations for an hour, numbness in her lower jaw/bottom jaw was half numb, weakness on her bottom

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| 1288395 | 5/5/2021 | NY | 46 | F | 4/19/2021 | 4/20/2021 | <p>lip which was difficult to move, causing her to have difficulty in talking, inner side of her leg, calf, and thigh was feeling hot; kind of a tightness in her chest/every next breath was getting weaker and they disappeared after an hour. she felt like someone was holding her chest, do not let her to deep breath, not destructions with breathing, tired, lightheadedness, didn't feel very comfortable, weak in the legs, she was warm or cold, hot then suddenly cold, chills, and fogginess was recovered on 08Apr2021; outcome of events weak again, dizziness, wasn't able to lift her hands, blood pressure was low was recovered on 14Apr2021; while outcome of allergic reaction was unknown.</p> <p>Experienced syncope approximately a half hour after getting out of bed; Passed out on kitchen floor; Dizziness episode lasted for approximately an hour, of which half was spent on the floor.; This is a spontaneous report from a contactable consumer (patient). A 46-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection) (at 46 years of age), via an unspecified route of administration, administered in arm left on 19Apr2021 17:00 (Batch/Lot Number: EW0164) as a single dose for COVID-19 immunisation. Medical history included covid-19 from an unknown date and unknown if ongoing as it was reported that the patient had covid prior vaccination. The patient's concomitant medications were not reported. The patient had not been given any other vaccine in four weeks prior to covid vaccine. The patient was not pregnant. On 20Apr2021 12:15 PM, the patient experienced syncope approximately a half hour after getting out of bed. She passed out on kitchen floor. Dizziness episode lasted for approximately an hour, of which half was spent on the floor. The outcome of 'Experienced syncope approximately a half hour after getting out of bed' and 'Passed out on kitchen floor' was recovering while Dizziness was recovered on 20Apr2021 13:15 (lasted for approximately an hour). No treatment received for the events. The patient had not been tested for covid post vaccination.</p> |
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| 1288407 | 5/5/2021 | CO | 59 | M | 3/31/2021 | 3/31/2021 | <p>Extreme fatigue; brain fog; Passed out; Told possible seizure; Felt ill shortly after receiving shot; Threw up; This is a spontaneous report from a contactable consumer (the patient) and then from a contactable consumer (the patient's wife). A 59-year-old male patient received the first dose of BNT162B2 (lot number not provided), via an unspecified route of administration in the left arm on 31Mar2021 10:00 (at the age of 59-years-old) as a single dose for COVID-19 immunization. The patient had no medical history. The patient did not have any known allergies. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medication included: fish oil (OMEGA 3 FISH OIL). The patient did not receive any other vaccines within four weeks prior to the vaccination. On 31Mar2021, the patient felt ill shortly after receiving the shot. Told to sit down. Passed out. Awoke on the floor. Told possible seizure. Sat up. Threw up. Told to lie back down. Ambulance came and took him to the hospital. He spent 90 minutes in the Emergency Room. He was unable to work for a couple of days. He had extreme fatigue and brain fog. He was not back to relatively normal for at least 10 days. Treatment received was reported as yes: ran tests including 3 EKGs, on an unspecified date. The outcome of the events was recovering. It was also reported that since the vaccination, the patient had not been tested for COVID-19. Information on the lot/batch number has been requested.</p> |

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| 1288409 | 5/5/2021 | DC | 47 | F | 4/5/2021 | 4/5/2021 | fainted; weak; tired; itching; trouble breathing; face swelling; unstable vital signs; This is a spontaneous report from a contactable consumer. A 47-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) lot number and expiration date not provided, via an unspecified route of administration, administered in left arm on 05Apr2021 10:00 as single dose for covid-19 immunisation. Medical history included hypothyroidism, high cholesterol, allergies to penicillin and shell seafood. here were no concomitant medications. The patient previously took Percocet [oxycodone hydrochloride;paracetamol] and experienced allergies. The patient experienced fainted, weak, tired, itching, trouble breathing, face swelling and unstable vital signs on 05Apr2021 21:30. The patient was hospitalized. It was unknown if the patient received any treatment. The outcome of the events was unknown. No follow-up attempts are possible, information about lot/batch number cannot be obtained. |

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| 1288129 | 5/5/2021 | GA | 68 | F | 3/26/2021 | 4/23/2021 | Passed out; Felt dizzy; Nasty taste in mouth; was feeling tired; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out) in a 68-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 038A21A and 037B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 26-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 23-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 23-Apr-2021, the patient experienced TASTE DISORDER (Nasty taste in mouth) and FATIGUE (was feeling tired). On 26-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (Passed out) (seriousness criterion medically significant) and DIZZINESS (Felt dizzy). At the time of the report, LOSS OF CONSCIOUSNESS (Passed out), DIZZINESS (Felt dizzy), TASTE DISORDER (Nasty taste in mouth) and FATIGUE (was feeling tired) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. The patient had acetaminophen for the events. Action taken with mRNA-1273 in response to the drug was not applicable. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested. This case was linked.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested Dose 1 case |
| 1291212 | 5/5/2021 | TX | 34 | M | 5/5/2021 | 5/5/2021 | Passed out after shot |
| 1290656 | 5/5/2021 | OH | 46 | F | 5/5/2021 | 5/5/2021 | PT FAINTED AND VOMITED |

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| 1290723 | 5/5/2021 | ME | 27 | F | 5/5/2021 | 5/5/2021 | <p>Patient administered Janssen vaccine on 5/5/21 at 1011AM by pharmacist on duty. Patient did not admit any anxiety surrounding vaccine during counseling prior to receiving the vaccine. After administration patient mentioned she has can get anxious sometimes and has tendency to create symptoms in her head. She asked what to be on the look out for for signs of syncope and described starting to feel nauseous, clammy, and tunnel vision. Within seconds she briefly lost consciousness and started to slump in chair within immunization room. Pharmacist prevented her from falling out of chair while opening door to waiting room and asked for assistance from patients boyfriend. Together we held patient in place on chair and propped feet up on another chair. Immediately patient regained consciousness enough to explain what she was feeling but then quickly lost consciousness again and started snoring as if she immediately fell asleep. Boyfriend said no history of sleep issues/narcolepsy, together we laid patient on floor of immunization room with feet slightly elevated and boyfriend at her head and again she immediately regained consciousness. Patient explained that she was immediately starting to feel better and felt dizzy and described having very odd dream like scenarios. She laid on floor for 10 min, Alert and orientedx4, moved to seated position for another 10 min, accepted offer for apple juice, moved to waiting area to sit for another 10min before OK leaving. MOD/PDM aware....Called patient at 6pm that same evening and patient reported feeling great.</p> |

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| 1290766 | 5/5/2021 | | | M | | 4/26/2021 | <p>Passed out; Abdominal pain; Trouble breathing; Sweats; Didn't feel well; Fatigue; death; This spontaneous case was reported by a consumer and describes the occurrence of DEATH (death) and LOSS OF CONSCIOUSNESS (Passed out) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced LOSS OF CONSCIOUSNESS (Passed out) (seriousness criterion medically significant), ABDOMINAL PAIN (Abdominal pain), DYSPNOEA (Trouble breathing), HYPERHIDROSIS (Sweats), VACCINATION COMPLICATION (Didn't feel well) and FATIGUE (Fatigue). The patient died on 26-Apr-2021. The reported cause of death was Passed out. It is unknown if an autopsy was performed. At the time of death, LOSS OF CONSCIOUSNESS (Passed out), ABDOMINAL PAIN (Abdominal pain), DYSPNOEA (Trouble breathing), HYPERHIDROSIS (Sweats), VACCINATION COMPLICATION (Didn't feel well) and FATIGUE (Fatigue) outcome was unknown. No treatment information provided by the reporter and no history of concomitant medication was reported. Regarding the events of loss of consciousness, malaise, abdominal pain, dyspnea, hyperhidrosis and fatigue, based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. However regarding the event of death, Very limited information regarding this event has been provided at this time. Further information has been requested; Sender's Comments: Regarding the events of loss of consciousness, malaise, abdominal pain, dyspnea, hyperhidrosis and fatigue, based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. However regarding the event of death, Very limited information regarding this event has been provided at this time. Further information has been requested; Reported Cause(s) of Death:</p> |

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| 1290878 | 5/5/2021 | TX | 30 | M | 5/5/2021 | 5/5/2021 | passed out He was doing fine when I escorted him to the waiting area. Upon a few minutes later, he started to fell down. I was called and came to check on him. He told me he closed his eyes for a bit and started to fall down. I was not sure if the fall was because he lost balance or the shot made him fainted. There was no respiratory distress or any anaphylactic reaction so no EpiPen was use. I applied cold pack to him and he recovered a few minutes later. |
| 1290992 | 5/5/2021 | CA | 18 | F | 5/5/2021 | 5/5/2021 | Patient fainted 5 minutes after vaccination. Patient said she felt a little dizziness. She rested and we monitored her for 1 hour and patient said she felt better afterward. We instructed her boyfriend to take her home, and not allowing her to drive. |
| 1290654 | 5/5/2021 | OK | 53 | F | 5/5/2021 | 5/5/2021 | patient felt a little dizzy after receiving her injection- gave patient a sucker (tends to help people to keep from fainting in certain conditions), cold paks to put on her neck and hands, a fan on her and for air circulation, a bottle of water..patient felt fine within a short time and rested for at least 30 minutes if not longer before leaving , said she was felt fine and was ready to leave |

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| 1291099 | 5/5/2021 | NY | 27 | M | 4/15/2021 | 4/15/2021 | syncope; fell from standing; hit head on table; This is a spontaneous report from a contactable health professional. A 27-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot: EW0164), intramuscular in the left arm on 15Apr2021 (at the age of 27-years-old) as a single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. It was unknown if the patient received any other vaccinations within 4 weeks of the vaccine. On 15Apr2021, immediately after the vaccine, the patient experienced syncope due to which he fell. He fell from standing and hit his head on a table. There were no signs of soft tissue injury. The patient was brought into the emergency department from the vaccination room. The patient was not treated for the events. The clinical outcome of syncope, fell from standing and hit head on table was resolved on Apr2021.; Sender's Comments: A contributory role of BNT162B2 to the reported events cannot be excluded based on temporal association. Case will be reassessed if additional information is received. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate. |
| 1291384 | 5/5/2021 | CO | 23 | F | 5/5/2021 | 5/5/2021 | After about 5 minutes after receiving the vaccine, the husband of the patient came to the pharmacy to notify the pharmacist that the patient had fainted. The pharmacist had technician call 911 and the pharmacist went to evaluate the patient. Upon arrival, the patient had gained consciousness. The pharmacist got a BP and HR. Talked to patient until EMS arrived. After talking with EMS, the patient left with the husband. |
| 1291245 | 5/5/2021 | NC | 17 | M | 5/5/2021 | 5/5/2021 | Passed out and had seizure lasting 45-60 seconds. |

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| 1291312 | 5/5/2021 | OH | 46 | F | 2/5/2021 | 2/5/2021 | Throwing up; nausea; chest pain & tightness to the point I could not move my arm to use my emergency inhaler prescribed after COVID/ I couldn't move; tremor increased; post COVID syndrome & orthostatic hypertension.; post COVID syndrome & orthostatic hypertension.; Lymph node pain; Tilt Table Testing confirmed Covid-induced POTS; mild injection site pain; COVID symptoms in same order as the Oct2020 COVID (upper respiratory, less intense headache, shortness of breath, chest pain); COVID symptoms in same order as the Oct2020 COVID (upper respiratory, less intense headache, shortness of breath, chest pain); COVID symptoms in same order as the Oct2020 COVID (upper respiratory, less intense headache, shortness of breath, chest pain); COVID symptoms in same order as the Oct2020 COVID (upper respiratory, less intense headache, shortness of breath, chest pain); COVID symptoms in same order as the Oct2020 COVID (upper respiratory, less intense headache, shortness of breath, chest pain); chest pain & tightness to the point I could not move my arm to use my emergency inhaler prescribed after COVID; dizzy; Fatigue; vasovagal response; Passed out; This is a spontaneous report from a contactable other health professional (patient). A 46-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in arm left on 05Feb2021 at 10:30 (Lot Number: EL9261) (at the age of 46-year-old) as single dose for COVID-19 immunisation. The patient was not pregnant. Medical history included infectious mononucleosis (Recent mono) in 2020 (Spring), urinary tract infection (UTI) in 2020 (Summer), venous Insufficiency on Dec2020, shingles in past on an unspecified date, lactose & gluten intolerance from an unknown date and unknown if ongoing, COVID-19 from Jun2020 to an unknown date (I had recovered from mild COVID in Jun and Oct2020 that required no hospitalization and was managed with DAYQUIL, XYZAL, Prednisone, Vit D and melatonin). Concomitant medications included ibuprofen at 2400 mg and 800 mg; pregabalin (LYRICA); progesterone; bifidobacterium bifidum/bifidobacterium lactis/bifidobacterium longum/lactobacillus acidophilus/lactobacillus rhamnosus (PROBIOTIC), all concomitants were taken for an unspecified indication, start and stop date were not reported. The patient experienced mild injection site pain, COVID symptoms in same order as the Oct2020 |

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COVID (upper respiratory, less intense headache, shortness of breath, chest pain), dizzy, fatigue, vasovagal response, passed out, nausea, throwing up, tremor increased, chest pain & tightness to the point I could not move my arm to use my emergency inhaler prescribed after COVID/ I couldn't move, post COVID syndrome and orthostatic hypertension, tilt table testing confirmed COVID-induced POTS (postural orthostatic tachycardia syndrome) and lymph node pain, all on 05Feb2021 at 11:00. All events were serious disabling and required hospitalization. The patient underwent lab tests and procedures which included computerized tomogram (CT): unknown results on an unspecified date, D-dimer: 1300 is very elevated, it shows that I have a lot of inflammation in my body or I could have the clot, 1300, almost 3 times the normal value; magnetic resonance imaging head (MRI): unknown results on an unspecified date, SARS-COV-2 test (nasal swab): negative on 19Feb2021, tilt table test: COVID-induced pots on 05Feb2021 . Unspecified therapeutic measures were taken as a result of the events. The patient outcome of the event passed out was unknown and not recovered for all the other events.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of reported events cannot be excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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| 1291318 | 5/5/2021 | PA | | M | 3/27/2021 | 4/17/2021 | passed out; This is a spontaneous report from a contactable consumer, the patient, from a Pfizer-sponsored program Covax Support. A male patient of an unspecified age received the first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 27Mar2021 (Batch/Lot number was not reported) as a single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient passed out on 17Apr2021. The patient was supposed to get the vaccine on 17Apr2021 but he passed out on that day and he missed the shot. The outcome of event, passed out, was unknown. The lot number for the vaccine, BNT162b2, was not provided and will be requested during follow up. |
| 1288941 | 5/5/2021 | IL | 22 | M | 5/4/2021 | 5/4/2021 | Systemic: Fainting / Unresponsive-Severe, Systemic: very pale, sweaty, feeling "hot"-Severe |
| 1291385 | 5/5/2021 | TX | 77 | M | 3/2/2021 | 3/5/2021 | Three days after vaccination, the patient was working outside when he suddenly died. Specific events are not known as he was alone at his work site. No bodily injuries were found. He was simply passed out and unresponsive when found. He had been deceased for hours upon his discovery. |
| 1288950 | 5/5/2021 | CA | 20 | F | 5/4/2021 | 5/4/2021 | Systemic: Seizure-Severe, Additional Details: Pharmacist was informed that she was uncomfortable with needles and blood, but had not had a severe reaction to any vaccine previously. RPh checked if she had fainted before and told her to sit for 15 minutes then will check on her and if she is lightheaded or dizzy extend to 30 minutes. RPh administered Janssen shot to patient and asked if she was okay. She confirmed then patient got up. Patient moved to another chair & started seizing. RPh and mother took care until well enough to get up. |

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| 1291093 | 5/5/2021 | NY | | F | 4/18/2021 | 4/19/2021 | fainting; Extreme pain in left arm to the point of barely moving; hitting head; vomiting; Slurred speech; Chills; sweats; aches; This is a spontaneous report from a contactable consumer (the patient). A 22-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number ER8731), via an unspecified route of administration in the left arm on 18Apr2021 at 12:30 (age at vaccination unknown) as a single dose for COVID-19 immunization. The patient had no medical history. The patient did not have any known allergies. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient was not pregnant at the time of vaccination. Concomitant medication included: sertraline hydrochloride (ZOLOFT). The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number not provided), via an unspecified route of administration an unspecified date (age at vaccination unknown) as a single dose for COVID-19 immunization. The patient did not receive any other vaccines within four weeks prior to the vaccination. On 19Apr2021 06:00, the patient experienced extreme pain in the left arm to the point of barely moving, fainting and hitting head, vomiting, slurred speech, chills, sweats, and aches. No treatment was received. The outcome of the events was recovering. It was also reported that since the vaccination, the patient had not been tested for COVID-19. |
| 1289097 | 5/5/2021 | TX | 40 | F | 5/4/2021 | 5/4/2021 | Systemic: Chills-Mild, Systemic: Dizziness / Lightheadness-Medium, Systemic: syncope episode, did not pass out, pale,sweating,visual changes-Mild, Systemic: Flushed / Sweating-Medium, Systemic: Shakiness-Mild, Systemic: Tingling (specify: facial area, extremities)-Mild, Systemic: Visual Changes/Disturbances-Mild, Additional Details: vaccine 2:40pm, CC@ 2:55pm, sweating, visual changes, sweating, feeling of going to pass out, cold compress, vitals BP 93/55 pulse 81. slight tingling feeling in hands, pale, laid on floor/feet elevated, monitored and after 30+ additional minutes felt better,sipped some water& walked out of store, advise lots of water/rest/come back or ER if further issues |

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| 1290465 | 5/5/2021 | VA | 70 | F | 3/8/2021 | 4/3/2021 | STARTING AROUND 4/3 she started to experience dizziness, nausea and memory loss. On 04/06 She passed out while sitting in her chair, woke up and began throwing up. Had extreme short term memory loss and low blood pressure. On 04/08 while at her primary care Dr, he suggested a hospital visit with suspicion of possible stroke. Was admitted and released the following day. Dr advised possible mini strokes but could also be dehydration. CBC with differential showed other results than dehydration. Starting around 04/20 she started having chest pains and thought it was heart burn, after medication and another visit to her pcp she was admitted to the hospital again on 04/23. Her troponin levels indicated a possible heart attack. She had a heart catherization and was found to have a healthy heart. Again, her blood pressure has been decreased since, her hgb and hct has also been low with a history of it being high. A high WBC since all of this has started among other unexplained blood results. |
| 1288960 | 5/5/2021 | CA | 33 | M | 5/4/2021 | 5/4/2021 | Systemic: Fainting / Unresponsive-Mild |
| 1289236 | 5/5/2021 | FL | 20 | F | 5/3/2021 | 5/3/2021 | Dizziness and quickened breath after injection and then fainted about a minute or so after injection |
| 1289317 | 5/5/2021 | | 17 | M | 5/4/2021 | 5/4/2021 | Syncope and dizziness. Stable and released. |
| 1289506 | 5/5/2021 | MI | 18 | F | 5/5/2021 | 5/5/2021 | Patient was waiting the 15 minutes after her vaccination and lost consciousness. She began to shake slightly which concerned me and we called 911. She came to within a minute and was aware of her surroundings. She stated she felt ok but her head hurt from hitting the floor. We gave her an ice pack for her head. After about 5 minutes she got back in the chair and was here until EMS arrived. While they were there questioning her she lost consciousness again two separate times and displayed potential seizure activity again. They put her on the stretcher and took her to the hospital. She reported she has not had seizures in the past but has fainted from a vaccination in the past but was younger and received 3 immunizations. |

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| 1289511 | 5/5/2021 | WY | 24 | F | 4/2/2021 | 4/2/2021 | That evening my arm swelled up and became very painful - not as much as the first vaccine. I had a hard time sleeping - nausea and headache throughout the night. 4/3 - extremely tired; felt like I couldn't get enough air (shortness of breath) body aches and muscles aches - over all lethargic. 4/4 - I was dizzy, short of breath . Those two symptoms lasted along with fatigue - which lasted for two days. I almost passed out that day - everything went black and I had to be assisted to the couch to recover from that. I used Tylenol for my symptoms when needed. I still have ongoing headaches - three weeks ago (about a week after I got the vaccine) - I noticed I was having ongoing headaches and I still have these. Pregnancy - 2nd pregnancy; 1st one was full term. Date of delivery expected - September 9, 2021. |
| 1289617 | 5/5/2021 | NY | 17 | F | 5/3/2021 | 5/3/2021 | Site: Pain at Injection Site-Mild, Systemic: Chills-Severe, Systemic: Exhaustion / Lethargy-Mild, Systemic: Fainting / Unresponsive-Severe, Systemic: Fever-Medium, Systemic: Headache-Severe, Systemic: Unable to Sleep-Mild, Additional Details: mom called to report adverse reaction to 2nd dose of pfizer vaccine. pt had chills on monday, fever on tuesday, wed morning child passed out in the kitchen mom heard her fall, she did call 911. child was transported via ambulance to strong ER. pt was diagnosed with syncope. pt is now home with mild headache/lethargy and recovering. mom has called pcp waiting to talk to her. |

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| 1289747 | 5/5/2021 | CA | 25 | M | 5/4/2021 | 5/4/2021 | Status post vaccination patient reported nausea, abdominal pain, and light headedness. Patient stated he went to car and was unsure whether he fainted or not as he felt weak. This occurred within a time frame of 20 minutes post vaccination. Vitals were checked and BP, temp, and pulse within normal range. Patient stated he was feeling much better and the event only lasted a short period of time. Patient was given a cold water bottle and observed at the pharmacy. Vitals were rechecked after another period of 15 minutes and were unremarkable. No medications were administered and no further medical attention required. Notably was a hot day (temperature in the 90s) and patient stated he had not eaten anything all day since cereal in the morning (vaccination administered at 5PM). Patient stated he was feeling much better. |
| 1289818 | 5/5/2021 | CA | 16 | M | 5/4/2021 | 5/4/2021 | Within 3 minutes of receiving the vaccine, Subject experienced syncope, had ringing in the ears, loss of vision, was pale, diaphoretic, and hyperventilation. BP 102/49 and 96/58. Staff responded, provided supportive care. Subject regained consciousness. Reported on 5/5/2021 made a full recovery. It is noted he reports he worked out that morning, had not eaten or had water that day. Did not seek medical attention. |
| 1290056 | 5/5/2021 | CO | 16 | M | 5/5/2021 | 5/5/2021 | Patient fainted minutes after receiving 2nd vaccine. |

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| 1290064 | 5/5/2021 | WI | 24 | M | 4/13/2021 | 4/15/2021 | <p>He states he had the first Pfizer COVID-19 vaccine in the series on 4/13/2021. He states that two days later on 4/15/2021 he felt like his feet were heavy. He continues to experience that sensation in his feet, and even feeling like his feet are asleep at nighttime and when he first gets up in the morning. The asleep feeling in the feet gets better when he gets up and moves around but the heavy sensation in the legs does not get better. He states that his mobility is affected though that his legs feel heavy and he is not as easily mobile as he used to be. He feels his balance is off. Patient later reported that he did have an episode of syncope about 5 minutes after he got the vaccine but otherwise was doing okay until 4/15/2021. He presented to the ED with these symptoms on 5/3/2021 at approximately 7:14pm and was admitted to the hospital for evaluation. Patient states that he normally exercises regularly and has been having a great deal of difficulty especially with squatting and now has difficulty walking up stairs, feels very weak and his legs feel heavy. He reports that the numbness and tingling sensation of his feet when sleeping is new and he has never had it in the past. Symptoms get worse with exertion and prolonged activity. Neurologist was consulted and several tests were ordered. Neurology consult noted that patient had a prior COVID 19 infection in November 2020. Per neurologist notes: His symptoms first started about two days after he received Pfizer COVID vaccine on April 13, 2021. He recalled feeling his feet heaviness and it was hard to pick them up. He also had some calf pain. He also had difficulty with doing his stretches and yoga positioning. A week ago, he began to have difficulty with picking up a ball or anything from the ground. He also developed pins and needles at the fingertips at the same time he developed tingling sensation of his feet. He also has lower back pain. He tested positive for SARS-COV-2 antigen on November 12, 2020. He recalled having symptoms lasting for a few days consisting of diaphoresis, cough, and flu-like symptoms. Per neurologist, symptoms seem to resemble acute inflammatory demyelinating polyneuropathy (AIDP). Patient was treated with IVIG for 5 days.</p> |

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| 1290078 | 5/5/2021 | CT | 42 | F | 4/27/2021 | 4/27/2021 | notes: times are approximate. I got the vaccine on day two of my period. I moved my arm a lot after getting the vaccine. My arm did not hurt, even though the rest of my body ached. 4-27-21 2:45pm: got the vaccine in my left arm. 4pm: felt fine. slightly more energy, clearer head than usual. this good mood and clear head only lasted a few hours. it ended before other symptoms began. 9pm: minor body aches, but not in arm where I got the vaccine. minor chills, shivering. 10pm: began to feel worse. moderate body aches, chills, dizzy. 10:40pm: suddenly felt much worse. severe chills, shaking, dizzy, then felt very hot, nausea. vasovagal syncope. sudden low blood pressure. did not actually faint since I know how to prevent fainting. took ginger, drank a lot of water, got ready for bed. lying in bed. felt nauseas for a few hours. this was the most uncomfortable symptom. frequent peeing. thirsty, but water went right through me. sweating. could not really sleep, not totally awake either. felt horrible. after a few hours, still lying in bed. nausea mostly went away. headache, muscle pain in jaw and face were the worse symptoms at this time. frequent peeing. thirsty, but water went right through me. sweating. felt like someone had turned the heat up. when I checked, the heat was off. felt like I had a fever for a few hours. 4-28-21 1:45pm: got out of bed. feel better than the previous night, but generally unwell. short of breath when moving. fatigue. 6pm: dizzy, weak. 4-29-21: 3pm: mild headache, feel mildly hot. 4-30-21: 10pm: tense muscles, especially in my face and head. 5-1-21: sore breasts. 5-4-21: hormones feel unbalanced. PMS symptoms, but it is a few days after my period ended. intense negative moods, spotting, sore breasts. |

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| 1290346 | 5/5/2021 | CA | 16 | F | 5/5/2021 | 5/5/2021 | Client received the Pfizer Covid-19 Vaccine (Lot #EW0167 Exp. 08/2021) at 1:51 PM. Approximately 10 minutes after receiving her first dose the patient fainted from her chair in the observation area. Patient did not strike her head. EMT and other nurses responded and sat the patient upright and began treatment. Patient was A&O X3, immediately after fainting. Patient was assisted to the gravity bed and vitals were taken, see below. Patient stated that she felt better almost immediately after laying in the gravity bed. Vital signs are as follows: 1400- BP: 100/80, O2: 98%, P: 80, Res: 18; 1405- BP: 106/74, O2: 98%, P:96, Res: 18; 1410- BP: 110/70, O2: 99%, P: 90, Res: 18; 1415- BP: 110/70, O2: 99%, P: 87, Res: 18; 1420- BP: 112/70, O2: 99%, P: 86, Res: 18; 1425- BP: 110/70, O2: 99%, P: 96, Res: 18. Patient's vitals improved over time after laying down. Patient was accompanied by her mother who was outside at the time of her fainting. Patient has a history of fainting after injections and getting blood drawn. Patient and Patient's mother felt comfortable after 30 minutes of observation to leave the vaccination site and return home. Client declined EMS transport. Patient and Patient's mother were instructed to seek medical attention if symptoms worsened or if symptoms returned. Patient left the facility in good condition with a steady gait. |
| 1289641 | 5/5/2021 | OH | 32 | M | 5/3/2021 | 5/3/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Nausea-Mild, Systemic: Vomiting-Mild, Additional Details: Patient came to pharmacy for Covid vaccine. He said he once fainted after giving blood and has a fear of needles. He was given his vaccine and after 10 minutes he felt nauseated and fainted. The patient awoke within 30 seconds but then vomited. EMS was called to make sure the pt was okay. After another 30 minutes of rest the patient was able to leave the pharmacy. |
| 1290366 | 5/5/2021 | MO | 16 | M | 5/5/2021 | 5/5/2021 | 16 y/o with needle phobia. 7 minutes after administering vaccine the patient fainted. the patient bit into his tongue and chipped 1 of his front teeth. |

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| 1285236 | 5/4/2021 | CA | 22 | M | 5/3/2021 | 5/3/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Hypotension-Severe, Additional Details: A few minutes after administration, pt was lightheaded and dizzy and reported possibly fainting for a very brief moment. Pt was pale and sweating and reported being short of breath briefly. Pt was hypotensive but blood pressure and heart rate normalized after 10 to 15 minutes after pt lied down and propped up feet in addition to drinking water and juice. Pt reported feeling "normal" after resting for about 30 minutes. |
| 1285147 | 5/4/2021 | TX | 28 | F | 5/3/2021 | 5/3/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: pt was feeling dizzy and put the pt on the floor she was breathing and concious called 911 and the felt better and put her on a sitting position to rest. Her husband said she has dizzinees and fainting problem. we get help they came and assessed her and pt was ok and walked to her car accompanied by her husband. Called her around 5:40p to make sure she is doing ok but no answer |
| 1285173 | 5/4/2021 | MA | 38 | M | 5/3/2021 | 5/3/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient lost consciousness for about 10 seconds. Pharmacist had patient lay down with feet up and patient was conscious and felt better. He ate 2 candies and drank 1 cup of water because pt felt lightheaded. Patient BP was 126/87 after lying down for 15 minutes. Patient insisted on leaving and felt ok to drive home. Patient stated he would grab something to eat before leaving the store. |
| 1285183 | 5/4/2021 | MD | 23 | M | 5/3/2021 | 5/3/2021 | Systemic: Chills-Severe, Systemic: Confusion-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Exhaustion / Lethargy-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Seizure-Severe |
| 1285189 | 5/4/2021 | OH | 23 | M | 5/3/2021 | 5/3/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: Vomiting-Medium, Additional Details: patient fainted for several seconds, when he came to, he was shaky and sweating. then vomited several times. completely recovered |

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| 1285201 | 5/4/2021 | MO | 37 | M | 5/3/2021 | 5/3/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Nausea-Mild, Systemic: Weakness-Medium, Additional Details: Patient fainted 2 minutes after dose administration followed by full body contraction which lasted 30 seconds. Patient indicated post-incident he had a needle phobia and had previously fainted during blood drawing appointments |
| 1285207 | 5/4/2021 | IL | 27 | M | 5/3/2021 | 5/3/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Severe, Additional Details: IMMEDIATELY UPON INJECT THE PT FAINTED. I GOT HIM ON THE FLOOR AND ELEVATED HIS FEET. CHECKED HIS PULSE AND BREATHING. GAVE HIM WATER. HIS MOTHER KEPT CALLING HIS NAME. WHEN HE SAID HE WAS FINE. HE SAT DOWN THEN FAINTED AGAIN. 911 WAS CALLED. EMT ARRIVED AND TOOK CARE OF HIM. HIS MOTHER DROVE HIM HOME. MOTHER STATED HE DOES THIS EVERY TIME HE GETS A SHOT |
| 1285214 | 5/4/2021 | PA | 27 | F | 5/3/2021 | 5/3/2021 | Systemic: Fainting / Unresponsive-Medium |
| 1285275 | 5/4/2021 | | 26 | M | 5/4/2021 | 5/4/2021 | Pfizer-BioNTech COVID-19 Vaccine The patient received the vaccine in his left arm, and 5 minutes later lost consciousness/passed out for several minutes then woke up feeling weak and tired |
| 1285227 | 5/4/2021 | CA | 35 | M | 5/1/2021 | 5/1/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Hypotension-Medium |
| 1285268 | 5/4/2021 | CA | 33 | M | 5/3/2021 | 5/3/2021 | Site: Pain at Injection Site-Medium, Systemic: Chills-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Fever-Medium, Additional Details: Wife of patient had called the pharmacy hours after patient had recieved his J&J vaccine to inform us of this symptoms a few hours when arrving at home. He experienced fainting, chills, fever, and pain and took a tylenol and symptoms started to subside and has been currently been resting in bed. Wife says they will continue to take tylenol around the clock if needed and will seek medical attention is symptoms worsen. |

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| 1284477 | 5/4/2021 | SC | 58 | F | 3/12/2021 | 3/13/2021 | Rash on face after first injection. Still have a rash. It comes and goes Shingles after 2nd shot. Dizziness for two weeks. Near syncope 24 hours after shot. And 4 days later. |

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| 1284724 | 5/4/2021 | OR | 56 | M | 4/21/2021 | 4/21/2021 | <p>passing out; blood pressure of 70/40; Feeling hot; Sweaty; Dizziness; Lethargy; Sore arm; Achy all over; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of LOSS OF CONSCIOUSNESS (passing out) in a 56-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 027B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 21-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 21-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (passing out) (seriousness criterion medically significant), BLOOD PRESSURE DECREASED (blood pressure of 70/40), FEELING HOT (Feeling hot), HYPERHIDROSIS (Sweaty), DIZZINESS (Dizziness), LETHARGY (Lethargy), PAIN IN EXTREMITY (Sore arm) and MYALGIA (Achy all over). On 21-Apr-2021, LOSS OF CONSCIOUSNESS (passing out) had resolved. At the time of the report, BLOOD PRESSURE DECREASED (blood pressure of 70/40), FEELING HOT (Feeling hot), HYPERHIDROSIS (Sweaty), DIZZINESS (Dizziness), LETHARGY (Lethargy), PAIN IN EXTREMITY (Sore arm) and MYALGIA (Achy all over) outcome was unknown. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No concomitant medications reported. Patient reports that paramedics had to come after he passed out. Treatment of the events included acetaminophen. Company comment: This case concerns a 56-year-old male with a serious unexpected event of loss of consciousness, and nonserious unexpected blood pressure decreased, feeling hot, hyperhidrosis, dizziness, lethargy and expected pain in extremity. Event onset the same day as first dose mRNA-1273. Events resolved. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.</p> |

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| 1285223 | 5/4/2021 | FL | 38 | F | 5/3/2021 | 5/3/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Additional Details: responsive within a minute and recovered within 10 minutes |
| 1284942 | 5/4/2021 | NE | 20 | M | 4/25/2021 | 4/25/2021 | Passed out; broke his wrist; Extremely dizzy; Nauseated; This spontaneous case was reported by a patient family member or friend and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out) in a 20-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 25-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 25-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (Passed out) (seriousness criterion medically significant), WRIST FRACTURE (broke his wrist), DIZZINESS (Extremely dizzy) and NAUSEA (Nauseated). At the time of the report, LOSS OF CONSCIOUSNESS (Passed out), WRIST FRACTURE (broke his wrist), DIZZINESS (Extremely dizzy) and NAUSEA (Nauseated) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No relevant concomitant medications were reported. No treatment information was provided. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events (loss of consciousness, dizziness and nausea), a causal relationship cannot be excluded. Based on reporter's causality the event of Wrist fracture is assessed as unlikely related to mRNA-1273..; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events (loss of consciousness, dizziness and nausea), a causal relationship cannot be excluded. Based on reporter's causality the event of Wrist fracture is assessed as unlikely related to mRNA-1273.. |

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| 1285080 | 5/4/2021 | VA | 42 | M | 5/3/2021 | 5/3/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: fainted but recovered right away, hit back of head on the floor, ice applied-Medium, Additional Details: waited 45 minutes before leaving, wife picked him up so he would not drive, patient stated he had a history of fainting after vaccines or giving blood, his head felt better after applying ice, temp 94.6 before leaving and felt his breathing normalize after incident |
| 1284802 | 5/4/2021 | PA | 63 | F | 4/12/2021 | 4/13/2021 | passed out at home; Migraine; chills; aches; tired; slight temp; This is a spontaneous report from a contactable consumer (patient). A 63-year-old female patient received the second dose of bnt162b2, via an unspecified route of administration, administered in right arm on 12Apr2021 (Lot Number: EW0151) as single dose for covid-19 immunisation. Medical history included High cholesterol, hypothyroidism. The patient's concomitant medications were not reported. The patient previously received the first dose of bnt162b2, at the age of 63-year-old, via an unspecified route of administration, administered in left arm on 20Mar2021 18:30 (Lot Number: ER8727) as single dose for covid-19 immunisation. The patient was not pregnant. The patient experienced migraine, chills, aches, slight temp and tired on 13Apr2021 10:00; passed out at home 22:30 13Apr2021. No treatment received. The outcome of the events was recovered in Apr2021. |
| 1284796 | 5/4/2021 | FL | | F | | | Passed Out; Felt Faint; This is a spontaneous report from a contactable consumer. A female patient of unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunisation. The relevant medical history and concomitant medications were not reported. The consumer's husband's adopted daughter, that passed out after receiving a Covid Vaccine. Stated she felt faint and because of her, she knew to get down on the floor and she passed out and woke up to her dogs licking her face but she didn't do any damage because she got down on the floor. The outcome of the events was unknown. Information about Lot/Batch number has been requested. |

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| 1284778 | 5/4/2021 | TX | 31 | M | 4/1/2021 | 4/1/2021 | <p>Passed out; blood pressure dropped to 70/50/ big blood pressure drop from 110/90 to 70/50; The initial safety information received was reporting only non-serious adverse drug reaction. Upon receipt of follow-up information on 19Apr2021, this case now contains serious adverse reaction. Information processed together. This is a spontaneous report from a contactable consumer (patient's father) via Medical Information team. A 31-year-old male patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), via an unspecified route of administration on 01Apr2021 (Batch/Lot number and Expiration date were not reported) at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was in excellent health and had no known allergies. The patient had took the Pfizer COVID-19 vaccine 18 days prior reporting (on 01Apr2021) and had blood pressure dropped to 70/50 and emergency medical services (EMS) was called an hour with him. The reporter was asking if the patient should take the second dose being that he had this reaction. The reporter further asked for the efficacy of one dose of the Pfizer COVID-19 vaccine and how long was the coverage of the vaccine as far as needing a booster shot. The reporter also asked about the 6 months topline analysis results of the Pfizer-BioNTech COVID-19 vaccine. It was further reported that fifteen minutes after the COVID-19 shot on 01Apr2021, the patient passed out; the patient had a big blood pressure drop from 110/90 to 70/50. The EMS was called in and attended to the patient. The patient was there for about an hour. The reporter was just calling to find out if the patient could get the second shot. The outcome of the events was unknown. Information on the batch/lot number has been requested.</p> |

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| 1284765 | 5/4/2021 | MA | 50 | F | 4/18/2021 | 4/18/2021 | fainting; hot burning sensation down left arm from injection site to wrist; hot burning sensation down left arm from injection site to wrist; hot burning sensation down left arm from injection site to wrist; dry throat; intense thirst; difficulty swallowing; vertigo; cloudy vision; waves of nausea; weak/numb hands; weak/numb hands; uncontrollable shaking; This is a spontaneous report from a contactable consumer (patient). A 50-year-old non-pregnant female patient received the first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in Arm Left on 18Apr2021 at 09:45 (Batch/Lot Number: EW0164) as single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient previously took pneumococcal vaccine for immunisation and experienced allergy, tylenol and experienced allergy, codeine and experienced allergy. The patient experienced fainting, hot burning sensation down left arm from injection site to wrist, dry throat, intense thirst, difficulty swallowing, vertigo, cloudy vision, waves of nausea, weak/numb hands, uncontrollable shaking; all on 18Apr2021 with outcome of recovered in Apr2021. No treatment received for the events. All events resulted in doctor or other healthcare professional office/clinic visit. |

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| 1284762 | 5/4/2021 | FL | 80 | F | 3/11/2021 | 3/11/2021 | I had an allergic reaction to the Pfizer Covid vaccine; I fell; Passed Out Without Warning and Hit her Face on the Tile Floor; Busted Mouth; Stitches in Mouth; Right Knee Very Sore /Left Shoulder Very Sore and Can't Use It; Black Left Eye; states it was black, blue, purple, green and yellow; Tiredness; Left Hand Pinky Sore; This is a spontaneous report from a contactable consumer (patient). An 80-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), second dose via an unspecified route of administration, administered in Arm Right on 11Mar2021 14:00 at age of 80-year-old (Batch/lot Number: EN6205) at single dose for COVID-19 immunization. The vaccine was not administered at Military Facility. Medical history included she has hearing aides but it is hard to hear or understand sometimes. There were no concomitant medications. Prior Vaccinations (within 4 weeks) was the first dose of Pfizer COVID Vaccine (Batch/lot number: EL9267) on 18Feb2021 at age of 80-year-old administered in right arm and no adverse events following prior vaccinations. The patient reported she had an allergic reaction to the Pfizer COVID vaccine, she fell on 11Mar2021, not fainted. On 11Mar2021, the patient passed out without warning and hit her face on the tile floor, experienced busted mouth/stitches in mouth, right knee and left shoulder were very sore, black left eye/it was black, blue, purple, green and yellow, tiredness, left hand pinky sore. The patient was calling about the Pfizer COVID Second Shot; verified Pfizer COVID Vaccine. Her second shot was on 11Mar2021 and on the same day she passed out without any warning whatsoever, and she hit the tile floor and ended up in the hospital for five days. She passed out and didn't remember falling or feeling anything before falling. The patient also has a primary physician, but she had been seeing the plastic surgeon for this. The patient asked what does she do if she needs to get a booster. It scared her to death if she would have to take another shot. The patient asked (name) to hand her a pair of glasses to read the plastic surgeons name. She stated the printing is so small on there. She was supposed to see the doctor on 19Apr2021, but she didn't feel good enough to go see the doctor. For busted Mouth, they put in 3 layers of stitches. The stiches have been giving her a fit because sometimes they come undone and hang down. She had to go back into him and |

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get them cut out twice, and she had another one from last night (18Apr2021). It is very sore. States the stiches inside the lip have not resolved and it was still hard. One part of her lip is soft and one part is hard. It was all hard in the beginning. The stitches on the inside are supposed to dissolve. For right Knee it was very sore and she can't hardly use it. For left shoulder it is very sore and she can't hardly use it. It made it awkward to get in and out of bed when she can't use her left arm or her right knee. Her left shoulder was really bothering her and she may have to go have some more work done. It has been popping and went in and out of the joint. That would be back with her primary doctor. Sore pinky on left hand had recovered it didn't stay that long. Black left eye, it was black and blue purple green and yellow. It cleared up in the last couple of days. She was lucky she didn't break the bone around her eye. Treatment included stitches, hospitalization, given antibiotics and blood clotting shots so she didn't get blood clots, she had 3 of those in her belly. She wasn't allowed to get out of the bed when she was in the hospital. She had a terrible experience in the hospital. For the event onset time, it was at 20:00, they drove home from (place name), which is an hour and something, and they stopped at (place name), came home and set outside and she said she had to go lay down because she was tired. She woke up an hour and half to 2 hours later, got out of bed, sat on side, stood up and got herself together and walked to bottom of bed and went out flat. The events required a visit to emergency room and physician office. For emergency room visit, it was reported on 11Mar2021 at (hospital name); the patient should've called redacted number but didn't, they drove in. The patient was hospitalized from 11Mar2021 to 16Mar2021 at (hospital name). The outcome of passed out, tiredness were resolved on 11Mar2021, outcome of 'black left eye/it was black, blue, purple, green and yellow' was resolved on 17Apr2021, outcome of left hand pinky sore was resolved in 2021, the outcome of fell, allergic reaction to the Pfizer COVID vaccine were unknow, outcome of busted mouth, right knee/left shoulder very sore were not resolved.

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| 1285280 | 5/4/2021 | VA | 59 | M | 5/3/2021 | 5/3/2021 | AFTER 5 MINUTES PATIENT RECEIVED THE VACCINE ,PATIENT FAINTED AND SUSTAINED SOME INJURIES AROUND HIS RIGHT EYEBROW WHILE HE IS IN THE WAITING AREA. PARAMESICS ARRIVED AT THE SCENE AND PATIENT REFUSED FURTHER TREATMENT. HE WAITED ABOUT 20 MINUTES AT THE WAITING AREA AND LEFT THE STORE. |

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| 1284737 | 5/4/2021 | KY | 37 | M | 2/19/2021 | 2/19/2021 | dizziness/dizzy/almost felt like fainting; felt like fainting; racing heart; sweating; This is a spontaneous report from contactable consumers (one is the patient). A 37-year-old male patient received bnt162b2 (BNT162B2), dose 1 via an unspecified route of administration in the left arm on 19Feb2021 13:00 [also reported as 26Feb2021 12:45 PM] (Lot Number: EL9267; Expiration Date: May2021) as a single dose for covid-19 immunisation. Medical history included drug penicillin allergies and low testosterone ongoing since 2018. Concomitant medication included testosterone cipionate (TESTOSTERONE CYPIONATE) for low testosterone, start and stop date were not reported. The patient previously took amoxicillin but had allergies. The patient reported that a few minutes after his first vaccination (19Feb2021), he experienced a racing heart, dizziness, sweating, and almost felt like fainting. A couple waves of this hit him and subsided after 10-15 minutes. The events required emergency room visit. The patient has not been covid tested post vaccination. The patient was not diagnosed with covid prior vaccination. The patient has his blood checked twice/year all normal levels (unspecified date). The patient mentioned that he became slightly dizzy after receiving his first COVID-19 vaccine and he was not nervous or scared prior to or following receiving the vaccine. He also does not have history or problems receiving other vaccines or blood draws when he received the second vaccine, he felt normal for a couple minutes although he would feel "something" thought his body immediately after the injection. A few minutes went suddenly, he became very dizzy or short of breath, EMS was on standby at this site, so they advised him to sit on the floor. They connected heart /O2 monitor to him (2021), and his heart rate was very highly (around 130 BPM) or then it would swing widely to less than 50 BPM. During these swings, he would get very dizzy or faint. This happened multiple times starting from less severe to severe with fainting, to finally going away, unfortunately after 30 minutes or so when the heart rate swings were observed, EMS administered Epinephrine and Benadryl in IV form. He was taken to a hospital via ambulance where he was later discharged after no issue in observation. The events tachycardia, dizziness and fainting were considered serious with seriousness criterion of hospitalization/prolongation of hospitalization |

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and important medical event. The outcome of the events was recovering.

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| 1284723 | 5/4/2021 | IN | 67 | M | 3/19/2021 | 4/23/2021 | <p>he couldn't pee; low appetite; he thought he may pass out; Chills; severe headache every time he got up; feel sick to his stomach but never vomited; low grade fever; tired; This spontaneous case was reported by a consumer and describes the occurrence of URINARY RETENTION (he couldn't pee) in a 67-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 037A21B and 030A2L1A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included COVID-19 in December 2020. Concomitant products included FLUOXETINE HYDROCHLORIDE (PROZAC) for an unknown indication. On 19-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 23-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 23-Apr-2021, the patient experienced URINARY RETENTION (he couldn't pee) (seriousness criterion medically significant), DECREASED APPETITE (low appetite), PRESYNCOPE (he thought he may pass out), CHILLS (Chills), HEADACHE (severe headache every time he got up), NAUSEA (feel sick to his stomach but never vomited), PYREXIA (low grade fever) and FATIGUE (tired). On 23-Apr-2021, DECREASED APPETITE (low appetite) had resolved. On 25-Apr-2021, URINARY RETENTION (he couldn't pee), PRESYNCOPE (he thought he may pass out), CHILLS (Chills), HEADACHE (severe headache every time he got up), NAUSEA (feel sick to his stomach but never vomited), PYREXIA (low grade fever) and FATIGUE (tired) had resolved. The reporter stated, the patient had similar side effect from what he had from the 1st dose. Additional concomitant medications included Blood pressure pills, Cholesterol pills and maybe back pain pill. Treatment medication included Tylenol. Based on the information provided which includes a strong temporal association between the use of mRNA-1273 vaccine and onset of the reported events, a causal relationship cannot be excluded. Chills, headache, pyrexia, fatigue and nausea are consistent with the product safety profile. Most recent FOLLOW-UP information incorporated above includes: On 26-Apr-2021: An additional document received on 26 Apr 2021</p> |

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has information Upgraded case to serious, updated suspect product details, concomitant medication, treatment medication and event details.; Sender's Comments: Based on the information provided which includes a strong temporal association between the use of mRNA-1273 vaccine and onset of the reported events, a causal relationship cannot be excluded. Chills, headache, pyrexia, fatigue and nausea are consistent with the product safety profile.

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| 1284654 | 5/4/2021 | PA | 71 | F | 4/1/2021 | | <p>BLOOD CLOT INSIDE THE BUMP (INJECTION SITE); WHEEZING; HIVES ON NECK; BLADDER INFECTION/ABDOMINAL PAIN TO GROIN; BLADDER INFECTION/ ABDOMINAL PAIN TO GROIN; INJECTOR PULLED THE NEEDLE BACK AND PUT IT IN AGAIN; COULD HARDLY WALK; COULDN'T TOUCH THE ARM; REDNESS IS STILL AS BIG AS A BASEBALL; NAUSEA; VOMITING; HALLUCINATIONS; DIARRHEA; This spontaneous report received from a consumer concerned a 71 year old white (Hispanic/Latino) female. The patient's height, and weight were not reported. The patient's past medical history included bladder infection, and concurrent conditions included high blood pressure, high cholesterol, and asthma/ bronchitis/ get asthma attacks often. The patient's other pre-existing medical conditions included that she had no history of heart attack or pain. The patient's family history included that her mother had bladder infection and lady part infections. The patient was not pregnant at the time of reporting. The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 202A21A and expiry: 23-JUN-2021) dose was not reported, 1 total administered on 10-APR-2021 around 10:00 AM for prophylactic vaccination on right arm. No concomitant medications were reported. On 10-APR-2021, the patient almost passed out after she got the shot (vaccination), they (vaccine facility) had to take her out to the car, and she could hardly walk. The patient reported that injector pulled the needle back and put it in again (Wrong injection technique). It was reported that right after injection when she turns around her arm was big as baseball, mushy, swollen and it was painful (injection site). The mushiness was going down, but it was still mushy. The patient's arm was hard as a marble, redness was still as big as a baseball and she could not touch her arm. On 20-APR-2021, the patient had bladder infection/abdominal pain to groin and had infection from lady's problem and further stated it as bladder infection. The patient think that the bladder infection was not because of the Janssen vaccine. On 21-APR-2021, the patient experienced hives on the neck and she applied Benadryl cream on it. The patient went to her physician on 22-APR-2021 (Thursday) and Nurse looked at her arm and said that it was perfusion and there was blood clot inside the bump. The patient's physician told her to</p> |

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take Benadryl and put ice and heating pad on it. The patient reported that she was already putting ice packs 3-4 times a day and heating pads 3 times a day. The patient also showed her hives to her physician and she was told to keep putting Benadryl on it. The patient had a follow up with her physician on 03-MAY-2021 for her arm checkup. On an unknown date in APR-2021 (reported as first night), she could see penguins walking around, marching up the stairs on first night (Hallucinations) and then no more penguins after the first night. On the same first night, the patient experienced nausea, diarrhea, and vomiting. On an unknown date, the patient experienced wheezing and she thinks that her wheezing was not related to the Janssen Covid-19 vaccine. According to patient her wheezing is related to her asthma. The patient did not have any trouble sleeping since she was taking the Benadryl. The patient stated that she could move her arm up and down, but she was scared to do so. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from hallucinations, bladder infection/abdominal pain to groin, diarrhea, vomiting, and nausea, and the outcome of almost passed out, hives on neck, couldn't touch the arm, blood clot inside the bump (injection site), wheezing, could hardly walk, injector pulled the needle back and put it in again and redness is still as big as a baseball was not reported. The reporter considered the causality between Covid-19 vaccine ad26.cov2.s and wheezing, and bladder infection as not related. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210452551-covid-19 vaccine ad26.cov2.s- blood clot inside the bump (injection site), hallucinations. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).

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| 1284602 | 5/4/2021 | WV | 51 | F | 1/14/2021 | 1/15/2021 | Loss of consciousness; single syncopal episode; tried to get ready for work; did not sleep much that night; pain/body aches; Tired; Awoke nauseated; This case was received via VAERS on 27-Apr-2021 and was forwarded to Moderna on 27-Apr-2021. This regulatory authority case was reported by an other health care professional (subsequently medically confirmed) and describes the occurrence of LOSS OF CONSCIOUSNESS (Loss of consciousness) and SYNCOPE (single syncopal episode) in a 51-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 013L20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Multiple organ dysfunction syndrome. Concurrent medical conditions included COPD and Asthma. Concomitant products included FLUTICASONE FUROATE, VILANTEROL TRIFENATATE (BREQ ELLIPTA) and FLUTICASONE for an unknown indication. On 14-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 15-Jan-2021, the patient experienced LOSS OF CONSCIOUSNESS (Loss of consciousness) (seriousness criterion medically significant), SYNCOPE (single syncopal episode) (seriousness criterion medically significant), IMPAIRED WORK ABILITY (tried to get ready for work), INSOMNIA (did not sleep much that night), MYALGIA (pain/body aches), FATIGUE (Tired) and NAUSEA (Awoke nauseated). At the time of the report, LOSS OF CONSCIOUSNESS (Loss of consciousness), SYNCOPE (single syncopal episode), IMPAIRED WORK ABILITY (tried to get ready for work), INSOMNIA (did not sleep much that night), MYALGIA (pain/body aches), FATIGUE (Tired) and NAUSEA (Awoke nauseated) had resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. The patient has done a telehealth visit with physician couple hours after the events. No further treatment was rendered. Treatment information was not provided. Based on the current available information and temporal association between the use of the product and the start date of the event, a |

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| 1284519 | 5/4/2021 | UT | 39 | F | 4/12/2021 | 4/26/2021 | causal relationship cannot be excluded. Patient's hx of multiple organ dysfunction syndrome is a confounding factor that may play a possible contributory role.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Patient's hx of multiple organ dysfunction syndrome is a confounding factor that may play a possible contributory role. |
| 1284511 | 5/4/2021 | TX | 44 | M | 5/3/2021 | 5/3/2021 | I'm three weeks post vaccine #2. During weeks 2 and 3 I have had vertigo off and on and almost fainted once. It wasn't clear that it was related to the vaccine until my husband started having the same symptom. I also had some leg tingling which may or may not be related. My blood pressure is normal. 70s / 120s. I am still currently having these symptoms and have not contacted my doctor. |
| 1284758 | 5/4/2021 | OR | 47 | M | 4/18/2021 | 4/19/2021 | Got up in night to use bathroom and fainted. |
| | | | | | | | passed out; extreme nausea; hit the bathroom floor; have a cut lip; extreme chills; This is a spontaneous report from a contactable consumer (patient). A 47-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) dose 2 via an unspecified route of administration, administered in left arm on 18Apr2021 10:45 (Lot Number: EW0164) as single dose for COVID-19 immunisation. Medical history included irritable bowel syndrome and allergy. Concomitant medications included chlorthalidone, clidinium bromide (LIBRAX), Multi-Vitamin, colecalciferol (D3), ascorbic acid (VIT C), fish oil. No other vaccine was received in four weeks. No COVID prior vaccination. No COVID tested post vaccination. The patient received first dose of BNT162B2 (lot# ER2613) in left arm on 27Mar2021 12:00 PM for COVID-19 immunization. The patient experienced extreme nausea 19Apr2021 00:30, then he passed out and hit the bathroom floor. The patient woke up a few moments later, when her wife found him. The patient had a cut lip. The patient then had extreme chills for 30-60 minutes. The events resulted in doctor or other healthcare professional office/clinic visit. It's unknown if treatment was received. The outcome of events was recovering. |

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| 1287970 | 5/4/2021 | TX | 32 | F | 5/4/2021 | 5/4/2021 | Pt fainted for 2 minutes immediately after getting the vaccine . Was okay after that |
| 1285492 | 5/4/2021 | CA | 47 | M | 4/30/2021 | 4/30/2021 | C/O SYNCOPE, SEIZURE ACTIVITY X 20 SECS, NAUSEA, NO HX PRIOR ALLERGIES, PROVIDED WATER AND SNACK, SX RESOLVED, NO TRANSPORT. |
| 1287983 | 5/4/2021 | UT | 52 | F | 4/21/2021 | 4/26/2021 | Around 4/26/21 patient developed difficulty breathing. This was progressive. On 5/2/21, the shortness of breath became severe and she had pre-syncope and chest pressure. She came to the ER at Hospital, where she was initially hypotensive and tachycardic. D-dimer was unreadably high (over 20) and CT pulmonary angiogram disclosed bilateral pulmonary emboli with right heart strain. She was initiated on heparin drip and admitted to ICU. She has stabilized but remains hospitalized at time of this report (5/4/21). |
| 1287657 | 5/4/2021 | | 36 | F | 5/1/2021 | 5/2/2021 | Lightheadedness, shortness of breath, and I passed out and had to go to the ER. |
| 1287640 | 5/4/2021 | CA | 18 | F | 5/4/2021 | 5/4/2021 | syncope |
| 1287356 | 5/4/2021 | FL | 35 | M | 5/4/2021 | 5/4/2021 | Within 2 minutes of patient receiving the vaccine he passed out and fell out of the post vaccine waiting chair onto the floor. He was unresponsive for approximately 10 seconds. Upon becoming responsive he was alert and oriented x3. Blood pressure was monitored while waiting for EMS to arrive. Blood pressure was 150/94 heart, heart rate of 98, he was diaphoretic. |
| 1287350 | 5/4/2021 | FL | 33 | F | 4/8/2021 | 4/8/2021 | Injection was very painful and felt immediately as if it was improperly administered causing my arm to go limp (so to speak) right away. The pain was so intense that I became extremely lightheaded almost to the point of fainting. Within 15 minutes following the vaccination, I started experiencing excruciating arm pain at the injection site . The pain has persisted for the past month with little to no relief, I now have limited range of motion and cannot make certain movements with my arm. |

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| 1287338 | 5/4/2021 | CA | 18 | M | 5/4/2021 | 5/4/2021 | About 5 minutes later after administration, pt complained dizzy/sweating. Pt 's face turned pale and shows syncope symptom. Pt was still alert but he looks like almost fainting. Mom requested 911 and pt was transferred to hospital with paramedic. we provided Pfizer Lot number to mom and advise to contact us if she need any other information from us. |
| 1287074 | 5/4/2021 | PA | 18 | F | 5/4/2021 | 5/4/2021 | Patient was given vaccine and about 5 minutes after felt faint. Patient passed out for a few seconds. Patient peed herself. Patient left pharmacy after 45 minutes and was fine |
| 1287061 | 5/4/2021 | IN | 40 | M | 5/3/2021 | 5/3/2021 | Patient passed out. dizziness, clammy skin, blood pressure low |
| 1287056 | 5/4/2021 | NY | 50 | M | 5/4/2021 | 5/4/2021 | patient fainted twice complaint of dizziness |
| 1286865 | 5/4/2021 | UT | 50 | M | 3/12/2021 | 3/13/2021 | I felt sick and fatigue after getting the shot. And the next morning I passed out on my way to work and wrecked my truck. |
| 1286855 | 5/4/2021 | MA | 40 | F | 5/4/2021 | 5/4/2021 | after administering the vaccine during the observation time pt had syncope |
| 1286744 | 5/4/2021 | TN | 18 | F | 5/3/2021 | 5/3/2021 | Patient received the shot. They felt dizzy and passed out after receiving the shot during the monitoring period. After establishing that the patient was conscious and breathing. We initiated the emergency protocol. The EMTs came and checked blood pressure and blood sugar. The patients dad also came in and after concluding that the patient was okay they decided to forgo going to the hospital. They went home on their own accord. I called them again after 3 hours to verify that they were still okay. |
| 1286642 | 5/4/2021 | MA | 16 | M | 5/4/2021 | 5/4/2021 | Syncope event |

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| 1285707 | 5/4/2021 | NH | 29 | F | 5/3/2021 | 5/3/2021 | Patient said she had a history of fainting with other injections and blood draws. She was sitting in a chair when she began to feel faint. She asked her sister to move her to the floor to lay down. She was out for about 3 minutes and then came to. She sat on the floor for a minute and then transitioned to the chair. We offered cold cloths which she refused. She did accept an orange juice. She was fine after waiting 15 minutes and left the store. |
| 1284866 | 5/4/2021 | | 27 | F | 3/28/2021 | | fainted; This is a spontaneous report from a contactable consumer (patient). A 28 year old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Solution for injection, Lot number and expiry date were not reported), via an unspecified route of administration, administered in left arm on 28Mar2021 (at the age of 27 years old) as a single dose for covid-19 immunization. The patient's medical history was not reported. Patient was not pregnant at the time of vaccination and the event. Prior to vaccination, the patient was not diagnosed with COVID-19. Patient had no allergies of any kind. The patient had no concomitant medications. Patient was not taking any medications/supplements. Patient had no other vaccine in four weeks prior to the COVID vaccine. The facility where the most recent COVID-19 vaccine was administered was in a pharmacy or drug store. Patient fainted on an unspecified date in 2021 after her first dose. No treatment was received in response to the event. Since the vaccination, the patient was not tested for COVID-19. The outcome of the event was unknown. Information on the batch/lot number has been requested. |
| 1286637 | 5/4/2021 | | 69 | F | 5/4/2021 | 5/4/2021 | passed out in car. felt weak and fell over (according to spouse) syncope. Evaluated by EMS- Transported to Emergency room/department or urgent care. |

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| 1285665 | 5/4/2021 | NE | 64 | F | 5/4/2021 | 5/4/2021 | PATIENT WAS ADVISED AFTER RECEIVING VACCINE TO SIT FOR 15 MINUTES. SHE THEN SAID SHE NEEDED TO GO TO THE BATHROOM. PERSON WATCHING HER SAID THIS IS OK, BUT SHE WOULD ESCORT PATIENT. PT THEN PASSED OUT ON THE WAY TO RESTROOM, BUT WAS CAUGHT BY PERSON WATCHING HER AND LAID TO THE GROUND. HER FEET WERE ELEVATED AND SHE WOKE UP WITHING A FEW SECONDS. HER MASK WAS REMOVED AND SHE WAS ALLOWED TO LAY DOWN A FEW MINUTES, THEN WAS SLOWLY BROUGHT BACK TO A SITTING POSITION, THEN EVENTUALLLY UP TO HER FEET AND TO THE BATHROOM, THEN BACK TO HER CHAIR TO SIT. SHE THEN SAT ANOTHER 25 MINUTES. |
| 1285829 | 5/4/2021 | TX | 45 | M | 4/3/2021 | 4/3/2021 | Started with nausea, then it followed. Migrane, unable to talk, unable been awake ,I even fainted I don't know for how long but when I woke up was on the floor and sweating, chills, fever, shortness of breath, tireness, muscle pain and cough. Did not go to the doctor or hospital, I have no insurance. Even until today I still have a light cough and shortness of breath. All this stopped me from going to work for 2 weeks, and unenployment did not pay. |
| 1285965 | 5/4/2021 | ID | 30 | M | 5/4/2021 | 5/4/2021 | He felt dizzy and passed out for about a minute. Paramedics observed him for an hour, checked BP and pulse frequently. He said he has a history of syncope after any injection or needle stick. He was escorted out to his ride, said he's fine. |
| 1286048 | 5/4/2021 | VA | 59 | M | 5/3/2021 | 5/3/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: PATIENT WAS WAITING IN THE OBSERVATION AREA WHERE HE FELL DOWN AND LOST CONSCIOUS FOR FEW SECONDS.911 WAS CALLED. HE WAS COHERENT, NO OTHER SYMPTOMS, VITALS WERE FINE, HE WAS NOT HOSPITALIZED. HE GOT A SCRATCH ON HIS LEFT EAR. |
| 1286206 | 5/4/2021 | NY | 57 | F | 5/4/2021 | 5/4/2021 | Patient passed out |

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| 1286545 | 5/4/2021 | OR | 81 | F | 4/7/2021 | 4/28/2021 | <p>Pt received vaccine in her home state, unable to get details of vaccine administration such as date, site, lot #, etc. Per ED MD note : 81-year-old female with reported history of atrial fibrillation found down at hotel room. Patient states she has been on the ground in the room for 3 days, she was found covered in feces. Alert and oriented x4 however intermittently appears confused and has varying history. She does not know how she got on the ground, however denies fall or syncope. No significant current complaints. Slightly tachycardic and febrile, slightly hypertensive, exam without any significant acute findings, no obvious skin source of ulcer or infection, no focal neurological deficits, no pain. Initiated aggressive fluid hydration and sepsis work-up. EKG appears normal with no signs of ischemia or arrhythmia. Labs show slightly elevated troponin, low magnesium, metabolic/lactic acidosis. VBG relatively normal. Urine negative for infection chest x-ray without evidence of pneumonia, no clinical signs or symptoms to identify source of infection. Nothing to suggest meningitis at this time. CT head is negative. Unclear source of fever however empirically treated with antibiotics and fluids. Patient remains hemodynamically stable with no hypotension. She did arrive slightly hypoxic and with increased respiratory rate however clear lung sounds and no indications of heart failure, COPD/asthma. CT chest without evidence of pulmonary embolism, focal pneumonia, or fluid overload. Respiratory status possibly related to compensation for metabolic acidosis that is likely due to lack of fluid intake due to being on the ground. CK is normal and kidney function is normal. Consulted medicine for admission for further evaluation and treatment. Cardiology was also consulted for NSTEMI, agrees with current plan. per H&P 4/28/21: Altered mental status (R41.82): Etiology is not clear. Patient states she had J&J Covid vaccine about 3 weeks ago. Need to rule out cerebral venous sinus thrombosis. Get a CT scan of the brain with contrast. If negative will get CT venogram or MRV and MRI of the head. Neuro checks. Request PT OT and speech therapy evaluation. Check urine drug screen. Check blood alcohol level. Non-STEMI (non-ST elevated myocardial infarction) (I21.4): Start argatroban drip until cerebral vein sinus thrombosis is excluded then we can switch to heparin drip. Start aspirin and statin. Check fasting lipid panel.</p> |

Monitor on telemetry. Trend troponin. Request echocardiogram. Cardiology to consult. Dr. was consulted from the ER. » Beta-Blocker Ordered: Beta-Blocker Ordered » Aspirin Ordered: Aspirin Ordered » Statin Ordered: Statin Ordered Fall (W19.XXXA): Plan as documented above. Rhabdomyolysis (M62.82): Hydrate and recheck CPK. Elevated liver enzymes (R74.8): Check hepatitis panel. Monitor levels. Fever (R50.9): No clear source of infection. Follow up on blood cultures. CT chest negative for infectious process. Check CT of the abdomen and pelvis. Start empiric antibiotics: Vancomycin and Zosyn. Hypomagnesemia (E83.42): Administer magnesium sulfate. Repeat level in the morning. Diabetes (E11.9): Start sliding scale insulin. Monitor fingersticks. Hypoglycemic protocol. Check hemoglobin A1c. Hypertension (I10): Fortunately patient is hemodynamically stable. We will cautiously start metoprolol. Adjust antihypertensives to optimal blood pressure control. Acidosis, lactic (E87.2): Likely due to profound volume depletion. Rule out sepsis. Hydrate and trend level. VTE: Argatroban. » VTE Prophylaxis Assessment: Risk Level documented as Low Risk Discharge Planning: » Discharge Planning: » Discharge To, Anticipated: Home independently Per Intensivist note 4/30/21: . Another consideration was TTP, however, patient has normal renal function with no significant evidence of microangiopathic hemolytic anemia (no schistocytes on smear). Also does not seem consistent with ITP. Suspect more a result from sepsis given bacteremia Per attending note 4/30/21: Altered mental status (R41.82): Likely septic encephalopathy due to sepsis. No cerebral venous sinus thrombosis. MRI negative for stroke. AMS has resolved. Continue antibiotics. Per attending note 5/2/21: Addendum by MD, on May 02, 2021 09:58:55 (Verified) Discussed with cardiologist, Dr. . Possible need for TEE with regards to persistent bacteremia. We will keep n.p.o. overnight for TEE tomorrow. Repeat blood culture from 4/30/2021 just came back positive for Enterococcus. Suspect endocarditis due to TAVR. ? need for TEE to evaluate the valves (TAVR) more closely. Duration of antibiotics depends on bacterial clearance: To be determined. Get another set of cultures. On Zosyn. per attending note 5/4/21: Enterococcal bacteremia (R78.81): Etiology not entirely

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| | | | | | | | clear but suspect GI source or endocarditis. Repeat blood culture from 4/30/2021 is positive for Enterococcus. PCP he is accepting to follow-up for IV antibiotics management: Will arrange home IV infusion through care . Antibiotics end date to be determined: Pending bacterial clearance. Repeat blood cultures pending. Infectious disease specialist following: Patient is currently on Unasyn. Will need 4 weeks of IV antibiotics. |
| 1286322 | 5/4/2021 | MA | 24 | F | 5/4/2021 | 5/4/2021 | Patient fainted, was fine in 30 minutes |
| 1286430 | 5/4/2021 | OH | 29 | F | 4/6/2021 | 4/6/2021 | Fainted 10 minutes after receiving shot. Next day, (starting 12 hours after vaccine) severe muscle aches, nausea, fatigue, slight fever, all for approximately 12 hours. Felt slightly fatigued the next day but back to normal after that. |
| 1286511 | 5/4/2021 | TX | 52 | F | 1/29/2021 | 2/1/2021 | MODERNA VACCINE - Began feeling very dizzy, off balance - this continued though out the first week 2/1 - 2/7/21. By Sunday Feb 7th my symptoms became worse more frequent. Monday Feb 8th. I could barely walk, so weak, ringing in my head, spinning, dizzy, could not form words; passed out. I was rushed to hospital where my blood pressure was so high. I was disoriented major brain pain - as if something popped in my head..Was admitted for 4 days could not walk. I am constantly feeling pain in my head. ringing, dizziness effecting my vision and balance and effecting my day to day life. It is effecting the vestibular part of my brain. Ear fullness, dizziness, balancing, vertigo and IT IS NOT GOING AWAY...I have never had high blood pressure nor dizzy/vestibular problems as soon as the vaccine was adminstered is when the problems began -- MY BOLOGICAL SISTER HAD A MASSIVE STROKE (A VERY RARE TYPE OF STROKE 2 DAYS AFTER THE MODERNA VACCINE) THAT HIT HER BALANCE PART OF HER BRAIN. I WANT SOMEONE TO REVEIW ALL RECORDS ; aS OF TODAY i AM STILL HAVE DEBILITATING ISSUES. THAT IS EFFECTING MY DAILY LIFE WITH NO ANSWERS |

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| 1286515 | 5/4/2021 | CA | 70 | F | 5/4/2021 | 5/4/2021 | First, the injection was far more painful than anticipated (and it bled down my arm). My arm immediately ached intensely. Approximately 10 minutes after injection, I began to sweat profusely, followed by intensifying extreme lightheadedness. I could not stand, or lift my head, as I would have definitely passed out. My shoulders and neck became extremely painful, as if ?frozen?, also preventing me from lifting my head. After about 35 minutes I very gradually began to recover. It was about an hour before I began to move around normally. Pharmacy and store staff debated calling the paramedics, but I refused. FYI, I had not been especially anxious about the vaccine, and I have never experienced such a reaction to anything in my life. It was a traumatic experience I would not wish to repeat. |
| 1286314 | 5/4/2021 | NC | 47 | F | 3/13/2021 | 3/13/2021 | Immediately felt overwhelmed with heat and fainted (within 5 minutes) of receiving the shot. I was scheduled to have my normal period within a week and have never had another period. I am experiencing full on menopause and I have never had a single symptom. I have full sweats and freezing temperatures all throughout the day. |
| 1286581 | 5/4/2021 | | 41 | F | 2/26/2021 | 3/16/2021 | Patient presented to the ED on 3/16/21 with syncope and was subsequently hospitalized. Patient also presented to the ED on 4/12/21. |
| 1281835 | 5/3/2021 | MN | 24 | F | 3/30/2021 | 3/30/2021 | Pt fainted after receiving the Covid vaccination. She was assisted to the Observation area per w/c. She fully oriented & BP 121/71. Pt left with no assistance. No known adverse reactions. |
| 1281891 | 5/3/2021 | TX | 41 | M | 4/11/2021 | 4/11/2021 | dizziness, near syncope |
| 1281934 | 5/3/2021 | GA | 46 | M | 5/3/2021 | 5/3/2021 | Immediately after patient was given vaccine, the patient passed out for 1-2 minutes, then vomited, became light-headed, and broke out into sweats. After 2 minutes the patient regained consciousness, however, the other symptoms persisted for about 10 minutes. |
| 1281938 | 5/3/2021 | PA | 35 | M | 5/3/2021 | 5/3/2021 | Patient passed out after receiving vaccine while waiting afterwards. He woke up disoriented, sweating. He said he had passed out previously and it felt the same. EMS checked him out and he left on his own. |

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| 1281950 | 5/3/2021 | WI | 18 | F | 4/27/2021 | 4/27/2021 | CLIENT PASSED OUT OR FAINTED AFTER RECEIVING THE VACCINE WHILE VACCINATOR WAS PROVIDING HER WITH INSTRUCTIONS. CLIENT WAS ASSISTED TO THE FLOOR. NO INJURIES OBTAINED. CLIENT CAME TO IN SECONDS AND EXPLAINED SHE OFTEN FAINTS AFTER VACCINATION. CLIENT REMAINED UPRIGHT FOR 10 MINUTES AND DRANK WATER. WHEN ABLE TO WALK, CLIENT WAS ESCORTED TO A COT IN THE MONITORING AREA AND LAID DOWN. CLIENT WAS STABLE AND REMAINED AT FACILITY FOR 30 MINUTES UNTIL ABLE TO WALK AND WAS NO LONGER LIGHT HEADED. |
| 1282053 | 5/3/2021 | KY | 64 | F | 4/30/2021 | 4/30/2021 | Patient reported that she had a history of fainting after receiving other vaccines, so she had her friend drive her and got the vaccine administered in her car. A few minutes after getting the vaccine, the patient appeared to have a vasovagal episode where she stared off into the distance and stopped responding to questions for about 30 seconds to 1 minute before coming to. She reported having some tingling in her fingers and feeling a little weak afterwards. Provided the patient with a wet cloth for her forehead and some candy. Patient was a little shaken up but seemed to be back to normal in a few minutes. Contacted EMS just to be sure, and they checked her pulse and blood pressure, which were a little elevated but within normal limits. Patient said she was feeling better and did not need to go with them to the hospital. After waiting a few more minutes, she reported that she was feeling mostly back to normal and her friend drove them back home. |
| 1282185 | 5/3/2021 | | 52 | M | 5/3/2021 | 5/3/2021 | After injection patient felt dizzy and fainted. Vasovagal episode. Patient has a history of vasovagal. Patient awoken after ammonia. Vital signs taken by EMS. Patient is hypotensive. Patient was placed on stretcher in trendelenburg . Patient recovered |
| 1282091 | 5/3/2021 | FL | 59 | F | 5/3/2021 | 5/3/2021 | Fainted, sweating, lightheaded, dizzy, tingling all over, felt like bugs were crawling under her skin |

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| 1282130 | 5/3/2021 | FL | 60 | M | 4/27/2021 | 4/27/2021 | Day 2 following the vaccine, patient began to experience flu-like symptoms (fatigue, head ache, body ache). Followed by a syncope episode, did not follow up with any emergency care. Did not contact primary care or go to the hospital, or take any medication to treat symptoms. Mentioned having eye soreness, eyes feeling fatigued which is not usual for the patient and coincide with timing of adverse effects. |
| 1281758 | 5/3/2021 | GA | 31 | M | 5/3/2021 | 5/3/2021 | Patient reported feeling light headed approximately 8 minutes after receiving the vaccine, then fainted. Patient came to 2-3 minutes later. Patient was provided water and orange juice, as he had mentioned he had only had a very small breakfast (one popart). Patient says he has not fainted post-vaccination before, but has fainted before after getting his blood drawn. |
| 1281272 | 5/3/2021 | TX | 33 | M | 5/1/2021 | 5/1/2021 | Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Additional Details: called 911 but patient recovered before paramedix arrived |
| 1282245 | 5/3/2021 | | 18 | F | 4/29/2021 | 4/29/2021 | patient had syncope episode and fever -- fever started with 4 hours of covid moderna vaccine and then had syncope four separate times |
| 1282077 | 5/3/2021 | AK | 16 | F | 4/30/2021 | 4/30/2021 | Vasovagal Syncope |
| 1281741 | 5/3/2021 | AZ | 52 | M | 4/29/2021 | 4/29/2021 | Patient received vaccine 4/29/21 at 16:45. He fainted for a short period of time during his observation time. EMS was called but patient was not transported. NKDA, no past medical history, no current medications. BP and HR were checked 4 times and all times were unremarkable. Blood sugar was checked by EMS and was 118. Patient did report having the same reaction back in college after receiving his MMR vaccine. Patient was driven home by his wife. |
| 1281645 | 5/3/2021 | MD | 33 | M | 4/27/2021 | 4/28/2021 | At an unknown time, I woke up to use the bathroom. During that time, I fainted and hit myhead on the floor resulting in a concussion. I regained consciousness around 3am after being unconscious for an unknown period of time. I then went to the ER at a Medical Center, where I was admitted. |

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| 1281604 | 5/3/2021 | TX | 31 | F | 4/11/2021 | 4/11/2021 | dizziness, near syncope, resolved |
| 1281531 | 5/3/2021 | TX | 35 | M | 4/5/2021 | 4/12/2021 | Received 2nd dose of vaccine, 5 days later his left leg started hurting and swelling. He had severe headache afterwards, dizzy and blurred vision. 04/24/2021 he complained of not feeling right, coughed and passed out. Had fever and chills when he came to. Wife called 911 and was talking and walking. Was awake and talking in ambulance, oxygen level was low. Once arrived at hospital, he became restless and passed away within 3 minutes. Autopsy was performed due to his age - 35 and no pre-existing illnesses - was determined he died of Pulmonary Thrombo Embolism |
| 1281515 | 5/3/2021 | NC | 19 | F | 5/1/2021 | 5/1/2021 | Vasovagal episode without syncope. Patient with dizziness and vomiting. |
| 1281433 | 5/3/2021 | TX | 40 | F | 4/11/2021 | 4/11/2021 | pt experienced a syncopal episode secondary to receiving Johnson and Johnson vaccinated. pt stated feeling "hot, dizzy" and her ears became "muffled" and she then became nauseated. pt sat down and "passed out" en route to the bathroom. History of Anxiety and Bi-Polar, unknown medications and pt stated NKDA. pt refused further treatment or transportation. |
| 1281287 | 5/3/2021 | NY | 17 | F | 4/29/2021 | 4/30/2021 | Fainting; syncope Emergency room visit: low blood pressure, high heart rate, administered a bag of fluids to hydrate High fever, chills and lightheadedness |
| 1281255 | 5/3/2021 | MD | 17 | M | 5/2/2021 | 5/2/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed/Sweating-Mild, Systemic: Weakness-Mild, Additional Details: FOLLOWED UP WITH PATIENT AT 6:30P ON 05/02/2021. DAD SAID PATIENT IS DOING OK NOW. HE EATS AND TALK NORMALLY. |
| 1281231 | 5/3/2021 | MN | 17 | F | 5/2/2021 | 5/2/2021 | Systemic: Allergic: Difficulty Breathing-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Mild, Systemic: Seizure-Medium, Systemic: Vomiting-Mild |
| 1281095 | 5/3/2021 | FL | 20 | F | 5/2/2021 | 5/2/2021 | Systemic: Fainting / Unresponsive-Medium, Additional Details: ems was called but patient refused |
| 1282299 | 5/3/2021 | NC | 29 | M | 5/3/2021 | 5/3/2021 | Pt fainted immediately after receiving Janssen covid shot |

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| 1281263 | 5/3/2021 | IN | 55 | F | 5/2/2021 | 5/2/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Additional Details: 911 was called when patient fainted. She was conscious when they arrived. They evaluated her at the store and did not take her to the ER |
| 1281374 | 5/3/2021 | OH | 79 | M | 2/19/2021 | 3/11/2021 | Woke up in the middle of the night dizzy on the evening of 3/11/21,started vomiting blood, syncope, when woke up had altered mental state, when reoriented he was able to call EMS, taken to hospital where he was diagnosed with an abdominal clot size of a grapefruit |
| 1283971 | 5/3/2021 | WY | 18 | M | 5/2/2021 | 5/2/2021 | I administered first dose of Pfizer covid 19 0.3 ml via intramuscular route to this patient. About 2 minutes after the administration, the patient had syncope for a second. When I arrived to the scene, the patient was conscious. When he passed out, he felt and landed on his head. He had an abrasion. He stated ?he felt hot and dizzy?. He hasn?t had anything to eat all day. Due to the abrasion, he was rushed to the hospital About 3 hours later, I called to check on the patient. At the time of calling, the patient was discharged from the hospital in good condition. He stated he felt perfectly ok and wasn?t sure what had happened. |
| 1282350 | 5/3/2021 | OH | 16 | F | 5/3/2021 | 5/3/2021 | Systemic: Allergic: Difficulty Breathing-Medium, Systemic: Confusion-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Severe |
| 1281248 | 5/3/2021 | TX | 16 | F | 5/2/2021 | 5/2/2021 | Site: Pain at Injection Site-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Headache-Mild, Systemic: Tingling (specify: facial area, extremities)-Mild, Additional Details: Tingling at site of injection. Patient was seated after receiving the vaccine and suddenly collapsed. Patient maintained consciousness throughout the episode and her symptoms have improved. |

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| 1284271 | 5/3/2021 | AZ | 57 | F | 4/30/2021 | 4/30/2021 | Patient experienced light fainting, lower blood pressure after getting her vaccine. Patient's vitals were normal, patient was observed for 30 min by EMS. Patient felt fine after 30 min. Patient didn't need any treatment. |
| 1284011 | 5/3/2021 | CO | 29 | M | 5/3/2021 | 5/3/2021 | At 1809, patient returned to vaccination site as passenger of personal vehicle with complaint of tingling sensation throughout his body that lasted for about 5 minutes. Patient denied loss of consciousness. Patient had received Janssen vaccination to his left deltoid at 17:56. Patient had reported history of feeling near syncope to vaccinations. Patient's level of consciousness, stroke scale, and vital signs were assessed. Patient was offered a call for emergency services on his behalf but patient denied emergency services. Patient stated that a mild tingling sensation continued on his left arm but that he did not feel any more tingling throughout his body at 18:10. At 18:14 patient stated that he wanted to continue to monitor himself at home and he was encouraged to call for emergency services if symptoms continued or worsened. Patient left as passenger of personal vehicle at 18:18 while his friend was driver of their vehicle. |
| 1284439 | 5/3/2021 | AK | 28 | M | 5/3/2021 | 5/3/2021 | Patient fainted 4 minutes after vaccine given. Patient was able to talk but described "eyes in back of head". Blood pressure reading taken 132/76 pulse 72 then 128/82 pulse 85. Patient was responsive to our questions sitting on floor for 5 minutes. We then we observed him for and additional 15 minutes in our waiting area before he left. |
| 1283967 | 5/3/2021 | RI | 41 | F | 4/11/2021 | 5/1/2021 | Syncope |
| 1283764 | 5/3/2021 | SC | 38 | F | 5/3/2021 | 5/3/2021 | Patient received dose in right arm with no complications. However, about 1-2 minutes after vaccination patient reported feeling lightheaded. As I was instructing her to remain seated, she passed out and was unresponsive. She appeared to be having a seizure immediately after that lasted about 1 minute. Once this episode passed, she became responsive and could talk. EMS arrived and took over. |

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| 1283753 | 5/3/2021 | FL | 32 | M | 5/3/2021 | 5/3/2021 | After receiving vaccine patient was about to sit in observation chair, he started seizing and fainting. Hit his nose and had nose bleed. He was having panic attack due to injection. Called 911. We made him comfortable and then in 5 minutes he started to faint. Ex-Ems was next to him, he started asking him questions and make sure he was awake. Within 5 minutes EMS arrived and they took over, checked all his vitals and found out patient did not eat or drink for whole day and had phobia with needles. Patient refused to go to hospital. Per EMS recommendation patient had drink and a bagel. Patient's relative came and took him home. |
| 1283662 | 5/3/2021 | FL | 24 | F | 5/3/2021 | 5/3/2021 | Patient fainted about a minute after receiving the immunization |
| 1283501 | 5/3/2021 | KS | 58 | F | 4/8/2021 | 4/8/2021 | 8 hours after vaccine chills and shivering uncontrollably; 13 hours after vaccine got up and went to another room to get a drink and fainted. Day after vaccine felt tired/weak and headache. All symptoms gone the following day |
| 1283475 | 5/3/2021 | VA | 17 | M | 5/3/2021 | 5/3/2021 | The 17 year-old patient fainted and lost the consciousness for approximately 3 minutes, 10 minutes after he received his first Pfizer vaccine. He was laid down on the ground, was given water and started to gain his consciousness slowly. He was palpitated, sweating, dehydrated, dizzy and nauseous. Blood pressure was checked 126/78, glucose 118. The reaction could be related to his diet as he has been fasting. He got better gradually when the medical team came. He was advise to keep hydrated and to eat. Patient was taken to the hospital for further check-up |
| 1283432 | 5/3/2021 | FL | 23 | M | 5/3/2021 | 5/3/2021 | Patient fainted after he got the J&J vaccine; as per patient, it had happened in the past after getting blood withdrawn or vaccines; Patient was conscious; 911 was called. Patient was fine and denied medical treatment. |
| 1283105 | 5/3/2021 | CA | 44 | F | 5/1/2021 | 5/1/2021 | Vasovagal response (pt fainted). BP: 110/45 HR: 68 All symptoms resolved. |

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| 1282370 | 5/3/2021 | FL | 23 | F | 5/2/2021 | 5/2/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: patient passed out due to anxiety-Mild, Systemic: Flushed / Sweating-Mild |
| 1282756 | 5/3/2021 | LA | 39 | M | 5/3/2021 | 5/3/2021 | Almost vasovagal syncope. Vaccine administered at 11:00. Vasovagal symptoms present at 11:03. Profuse sweating, decreased ability to see (tunnel vision), ringing in the ears (subsequent hearing loss). Fainting did not present, and symptoms completely subsided at 11:08. |
| 1283993 | 5/3/2021 | OR | 67 | M | 5/3/2021 | 5/3/2021 | Patient and wife stated that he has had many vasovagal syncope events when he has had vaccines administered, both more recently, and in the past. The patient was seated in a chair with arms. Within a couple of minutes of administering the vaccine, his eyes rolled back in his head, he broke out in a cold sweat, BP was 75/55, pulse 55. He never stopped breathing (was snoring); epinephrine for an anaphylactic reaction was not indicated. I offered to call 911 multiple times but his wife said this was the normal course of his reaction and held an icepack on his neck for the duration. After 5-10 minutes the patient was once again responsive. He sat for an additional 10 minutes and then said he was ready to leave. His wife walked him out of the store. |
| 1282465 | 5/3/2021 | FL | 29 | M | 5/2/2021 | 5/2/2021 | Patient had fainted, pharmacist used ammonia salt to wake pt up and pharmacist had called 911. Patient was fine when he left. |
| 1283426 | 5/3/2021 | CO | 33 | F | 4/3/2021 | 4/3/2021 | Patient ended up light headed and fainted in the pharmacy waiting area. she recovered within seconds and didn't need us to call 911. She stated that she had just gone on a bike ride and hadn't eaten anything all day before she received her vaccination, which is what she thought was the cause of her fainting.. She waited in the area for at least 20 minutes before she said she felt ok to leave. She was eating a protein bar while waiting, to help with the low blood sugar. |

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| 1283016 | 5/3/2021 | NC | 25 | M | 5/2/2021 | 5/2/2021 | on the patients PQCF every question was a no,pt showed no fears for needles or signs of aversion,afetr administeru=ing the vaccine pt was waiting for 15 mins sitted ,after 5 mins or more he stated that he could not see,he went blind momentarily, would not blink after a waved my hands across his eyes,we initiated a call to 911 and made him comfortable no other signs of syncope was observed ,he was very aware and calm,after acouple more minutes he regained his sight and at this time he broke out in sweat and was clammy, he felt a lot better with the fan on him and drank some water and ate some chocolate and after a couple more mins he was good to go home,checked up him again the next day and everything is normal |
| 1282868 | 5/3/2021 | NY | 25 | M | 4/9/2021 | 4/9/2021 | Patient has a history of vasovagal syncope when getting vaccines. Patient received COVID vaccine and about 30 seconds later passed out. Patient did not fall. Nurse was able to stabilize him. Within 15 seconds patient regained consciousness and was fine. Patient with no injuries or issues after. Was able to ambulate with no issues. |
| 1283117 | 5/3/2021 | IL | 32 | M | 5/2/2021 | 5/2/2021 | Patient had vasovagal syncope reaction to a Janssen Covid 19 vaccine. Patient was waiting in a chair in the pharmacy's waiting area where he fainted a few minutes after receiving his vaccine. The pharmacist rushed to assist the patient while staff called EMS. Patient recovered and was aware of where he was and what happened. Patient was pale and sweating. Patient was given a few sips of water and concentrated on deep breathing. Shortly after this, patient fainted again while waiting on ambulance. Patient was lucid and conscious when paramedics arrived. The paramedics checked patient vitals and took patient away by ambulance. |
| 1283208 | 5/3/2021 | | 50 | M | 5/3/2021 | 5/3/2021 | Pt waiting his 15 minutes, cam to the counter asking for a water because patient was filling light headed. Patient fainted, with seconds patient was awake and knew where he was. he was clammy and in the face. Gave patient a water, he immediately felt better. |
| 1283209 | 5/3/2021 | CT | 40 | M | 5/3/2021 | 5/3/2021 | PATIENT FAINTED AFTER ADMINISTRATION, HE CAME TO , AND WAS FINE BUT EMBARRASSED BY THE INCIDENT |

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| 1283212 | 5/3/2021 | KS | 47 | F | 5/1/2021 | 5/2/2021 | At 7:30 am on May 2nd, I had blurry vision, dizziness, pressure on my chest and neck and difficulty breathing, ?blue? face color. My entire body was painful when moving. Difficulty breathing became extreme and I passed out. My husband called 911. I regained consciousness and was breathing with difficulty when paramedics arrived. Symptoms disappeared without treatment shortly after I was admitted to the ER around 8:20 am. After an additional day of fever and body aches, all symptoms have now disappeared. |
| 1283216 | 5/3/2021 | | 21 | M | 5/3/2021 | 5/3/2021 | Approximately two minutes after receiving vaccination patient fainted. He came to consciousness within one minute of fainting where he was sweaty. He did not seem disoriented and stated that the injection site radiated and had pain for a moment prior to his fainting. |
| 1283373 | 5/3/2021 | TX | 18 | F | 5/3/2021 | 5/3/2021 | The patient received the shot, and after a few minutes the patient passed out on the chair. After noticing the patient slumped over we made sure the patient was still breathing. We got the emergency equipment and contacted the emergency protocol, and the patient woke back up promptly and communicated that they felt dizzy. We allowed the patient to lay down and waited for the emergency services. She felt better as time passed and by the time her dad made, they refused to go to the hospital and made it home on their own accord |
| 1279816 | 5/2/2021 | NY | 59 | F | 5/1/2021 | 5/1/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Mild, Systemic: Nausea-Medium, Systemic: Vomiting-Medium |
| 1279814 | 5/2/2021 | MN | 18 | M | 5/1/2021 | 5/1/2021 | Systemic: Confusion-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Loss of consciousness for less than 1 minute-Medium, Additional Details: The patient lost consciousness within a minute of receiving vaccine. Rph notified and immediately ran to patient. Rph tapped on patients shoulder and asked \"are you okay!\" and patient regained consciousness immediately. Patient was confused and did not realize he lost consciousness. Patient felt oaky after regaining consciousness, but Rph helped patient lay down and elevated feet. Vital signs were monitored and were normal. |

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| 1279823 | 5/2/2021 | MD | 50 | F | 5/1/2021 | 5/1/2021 | Systemic: Abdominal Pain-Medium, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Medium, Systemic: Nausea-Medium, Systemic: Vomiting-Severe, Systemic: Weakness-Medium, Additional Details: Called 911 once I discovered pt. Pt was vomiting severely and had her laying on her side on the floor. She complained of abdominal pain and severe nausea when I initially got to her. Paramedics arrived about 10-15 mins from initial discovery of the patient fainting. The paramedics took over the care of the patient. |
| 1279810 | 5/2/2021 | IL | 54 | F | 5/1/2021 | 5/1/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Hypotension-Medium |
| 1279832 | 5/2/2021 | CA | 19 | M | 4/30/2021 | 4/30/2021 | Systemic: Fainting / Unresponsive-Medium, Additional Details: Pt. fainted a few minutes after he received the vaccine ~12:30pm. The pharmacist and family members attended to him until 911 emergency responders arrived. When he woke up, he told them he had not eaten, or had anything to drink all day. He also stated he had fainted in the past when receiving previous vaccinations. He declined to be brought to the hospital, and went home w/ his family. Pharmacist checked up on him at the end of the day and he stated he was feeling fine. |
| 1279640 | 5/2/2021 | FL | 21 | M | 5/2/2021 | 5/2/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Shakiness-Mild, Additional Details: he fell |

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| 1279836 | 5/2/2021 | CA | 53 | F | 5/1/2021 | 5/1/2021 | Systemic: Chills-Mild, Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Severe, Systemic: Exhaustion / Lethargy-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Hypotension-Severe, Systemic: Nausea-Severe, Systemic: Shakiness-Medium, Systemic: Tingling (specify: facial area, extremities)-Severe, Systemic: Vomiting-Severe, Systemic: Weakness-Medium, Additional Details: Patient self-reported that she \"doesn't do well with needles\". After about 5-10 minutes post-vaccine, she called for help feeling tingling all down her arms into her fingers. She was shaky and it seemed like she fainted but was still somewhat responsive. She was also dazed and shaking. After vomiting, she was more lucid but still felt poorly. EMTs arrived on scene and took her blood pressure & found that she was very hypotensive. Recommended that she be transported to hospital due to low BP. |
| 1279827 | 5/2/2021 | MN | 34 | M | 5/1/2021 | 5/1/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Mild, Additional Details: Pt received shot, went to monitoring area, sat, leaned to right and passed out, pharmacist ran out, made sounds like gasping for breath/eyes rolled back/not responsive but breathing, asked tech to call 911, had bystander help lower to ground, pt regained consciousness, mother came around and said he has a history of doing this/phobia of vaccines, no one informed us |
| 1279809 | 5/2/2021 | MD | 29 | M | 5/1/2021 | 5/1/2021 | Systemic: Allergic: Difficulty Breathing-Medium, Systemic: Body Aches Generalized-Medium, Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Severe, Systemic: Exhaustion / Lethargy-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Seizure-Severe, Systemic: Shakiness-Severe, Systemic: Tachycardia-Severe, Systemic: Tingling (specify: facial area, extremities)-Severe, Systemic: Visual Changes/Disturbances-Medium, Systemic: Weakness-Severe |

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| 1279800 | 5/2/2021 | VA | 19 | M | 5/1/2021 | 5/1/2021 | Systemic: Fainting / Unresponsive-Medium, Additional Details: Patient experienced syncopal episode within 10 minutes after immunization. He was standing at the time, and fell into the floor. He was not injured. 911 was called out of precation. His vital signs were good. Patient left store on his own accord after being checked by EMT. |
| 1279798 | 5/2/2021 | NY | 25 | F | 5/1/2021 | 5/1/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Mild, Systemic: Patient became pale after injection was given. She did not faint, and stayed responsive throughout event.-Mild, Systemic: Weakness-Mild, Additional Details: Patient became pale after injection was given. She did not faint, and did not become unresponsive. She was given water and orange juice and regained color and felt better afterwards. We sat with patient for about a half hour until she felt fully fine to go home. Patient says she has a history of fainting, especially when giving blood. |
| 1279797 | 5/2/2021 | MA | 25 | F | 5/1/2021 | 5/1/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Nausea-Mild, Additional Details: Patient fainted about 5 minutes after vaccination. patient was immediately repositioned on the floor on her back and regained consciousness right away. She stated she felt dizzy, nauseated and sweaty before the fainting. Patient was observed additional 15 minutes before letting go.Followed up with patient 3 hours later and she states that she is feeling fine. |
| 1279782 | 5/2/2021 | FL | 16 | F | 5/1/2021 | 5/1/2021 | Systemic: Confusion-Mild, Systemic: Fainting / Unresponsive-Medium, Systemic: Nausea-Mild, Systemic: Tingling (specify: facial area, extemities)-Mild, Additional Details: Patient had fainting episode immediately after vaccine administration. She became responsive in few seconds. she said before fainting she felt tingling, rapid HR and really cold. she reports nausea and confusion right after becoming responsive. Mother denied the need for EMS said she is fine and she has had fainted once after flu shot. Her blood pressure was 100/62 and 95/82 with Heart rate of 99 and 89. She lied down for 30 minutes. she reported feeling fine before leaving. |

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| 1279636 | 5/2/2021 | OH | 26 | M | 5/2/2021 | 5/2/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Additional Details: Patient had a syncope event shortly after receiving Janssen Covid vaccine. Patient put feet up and laid back for additional 10 minutes after initial 15 minute observation. BP and Pulse were not significant (176/79 and 79). Patient recovered after 25 minutes and went home. |
| 1279428 | 5/2/2021 | | | F | | 4/1/2021 | fainted; rash; died 2 weeks ago after receiving the covid vaccine/ passed away;This is a spontaneous report received from a non-contactable consumer reporting on behalf of the patient via a Pfizer-sponsored program. A female patient of unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), first and second dose, both via unspecified route of administration on unspecified dates (Batch/Lot number was not reported) as a single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The reporter mentioned that she had a friend that died 2 weeks ago after receiving the COVID vaccine. They are going to search for the cause of death (autopsy) because after the vaccine she had a rash, fainted, and went to the hospital, and she recovered (unspecified dates). But after a month or so, she passed away. The reporter mentioned that the patient was born very unhealthy person. Outcome of rash and fainted was recovered on unspecified dates. The patient died in Apr2021. It was unknown if an autopsy was performed. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: died 2 weeks ago after receiving the covid vaccine/ passed away |
| 1279951 | 5/2/2021 | NY | 18 | F | 5/2/2021 | 5/2/2021 | Patient; writer was called by family member, patient observed sitting in chair with episode of unresponsiveness. No head trauma, No SOB, No respiratory distress. Paramedic notified. Patient had episode of fainting lasting about 30secs then returned to baseline mental status post covid vaccination. MD notified. Family member present stated that she history of fainting. Patient discharged home, in stable condition. |

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| 1279824 | 5/2/2021 | MN | 34 | M | 5/1/2021 | 5/1/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Mild, Additional Details: Patient received vaccine, went out to sit on chair in waiting area. Leaned over and passed out, pharmacist ran out to patient, bystander helped lower patient to ground, all the while the patient was breathing very heavily, sounded seizure like or that he was gasping for breath. Asked tech to call 911. While being lowered to ground patient regained consciousness. Mother came around the corner and stated patient has history of reacting this way to vaccines, neither pt nor mom told us this before. |
| 1279794 | 5/2/2021 | PA | 29 | F | 5/1/2021 | 5/1/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Hypotension-Mild, Additional Details: Patient had a vasovagal reaction about 5 minutes post-vaccination. Patient fainted briefly for about 10-15 seconds. Clinic nurse and paramedics came and examined patient. Patient recovered within a few minutes. |
| 1280548 | 5/2/2021 | WA | 53 | M | 3/23/2021 | 3/30/2021 | 3.30.21 vasovagal syncope, dyspnea during jiu-jitsu. General fatigue, thought from vaccine. 4.1.21 same 4.3.21 same 4.6.21 same 4.8.21 same 4.11.21 same but during boxing 4.12.21 same but during jumping rope 4.13.21 second vaccine Pfizer same clinic at 12:00pm ER2613 4.14.21 same but during boxing 4.15.21 same but during, boxing, jumping rope, and rowing 4.18.21 same but during bike ride and walking 4.19.21 same but during coaching 4.20.21 admitted to ED 4.22.21 diagnosed with third degree heart block and dual chamber pacemaker fitted 4.23.21 DC |
| 1279819 | 5/2/2021 | FL | 33 | M | 5/1/2021 | 5/1/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild |

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| 1280794 | 5/2/2021 | VA | 16 | M | 5/2/2021 | 5/2/2021 | Patient came into the immunization room for his shot along with his mom. He did state he hated needles, but was in good spirits. He got the shot, I filled out his card, and directed him and his mom to sit in the waiting area for 15 mins in case of dizziness or a reaction. They were walking out of the room to the waiting area and he almost immediately fainted. He fell and possibly hit his head on the chair/ floor when he went down. (This was maybe 2 mins post-injection). He almost looked like he was going to have a seizure (arms were tensed up, his eyes were not focused, was starting to shake) but then he suddenly came-to. He seemed to be pretty coherent after he woke back up but 911 was called since he was bleeding |
| 1280705 | 5/2/2021 | OR | 16 | F | 5/2/2021 | 5/2/2021 | Within about 5 minutes of receiving her first Pfizer Covid19 vaccine, the patient passed out and hit her head on the floor. She regained consciousness quickly (within seconds) after I got to her. She stated she had felt nauseas and tingly before fainting. She has not experienced this before with other vaccines. Ambulance was dispatched due to her hitting her head. Parents and paramedics determined she was ok to go home. |
| 1279957 | 5/2/2021 | NY | 18 | F | 5/2/2021 | 5/2/2021 | writer was called by family member, patient observed sitting in chair with episode of unresponsiveness. No head trauma, No SOB, No respiratory distress. Paramedic notified. Patient had episode of fainting lasting about 30secs then returned to baseline mental status post covid vaccination. MD notified. Family member present stated that she history of fainting. Patient discharged home, in stable condition. |
| 1280571 | 5/2/2021 | | 39 | F | 5/2/2021 | 5/2/2021 | The patient was vaccinated and said that she feels dizzy, nervous. The patient sat on the chair ,passed out and had a seizure. |

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| 1280839 | 5/2/2021 | TX | 39 | F | 3/27/2021 | 4/7/2021 | I had the first vaccine on March 27, that night just felt flu-like symptoms, and my left arm was sore. My left arm was still sore from the 27 through April 11. April 7, I was having a hard time breathing, and my left arm swelled up where the injection was given. My husband took me to Hospital, and they said I was having a reaction to the COVID vaccine and gave me prednisone to help with the reaction. I went back to the same ER on April 9 and April 11 with the same problem, but worse. April 14, I went to work and passed out in the bathroom and called my husband to come to pick me up from work. He said our primary doctor, and then I went to . There they discovered a blood clot in my lungs. The doctor said it was a combination of my birth control pill and the COVID vaccine. |
| 1280533 | 5/2/2021 | FL | 18 | F | 5/1/2021 | 5/1/2021 | Pt explained on Covid-19 consent form that she has syncope when seeing a needle. She explained she has an intense fear of needles and has fainted in the past when getting vaccinations. She also explained that she has anxiety. She explained that when she faints it looks like a seizure but it is not. When pt was given shot she was responsive during the needle going in. She was in a seated position. We talked the entire time of administration. After putting the the bandage on her right arm she explained she felt sick (about 40 seconds after injection). She was still responsive for about two minutes then she fainted and her body shook about two times. My coworker and I got her on the ground, she was still responsive enough to ask for a cup of water. Which we gave her, she then went unresponsive for 20 seconds and spilled the water. After this we sat with her on the ground for another 5 minutes and she said she was fine. We helped her to a seated position. We then made her wait another 30 minutes in our waiting area. She assured us she was fine and reiterated that this has happened before in the past anytime a needle was involved. On 5/2/2021 she was contacted and she explained she looked a little pale throughout the day of vaccination, but feels fine now and just has a sore arm. |

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| 1280492 | 5/2/2021 | NY | 16 | F | 5/2/2021 | 5/2/2021 | 16 y/o female with NO PMH and no h/o similar prior experiences/syncope c/o "feeling tired" ~3 min after receiving the 1st dose of pfizer vaccine. Pt LOC, "gently" falling onto the floor, landing on her face ~5 min after receiving the vaccine. Pt reported feeling tired before LOC, not associated with any other symptoms (dizziness, changes in vision/hearing). LOC lasted ~10 seconds, pt immediately returned to baseline. She was sat up with the help of her mother and nurse and the clinical lead was notified. Pt was laid down on a cot, VS were taken, ice was applied to her pressure points. Pt reported complete resolution of symptoms within ~5 min. Pt was progressively moved from lying down to sitting to standing. Pt denies eating or drinking anything today and was given fluids and snacks. Pt was monitored for a total duration of 45 min. Pt was driven home by parents. Pt was advised to eat and hydrate today and for the next dose. Pt and parents were advised to call PCP / 911 if symptoms return/persist/worsen or if pt develops concussive symptoms. Pt was instructed to inform the nurse that she fainted ater 1st dose and to prophylactically lay down prior to receiving prior to second dose vaccination. |

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| 1280487 | 5/2/2021 | OR | 23 | F | 5/1/2021 | 5/1/2021 | Immediately after receiving the shot I began to have fairly intense pain at injection site. It continued in waves. I began to walk around the store for the allotted 15 minutes. I began to feel very dizzy and faint. My ears began ringing and I didn't feel well. I stumbled back to the pharmacy to ask for help. At this point I was also feeling like it was very hard to breathe. I explained all these symptoms to the pharmacists on duty and they told me to just sit down. After sitting down I still felt faint but suddenly felt the need to vomit. I stumbled to the bathroom where I collapsed in front of the toilet and passed out twice, striking my head and throat on the bowl. After awaking I was very disoriented and felt very hot and clammy. The pharmacist then came and found me and told me to once again sit down and continue waiting. After sitting down for about 5 more minutes I began to feel less dizzy and was having an easier time breathing. I left the store as the pharmacist was ignoring me and didn't seem concerned about my symptoms. After arriving home I was tired and weak and very very cold. I noted my body temp was lower than usual. I took a nap and then these symptoms continued for about 24 hours. I am now feeling much better. |
| 1280332 | 5/2/2021 | CT | 19 | M | 5/1/2021 | 5/1/2021 | Patient felt dizzy and fainted after 5 minutes of vaccination. |
| 1280277 | 5/2/2021 | CA | 16 | F | 5/2/2021 | 5/2/2021 | Patient passed out with associated convulsions within 2 minutes of vaccine being administered. No previous Hx of this post vaccination but did occur once after donating blood. Patient was lowered to flat position on floor. |

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| 1280215 | 5/2/2021 | TX | 66 | M | 5/2/2021 | 5/2/2021 | Patient was administered the Johnson and Johnson Janssen COVID-19 vaccine. Shortly after, a few seconds, the patient stated he felt flushed and head started to fall back. Staff member cradled his head and called another staff member over. Staff member called 9-1-1. Patient went unconscious and his eyes rolled back for approximately 30 seconds. When aware, we (staff members) transferred patient from the chair to the floor where staff member supported his back and fanned him due to his profuse sweating. Staff member continued talking to him when he became unconscious again, this time gasping for air and turning pale. We kept saying his name until he came to again and was somewhat aware of his surroundings. He fainted one last time. After this time, he sat up on his own and seemed to be very coherent. The EMS arrived shortly after and took over. They said they would take him out to check him out but he seemed to be doing better. An EMS personnel let us know the patient did tell him that he has fainted from vaccines before. However, he did not disclose this to us on the PQCF form or when asked verbally. |
| 1280207 | 5/2/2021 | NV | 71 | M | 2/1/2021 | 4/7/2021 | Awoke unable to breathe, severe weight in right lung. Called Clinic, advised to go to ER at Hospital. Chest CT showed multiple pulmonary embolli in both lungs-placed on Eliquis. 19 days later had severe nausea, vomiting, fainting. Clinic nurse again advised going to ER where cerebral hemorrhage was diagnosed. Patient life flighted to Hospital. Eliquis discontinued, Keppra started to prevent seizures. In ICU 4/26-28, released to home. |
| 1280061 | 5/2/2021 | NY | 68 | M | 3/11/2021 | 3/11/2021 | Pain in left side of chest, light headed, cold sweats and fainted. Taken to Hospital and released in about 3 hours. Two days later started getting back pains on my left side. Pain got worse and after another couple of days I started coughing up some blood. On March 17th 2021 I was admitted to the hospital with a pulmonary embolism. |
| 1280039 | 5/2/2021 | VA | 54 | F | 4/9/2021 | 4/10/2021 | Headaches, fainted, boils |

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| 1280018 | 5/2/2021 | IL | 38 | M | 5/2/2021 | 5/2/2021 | Patient fainted for a moment and felt down while standing. Patient was conscious right after falling, was able to talk and did not feel any symptoms other than sweetness which could have caused by wearing hat that he was wearing. EMS took patient. |
| 1280412 | 5/2/2021 | CT | 16 | M | 5/2/2021 | 5/2/2021 | Patient was sitting down and said he felt dizzy, guardian with him stated that he passed out briefly and then just said he felt dizzy. He wanted to get some air so him, myself, and his mom went outside and waited for the paramedics to arrive . Once outside, patient said he felt better but a little dizzy. Paramedics came to make sure he was okay, he went to the hospital after that, |
| 1280661 | 5/2/2021 | MD | 18 | F | 5/1/2021 | 5/2/2021 | Slight fever 100.3F One fainting episode |
| 1279968 | 5/2/2021 | NJ | 18 | M | 5/2/2021 | 5/2/2021 | The patient received the vaccine and waited in the room while the parent received the vaccine. The patient then walked to sit in the waiting area, lost vision while walking, sat down, eyes began to roll, and the patient passed out momentarily (less than a minute). Was moved to an area to lie down and remained there for approximately 15 minutes. |

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| 1276771 | 5/1/2021 | OR | 61 | M | 3/28/2021 | 3/28/2021 | Fainting; vertigo; spins; dizziness; confusion; fogginess; the craps; heart running; headache; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of SYNCOPE (Fainting) in a 61-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 018B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No relevant medical history reported. Concomitant products included LOSARTAN, METOPROLOL and HYDROCHLOROTHIAZIDE for an unknown indication. On 28-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 28-Mar-2021, the patient experienced VERTIGO (vertigo; spins), DIZZINESS (dizziness), CONFUSIONAL STATE (confusion), FEELING ABNORMAL (fogginess), DIARRHOEA (the craps), HEART RATE INCREASED (heart running) and HEADACHE (headache). On an unknown date, the patient experienced SYNCOPE (Fainting) (seriousness criterion medically significant). At the time of the report, SYNCOPE (Fainting), VERTIGO (vertigo; spins), DIZZINESS (dizziness), CONFUSIONAL STATE (confusion), FEELING ABNORMAL (fogginess), DIARRHOEA (the craps), HEART RATE INCREASED (heart running) and HEADACHE (headache) was resolving. mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was withdrawn on an unknown date. Treatment in the ER included "methazine." The patient noted that he will not be getting the second planned vaccine dose. Company Comment: This case concerns a 61-year-old male with a serious unexpected event of syncope, and nonserious unexpected vertigo, dizziness, heart rate increased, diarrhea, confusional state, feeling abnormal, and expected headache. Event onset with unknown latency after first dose mRNA-1273. Events resolving. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.; Sender's Comments: This case concerns a 61-year-old male with a serious unexpected event of syncope, and nonserious unexpected vertigo, dizziness, heart rate increased, diarrhea, confusional state, feeling abnormal, and expected headache. Event onset with unknown latency after first dose mRNA-1273. |

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| | | | | | | | Events resolving. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. |
| 1276934 | 5/1/2021 | OH | 37 | F | 4/1/2021 | 4/2/2021 | The next morning I woke up and felt very groggy and slightly chilled. I decided to take a shower to warm up. While in the shower I became dizzy and light headed to the point I fainted. I contacted my family physician. I was told as long as I was feeling okay to be on bed rest for the day with my feet elevated and to continue to drink lots of fluids. I was fine the following day. |
| 1276852 | 5/1/2021 | CA | | U | 2/16/2021 | 2/1/2021 | unconscious about 2 minutes; moderate headache; I had a general unwell feeling; nauseated; incontinent; I became faint; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received bnt162b2 (BNT162B2, solution for injection), dose 2 via an unspecified route of administration on 16Feb2021 (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunization. The patient medical history and concomitant medications were not reported. The patient had received first dose of COVID-19 vaccine previously. The patient stated that they had their second Covid-19 vaccine on 16Feb2021. Approximately 10 hours (on 16Feb2021) afterward the patient developed a moderate headache, which 400 mg of ibuprofen eased. The patient had a general unwell feeling much of the following day (16Feb2021), so the patient rested and napped. About 36 hours after the injection the patient became faint, nauseated, and incontinent. The patient was unconscious about 2 minutes. The patient was taken by ambulance to the hospital and remained through the night for observation for the event loss of consciousness. To date, all the tests were negative. The patient received treatment for the event headache. The outcome of the event headache was recovering. The outcome of the events loss of consciousness, syncope, malaise and nausea was unknown. Information about Lot/Batch number has been requested. |

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| 1276791 | 5/1/2021 | FL | 55 | M | 3/1/2021 | 3/29/2021 | hard to think, it has been very disturbing because he has to think for work, and it has been very difficult; Continued bad and strange dizziness; vertigo that lasted about 3 weeks and was very disturbing; heart was pounding but heart rate was normal; couldn't sleep; brain fogs; hard to think and remember things; feeling of anxiety; There were times when he feels detached from reality; strange feeling of dizziness and nausea feeling; At some point felt like he was almost going to lose consciousness; felling sick like he had the flu; significant pain in arm; fever; chills; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of MENTAL IMPAIRMENT (hard to think, it has been very disturbing because he has to think for work, and it has been very difficult), DIZZINESS (Continued bad and strange dizziness), VERTIGO (vertigo that lasted about 3 weeks and was very disturbing), PALPITATIONS (heart was pounding but heart rate was normal), INSOMNIA (couldn't sleep), FEELING ABNORMAL (brain fogs), MEMORY IMPAIRMENT (hard to think and remember things), ANXIETY (feeling of anxiety), DISSOCIATION (There were times when he feels detached from reality) and NAUSEA (strange feeling of dizziness and nausea feeling) in a 55-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 044A21A and 011A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Allergy (Respiratory allergies). On 01-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 29-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 29-Mar-2021, the patient experienced INFLUENZA LIKE ILLNESS (felling sick like he had the flu), PAIN IN EXTREMITY (significant pain in arm), PYREXIA (fever) and CHILLS (chills). In April 2021, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced MENTAL IMPAIRMENT (hard to think, it has been very disturbing because he has to think for work, and it has been very difficult) (seriousness criterion medically significant), DIZZINESS (Continued bad and strange dizziness) (seriousness criterion medically significant), VERTIGO |

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(vertigo that lasted about 3 weeks and was very disturbing) (seriousness criterion medically significant), PALPITATIONS (heart was pounding but heart rate was normal) (seriousness criterion medically significant), INSOMNIA (couldn't sleep) (seriousness criterion medically significant), FEELING ABNORMAL (brain fogs) (seriousness criterion medically significant), MEMORY IMPAIRMENT (hard to think and remember things) (seriousness criterion medically significant), ANXIETY (feeling of anxiety) (seriousness criterion medically significant), DISSOCIATION (There were times when he feels detached from reality) (seriousness criterion medically significant), NAUSEA (strange feeling of dizziness and nausea feeling) (seriousness criterion medically significant) and PRESYNCOPE (At some point felt like he was almost going to lose consciousness). At the time of the report, MENTAL IMPAIRMENT (hard to think, it has been very disturbing because he has to think for work, and it has been very difficult), PALPITATIONS (heart was pounding but heart rate was normal), INSOMNIA (couldn't sleep), FEELING ABNORMAL (brain fogs), MEMORY IMPAIRMENT (hard to think and remember things), ANXIETY (feeling of anxiety), DISSOCIATION (There were times when he feels detached from reality), NAUSEA (strange feeling of dizziness and nausea feeling), PRESYNCOPE (At some point felt like he was almost going to lose consciousness), INFLUENZA LIKE ILLNESS (feeling sick like he had the flu), PAIN IN EXTREMITY (significant pain in arm), PYREXIA (fever) and CHILLS (chills) outcome was unknown, DIZZINESS (Continued bad and strange dizziness) had not resolved and VERTIGO (vertigo that lasted about 3 weeks and was very disturbing) had resolved. Patient reports he takes supplements as concomitant medications Patient was prescribed clonazepam for his anxiety and took ibuprofen for his symptoms. Patient went to the ER two weeks after receiving the second dose of the vaccine, he was checked out, ran some tests and everything was within normal limits. Blood work was normal. The patient received both scheduled doses of mRNA-1273 prior to the events therefore, action taken with the drug in response to the events was not applicable. Company comment: Based on the information provided which includes a strong temporal association between the use

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of mRNA-1273 vaccine and onset of the reported events, a causal relationship cannot be excluded. Chills and pyrexia are consistent with the product safety profile. This case was linked to MOD-2021-090675 (Patient Link).; Sender's Comments: Based on the information provided which includes a strong temporal association between the use of mRNA-1273 vaccine and onset of the reported events, a causal relationship cannot be excluded. Chills and pyrexia are consistent with the product safety profile

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| 1276790 | 5/1/2021 | NJ | 56 | F | 2/12/2021 | 3/29/2021 | having a blood clot down whole right leg / up right side into right chest / under right breast / several clots in her lower abdomen; she almost died; urinary tract infection; right leg is very swollen; Kept losing consciousness/Passed out; hard time walking; had to use a walker; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of THROMBOSIS (having a blood clot down whole right leg / up right side into right chest / under right breast / several clots in her lower abdomen), LOSS OF CONSCIOUSNESS (Kept losing consciousness/Passed out) and FEELING ABNORMAL (she almost died) in a 56-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 002b21a and 004m20a) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concomitant products included LEVOFLOXACIN, RIVAROXABAN (XARELTO), LISINOPRIL, HYDROCHLOROTHIAZIDE, OXYCODONE and LEVOTHYROXINE SODIUM (SYNTHROID) for an unknown indication. On 12-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 12-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 29-Mar-2021, the patient experienced GAIT DISTURBANCE (hard time walking) and WALKING AID USER (had to use a walker). On 12-Apr-2021, the patient experienced THROMBOSIS (having a blood clot down whole right leg / up right side into right chest / under right breast / several clots in her lower abdomen) (seriousness criteria hospitalization prolonged, medically significant, life threatening and intervention required) and LOSS OF CONSCIOUSNESS (Kept losing consciousness/Passed out) (seriousness criterion medically significant). 12-Apr-2021, the patient experienced FEELING ABNORMAL (she almost died) (seriousness criteria hospitalization and medically significant). On 26-Apr-2021, the patient experienced PERIPHERAL SWELLING (right leg is very swollen). On an unknown date, the patient experienced URINARY TRACT INFECTION (urinary tract infection). The patient was hospitalized from 12-Apr-2021 to 19-Apr-2021 due to FEELING ABNORMAL and THROMBOSIS. On 12-Apr-2021, LOSS OF CONSCIOUSNESS (Kept losing |

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consciousness/Passed out) had resolved. At the time of the report, THROMBOSIS (having a blood clot down whole right leg / up right side into right chest / under right breast / several clots in her lower abdomen) was resolving and FEELING ABNORMAL (she almost died), URINARY TRACT INFECTION (urinary tract infection), GAIT DISTURBANCE (hard time walking), PERIPHERAL SWELLING (right leg is very swollen) and WALKING AID USER (had to use a walker) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 12-Apr-2021, Computerised tomogram: blood clots (abnormal) blood clot. On 12-Apr-2021, Ultrasound scan: blood clots (abnormal) blood clots. Action taken with mRNA-1273 in response to the events was not applicable. Patient stated she was in the ICU24-48 hours then transferred to another area of the hospital where she spent another 5-6days. She is still having to use a walker. Her right leg is very swollen. She has to walk and keep her right leg elevated. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. However, Further information has been requested. This case was linked to MOD-2021-090647 (Patient Link).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. However, Further information has been requested.

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| 1276788 | 5/1/2021 | TX | | U | | | <p>This spontaneous case was reported by a consumer and describes the occurrence of SYNCOPE (Fainting reaction) in a patient of an unknown age and gender who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced SYNCOPE (Fainting reaction) (seriousness criterion medically significant). At the time of the report, SYNCOPE (Fainting reaction) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Treatment information was not provided. Very limited information regarding this event/s has been provided at this time. Further information has been requested.; Sender's Comments: Very limited information regarding this event/s has been provided at this time. Further information has been requested.</p> |

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| 1276781 | 5/1/2021 | | 24 | M | 4/23/2021 | 4/23/2021 | Passed out for a little bit; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out for a little bit) in a 24-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 017C21A) for COVID-19 vaccination. No Medical History information was reported. On 23-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 23-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (Passed out for a little bit) (seriousness criterion medically significant). At the time of the report, LOSS OF CONSCIOUSNESS (Passed out for a little bit) had resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Concomitant medication information was not provided. Patient passed out for a little bit after his shot. After he came to, he felt thirsty and got some food. No treatment information was provided. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. |

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| 1276782 | 5/1/2021 | CA | 59 | F | | 4/12/2021 | <p>This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (passed out) in a 59-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 11-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 12-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (passed out) (seriousness criterion medically significant), BACK PAIN (backache), CONCUSSION (concussion), EYE INJURY (injured bone under eye), CONTUSION (bruised hip), PAIN (face still sore) and PYREXIA (fever). At the time of the report, LOSS OF CONSCIOUSNESS (passed out), BACK PAIN (backache), CONCUSSION (concussion), EYE INJURY (injured bone under eye), CONTUSION (bruised hip), PAIN (face still sore) and PYREXIA (fever) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Computerised tomogram: unknown (Inconclusive) Unknown. On an unknown date, Magnetic resonance imaging: unknown (Inconclusive) Unknown.</p> <p>Company comment :Based on the information provided which includes a strong temporal association between the use of mRNA-1273 vaccine and onset of the reported events, a causal relationship cannot be excluded. Fever is consistent with the product safety profile; Sender's Comments: Based on the information provided which includes a strong temporal association between the use of mRNA-1273 vaccine and onset of the reported events, a causal relationship cannot be excluded. Fever is consistent with the product safety profile</p> |

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| 1277206 | 5/1/2021 | WA | 33 | M | 3/25/2021 | 3/25/2021 | <p>Passed out; Felt strange/weird; Nauseous; Dizzy; ears rang; Blood pressure drop; This is a spontaneous report from a contactable consumer, reporting for himself. A 33-year-old male patient received the first dose of the bnt162b2 (BNT162B2; Lot Number: EN6208), via an unspecified route of administration in the left arm on 25Mar2021 at 11:00 at a single dose for covid-19 immunisation. The patient received the vaccination in the pharmacy. There was no medical history or concomitant medications. There were no other vaccines administered in the last four weeks. On 25Mar2021 at 23:30, the patient experienced passed out, felt strange/weird, nauseous, dizzy, ears rang, and blood pressure drop. The clinical course was as follows: the patient was advised to wait 15 minutes before leaving. He set an alarm. He bought some food to eat (potatoes and jerky) and waited to leave the site until 11:22. He felt strange/weird, but this was not an unusual feeling after receiving any kind of shot/vaccine for the patient. He was driving to work and started to get a little nauseous but nothing too bad. Thirty seconds later, he started to get dizzy, ears rang, felt blood pressure drop, and passed out going freeway speeds. He was treated in the emergency department and released the same day. There was no treatment given in response to the events. There was no covid prior to or post vaccination. The clinical outcome of the events was recovering. No follow-up attempts are needed. No further information is expected.</p> |

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| 1277219 | 5/1/2021 | CA | 44 | F | 4/4/2021 | 4/5/2021 | <p>passed out at work; abnormal (more than usual) vaginal bleeding; she felt uncomfortable on the morning of 05Apr2021; her hands and feet were cold; she was kind of sweating; she felt sick on 05Apr2021; her body temperature went up; her body felt warm; This is a spontaneous report from a contactable consumer (patient). A 44-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), second dose via an unspecified route of administration, administered in Arm Left on 04Apr2021 15:45 (3:45 PM) (Batch/Lot Number: ER8734) as SINGLE DOSE for covid-19 immunisation. The patient medical history includes Shellfish Allergy (Reported she has had a shellfish allergy for a long time, approximately 7-8 years). She said as long as she had no shellfish, she was completely fine. There were no concomitant medications. There were no prior vaccinations (within 4 weeks). There was no additional vaccine administered on the same date as the COVID-19 Vaccine. The patient previously took bnt162b2 for COVID-19 immunization on 14Mar2021 first dose intramuscular at the left arm (Lot Number: EN6208). It was reported that the patient has received both doses of the Pfizer Covid 19 Vaccine. Her second Pfizer Covid vaccine was received on 04Apr2021. Caller started her menstrual cycle on 07Apr2021. She experienced abnormal vaginal bleeding that night. The following day on 08Apr2021 she passed out at work and was transported to the ER via ambulance. She was advised by the ER provider that her symptom was not related to the Covid 19 vaccine. However, she spoke with her OBGYN and was advised they have heard that abnormal bleeding maybe caused by the Covid 19 vaccine. The patient asked if symptom has been reported? It was further reported that she had her first COVID-19 Vaccine shot on 14Mar2021, and her second COVID-19 Vaccine dose on 04Apr2021 at 3:45 PM (PST). She clarified later in the day on 04Apr2021, the COVID-19 Vaccine kicked in. She said she felt sick on 05Apr2021. She said she felt uncomfortable on the morning of 05Apr2021, but still went to work. She said she felt OK once she got to work, but then took time off from work (on 05Apr2021) because she felt uncomfortable. She said when she got home from work (on 05Apr2021), she took 2 Tylenol. She said she was cold, and her body temperature went up, and she was kind of sweating. She clarified her hands and</p> |

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feet were cold, and later in the day (05Apr2021) her body temperature went up. She said she was aware of the COVID-19 side effects because some of her friends had similar symptoms, so she was kind of expecting the symptoms. She said later in the evening on 05Apr2021, she took 2 Advil and went to bed. She said her body felt warm, but she thought her symptoms were to be expected. She said on 07Apr2021, her (menstrual) period started at 10:00 PM. She said she had abnormal (more than usual) vaginal bleeding for the whole night. She said on 08Apr2021, she felt uncomfortable in the morning when she was getting ready for work. She said she went to work (on 08Apr2021), and at 1:30 PM passed out while at work. She said from her work, she was sent by ambulance to the Emergency Room. She said she was not sure if her passing out had anything to do with the COVID-19 Vaccine, but she had never passed out at work before. She said she asked the Emergency Room doctor about the COVID-19 Vaccine and her passing out. She said the Emergency Room doctor said her passing out had nothing to do with her second COVID-19 Vaccine dose. She said she read more online about the COVID-19 Vaccine. She said she then asked the nurse at her OBGYN's office about abnormal bleeding after getting the COVID-19 Vaccine. She said the nurse had heard of some cases of abnormal bleeding after getting the COVID-19 Vaccine. She said her OBGYN's nurse told her to call to find out if her abnormal bleeding had anything to do with her second COVID-19 Vaccine. She said her OBGYN's nurse provided her with the number to get more information about the COVID-19 Vaccine. It was added that while she was at the Emergency Room, she had 7 vials of blood taken, 2 ultrasounds; an external one of her tummy (abdominal ultrasound), and an internal one where something was stuck in her (transvaginal ultrasound). She said she did not know the results of her testing, and was waiting for a copy of her medical records. The patient also weighed 165 lbs on an unspecified date. It was reported that for the treatment she had taken 2 Tylenol and 2 Advil at different times while at home, but was at work, and didn't have the Tylenol or Advil to provide the dosing, NDC, Lot, and Expiration Dates. For the Emergency Room treatment she reported an EKG was done, and she was given an IV drip. She said she

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| 1277403 | 5/1/2021 | IL | 61 | M | 4/30/2021 | 4/30/2021 | was not sure what IV fluids were given to her. The patient required visit to Emergency Room and stated she was taken by ambulance on 08Apr2021 and discharged from the Emergency Room at 6:00 PM the same day. The patient also visited Physician Office and stated she went for a follow-up with her OBGYN doctor at between 9:00 AM-10:00 AM on 09Apr2021. She said the Emergency Room doctor had called her OBGYN doctor on 08Apr2021, while she was in the Emergency Room. The patient underwent laboratory tests which includes: EKG, Blood Test, Abdominal Ultrasound, Transvaginal Ultrasound (All tests were performed while at the Emergency Room on 08Apr2021. Patient stated she was waiting for a copy of her medical records with the test results). The outcome of the events was recovered on Apr2021. |
| 1277435 | 5/1/2021 | FL | 55 | F | 4/30/2021 | 4/30/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Hypotension-Medium |
| 1277508 | 5/1/2021 | MA | 55 | M | 4/30/2021 | 4/30/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Hypertension-Severe, Systemic: Seizure-Severe |
| 1277512 | 5/1/2021 | MA | 19 | M | 4/30/2021 | 4/30/2021 | Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Severe |
| 1277515 | 5/1/2021 | MA | 31 | F | 4/29/2021 | 4/29/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Hypotension-Mild, Systemic: Weakness-Mild, Additional Details: PATIENT STATED HE'S AFRAID OF NEEDLES. |
| | | | | | | | Systemic: Fainting / Unresponsive-Medium, Systemic: Nausea-Mild, Systemic: Weakness-Mild, Additional Details: pt gets nervous during shots |

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| 1276760 | 5/1/2021 | DE | 52 | M | 4/20/2021 | 4/20/2021 | Headache; Patient developed a cough on Friday; Patient reports he rarely has an appetite; urinary track infection/felt his urinary track and kidneys were being attacked/urge to urinate; urinary incontinence; patient had projectile vomiting after waking up; violet shaking the next morning; heavy sweat; passed out after vomiting; upper gum was numb; tip of tongue was tingling; feel like having a flu; neck was sore; odd supersmell; testicle started to hurt and are swollen; patient reports having lethargy; Patient reported blood in urine; Patient had fever of 101 F; having joint pain in knees and shoulder; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (passed out after vomiting) in a 52-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 002C21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No medical history was provided by the reporter. Concomitant products included LISINOPRIL for Hypertension. On 20-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 20-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (passed out after vomiting) (seriousness criterion medically significant), HYPOAESTHESIA ORAL (upper gum was numb), PARAESTHESIA ORAL (tip of tongue was tingling), INFLUENZA LIKE ILLNESS (feel like having a flu), NECK PAIN (neck was sore), PAROSMIA (odd supersmell), TREMOR (violet shaking the next morning), HYPERHIDROSIS (heavy sweat), TESTICULAR PAIN (testicle started to hurt and are swollen), LETHARGY (patient reports having lethargy), HAEMATURIA (Patient reported blood in urine), PYREXIA (Patient had fever of 101 F) and ARTHRALGIA (having joint pain in knees and shoulder). On 21-Apr-2021, the patient experienced URINARY TRACT INFECTION (urinary track infection/felt his urinary track and kidneys were being attacked/urge to urinate), URINARY INCONTINENCE (urinary incontinence) and VOMITING PROJECTILE (patient had projectile vomiting after waking up). On 22-Apr-2021, the patient experienced DECREASED APPETITE (Patient reports he rarely has an appetite). On 23-Apr-2021, the patient experienced COUGH (Patient developed a cough on Friday). On an unknown date, the patient experienced |

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HEADACHE (Headache). On 20-Apr-2021, HYPOAESTHESIA ORAL (upper gum was numb) and PARAEESTHESIA ORAL (tip of tongue was tingling) had resolved. On 23-Apr-2021, HAEMATURIA (Patient reported blood in urine) outcome was unknown. On 24-Apr-2021, DECREASED APPETITE (Patient reports he rarely has an appetite) had resolved. On 25-Apr-2021, COUGH (Patient developed a cough on Friday) outcome was unknown. At the time of the report, LOSS OF CONSCIOUSNESS (passed out after vomiting), INFLUENZA LIKE ILLNESS (feel like having a flu), NECK PAIN (neck was sore), PAROSMIA (odd supersmell), URINARY TRACT INFECTION (urinary tract infection/felt his urinary track and kidneys were being attacked/urge to urinate), URINARY INCONTINENCE (urinary incontinence), VOMITING PROJECTILE (patient had projectile vomiting after waking up), TREMOR (violet shaking the next morning), HYPERHIDROSIS (heavy sweat), TESTICULAR PAIN (testicle started to hurt and are swollen), LETHARGY (patient reports having lethargy), PYREXIA (Patient had fever of 101 F), ARTHRALGIA (having joint pain in knees and shoulder) and HEADACHE (Headache) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Treatment with ciprofloxacin for urinary tract infection and Flomax for prostate, were provided. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. However, Further information has been requested.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. However, Further information has been requested.

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| 1277525 | 5/1/2021 | NC | 25 | M | 4/30/2021 | 4/30/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Additional Details: Patient was sitting on the bench waiting for his 15 minute interval. A few minutes after sitting there, he passed out & fell on the floor. Said he got dizzy & didn't remember falling: was able to talk & answer questions within a few seconds. He was extremely pale, sweaty but remained responsive & stayed on floor until EMS arrived. Unsure if he hit his head or injured during fall. EMS assessed as syncope & possible dehydration. BP didn't stabilize so he went to ER for fluids & was released. |

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| 1276719 | 5/1/2021 | FL | 76 | F | 1/6/2021 | | <p>Fainting; frequent urination; MODERNA toes/dots on her foot which still persist; itchiness; Dehydration; Fever; This spontaneous case was reported by a consumer and describes the occurrence of SYNCOPE (Fainting) in a 76-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No medical history reported by the reporter. Concomitant products included DORZOLAMIDE HYDROCHLORIDE (DORZOLOMIDE HYDROCHLORIDE), TIMOLOL and ASPIRIN [ACETYLSALICYLIC ACID] for an unknown indication. On 06-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced SYNCOPE (Fainting) (seriousness criterion medically significant), POLLAKIURIA (frequent urination), VACCINATION COMPLICATION (MODERNA toes/dots on her foot which still persist), PRURITUS (itchiness), DEHYDRATION (Dehydration) and PYREXIA (Fever). At the time of the report, SYNCOPE (Fainting), POLLAKIURIA (frequent urination), DEHYDRATION (Dehydration) and PYREXIA (Fever) outcome was unknown, VACCINATION COMPLICATION (MODERNA toes/dots on her foot which still persist) had not resolved and PRURITUS (itchiness) had resolved. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Treatment medications were not reported. The patient received both scheduled doses of mRNA-1273 prior to the event, therefore action taken with the drug in response to the event is not applicable. Based on current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded. This case was linked to MODERNATX, INC.-MOD-2021-089293 (E2B Linked Report).; Sender's Comments: Based on current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded. MODERNATX, INC.-MOD-2021-089293:Husband case</p> |

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| 1277522 | 5/1/2021 | TX | 32 | M | 4/30/2021 | 4/30/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Severe, Systemic: Hypertension-Severe, Systemic: Nausea-Medium, Systemic: Numbness (specify: facial area, extremities)-Medium, Systemic: Shakiness-Medium, Systemic: Tingling (specify: facial area, extremities)-Severe, Additional Details: Within 10 minutes of administration patient became very overheated and passed out. I provided and ice pack and cold water to help revive the patient. I monitored the blood pressure which was elevated at 126/93 at the time of the event. I monitored him as he revived and his blood pressure came down to 110/68 then normalized at 118/81. He reported feeling nauseas before he lost consciousness. Conciousness was lost for a matter of seconds. Patient also reported numbness/tingling in both arms. |

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| 1276721 | 5/1/2021 | MA | 68 | F | 4/13/2021 | 4/17/2021 | <p>Passed out, blacked out, landed flat on her face, hospitalized due to the events; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out, blacked out, landed flat on her face, hospitalized due to the events) in a 68-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 040B21A) for COVID-19 vaccination. The patient's past medical history included Nerve pain in July 2020, Carpal tunnel syndrome, Broken foot (40 years prior to reporting time.), Lung operation NOS in July 2020, Hip replacement in 2017, Hip replacement in December 2020, Bladder operation NOS in November 2020, Foot surgery, Knee surgery NOS, Shoulder operation NOS and Tubal ligation. Concurrent medical conditions included Allergy to antibiotic and Allergy. Concomitant products included ASPIRIN [ACETYLSALICYLIC ACID], SERTRALINE, GABAPENTIN and ASCORBIC ACID, RETINOL, TOCOPHEROL (OCUVITE [ASCORBIC ACID;RETINOL;TOCOPHEROL]) for an unknown indication. On 13-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 17-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (Passed out, blacked out, landed flat on her face, hospitalized due to the events) (seriousness criterion hospitalization). The patient was hospitalized from 17-Apr-2021 to 19-Apr-2021 due to LOSS OF CONSCIOUSNESS. On 19-Apr-2021, LOSS OF CONSCIOUSNESS (Passed out, blacked out, landed flat on her face, hospitalized due to the events) had resolved. Not Provided DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood test: normal (normal) normal. On an unknown date, Cardiac function test: normal (normal) normal. On an unknown date, Chest X-ray: normal (normal) normal. On an unknown date, Computerised tomogram: normal (normal) normal, normal (normal) normal and normal (normal) CT Scan Head/Brain with Contrast. On an unknown date, Echocardiogram: normal (normal) normal. On an unknown date, X-ray: normal (normal) normal. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Patient's Primary Care Physician scheduled an MRI and Carotid</p> |

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1277579 5/1/2021 NH

33 F

4/10/2021

4/20/2021

Artery Ultrasound after a week from the reporting time. She was also placed on a heart monitor for 30 days. This case concerns a 68-year-old female hospitalized with a serious unexpected event of Loss of consciousness. Event latency 5 days after first dose mRNA-1273. Event resolved. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.; Sender's Comments: This case concerns a 68-year-old female hospitalized with a serious unexpected event of Loss of consciousness. Event latency 5 days after first dose mRNA-1273. Event resolved. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.

Vasovagal syncope reaction Sweating nausea diarrhea paleness blurred vision ringing in ears etc

| <u>VAERS_ID</u> | <u>RECVDATE</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
|-----------------|-----------------|--------------|----------------|------------|-----------------|-------------------|--|
| 1276393 | 5/1/2021 | | 50 | F | 4/1/2021 | | TACHYCARDIA; DRY MOUTH; DIZZINESS WITH STANDING AND INTERMITTENTLY WITH SITTING; PULMONARY EMBOLISM; FEELING OF DOOM/ FEELING OF PASSED OUT; FATIGUE; This spontaneous report received from a patient via a company representative via the VAERS (Vaccine Adverse Event Reporting System) concerned a 50 year old female unknown ethnicity . The patient's height, and weight were not reported. The patient's concurrent conditions included osteoarthritis, gluten intolerance, and diflucan allergy. The patient was previously treated with fluconazole. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 1805029, expiry: UNKNOWN) with unspecified dose on left arm, on 27-MAR-2021 11:00 for prophylactic vaccination. Concomitant medications included amino acids NOS, biotin, cannabidiol, collagen, ethinylestradiol/norethisterone acetate, and hyaluronic acid. On 07-APR-2021, the patient experienced dizziness with standing and intermittently with sitting, tachycardia, dry mouth, chest pressure, shortness of breath, and feeling of extreme doom. On an unspecified date, the patient was transported to the clinic. In the clinic the patient had heart rate of about 140 with irregular beats. The patient had undergone Electrocardiography test which showed ST Depression. The patient's symptoms were improved by taking nitroglycerin. As the clinic did not have the technology to provide care so the patient was emergently transported to the hospital. In the hospital the patient's D-dimer level was positive. Later the patient undergone Computerized Angiogram for lungs which showed pulmonary embolism. The patient undergone Dopplers studies of both legs which showed as negative. The patient had received Heparin treatment for several hours and then later switched to Eliquis. After 6 hours being on Eliquis treatment the patient had same original symptoms and for that again nitroglycerin was administered. The patient was placed back on heparin for a longer period of time. Later on the patient got switched to Eliquis 10 mg twice daily for 7 days and further to 5 mg twice daily for 6 to 9 months. The patient had undergone Angiogram of head and neck which was normal. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from tachycardia, feeling of doom/ feeling of passed out and dry mouth on |

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APR-2021, had not recovered from fatigue, dizziness with standing and intermittently with sitting and pulmonary embolism. This report was serious (Hospitalization Caused / Prolonged, Other Medically Important Condition, and Life Threatening). Sender's Comments: V0 -covid-19 vaccine ad26.cov2.s- Pulmonary embolism , Feeling doom, Tachycardia, Dry mouth, Dizziness with standing, Fatigue This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).

| <u>VAERS_ID</u> | <u>RECVDATE</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1276400 | 5/1/2021 | | 54 | M | 3/1/2021 | | <p>CONFIRMED COVID-19 INFECTION; PASSED OUT TWO TO THREE TIMES; This spontaneous report received from a patient concerned a 54 year old male. The patient's weight was 250 pounds, and height was 70 inches. The patient's past medical history included alcohol use, and concurrent conditions included high blood pressure, and patient had no known allergy. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number was not reported) dose was not reported, administered on 08-MAR-2021 for covid-19 vaccination. The batch number was not reported. Per procedure no follow up will be requested for this case. Non-company suspect drugs included: adalimumab (suspension for injection in pre-filled syringe, subcutaneous, batch number was not reported) 40 mg, 1 time every 2 weeks, therapy dates were not reported for moderate to severe rheumatoid arthritis. Concomitant medications included valsartan for high blood pressure. On MAR-2021, the patient passed out two to three times. On 17-MAR-2021, the patient experienced shortness of breath, cough, fatigue, taste changed. On 18-MAR-2021, patient tested positive for covid 19 (coded as confirmed covid-19 infection). On 18-MAR-2021, patient had nasal swab test, mouth swab test, and covid 19 test (result was positive). On 19-MAR-2021, patient had chest X-ray, heart ultrasound and electrocardiogram and there was no problem as per result. The action taken with covid-19 vaccine ad26.cov2.s was not applicable; and dose of adalimumab was not changed. The outcome of the confirmed covid-19 infection and passed out two to three times was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: 20210441069-covid-19 vaccine ad26.cov2.s-Passed out two to three times, confirmed COVID 19 . This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p> |

| <i>VAERS_ID</i> | <i>RECVDATE</i> | <i>STATE</i> | <i>AGE_YRS</i> | <i>SEX</i> | <i>VAX_DATE</i> | <i>ONSET_DATE</i> | <i>SYMPTOM_TEXT</i> |
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| 1276520 | 5/1/2021 | | | M | | | <p>PASSED OUT; This spontaneous report received from a patient via via social media concerned a male of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported ,1 total administered for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, the patient was passed out in the mandatory waiting area immediately after getting the vaccine. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of passed out was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0 20210453029 - Covid-19 vaccine ad26.cov2.s-Passed out. This event(s) is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.</p> |

| <u>VAERS_ID</u> | <u>RECVDATE</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1276531 | 5/1/2021 | OR | 44 | M | 4/1/2021 | | <p>SHORTNESS OF BREATH; ASTHMA ATTACK; DIZZINESS; EXPERIENCING HOT FLASHES; SORE ARM; SWEATING; PASSING OUT RIGHT AFTER VACCINATION; SLEEPY; LOW ENERGY; WEAKNESS; TIRED; This spontaneous report received from a patient concerned a 44 year old male. The patient's height, and weight were not reported. The patient's concurrent conditions included codeine allergy, penicillin allergy, anxiety, smoker, and alcohol user. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, and batch number: 042A21A expiry: UNKNOWN) dose was not reported, administered on 12-APR-2021 on right arm for prophylactic vaccination. Concomitant medications included clonazepam for anxiety, and ibuprofen for pain/ and inflammation. On 12-APR-2021, after 5 minutes, the patient started feeling dizzy and passed out. He woke up as nurse pulling his chest hair and nurse was about to give him adrenaline shot. The patient was for his vitals until restabilized and was asked to walk around for sometime. The patient had sore arm. The patient was at facility for 2 hours. On 12-APR-2021, at night, he woke up sweating and experiencing hot flashes as if med going through his body. On 16-APR-2021, the patient was not breathing well at night and woke up with an asthma attack which lasted for about 3 hours and the whole next day. He visited clinic for asthma attack and was prescribed with medicines. He had a week and half of low energy. On 27-APR-2021, the patient stated that he was still feeling sleepy, dizzy and tired sometimes. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from passing out right after vaccination on 12-APR-2021, experiencing hot flashes, shortness of breath, asthma attack, and sweating, and sore arm on 19-APR-2021, and had not recovered from dizziness, weakness, sleepy, tired, and half of low energy. This report was serious (Other Medically Important Condition).; Sender's Comments: 20210453787-COVID vaccine-loss of consciousness. This event(s) is considered not related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: MEDICAL HISTORY</p> |

| <u>VAERS_ID</u> | <u>RECVDATE</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1276545 | 5/1/2021 | PA | 29 | M | 3/16/2021 | | <p>DEHYDRATION; PASSED OUT TWICE; COULDN'T SLEEP; VERY UNCOMFORTABLE; SUPER BAD CHILLS; REALLY, REALLY TIREDNESS; This spontaneous report received from a patient concerned a 29 year old white and not hispanic or latino male. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805022, and expiry: UNKNOWN) dose was not reported, administered on 16-MAR-2021, 1 total at left arm for prophylactic vaccination. No concomitant medications were reported. On 16-MAR-2021, patient experienced super bad chills for 7 to 8 hours after the vaccine for 10 minutes, subsided and got again 24 hours later, but not as bad as night before, could not sleep it was very uncomfortable. On 16-MAR-2021, patient also felt really tired. On 17-MAR-2021, the patient experienced passed out twice back to back in about 10 minutes of each other and on same day patient went to emergency room. On 19-MAR-2021, the patient experienced dehydration. Patient had never tested for COVID-19. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from passed out twice on 18-MAR-2021, couldn't sleep, and super bad chills on 17-MAR-2021, dehydration on 2021, and really, really tiredness on 20-MAR-2021, and the outcome of very uncomfortable was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0:20210454256-Covid-19 vaccine ad26.cov2.s-PASSED OUT TWICE. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p> |

| <u>VAERS_ID</u> | <u>RECVDATE</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1276687 | 5/1/2021 | OH | 53 | F | 1/12/2021 | 1/12/2021 | Felt upper neck getting squeezing; Heart palpitation; Shortness of breath/Unable to breath/Shortness of breath while walking in normal pace or going upstairs; Side effects; Anxiousness getting worse/weakness of hands getting worse; Heaviness; Syncope; Feeling of cold/warm; Heart burn/Burning sensation upto throat; Dizziness; Position changed to standing from sitting; Passed out; No appetite; Heartburn; POTS(Postural orthostatic tachycardia syndrome); Autonomic nerve disorder; Fatigue; Unable to perform work; Feel tingling with both hands; Nervousness; Anxiousness; Weakness of upper arm/Leg weakness; Squeezing sensation of upper chest; Soreness of arm; Headache interferes with sleep/Inability to fall asleep; Pressure headache at nose and forehead/Severe headache; This spontaneous case was reported by a consumer and describes the occurrence of MUSCULOSKELETAL DISCOMFORT (Felt upper neck getting squeezing), DYSпноEA (Shortness of breath/Unable to breath/Shortness of breath while walking in normal pace or going upstairs), PALPITATIONS (Heart palpitation), LOSS OF CONSCIOUSNESS (Passed out) and SYNCОPE (Syncope) in a 53-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Penicillin allergy. Concomitant products included CALCIUM CARBONATE (CALTRATE [CALCIUM CARBONATE]) from 10-Jan-2020 to an unknown date for Calcium supplementation. On 12-Jan-2021 at 11:00 AM, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 12-Jan-2021, the patient experienced PAIN IN EXTREMITY (Soreness of arm), INSOMNIA (Headache interferes with sleep/Inability to fall asleep) and HEADACHE (Pressure headache at nose and forehead/Severe headache). On 19-Jan-2021, the patient experienced DYSпноEA (Shortness of breath/Unable to breath/Shortness of breath while walking in normal pace or going upstairs) (seriousness criterion hospitalization) and CHEST DISCOMFORT (Squeezing sensation of upper chest). On 21-Jan-2021, the patient experienced MUSCULAR WEAKNESS (Weakness of upper arm/Leg weakness) and ANXIETY (Anxiousness). On 22-Jan-2021, the |

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patient experienced PARAESTHESIA (Feel tingling with both hands) and NERVOUSNESS (Nervousness). On 27-Jan-2021, the patient experienced IMPAIRED WORK ABILITY (Unable to perform work). On 10-Feb-2021, the patient experienced PALPITATIONS (Heart palpitation) (seriousness criterion hospitalization). On 13-Feb-2021, the patient experienced LOSS OF CONSCIOUSNESS (Passed out) (seriousness criterion medically significant), DIZZINESS (Dizziness) and SITTING DISABILITY (Position changed to standing from sitting). On 14-Feb-2021, the patient experienced MUSCULOSKELETAL DISCOMFORT (Felt upper neck getting squeezing) (seriousness criterion hospitalization), FEELING OF BODY TEMPERATURE CHANGE (Feeling of cold/warm) and BURNING SENSATION (Heart burn/Burning sensation upto throat). In February 2021, the patient experienced DECREASED APPETITE (No appetite). February 2021, the patient experienced DYSPEPSIA (Heartburn), POSTURAL ORTHOSTATIC TACHYCARDIA SYNDROME (POTS(Postural orthostatic tachycardia syndrome)) and FATIGUE (Fatigue). February 2021, the patient experienced AUTONOMIC NERVOUS SYSTEM IMBALANCE (Autonomic nerve disorder). On 24-Feb-2021, the patient experienced SYNCOPE (Syncope) (seriousness criterion medically significant). On 26-Mar-2021, the patient experienced CHEST DISCOMFORT (Heaviness). On an unknown date, the patient experienced VACCINATION COMPLICATION (Side effects) and CONDITION AGGRAVATED (Anxiousness getting worse/weakness of hands getting worse). The patient was hospitalized from 14-Feb-2021 to 17-Feb-2021 due to DYSPNOEA, MUSCULOSKELETAL DISCOMFORT and PALPITATIONS. On 14-Jan-2021, PAIN IN EXTREMITY (Soreness of arm) had resolved. On 19-Jan-2021, DYSPNOEA (Shortness of breath/Unable to breath/Shortness of breath while walking in normal pace or going upstairs) had resolved. At the time of the report, MUSCULOSKELETAL DISCOMFORT (Felt upper neck getting squeezing), LOSS OF CONSCIOUSNESS (Passed out), SYNCOPE (Syncope), INSOMNIA (Headache interferes with sleep/Inability to fall asleep), CHEST DISCOMFORT (Squeezing sensation of upper chest), DIZZINESS (Dizziness), FEELING OF BODY TEMPERATURE CHANGE (Feeling of cold/warm),

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DECREASED APPETITE (No appetite), DYSPEPSIA (Heartburn), POSTURAL ORTHOSTATIC TACHYCARDIA SYNDROME (POTS(Postural orthostatic tachycardia syndrome)), AUTONOMIC NERVOUS SYSTEM IMBALANCE (Autonomic nerve disorder), VACCINATION COMPLICATION (Side effects), SITTING DISABILITY (Position changed to standing from sitting), BURNING SENSATION (Heart burn/Burning sensation upto throat), CHEST DISCOMFORT (Heaviness), NERVOUSNESS (Nervousness), CONDITION AGGRAVATED (Anxiousness getting worse/weakness of hands getting worse) and FATIGUE (Fatigue) outcome was unknown and PALPITATIONS (Heart palpitation), MUSCULAR WEAKNESS (Weakness of upper arm/Leg weakness), PARAESTHESIA (Feel tingling with both hands), ANXIETY (Anxiousness), IMPAIRED WORK ABILITY (Unable to perform work) and HEADACHE (Pressure headache at nose and forehead/Severe headache) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 23-Jan-2021, Blood test: negative (Negative) Negative. On 23-Jan-2021, Computerised tomogram: negative (Negative) Negative. On 27-Jan-2021, Blood test: normal (normal) normal. On 13-Feb-2021, Electrocardiogram: normal (normal) normal. On 13-Feb-2021, Heart rate: 108 (High) Went up from 70s to 108.. On 13-Feb-2021, X-ray: normal (normal) normal. On 14-Feb-2021, Magnetic resonance imaging: postural orthostatic tachycardia syndrome. (normal) Diagnosis: Postural orthostatic tachycardia syndrome.. On 14-Feb-2021, Ultrasound scan: postural orthostatic tachycardia syndrome. (normal) Diagnosis: Postural orthostatic tachycardia syndrome.. On 24-Feb-2021, Electromyogram: autonomic nerve disorder and syncope. (Inconclusive) Autonomic nerve disorder and syncope.. On 24-Feb-2021, Quantitative sudomotor axon reflex test: autonomic nerve disorder and syncope (Inconclusive) Autonomic nerve disorder and syncope.. On 24-Feb-2021, Reflex test: autonomic nerve disorder and syncope. (Inconclusive) Autonomic nerve disorder and syncope.. On 28-Mar-2021, Laboratory test: ruled out heart attack (Inconclusive) Ruled out heart attack. On 28-Mar-2021, X-ray: ruled out heart attack. (normal) Ruled out heart attack.. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was

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unknown. Additional laboratory investigations included neurology study. Treatment for the event included acetaminophen, naproxen, lorazepam, metoprolol and fludrocortisone. The patient consulted rheumatologist and no significant abnormal findings. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 22-Apr-2021: Added reporter details, medical history, laboratory investigations, concomitant medication, new adverse events, seriousness of the events, outcome of events and treatment medication.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1276723 | 5/1/2021 | FL | 75 | M | 1/6/2021 | | fainting; fall; Dehydration; itchiness; frequent urination; Fever; This spontaneous case was reported by a consumer and describes the occurrence of SYNCOPE (fainting) in a 75-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical history reported. Concomitant products included DORZOLAMIDE HYDROCHLORIDE (DORZOLOMIDE HYDROCHLORIDE), TIMOLOL and LATANOPROST for an unknown indication. On 06-Jan-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced SYNCOPE (fainting) (seriousness criterion medically significant), FALL (fall), DEHYDRATION (Dehydration), PRURITUS (itchiness), POLLAKIURIA (frequent urination) and PYREXIA (Fever). At the time of the report, SYNCOPE (fainting), FALL (fall), DEHYDRATION (Dehydration), PRURITUS (itchiness), POLLAKIURIA (frequent urination) and PYREXIA (Fever) outcome was unknown. Treatment of the events were not provided. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Company comment Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. This case was linked to MODERNATX, INC.-MOD-2021-089270 (E2B Linked Report). Reporter did not allow further contact; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded MODERNATX, INC.-MOD-2021-089270:Wife case |

| <u>VAERS_ID</u> | <u>RECVDATE</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1276718 | 5/1/2021 | AL | 55 | F | 4/18/2021 | 4/18/2021 | cold like symptoms; stuffy nose; sore arm; headache; unconscious; fainted; blood pressure was low; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (unconscious) and SYNCOPE (fainted) in a 55-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 002B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No medical history was provided by the reporter. On 18-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 18-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (unconscious) (seriousness criterion medically significant), SYNCOPE (fainted) (seriousness criterion medically significant) and HYPOTENSION (blood pressure was low). On 19-Apr-2021, the patient experienced NASOPHARYNGITIS (cold like symptoms), NASAL CONGESTION (stuffy nose), PAIN IN EXTREMITY (sore arm) and HEADACHE (headache). On 23-Apr-2021, PAIN IN EXTREMITY (sore arm) and HEADACHE (headache) had resolved. At the time of the report, LOSS OF CONSCIOUSNESS (unconscious), SYNCOPE (fainted) and HYPOTENSION (blood pressure was low) had resolved and NASOPHARYNGITIS (cold like symptoms) and NASAL CONGESTION (stuffy nose) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No concomitant medications were reported. As treatment, the patient took acetaminophen, ibuprofen and antihistamine. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1276749 | 5/1/2021 | IN | | M | 3/5/2021 | 3/19/2021 | Blood clots in the legs and lungs; he passed out and still currently admitted in hospital; Blood clots in the legs and lungs; 2nd dose given 2 weeks from the 1st dose; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PULMONARY EMBOLISM (Blood clots in the legs and lungs), LOSS OF CONSCIOUSNESS (he passed out and still currently admitted in hospital) and DEEP VEIN THROMBOSIS (Blood clots in the legs and lungs) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 05-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 19-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 19-Mar-2021, the patient experienced PRODUCT ADMINISTRATION ERROR (2nd dose given 2 weeks from the 1st dose). On 22-Apr-2021, the patient experienced PULMONARY EMBOLISM (Blood clots in the legs and lungs) (seriousness criteria hospitalization and medically significant), LOSS OF CONSCIOUSNESS (he passed out and still currently admitted in hospital) (seriousness criteria hospitalization and medically significant) and DEEP VEIN THROMBOSIS (Blood clots in the legs and lungs) (seriousness criteria hospitalization and medically significant). The patient was hospitalized on 22-Apr-2021 due to DEEP VEIN THROMBOSIS, LOSS OF CONSCIOUSNESS and PULMONARY EMBOLISM. On 19-Mar-2021, PRODUCT ADMINISTRATION ERROR (2nd dose given 2 weeks from the 1st dose) had resolved. On 22-Apr-2021, LOSS OF CONSCIOUSNESS (he passed out and still currently admitted in hospital) had resolved. At the time of the report, PULMONARY EMBOLISM (Blood clots in the legs and lungs) and DEEP VEIN THROMBOSIS (Blood clots in the legs and lungs) outcome was unknown. Not Provided For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication was reported by the reporter. Patient reported that he had diagnosed to have blood clots in the leg and lungs and had unspecified |

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procedure. Patient reported that he was given a unknown medication.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. However, the reported drug administration error (2nd dose administered 2 weeks from 1st dose) may remain a confounder.

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| 1276728 | 5/1/2021 | NJ | 58 | F | 3/2/2021 | 3/4/2021 | This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of ARRHYTHMIA (arrhythmia), TACHYCARDIA (tachycardia) and HEART RATE INCREASED (190bpm heart rate) in a 58-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 027A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Arrhythmia (No symptoms over the past six years.). Concomitant products included OLOPATADINE HYDROCHLORIDE for an unknown indication. On 02-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 04-Mar-2021, the patient experienced ARRHYTHMIA (arrhythmia) (seriousness criterion hospitalization prolonged), TACHYCARDIA (tachycardia) (seriousness criterion hospitalization prolonged) and HEART RATE INCREASED (190bpm heart rate) (seriousness criterion hospitalization prolonged). On 23-Mar-2021, the patient experienced SUPRAVENTRICULAR EXTRASYSTOLES (premature arterio contraction) and SUPRAVENTRICULAR TACHYCARDIA (supraventricular tachycardia). On an unknown date, the patient experienced PRESYNCOPE (almost passed out), LIMB DISCOMFORT (legs feel heavy) and CHEST PAIN (chest feel sore). The patient was hospitalized on 08-Apr-2021 due to ARRHYTHMIA, HEART RATE INCREASED and TACHYCARDIA. At the time of the report, ARRHYTHMIA (arrhythmia), TACHYCARDIA (tachycardia), HEART RATE INCREASED (190bpm heart rate), SUPRAVENTRICULAR EXTRASYSTOLES (premature arterio contraction), SUPRAVENTRICULAR TACHYCARDIA (supraventricular tachycardia), PRESYNCOPE (almost passed out), LIMB DISCOMFORT (legs feel heavy) and CHEST PAIN (chest feel sore) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 04-Mar-2021, Tachycardia: 190 (High) increased. On 23-Mar-2021, Electrocardiogram ambulatory: abnormal (abnormal) abnormal. On 08-Apr-2021, Tachycardia: 190 (High) increased. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was |

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unknown. On 23-Mar-2021, the patient saw the cardiologist and reported that testing, including Holter monitoring was performed. On 14-Apr-2021, ablation surgery was performed.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

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| 1276729 | 5/1/2021 | TX | 31 | F | 3/8/2021 | 4/19/2021 | Fainted after 2nd dose; there was a delay (late) in her receiving her 2nd dose due to a hailstorm; there was a delay (late) in her receiving her 2nd dose due to a hailstorm; This spontaneous case was reported by a consumer and describes the occurrence of SYNCOPE (Fainted after 2nd dose) in a 31-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 047B21A and 027A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No medical history was provided by the reporter. Concomitant products included CETIRIZINE HYDROCHLORIDE (ZYRTEC ALLERGY) for Allergy. On 08-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 19-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 19-Apr-2021, the patient experienced INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (there was a delay (late) in her receiving her 2nd dose due to a hailstorm) and PRODUCT AVAILABILITY ISSUE (there was a delay (late) in her receiving her 2nd dose due to a hailstorm). On 20-Apr-2021, the patient experienced SYNCOPE (Fainted after 2nd dose) (seriousness criterion medically significant). On 19-Apr-2021, INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (there was a delay (late) in her receiving her 2nd dose due to a hailstorm) and PRODUCT AVAILABILITY ISSUE (there was a delay (late) in her receiving her 2nd dose due to a hailstorm) had resolved. On 20-Apr-2021, SYNCOPE (Fainted after 2nd dose) had resolved. No treatment information for the event was reported. Company comment:This case of 31- year-old female patient who experienced unexpected event of syncope and there was a delay in her receiving her 2nd dose due to a hailstorm (product availability issue, inappropriate schedule of vaccine administered). There were no reported AEs associated with the events of product availability issue/inappropriate schedule of vaccine administered. Based on temporal association with the use of mRNA-1273 vaccine and onset of syncope, a causal relationship cannot be excluded.; Sender's Comments: This case of 31- year-old female patient who experienced unexpected event of syncope and there was |

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a delay in her receiving her 2nd dose due to a hailstorm (product availability issue, inappropriate schedule of vaccine administered). There were no reported AEs associated with the events of product availability issue/inappropriate schedule of vaccine administered. Based on temporal association with the use of mRNA-1273 vaccine and onset of syncope, a causal relationship cannot be excluded.

2 additional people passed out at vaccination facility; Based on the current case data, this case has been classified as invalid. This spontaneous case was reported by a non-health professional and describes the occurrence of LOSS OF CONSCIOUSNESS (2 additional people passed out at vaccination facility) in a patient of an unknown age and gender who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 01-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (2 additional people passed out at vaccination facility) (seriousness criterion medically significant). At the time of the report, LOSS OF CONSCIOUSNESS (2 additional people passed out at vaccination facility) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. Concomitant product use was not provided by the reporter. Treatment information was not provided. NO relevant medical history provided. Company comment: Very limited information regarding this case has been provided at this time. Further information has been requested. This case was linked to MODERNATX, INC.-MOD-2021-089124 (E2B Linked Report).; Sender's Comments: Very limited information regarding this case has been provided at this time. Further information has been requested. MODERNATX, INC.-MOD-2021-089124:Case for patient

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| 1278690 | 5/1/2021 | TX | 24 | M | 4/17/2021 | 4/17/2021 | Fainted about 15 to 20 minutes after dose; This is a spontaneous report from a contactable consumer (patient himself). A 24-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), via an unspecified route of administration, administered in the right arm on 17Apr2021 at 11:15 AM (Batch/Lot Number: ERB8729) as a single dose for COVID-19 immunization. The patient had no medical history. The patient had no known allergies. Concomitant medication included diphenhydramine taken for an unspecified indication, start and stop date were not reported. The patient had no other vaccine in four weeks. The patient had no COVID-19 prior vaccination. The patient was not tested for COVID-19 post vaccination. On 17Apr2021 at 11:30 AM, the patient fainted about 15 to 20 minutes after dose. The patient did not receive any treatment for the adverse event (AE). The patient recovered from the event on an unspecified date. |

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| 1276739 | 5/1/2021 | NY | 66 | F | 3/12/2021 | 4/9/2021 | Blacked out and passed out completely; Next morning, around 6:30am, I woke up feeling dizzy; Morning after second dose, my temperature was 99.3degF; Breast pain on my left side which has been there for a while after the second shot; Felt so dehydrated after the second shot; My head felt a little muddled; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (Blacked out and passed out completely) in a 66-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 036B21A and 038A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 12-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 09-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 09-Apr-2021, the patient experienced FEELING ABNORMAL (My head felt a little muddled), BREAST PAIN (Breast pain on my left side which has been there for a while after the second shot) and DEHYDRATION (Felt so dehydrated after the second shot). On 10-Apr-2021, the patient experienced PYREXIA (Morning after second dose, my temperature was 99.3degF). On 10-Apr-2021 at 6:30 AM, the patient experienced DIZZINESS (Next morning, around 6:30am, I woke up feeling dizzy). On 10-Apr-2021 at 9:45 AM, the patient experienced LOSS OF CONSCIOUSNESS (Blacked out and passed out completely) (seriousness criterion medically significant). At the time of the report, LOSS OF CONSCIOUSNESS (Blacked out and passed out completely) had resolved, FEELING ABNORMAL (My head felt a little muddled), BREAST PAIN (Breast pain on my left side which has been there for a while after the second shot) and DEHYDRATION (Felt so dehydrated after the second shot) had not resolved and DIZZINESS (Next morning, around 6:30am, I woke up feeling dizzy) and PYREXIA (Morning after second dose, my temperature was 99.3degF) outcome was unknown. Not Provided DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Physical examination: normal. On 10-Apr-2021, the patient blacked out and passed out completely. She gained consciousness as her family members were |

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carrying her. Her regular body temperature is 97.6degF. The patient felt so dehydrated after the second shot that her son had to keep on giving her water every 15 minutes. The patient took Tylenol for the symptoms. The patient also had physical examination with her gynecologist before first shot and it was normal. This case was linked to MOD-2021-089609 (Patient Link).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

PASSED OUT (FAINTED); HEART RATE OF 43; HEART RATE AS HIGH AS 149; TIREDNESS; HOT FLASHES; CHILLS; This spontaneous report received from a patient concerned a 59 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included seasonal allergies, and penicillin allergy. The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, and batch number: 205A21A expiry: UNKNOWN) dose was not reported, 1 total dose administered on 11-APR-2021 on left deltoid for prophylactic vaccination. No concomitant medications were reported. On 11-APR-2021, the patient experienced hot flashes and chills which would come and come. She did not had temperature, but she took paracetamol (Tylenol) for her side effects. On 12-APR-2021 (within 24 hours of getting the vaccine), she passed out (fainted), which occurred once. While passed out her heart rate was 43 which she said lasted for minutes. Her heart rate was as high as 149 since she has received the vaccine. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from passed out (fainted), had not recovered from hot flashes, chills, and tiredness, and the outcome of heart rate of 43 and heart rate as high as 149 was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0. 20210424060-covid-19 vaccine ad26.cov2.s -Passed out (fainted). This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).

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| 1276741 | 5/1/2021 | NY | 63 | F | 4/14/2021 | 4/21/2021 | <p>became unresponsive; hemorrhagic shock; syncope; abdominal pain; wasn't feeling good; nausea; vomiting; This spontaneous case was reported by an other health care professional (subsequently medically confirmed) and describes the occurrence of LOSS OF CONSCIOUSNESS (became unresponsive), SHOCK HAEMORRHAGIC (hemorrhagic shock), SYNCOPE (syncope), ABDOMINAL PAIN (abdominal pain), FEELING ABNORMAL (wasn't feeling good), NAUSEA (nausea) and VOMITING (vomiting) in a 63-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Splenectomy (did get embolization but progressed to further bleeding) on 24-Apr-2021. On 14-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 21-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (became unresponsive) (seriousness criterion hospitalization), SHOCK HAEMORRHAGIC (hemorrhagic shock) (seriousness criterion hospitalization), SYNCOPE (syncope) (seriousness criterion hospitalization), ABDOMINAL PAIN (abdominal pain) (seriousness criterion hospitalization), FEELING ABNORMAL (wasn't feeling good) (seriousness criterion hospitalization), NAUSEA (nausea) (seriousness criterion hospitalization) and VOMITING (vomiting) (seriousness criterion hospitalization). The patient was hospitalized on 21-Apr-2021 due to ABDOMINAL PAIN, FEELING ABNORMAL, LOSS OF CONSCIOUSNESS, NAUSEA, SHOCK HAEMORRHAGIC, SYNCOPE and VOMITING. At the time of the report, LOSS OF CONSCIOUSNESS (became unresponsive), SHOCK HAEMORRHAGIC (hemorrhagic shock), SYNCOPE (syncope), ABDOMINAL PAIN (abdominal pain), FEELING ABNORMAL (wasn't feeling good), NAUSEA (nausea) and VOMITING (vomiting) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Imaging procedure: (abnormal) abd imaging showed a large splenic subcapsular hematoma of unclear etiology (no hx of trauma) with hemoperitoneum. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the</p> |

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reporter considered ABDOMINAL PAIN (abdominal pain), NAUSEA (nausea) and VOMITING (vomiting) to have an unknown relationship. No further causality assessments were provided for LOSS OF CONSCIOUSNESS (became unresponsive), SHOCK HAEMORRHAGIC (hemorrhagic shock), SYNCOPE (syncope) and FEELING ABNORMAL (wasn't feeling good). Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. However, Very limited information regarding these events has been provide at this time. Further information has been requested.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. However, Very limited information regarding these events has been provide at this time. Further information has been requested.

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| 1276712 | 5/1/2021 | AL | 69 | F | 2/12/2021 | 2/12/2021 | fainting; hitting the floor; "knocking out" both of her front teeth when she fainted and hit the floor; This spontaneous case was reported by a consumer and describes the occurrence of SYNCOPE (fainting) in a 69-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 12-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 12-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 12-Feb-2021, the patient experienced SYNCOPE (fainting) (seriousness criterion medically significant), FALL (hitting the floor) and TOOTH INJURY ("knocking out" both of her front teeth when she fainted and hit the floor). On 12-Feb-2021, SYNCOPE (fainting) and FALL (hitting the floor) had resolved. At the time of the report, TOOTH INJURY ("knocking out" both of her front teeth when she fainted and hit the floor) was resolving. Unknown She had a visit to Family Practice Physician, visit to Dentist and need for dental work. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, fainting and falling down, a causal relationship cannot be excluded. The event of tooth injury is unlikely related to mRNA-1273 since this was directly related to the event, falling down.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, fainting and falling down, a causal relationship cannot be excluded. The event of tooth injury is unlikely related to mRNA-1273 since this was directly related to the event, falling down. |

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| 1278949 | 5/1/2021 | NY | 45 | F | 4/5/2021 | 4/5/2021 | it could have been a seizure; Unconscious/Collapsed/ diagnosed her as having a Syncopal Episode; Urinated on self/Wet her pants; Headaches; Feeling light headed; Felt her heart beat faster; Sore arm; This is a spontaneous report from a contactable nurse (patient mother). A 45-year-old female patient received bnt162b2 (BNT162B2, lot number EW0150 and expiration date was not provided), via an unspecified route of administration first dose on 05Apr2021 15:00 at single dose for covid-19 immunisation. The patient's medical history included ongoing Hypertension (Patient diagnosed in her late 30's), ongoing Hypothyroid (Patient diagnosed when she was around 20 years old), ongoing Allergies, ongoing Gastroesophageal reflux disease (The patient was exposed to a chemical in her 20's that caused this condition), ongoing Birth control, ongoing Allergic to eggs (States patient has never received the flu vaccine due to her egg allergy), and ongoing Allergic to shellfish. The patient's concomitant medications included ongoing levothyroxine at 150 ug, 1x/day for Hypothyroid, ongoing Hydrochlorothiazide at 12.5 mg, 1x/day for hypertension, ongoing omeprazole at 20 mg, 1x/day for gastroesophageal reflux disease, ongoing losartan at 100 mg, 1x/day for hypertension, ongoing norethisterone (SHAROBEL) for Birth control. On 06Apr2021 13:00, the reporter stated that her daughter fainted at work, lost her urine, and was unconscious and was taken to the Emergency Room. Primary Care Physician told her daughter she should have no problem getting the second vaccine. States that she was not certain if her daughter should get the second shot. It was scheduled for next week. Also, reported that after lunch reporter stated that her daughter fainted in her office at work. She had urinated on herself and was unconscious. Caller was concerned it could have been a seizure. Her daughter was taken to the Emergency Room and they diagnosed her as having a Syncopal Episode. On 06Apr2021, the patient had headaches that continue since these events. The reporter stated that her daughter's doctor told her daughter that the blood work and electrocardiogram done at the Emergency Room were normal. The Emergency Room and her daughter's doctor acted like her symptoms were not serious. The reporter looked at the Vaccine Adverse Event Reporting System website and it said that a syncopal episode is a reportable event. Says that her |

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daughter's doctors did not report this event. Says doctors need to have training on the importance of reporting events. The reporter called the Food and Drug Administration last week but she hasn't heard anything from them. States they told her it could take 5-7 business days. Says she called Pfizer today to see if there was any further information or guidance she could get as she is concerned about her daughter. She says her daughter has her own office so she was in there alone when she collapsed. Someone found her on the floor. The reporter was asking for guidance on administration of the second vaccine dose following a syncopal episode after the first. The patient received her first vaccine dose on 05Apr2021 15:00 and she was fine, she had a sore arm, but went to work the next day (06Apr2021) and after lunch she reported feeling light headed and felt her heart beat faster and went to get up and a colleague later found her on the floor and she had wet her pants. They took her to the ER around 1 pm the day after her vaccination and diagnosed her with a syncopal episode stating that they didn't think it was from the shot. The events syncope, urinary incontinence, seizure, and headache were considered as serious (medically significant) by the reporter. The events syncope, and urinary incontinence caused emergency room visit and physician office visit. The outcome of the events syncope, urinary incontinence was recovered on 06Apr2021. The outcome of the event Headache was not recovered. The outcome of the remaining events was unknown.; Sender's Comments: Based on the information currently available, a causal association between the reported events and bnt162b2 cannot be fully excluded. Case will be reassessed when additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and investigators, as appropriate.

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| 1278533 | 5/1/2021 | NY | 48 | M | 4/14/2021 | 4/15/2021 | syncope; Soreness overnight in left arm; expanding pain to left shoulder; Strong Fever/low fever; body pain; headache; felt uneasy; nausea/Felt like throwing up; dizzy/lightheaded; Profuse sweating; EKG showed low heart rate, blood pressure; EKG showed low heart rate, blood pressure; feeling weak; could not stand; Feeling worse; This is a spontaneous report from a contactable consumer. A 48-year-old male patient received second dose of BNT162B2 (BNT162B2), via an unspecified route of administration, administered in Arm Left on 14Apr2021 at 16:00 (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunization. Medical history included Cholesterol (blood cholesterol abnormal) from an unknown date. There were no concomitant medications. The patient previously received first dose of BNT162B2 for covid-19 immunisation on 24Mar2021. The patient also previously received naproxen and experienced allergies. The patient experienced syncope, soreness overnight in left arm, expanding pain to left shoulder, strong fever/low fever, body pain, headache, felt uneasy, nausea/felt like throwing up, dizzy/lightheaded, profuse sweating, ekg showed low heart rate, blood pressure, feeling weak, could not stand and feeling worse all on 15Apr2021 at 13:00. All the reported events caused hospitalization for 1 day. It was reported that After receiving Pfizer vaccine at 4pm developed Soreness overnight in left arm, expanding pain to left shoulder. Strong Fever and body pain in morning. Feeling worse throughout morning after breakfast of tea and fruits. While having lunch at 1.30 pm felt uneasy and nausea and could not complete lunch. Felt like throwing up and got up feeling dizzy and lightheaded. Experienced syncope and had to lie down on kitchen floor. Tried to get up with help from family members but could not stand and had to lie down again on floor. Profuse sweating. Wife called 911 and ambulance who arrived and checked pulse, EKG showed low heart rate, blood pressure. Taken by ambulance and paramedics to hospital Emergency where IV fluids were given to stabilize and discharged after 4 hours of observation. Still feeling weak, headache, low fever. Taking Tylenol and fluids while recovering. Adverse event start date: 15Apr2021. Adverse event start time: 01:00 PM. The patient underwent lab tests and procedures which included blood pressure (blood |

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pressure measurement): low on 15Apr2021, EKG (electrocardiogram): showed low heart rate, blood pressure on 15Apr2021 and pulse/heart rate (heart rate): low on 15Apr2021. Therapeutic measures were taken as a result of all the events which includes IV fluids and Tylenol. Outcome of all the events was recovering Information on batch/lot number was requested.

pt got shot at 11.45 am, at 11.47 am, pt felt lightheadedness, dizziness, sweating. we gave him water and elevated his feet to a chair. after 3 minutes, he left the immunization room, and pt was on the observation area for 20 minutes. pt mom was with him. on the vaccination adm record and consent form: the pt denies any: has the person vaccinated had a reaction or fainted, or felt dizzy after receiving any vaccination, pt said no. these is ask also , before the pt is adm the injections. We talk to mom, and told her to look for any shortness of breath , hives, rashes to take him to hospital

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| 1278666 | 5/1/2021 | CA | 62 | F | 4/13/2021 | 4/13/2021 | felt low blood pressure; weak; confused; When fell hit self on head, lip, nose, and eye; When fell hit self on head; bruises on face; had burst lip; diarrhea; leg pain; fainted; seizure; felt hot; chills/shaking.; This is a spontaneous report from a contactable consumer (patient herself). This 62-year-old female patient (not pregnant) received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Lot number not provided), via an unspecified route of administration in the left arm, on 13Apr2021 at 21:00 (at the age of 62-year-old) as single dose for COVID-19 immunisation. Historical vaccine includes the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Lot number EP6775 MS 389) administered via an unknown route in the left arm on 17Mar2021 (at 10:00 AM) for COVID-19 immunisation. No other vaccine was received in four weeks. Relevant medical history included gastritis and anxiety. Past drug history included allergy to mirtazapine (REMERON). Relevant concomitant medications included diazepam (VALIUM), vitamins and probiotics. On 13Apr2021 at 23:00 the patient had chills / shaking. On 14Apr2021 at 02:00 AM, she felt hot. She went to bathroom, felt low blood pressure, weak, and fainted. Woke up, felt disoriented, not know where she was, confused. When fell hit self on head, lip, nose, and eye. She suffered various bruises on face. May have had seizure, had burst lip and felt was biting. Then suffered diarrhea that day. She also experienced leg pain. She went to the doctor on 16Apr2021. On unknown date, blood work up was done and results were not provided. The patient was recovering from the events. Information on the lot/batch number has been requested. |

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| 1278693 | 5/1/2021 | MA | 57 | M | 4/17/2021 | 4/17/2021 | <p>Syncope; This is a spontaneous report from a contactable nurse (patient). A 57-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 1 via an unspecified route of administration, administered in left arm on 17Apr2021 11:30 (Batch/Lot Number: ER8735) as single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient was not diagnosed with COVID-19 prior to vaccination and had not been tested for COVID-19 since the vaccination. The patient experienced syncope on 17Apr2021 11:45. The event resulted in emergency room/department or urgent care. Therapeutic measures were taken as a result of syncope. Outcome of the event was unknown. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Based on the information currently available and the close temporal relationship, a possible contributory role of suspect product BNT162B2 to the reported 'syncope' cannot be completely excluded. Case will be reassessed if additional information is received. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.</p> |

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| 1278754 | 5/1/2021 | NY | 33 | F | 4/17/2021 | 4/18/2021 | <p>Sometime after 8 am on 18Apr2021, more than 13 hrs after receiving the Pfizer vaccine, the patient fainted in her bathroom and hurt her forehead; hurt her forehead; This is a spontaneous report from a contactable consumer. A 33-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Lot Number: ER8731), via an unspecified route of administration, on 17Apr2021 at 16:15 (at the age of 33-years-old) as a single dose in the right arm for COVID-19 immunization. Medical history included contraception from an unknown date and unknown if ongoing. The patient has no known allergies. The patient was not pregnant at the time of vaccination. Prior to vaccination the patient had not been diagnosed with COVID-19. Concomitant medication included desogestrel, ethinylestradiol (RECLIPSEN) taken for contraception, start and stop date were not reported. On 18Apr2021 at 08:15, more than 13 hours after receiving the Pfizer vaccine, the patient fainted in her bathroom and hurt her forehead. Treatment for the event fainted included wetting the patient's face as well as the application of a cold towel to the patient's forehead. Since the vaccination the patient has not tested positive for COVID-19. The clinical outcome of syncope was reported as recovering. The clinical outcome of injury was not provided.</p> |
| 1278771 | 5/1/2021 | | | F | 4/17/2021 | 4/18/2021 | <p>passed out at work; extreme fatigue; body aches for a few hours; This is a spontaneous report from a contactable consumer. An 18-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), first dose via an unspecified route of administration on 17Apr2021 (Batch/Lot number was not reported) as single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. It was reported that the following day, 18Apr2021, the patient experienced extreme fatigue and body aches for a few hours, then she passed out at work. The outcome of the events was unknown. Information about lot/batch has been requested.</p> |

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| 1278775 | 5/1/2021 | | 28 | F | 4/18/2021 | 4/18/2021 | fainted; dizzy; warm; arms had seized up and were twitching; leg and body had also briefly been shaking; eyes were dilated; vomiting; arm is sore; sweaty; This is a spontaneous report from a non-contactable consumer (patient). A 28-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), dose 2 via an unspecified route of administration, administered in Arm Left on 18Apr2021 11:00 (Batch/Lot Number: Unknown) as SINGLE DOSE for COVID-19 immunisation. The patient was not pregnant at time of vaccination. Medical history was reported as none. There were no concomitant medications. The patient previously had first dose of BNT162B2 (Lot number: ER8727) on 28Mar2021 01:00 PM in the left arm at 28 years old for COVID-19 immunisation and experienced fainted. On 18Apr2021 11:15 AM, the patient fainted about 10 minutes after second dose was vaccinated. The patient became dizzy and very warm and then woke up about 5-7 seconds after had fainted. The patient's arms had seized up and were twitching and leg and body had also briefly been shaking. The patient was very sweaty and warm. The patient's eyes were dilated when woke up according to the overseeing nurse. The patient said it was scary. Half hour after, the patient felt fine but then began vomiting when got home. The patient's arm is sore but nothing else has happened. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The outcome of the events was recovering. No treatment was given to the patient for the events. No follow-up attempts are possible; information about lot/batch number cannot be obtained. |

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| 1278495 | 5/1/2021 | TX | 38 | F | 4/15/2021 | 4/16/2021 | This is a spontaneous report from a contactable nurse (patient). A 38-year-old female patient, not pregnant, received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date unknown) via an unspecified route of administration, administered in the left arm on 15-Apr-2021 08:00 at a single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number unknown) on 25-Mar-2021 08:00 AM administered in the left arm for Covid-19 immunization at the age of 38-years-old. There were no other vaccines received in four weeks. The patient did not have Covid prior vaccination. The patient experienced syncope on 16-Apr-2021 12:30 AM (00:30 military time) with outcome of unknown. No treatment was received for the adverse event. The patient was not tested for Covid post-vaccination. Information on the lot/batch number has been requested.; Sender's Comments: A causal association between BNT162B2 and the reported syncope cannot be excluded based on a temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate. |

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| 1278946 | 5/1/2021 | AZ | | F | 3/18/2021 | 4/2/2021 | fatigue; headaches; 5 episodes of micro fainting spells; This is a spontaneous report from a contactable consumer (patient). A 71-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EP7534), via an unspecified route of administration on 18Mar2021 at 16:00 at a single dose in the left arm for COVID-19 immunization. Medical history included blood pressure, cholesterol, GI, and anxiety (as reported, for clarification). Patient also experienced some positional and vasovagal fainting spells from Jan2020 to an unknown date (also reported as every 6-8 weeks and had tapered off then on 06Mar2021, had 7 episodes and many near misses, pending clarification). Concomitant medications included metoprolol; aspirin [acetylsalicylic acid] (ASPIRIN [ACETYLSALICYLIC ACID]); polycarbofil calcium (FIBER); escitalopram oxalate (LEXAPRO); simvastatin (ZOCOR) and unspecified supplements. The patient previously took the first dose of BNT162B2 (lot number: EN6202) in the left arm for COVID-19 immunization. The patient was not diagnosed with COVID-19 prior to vaccination. The patient was not pregnant at the time of vaccination. It was reported that patient had 5 episodes of micro fainting spells since 02Apr2021. On an unspecified date, the patient experienced fatigue and headaches. The events resulted in doctor or other healthcare professional office/clinic visit. The patient did not receive any treatment for the reported events. Since the vaccination, the patient has not been tested for COVID-19. The outcome of 5 episodes of micro fainting spells was not recovered; while the other events was unknown. |

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| 1278990 | 5/1/2021 | NJ | | F | 4/7/2021 | 4/7/2021 | <p>She started to feel like she was fainting; chest pain; she was seeing stars; she had trouble breathing; She was very hot; She also had a sore throat and some congestion; She also had a sore throat and some congestion; This is a spontaneous report from a contactable consumer (patient's parent). A female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 07Apr2021 at 17:30 at a single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient had the first Pfizer covid-19 vaccine on 07Apr2021 and that night (as reported), patient had some troubling side effects; she had trouble breathing and was very hot. She also had a sore throat and some congestion. They thought these were very normal side effects; however, the side effects happened again on 12Apr2021, but it was worst. All of a sudden patient had trouble breathing, chest pain and she started to feel like she was fainting, she was seeing stars. She sat down, put her head down in her knees and the same thing stopped and it worked; it was about 5 to 10 minutes for her breathing to be okay again (for clarification). On an unspecified date, they called her health care providers and went to her urgent care location due to the events. They took her X-ray and EKG and was normal. They also did a Covid test which was negative. The reporter wanted to know if it is safe for the patient to get the second dose. The final outcome of the events she started to feel like she was fainting and she had trouble breathing was recovered (for clarification); while the other events was unknown. Information on lot/batch number has been requested.</p> |

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| 1279144 | 5/1/2021 | NY | 48 | U | 1/21/2021 | 1/31/2021 | Passed out; Blood clots in lungs; almost died from the vaccine; Problem in breathing; This is a spontaneous report from a contactable consumer (patient) reported that a 48-year-old patient of an unspecified gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL3247), via an unspecified route of administration, administered in arm right on 21Jan2021 (at the age of 48-years-old) as a single dose for covid-19 immunisation. The patient was healthy and had no suffering from any medical condition. Concomitant medication included sertraline hydrochloride (ZOLOFT) taken for an unspecified indication, start and stop date were not reported. The patient had his/her shot on 21Jan2021 and about 10 days later he/she was having problem in breathing. When the patient went to work, he/she passed out at work and they sent him/her to the hospital and he/she wound up in the hospital on 12Feb2021 and they found out that he/she have blood clots in his/her lungs. The patient added that the matter of concern was he/she almost died from the vaccine. The patient was discharged on 14Feb2021 and he/she went in on 12Feb2021 and they did the catheter to remove the blood clot. The patient was hospitalized due to blood clots in his/her lungs and prior to going to the hospital, a week, and a half before that he/she was having breathing issues. The patient underwent lab tests and procedures which included blood test with unknown results on Feb2021. The patient was supposed to get the 2nd dose on 11Feb2021, but he/she never went because he/she wound up in hospital. The patient right now was taking blood thinner named Eliquis after he/she wind up with clot. The outcome of the events was unknown. |

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| 1279196 | 5/1/2021 | NJ | 61 | F | 3/10/2021 | 3/10/2021 | heart was racing; tingling feeling; passed out; dizzy; queasy; I am diabetic; sick; This is a spontaneous report from a contactable consumer (patient). A 61-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration on 10Mar2021 (Lot Number: EN6201; Expiration Date: 30Jun2021) as single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. Historical vaccine included 1st dose of BNT162B2 (lot number: EN9581, Expiry Date: 31May2021) on 17Feb2021 and 13 days later patient started feeling sick and wholly got sick. Patient went for the second vaccine and passed out as she got the vaccine right there in the hospital (10Mar2021), so they gave her the vaccine and then patient sick for the next three weeks 3 and half weeks. The first-time patient passed out they took her to the emergency room for whole afternoon on 10Mar2021 because patient was so dizzy and queasy and she guessed they did like 'A1C' on her. They made sure that took blood for her they made sure patient was diabetic. They wanted to make sure there was nothing wrong with patient and then they sent patient home at same afternoon and patient went home and another whole week she was so dizzy and nauseous and now she was tingling feeling. All kind of weird things happened to patient and her heart was racing. Patient took herself back to the hospital after a week. Patient had to stay in the hospital for two days. And then they did MRI on her and a CAT scan and then they sent patient to neurologist and then patient to do another MRI. Patient been for past six weeks was being turmoil. Outcome of the events was unknown. |

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| 1279202 | 5/1/2021 | MO | 29 | F | 4/7/2021 | 4/7/2021 | fainted five minutes after the vaccination; pale; diaphoretic; vomited; she was extremely anxious about receiving the vaccine; This is a spontaneous report from a contactable nurse. A 29-years-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Solution for injection, Lot Number: PAA165969, expiry date not reported), intramuscular, administered in left arm on 07Apr2021 10:30 as a single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. It was unknown if patient had known allergies or other medical history. It was unknown if patient had Covid prior vaccination. The patient was not pregnant at the time of the vaccination and report. It was unknown if patient received other vaccine in four weeks and other medications in two weeks. The patient received the vaccine at the doctor's office/urgent care. The patient fainted five minutes after the vaccination on 07Apr2021 10:30. She was pale and diaphoretic. She became responsive within one minute. She was given water and a cold compress, and reported she felt better, but then vomited a small amount of emesis 15 minutes later (07Apr2021). She was evaluated by the physician who determined it was an emotional response to the vaccine. The patient had reported she was extremely anxious about receiving the vaccine (07Apr2021), and had fainted when she tried to give blood, and hadn't eaten anything that day. After sitting for 45 minutes, the doctor felt comfortable letting her leave. A call was placed to the patient at 4:00 pm to check on her. She reported she felt fine. The patient received no treatment for the event vomited, while therapeutic measures were taken as a result of the other reported events. It was unknown if patient was tested for Covid post vaccination. The patient recovered on an unspecified date in 2021 from the events reported.; Sender's Comments: Based on the information available and a close temporal association, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported events of syncope. The case will be reassessed once new information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as |

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any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate

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| 1279247 | 5/1/2021 | NJ | 79 | M | 3/26/2021 | 4/7/2021 | <p>he fell in the bathroom and passed out; he fell in the bathroom and passed out; tested positive for Covid; This is a spontaneous report from a contactable consumer (patient's son). This consumer reported similar event for two patients (father and mother). This is the first (father) of the two reports. A 79-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Dose 1) via an unspecified route of administration, administered in the left arm on 26Mar2021 (batch/lot number: ER8727) at 79 years old as SINGLE DOSE for COVID-19 immunization. Medical history included ongoing AFib (atrial fibrillation) diagnosed between 1 and 2 years ago. Patient also has a pacemaker from an unknown date. Patient was exposed to COVID-19 prior to vaccination. Concomitant medication included apixaban (ELIQUIS) oral from an unspecified start date and ongoing at 5 mg twice a day taken for AFib (atrial fibrillation). On 07Apr2021, the patient was admitted to the hospital due to a fall; he fell in the bathroom and passed out. The patient is on Eliquis, so they were worried about bleeding. He tested positive for COVID on 07Apr2021, this was the same day he was admitted to the hospital. He was discharged on 10Apr2021 and was improving. It was reported that the reporter (patient's son) tested positive for COVID on 27Mar2021, so it was likely his parents were exposed or infected prior to their first dose of the vaccine. The reporter confirmed he has not been vaccinated. The patient was due to get the second shot today, but the reporter cancelled the appointment since his dad was still in quarantine. The reporter heard different things about when to get the second dose, everyone says to wait 90 days, they're getting mixed information, then he has heard 3 weeks is long enough to wait. The reporter wanted to know when his dad can get the second dose of the vaccine after having the COVID-19 infection. The patient is recovering from "he fell in the bathroom and passed out." Outcome of the event "tested positive for Covid" was unknown. This case involves a Product Complaint: Consumer reported that his father and mother tested positive for Covid infection on 07Apr2021 after receiving the first dose of the Pfizer COVID vaccine on 26Mar2021. It was not provided if a sample of the product was available to be returned, if requested and if packaging was sealed and intact.; Sender's Comments: Linked Report(s) : US-PFIZER INC-</p> |

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| 1279386 | 5/1/2021 | NC | 23 | F | 4/30/2021 | 4/30/2021 | 2021443810 same reporter, same drug, same event, different patient Patient reports immediately after receiving vaccine, she felt "woozy." Within 3-4 minutes post-vaccination, she attempted to get out of car to get water/juice from vaccine staff and patient lost consciousness and was caught and lowered to ground by staff at vaccine site. She regain consciousness prior to being lowered on ground. VITALS at time of event: HR 60, RR 16 even and unlabored, BP 90/62 lying down. Feet were elevated until patient felt she could sit up. No c/o of n/v/diaphoresis. No dermatological changes. After lying down for approximately 5 mins, patient was able to stand and get into chair at 10:45 AM. BP at that time 98/60, HR 74, RR 16. At 10:50 AM, patient reports she felt back at baseline in NAD. A&O x 4, her parents did come and pick up her for transport home. Patient self reported history of syncope with medical procedures and events in past. |
| 1277606 | 5/1/2021 | | 26 | F | 4/9/2021 | 4/9/2021 | client observed sitting in chair when suddenly she loses consciousness and collapses to floor. Vaccine crew arrives immediately and she is assessed. No skin lesions, redness, swelling noted. Client gains consciousness and when asked about incident, she states: "I have fainted before when receiving a vaccine. EMS arrives and further assesses client taking over patient care. |

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| 1278636 | 5/1/2021 | TX | 16 | F | 4/16/2021 | 4/16/2021 | fainted for a few seconds; I started seeing blurry; my ears were ringing; This is a spontaneous report from a contactable consumer (patient). A 16-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EW0161, expiry date not reported), via an unspecified route of administration, administered in the right arm on 16Apr2021 16:45 (age at vaccination was 16 years) as single dose for COVID-19 immunization. Medical history was none. The patient had no known allergies. The patient was not pregnant at the time of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was vaccinated at a pharmacy or drugstore. The patient was not diagnosed with COVID-19 prior to vaccination. Since the vaccination, the patient has not been tested for COVID-19. Concomitant medications were not reported. The patient reported that on 16Apr2021 17:00, "I started seeing blurry. I stood still so my vision would clear. Then I fainted for a few seconds. When I came to my ears were ringing." The events resulted to emergency room/department or urgent care. Therapeutic measure was taken as a result of the events that was seen by a doctor. Clinical outcome of the events was unknown. No follow-up attempts are required. No further information is expected. |

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| 1278916 | 5/1/2021 | MA | 60 | F | 3/26/2021 | 3/27/2021 | DVT blood clot; ankle was still swollen and uncomfortable; ankle was still swollen and uncomfortable/discomfort; nights were the worst for the pain; pulse ox was low; d-dimer was very high; fainted; Fracture of ankle/two fractures on her ankle; severely nauseous; Vomiting; Diarrhea; deathly sick; This is a spontaneous report from a contactable consumer, reporting for herself. A 60-year-old female patient received the first dose of the bnt162b2 (BNT162B2; Lot Number: ER8727), via an unspecified route of administration in the left arm on 26Mar2021 at 14:00 at a single dose for covid-19 immunisation. Medical history included osteoporosis at least 10 years, terrible nausea, mild case of covid from Nov2020 to an unknown date. There were no concomitant medications. The patient previously took alendronate from 2008 to an unknown date and experienced very sick, nausea, diarrhoea and zoledronic acid (RECLAST) from Dec2017 and experienced nausea and vomiting. On 27Mar2021 at 2:00, the patient experienced deathly sick, fainted, fracture of ankle/two fractures on her ankle, severely nauseous, vomiting, and diarrhea. On an unknown date, the patient experienced dvt blood clot, ankle was still swollen and uncomfortable/discomfort, the nights are the worst for the pain, pulse ox was low, and d-dimer was very high. The event, deathly sick, was life-threatening. The clinical course was as follows: the patient had the first dose of the vaccine on 26Mar2021 at 14:00 in the afternoon in her left arm. Twelve hours after the first dose, later in the night about 02:00 AM she woke up deathly sick; and severely nauseous. She remembered she was going to the bathroom then she must have fainted because they were taking her to the hospital. She went to the ER and they found she had a fractured ankle. She was not admitted to the hospital. She was in the ER from about 03:00 AM to noon the next day. There must have been something in there; she knew there must be something in the vaccine because of her reaction. Adds a few years ago, something like this happened before. She had osteoporosis and had similar reactions with other products she had tried for osteoporosis; she had terrible nausea. The other products she tried included: in 2008 she took alendronate, it made her very sick but not as severe as this time, she never fainted. She had nausea and diarrhea. Then in Dec2017 she had zoledronic acid. |

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She went for an infusion at the hospital then went shopping, and was fine until the early morning, when she woke up with nausea and vomiting. In the ambulance, they gave her ondasetron (ZOFTRAN) for the nausea so the vomiting stopped. With regard to her ankle, first they thought it was a DVT blood clot. They did the xray and saw actually two fractures on her ankle but she does not need surgery. She saw the orthopedic doctor the other day and he said her ankle was healing but she still will have no weight bearing for 6 weeks and she was in a boot. Adds her ankle was still swollen and uncomfortable. She hated to take medications and they gave her oxy but she didn't want to take it. She was taking ibuprofen but that messed up her stomach. The nights are the worst for the pain and discomfort. Doctor at the hospital and primary care agreed she should not have the second dose. She did have mild case of COVID in Nov2020 and they are hoping she had antibodies from the infection and the first dose. Her primary care doctor was reviewing the blood work she had done at the hospital and told her they were surprised the hospital didn't admit her for observation because her pulse ox was low and there was another test that she was questioning because the d-dimer was very high. They did a chest x ray with unknown results. The doctor was questioning why they didn't do something else to rule out a blood clot. Therapeutic measures were taken as a result of the events, deathly sick, DVT blood clot, fainted, fracture of ankle/two fractures on her ankle, severely nauseous, vomiting, diarrhea, ankle was still swollen and uncomfortable/discomfort, nights were the worst for the pain, pulse ox was low, and d-dimer was very high. The clinical outcome of the events, deathly sick, fainted, severely nauseous, vomiting, diarrhea, was recovered on 27Mar2021. The clinical outcome of the events, DVT blood clot and nights were the worst for the pain, pulse ox was low, and d-dimer was very high, was unknown. The clinical outcome of the event, fracture of ankle/two fractures on her ankle, was recovering. The clinical outcome of the event, ankle was still swollen and uncomfortable/discomfort, was not recovered. No follow-up attempts are needed. No further information is expected.

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| 1277851 | 5/1/2021 | IN | 18 | F | 5/1/2021 | 5/1/2021 | Administered vaccine at 12 noon. At roughly 12:03pm the patient started experiencing signs of syncope. She had pale blue lips, ringing in ears, changes in vision/blurry vision, she felt dizzy/light headed. The symptoms began improving at roughly 12:10 and had almost completely resolved by 12:15. I kept the patient for an additional 15 minutes for monitoring. I counseled patient on what to do if they felt as though they were going to pass out. I provided a cold compress for the back of the patient's neck, and had ammonia inhalant on standby but didn't have to use to help keep patient conscious. By 12:30 the patient was feeling completely normal again. Her mom/stepmom was with her and was able to drive her home. I asked them to reach out in case of any other symptoms developed. |
| 1277722 | 5/1/2021 | NC | 19 | F | 5/1/2021 | 5/1/2021 | Pt was leaving vaccination area when she passed out. She described it like she was listening to music and woke up with her mom over top of her. Patient has a history of fainting when seeing needle. Ate water and crackers; color improved - released with mom |

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| 1279184 | 5/1/2021 | CA | 32 | F | 4/9/2021 | 4/9/2021 | tingling; numbing; diarrhea; feel the liquid squirting into my arm which is unusual; Fainted; nauseous; Memory lapse upon waking up; Breathing was slow; hot; sweaty; Arm pain; This is a spontaneous report from a non-contactable consumer (patient). A 32-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection; Batch/Lot Number: EW0158), via an unspecified route of administration, administered in the left arm on 09Apr2021 at 10:30 AM at the age of 32-years-old as single dose for COVID-19 immunization. Vaccine facility type was reported as "Other". The patient had no COVID prior vaccination. The patient was not pregnant. The patient had no medical history and no known allergies. There were no concomitant medications. The patient had no other vaccine in four weeks and had no other medications in two weeks. On 09Apr2021, the patient fainted within 2 minutes if receiving vaccine. The patient had memory lapse upon waking up. Her breathing was slow. The patient was extremely nauseous, hot, sweaty. The patient was unable to sit up due to nausea for 1 hour. The following 2 days, the patient experienced nausea and diarrhea. Arm pain lasted for 7 days including tingling/numbing sensation down her entire arm on the 4th day (13Apr2021). At time of vaccine (09Apr2021 at 10:30 AM), she could feel the liquid squirting into her arm which was unusual. The patient reported that she gets lots of vaccines for traveling and have never had these reactions or sensations. The patient has not been tested for COVID post vaccination. The events resulted in doctor or other healthcare professional office/clinic visit. Therapeutic measures (unspecified) were taken as a result of the events. The outcome of the events was unknown. No follow-up attempts are possible. No further information is expected. |
| 1278206 | 5/1/2021 | NY | 17 | F | 5/1/2021 | 5/1/2021 | ~~Approximately 2 minutes after vaccination the 17 year old female had a "tonic seizure". Became unresponsive for about 2 minutes. Mother reports daughter has a history of fainting/seizure after blood draws ("she's afraid of needles")" Patient left with family ambulating. |

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1277655 | 5/1/2021 | NY | 16 | M | 5/1/2021 | 5/1/2021 | After waiting in the waiting area for about 10 minutes the PT said he felt light headed and passed out falling to the floor. Mom was at his side and stated that he went to 'dead weight' and then she lowered him to the floor as best as she could. Mom said that she started 'shaking' and then stopped after about 15 seconds. After PT was stood up he felt like he was going to vomit but he did not. PT was extremely diaphoretic. |
| 1277726 | 5/1/2021 | MA | 16 | M | 5/1/2021 | 5/1/2021 | SYNCOPE WHILE UNDER SUPERVISION |
| 1277758 | 5/1/2021 | | 17 | F | 5/1/2021 | 5/1/2021 | Immediately after administration of vaccine, patient fainted. Patient assisted in to wheelchair and wheeled to private observation area. Patient assisted to gurney. Patient has cool compress to forehead. Patient also nauseous, pale, and sweaty. Patient mother reports patient did not eat today. Given water and apple juice. Patient declined granola bar. Vital signs as follows: 0950-BP 88/59, P 86, RR 20, 95% RA, no pain. 0955-BP 92/60, P 69, 99% RA. 1000-BP 96/67, P 75, 100% RA. Education given to patient and mother regarding eating/drinking before next dose and to tell the vaccinator that patient passed out at last vaccine and to lay on gurney before second dose is given. Patient and mother acknowledged understanding. Patient back to baseline at 1010. |
| 1277870 | 5/1/2021 | MA | 28 | M | 5/1/2021 | 5/1/2021 | Patient disclosed that he has passed out before from vaccination. He sat on the floor after vaccinated and even told me just before he fainted that he was going to pass out. He was out for maybe 15 seconds. No injuries. Monitored his blood pressure for approximately 15 minutes. Patient reported he was fine but had him wait another 15 minutes before leaving. |
| 1277947 | 5/1/2021 | VA | 55 | F | 5/1/2021 | 5/1/2021 | fainted after 5 minutes of sitting in chair for 15 minute wait |
| 1277999 | 5/1/2021 | PA | 38 | F | 5/1/2021 | 5/1/2021 | fainted, sweating- hx: fainting at site of needles per mom |

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| 1278157 | 5/1/2021 | VA | 16 | M | 5/1/2021 | 5/1/2021 | Vasovagal with syncope after receiving vaccine and still with vaccinator and father. Regained consciousness after "a few seconds" per vaccinator. Transferred to EMS observation area for evaluation. Placed supine with feet elevated. 1522-BP 108/59; P 74. Pale color to face. Alert and oriented, departed EMS observation after approximately 20 minutes. Able to ambulate without difficulty and departed vaccine clinic accompanied by father. |
| 1278076 | 5/1/2021 | TX | 16 | F | 4/27/2021 | 4/27/2021 | Patient received second dose of Pfizer vaccine and was waiting in the observation area when she fainted and was held to chair by Security Guard and mother. Patient reports that she had not eaten and that she has a history of fainting with other injections/blood draws. Patient was given orange juice and a snack and reported feeling better. RN remained with patient in observation until patient and mother left. |
| 1277747 | 5/1/2021 | MA | 16 | F | 4/29/2021 | 5/1/2021 | Fainted 48 hours after shot, sweats, slumped over. Luckily I was there to catch her. Complete loss of color. Came on very suddenly. Could have been catastrophic if she was driving. |
| 1278050 | 5/1/2021 | VA | 24 | M | 5/1/2021 | 5/1/2021 | After patient got vaccine a few minutes later he fainted while sitting in chair and fell to the floor. He came back quickly. He stated he started to feel hot before he fainted. He said he was now cold. Pt also said he was nauseated and felt clammy. WE eventually moved him to vaccination area to take blood pressure. While taking Blood pressure, he fainted again and was having seizure like symptoms(flailing arms, fit kicking and his head falling back) 911 was called.He came back quickly. He was monitored at scene by EMT. His blood glucose was 115 and initially they were only able to get systolic of 75. They removed him from pharmacy on stretcher and monitored him outside. His blood pressure was fine and they released him. He came back to the pharmacy and was fine |

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| 1277950 | 5/1/2021 | IL | 31 | M | 4/30/2021 | 4/30/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Shakiness-Medium, Additional Details: Vitals : BP 130/87 HR 69 BS 103. EMT arrived to evaluate pt. Pt refused hospital care. Pharmacy had pt wait 30 minutes before leaving. EMT confirmed pt ok to stand, walk, drive, and state date/location/president. |
| 1277971 | 5/1/2021 | NC | 57 | F | 5/1/2021 | 5/1/2021 | within 2 minutes having the J and J covid vaccine, patient became pale, clammy and almost fainted. She was non verbally communicative to her spouse and I, she was "zoned out and incoherent" . Paramedics were called, but after 10 minutes she became sick, vomited and then color came back and then she was fine. Patients says she doesn't remember even getting the shot. |
| 1277961 | 5/1/2021 | NY | 32 | M | 5/1/2021 | 5/1/2021 | Site: Redness at Injection Site-Mild, Site: Swelling at Injection Site-Mild, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium |
| 1277958 | 5/1/2021 | MA | 31 | M | 5/1/2021 | 5/1/2021 | Site: Pain at Injection Site-Mild, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting/ responsive-Medium, Additional Details: Pt fainted due to vaccine. Was responsive 1 minute after fainting. Woke up and stayed prone on ground until EMS arrival. |
| 1277953 | 5/1/2021 | CA | 18 | F | 5/1/2021 | 5/1/2021 | PATIENT RECEIVED THE VACCINE AND ABOUT 2 MINUTES LATER SHE IS FAINTED AND LOST CONSCIOUS. THE MOTHER HAS TO HELP HER TO SIT UP. SHE REGAINED CONSCIOUSNESS QUICKLY. WE CALLED 911 ANYWAY. THEY CHECKED HER AND EVERYTHING IS OK. THIS IS PROBABLY A CASE SYNCOPE. |
| 1273058 | 4/30/2021 | ME | 24 | M | 4/29/2021 | 4/29/2021 | Systemic: Fainting / Unresponsive-Medium, Additional Details: Pateint fainted within 5 minutes of receiving the vaccine. 911 was called and responded but he had quickly come to. He felt better within 10 minutes but the paramedics examined him anyway. He left of his own accord. |

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| 1272634 | 4/30/2021 | CA | 91 | F | 2/14/2021 | 2/15/2021 | 91 year old female was sitting across the table from her husband while eating lunch when she passed out. She had slurred speech. 911 was called. She was taken to the ER and was diagnose with acute stroke. Her symptoms subsided on presentation to the ER. She was started on Plavix. Had negagive carotid duplex. MRI brain showed suspected subtle nonhemorrhagic punctuate left frontal lobe, Cortical 2-3mm acute - subacute vascular insult vs image artifact. |
| 1273859 | 4/30/2021 | MA | 17 | F | 4/28/2021 | 4/29/2021 | Fainted- Started feeling sick and other common side effects after 7 hours continuing throughout the next day, and passed out at 8pm about 30 hours after the shot. And continuing to feel common side effects throughout night 2 and next day (aprox. 48 hours after shot) |
| 1273336 | 4/30/2021 | MD | 50 | F | 4/2/2021 | 4/2/2021 | Extreme dizziness, fainted, face hit wooden floor, broke and fractured several teeth, soft tissue injuries on my chin, cheek and nose |
| 1273999 | 4/30/2021 | WA | 37 | F | 4/8/2021 | 4/8/2021 | nauseated, sweating, passed out while driving, sharp pain in abdomen |
| 1273306 | 4/30/2021 | NY | 21 | M | 4/30/2021 | 4/30/2021 | Patient starting feeling very sweaty, nauseous, light headed, dizzy almost immediately after sitting in the post vaccination chair. I had already instructed him to sit on the floor if he started feeling faint as he stated previous fainting episodes as a kid. He sat on the floor, then laid on the floor. I brought him a garbage can in case he got sick, an ice pack, wet paper towels, and a bottle of water. After 5 minutes or so the color came back to his face and he started feeling much better. He then sat back in the chair, then stood up and stated he was feeling back to normal. I asked him to stay standing an extra minute just to make sure he was good, then he left with the woman who was with him during the vaccine. |
| 1273117 | 4/30/2021 | WA | 44 | M | 4/29/2021 | 4/29/2021 | Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Mild, Systemic: Nausea-Medium, Systemic: Vomiting-Severe |

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| 1273084 | 4/30/2021 | WA | 47 | F | 4/29/2021 | 4/29/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient has history of fainting with all vaccines. Once receiving vaccine, passed out for 10 seconds and regained consciousness. Vitals were monitored, patient was fine and left after 30mins |
| 1273076 | 4/30/2021 | MO | 27 | M | 4/29/2021 | 4/29/2021 | Site: Pain at Injection Site-Mild, Systemic: Fainting / Unresponsive-Medium, Systemic: Hypotension-Medium, Additional Details: this patient has had similar events with all vaccines administered in the past. he has even had a similar event at work recently due to a cut on his hand. |
| 1273065 | 4/30/2021 | WA | 43 | F | 4/29/2021 | 4/29/2021 | Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Mild, Systemic: Weakness-Mild |
| 1273461 | 4/30/2021 | MD | 20 | F | 4/17/2021 | 4/18/2021 | Patient became very dizzy and fainted. |
| 1273049 | 4/30/2021 | OR | 55 | M | 4/29/2021 | 4/29/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Additional Details: Approximately 10-12mins after the J&J shot was administered, the patient got our attention to let us know he wasn't feeling well and might faint. I quickly tended to him as he slowly passed out. I craddled his head to make sure he did not hit it on the countertop. Pateint was seated. After approximately 30 second the patient started to come to. We gave him some water, took his bp, had him wait 30mins and took his bp again before he left with his wife. |
| 1273044 | 4/30/2021 | FL | 44 | F | 4/29/2021 | 4/29/2021 | Systemic: Fainting / Unresponsive-Severe |
| 1273036 | 4/30/2021 | PA | 37 | M | 4/29/2021 | 4/29/2021 | Systemic: Chills-Mild, Systemic: Confusion-Mild, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Mild, Systemic: Hypotension-Severe, Additional Details: Pt experienced syncope and had a blood pressure reading of 70/40 and a pulse of 44. EMT was called and pt resolved to blood pressure of 105/65 and a pulse of 55. Pt was chose not to go to hospital after filing consent with EMT, he was then pickd up by a coworker and will return for his car later. Pt noted to have a history of low BP in the past but has not see a MD recently and was advised to follow up with new pcp. |

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| 1273010 | 4/30/2021 | MI | 18 | M | 4/29/2021 | 4/29/2021 | Patient felt light headed and dizzy and passed out briefly following administration of vaccine. Patient had history of passing out during vaccination and blood draws. Patient felt sweaty and turned white. His color returned after a minute, I talked to his mother who was there during the incident. Did not eat or drink the morning of vaccine. I checked his pulse and blood pressure and it was 129/72 and pulse of 78. We gave him some water and orange juice. He felt much better. Then his mom bought him some muffins. He sat and ate for about 30 minutes and left feeling back to normal. |
| 1273004 | 4/30/2021 | MI | 43 | M | 4/29/2021 | 4/29/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Hypertension-Severe, Systemic: Hyperventilation-Medium, Systemic: Tachycardia-Severe, Additional Details: Patient was unconscious for few seconds after the shot administration. he then became conscious but was dizzy, weak, pale. He was given water and sat down for few minutes. we called 911 and he continued to feel weak and dizzy. EMS said he had high blood pressure, high heart rate , they thought he possibly was in cardiac arrest. Patient was taken to the hospital via ambulance |
| 1272979 | 4/30/2021 | MA | 16 | M | 4/29/2021 | 4/29/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Mild, Systemic: Hypotension-Severe, Additional Details: Patient passed out and lost consciousness. EMS called. Patient was breathing. O2Sat >95%. EMS arrived after patient regained consciousness. Patient refused transport to hospital. |
| 1272944 | 4/30/2021 | CA | 16 | M | 4/26/2021 | 4/26/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Additional Details: pt fainted after injection but was fine after laying down for roughly 15 min. gave h2o and waited 30 min before ok to drive home. consulted parents... will drive son to next appt. |
| 1272910 | 4/30/2021 | TX | 16 | F | 4/29/2021 | 4/29/2021 | Systemic: Allergic: Difficulty Breathing-Mild, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium |

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| 1272628 | 4/30/2021 | WA | 54 | F | 4/21/2021 | 4/21/2021 | Became slightly dizzy within ten minutes of vaccination. Increasing dizziness became severe. Passed out completely while sitting down. Woke up with an IV in my arm. Medic said my blood pressure had dropped dangerously low. Was loaded onto stretcher and transported by ambulance to the hospital ER. Blood pressure and pulse monitored. Received EKG, blood, and urine tests. No reported abnormalities. Discharged after three hours. Formal diagnosis was Syncope, a fainting episode. |
| 1272626 | 4/30/2021 | FL | 25 | F | 4/6/2021 | 4/6/2021 | Passed out as soon as the vaccine given. I had nausea dizziness and blurry vision that lasted for 15 minutes |
| 1274025 | 4/30/2021 | PA | 19 | F | 4/30/2021 | 4/30/2021 | Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Shakiness-Mild, Systemic: Tingling (specify: facial area, extremities)-Mild, Systemic: Tinnitus-Mild, Systemic: Visual Changes/Disturbances-Mild, Systemic: Weakness-Mild, Additional Details: 5 minutes after vaccine pt felt lightheaded and blurred vision. then passed out. patient advised to sit down then passed out again and started to shake head (seizure like symptoms) for a few seconds. patient was pale, confused and started sweating, fingers were cold to touch. Then her fingers started to get numb and tingly. she was having a hard time seeing colors and she started having ringing in ears. Ambulance was called and they took over. |
| 1274452 | 4/30/2021 | TX | 35 | M | 4/8/2021 | 4/8/2021 | PATIENT RECEIVED DOSE IN ARM AND QUICKLY BECAME LIGHTHEADED, ASKED FOR WATER, THEN PASSED OUT. PATIENT FELL ONTO FLOOR, AT WHICH POINT TECHNICIAN ADMINISTERING THE VACCINE CHECKED PATIENT FOR PULSE/BREATHING - NOTED PT WAS OK, AND CALLED FOR PHARMACIST FOR HELP. PT AWAKE BUT CONFUSED ON FLOOR WHEN PHARMACIST ARRIVED, SLOWLY REGAINED AWARENESS AFTER LEGS PROPPED UP. HE DECIDED TO GET UP ONTO A CHAIR AND DRINK SOME WATER, PHARMACIST SAT WITH PATIENT UNTIL HE WAS FINE TO WALK TO WAITING AREA OUTSIDE OF PHARMACY. HE WAS OBSERVED FOR 25 MORE MINUTES (TOTAL 30) AND FELT FINE TO LEAVE ON HIS OWN ACCORD |

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| 1272941 | 4/30/2021 | CA | 16 | F | 4/26/2021 | 4/26/2021 | Site: Pain at Injection Site-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: shakes-Mild, Systemic: Shakiness-Mild, Additional Details: pt fainted and had shakes/ convulsions for a few seconds. after 30 seconds pt awake and stated ok , after 30 min pt stated ok after 30 min observation. mom n dad brought to hospital dad called and said pt was ok . no unusual findings |
| 1275224 | 4/30/2021 | VA | 29 | M | 4/30/2021 | 4/30/2021 | Patient passed out during 15 minute wait time and began to have a seizure after receiving the J&J vaccine. Seizure last about 5-10 seconds. Pt was turned to his side and remained in the same position until EMS arrived. He was conscious after the seizure and was responding and speaking full sentences. EMS was on the line until they arrived in person. Medical EMS personnel were called and responded. They advised pt had a history of seizures. Pt refused to go to the hospital with EMS. EMS cleared pt to continue regular activities. Event time approximately 3:00-3:20pm. |
| 1274352 | 4/30/2021 | CA | 17 | F | 4/28/2021 | 4/28/2021 | Headache (4/10). Fear of needles, with history of fainting. O2 sat 100%. BP 91/74 (pulse 63). |
| 1274034 | 4/30/2021 | NJ | 61 | F | 1/14/2021 | 1/21/2021 | After my vaccine, I passed out. I went to the hospital for three days and they told me I had an ocular migraine. I also had a post concussion syndrome and was out of work till 04-12-2021 with nausea and severe migraine headaches. I still have headaches today and I am on migraine medication. |
| 1275533 | 4/30/2021 | MO | 16 | F | 4/30/2021 | 4/30/2021 | Patient started seeing stars, fell up against silver anti-theft gates by front doors, then passed out. Did not hit head, and was awake and alert by the time I reached her. |
| 1275502 | 4/30/2021 | PA | 28 | F | 4/7/2021 | 4/7/2021 | Hours after receiving the vaccine, I became dizzy, and nearly fainted several times. This was resolved once j was able to lay down and elevated my legs. I had no adverse effects in the first 15 minutes after the vaccine, the fainting spells were several hours after I was vaccinated. |
| 1275265 | 4/30/2021 | AZ | 20 | F | 4/30/2021 | 4/30/2021 | Patient fainted less than 30 seconds after administration. |
| 1275253 | 4/30/2021 | | 18 | F | 4/29/2021 | 4/29/2021 | Fainted, soon after it was administered |

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| 1275048 | 4/30/2021 | TX | 75 | M | 3/8/2021 | 3/17/2021 | Patient was a healthy 75 year old male when he got the shot. Within 5 hours, he began to feel TIRED, which was an expected side effect. He felt tired for several days. Nine days later he went to Memorial Hermann ER in Kingwood, and they said he had pneumonia. They also said he had a "small mass" at the bottom of his lung and might want to get it checked out. On March 20, he developed a cough. On March 21 we went to a different ER and a CT scan showed he had plureal effusion. On the next day he was short winded. He went back to the ER and they admitted him and transferred him to hospital by ambulance. On March 23, 1.7 liters of fluid was drained from his lung and sent to be tested. On March 26 he was diagnosed with malignant plureal effusion. He passed out at the doctor office and tranferred to to another facility by ambulance. He remained there for 4 days for tests, and a port was put in to drain the fluid. On March 29 he was transferred . They repeated many tests and did a bronchoscopy. On April 1 they told him he had squamous cell carcinoma. He came home on April 2. The doctor called and said they made a mistake he had small cell carcinoma. He remained home until April 11, when he was taken back to by ambulance. He had gone from a healthy appearing individual on March 17 to a critically ill individual and he died on April 15. Doctors had never seen cancer overtake a man in 28 days. On March 22, he had a small mass at the bottom of his lung, and one week later, it was a mass so large, his lung could not be seen and his lung had collapsed. Doctors assumed that the cancer was dormant and that the vaccine did something to wake it. It attacked my husband with a vengeance. He never smoked. |
| 1274974 | 4/30/2021 | WA | 24 | F | 4/30/2021 | 4/30/2021 | History of fainting, showed signs of fainting, then had multiple seizures, LOC, incontinence, hypotensive, normal HR. Taken by ambulance to hospital. Unknown results or whether admitted patient was admitted. |
| 1274821 | 4/30/2021 | NY | 42 | F | 4/30/2021 | 4/30/2021 | POST VACCINATION PT C/O DIZZINESS HAD A SYNCOPE EPISODE , UNRESPONSIVE. PT REPORTED NUMBNESS TO BILATERAL ARMS AND LIPS, POSITIVE GRASP BILATERALLY. PT, ABLE TO RAISE RIGHT ARM , UNABLE TO RAISE LEFT AR. COOL TO TOUCH. |

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| 1274801 | 4/30/2021 | VT | 33 | M | 4/29/2021 | 4/29/2021 | Patient received vaccine at 545pm. Administration noted as normal per pharmacist (rph), pt walked to waiting area chair. Approximately 7 minutes later pt asked for water. Pharmacist brought water to pt and asked if he was feeling okay. Pt stated he was having trouble hearing the rph. Rph walked back to pharmacy and continued to observe patient. approx 2 min later, pt passed out from seated position. rph did not see fall. both technician and rph ran out to pt. pt face down and water bottle spilled. assistant store manager reported as well. pt came to immediately and sat up on floor. He attempted to stand to sit in chair, but rph asked him to remain on floor. rph went to get emergency kit while tech observed patient. rph came back with instant ice pack. First pack did not activate but second pack did and had patient hold to his head as there was a visible red spot. Patient continued to be observed and was texting on phone during observation. Patient came up to pharmacist at 6:15 to ask to leave and Rph asked if pharmacy representative to could walk him to his car. Patient denied and Rph asked him to wait additional 5 minutes for observation. After 5 minutes, patient left. Today I called patient. He said he is feeling better and still has mild pain and a headache today. |
| 1274799 | 4/30/2021 | CA | 16 | F | 4/30/2021 | 4/30/2021 | Patient fainted post-vaccination. Observed patient beginning to lean forward and RN was able to prevent her from falling. Patient's eyes observed to roll upward while patient became unresponsive to stimuli and diaphoretic. No incontinence. EMS called while patient assisted simultaneously to gurney by multiple staff. Upon lying down, patient awoke and become alert and oriented to person, place, time, and situation, though stayed pale and diaphoretic for several minutes. VS @ 12:55: BP 120/80, P 59, SAO2 99%, resp unlabored. VS @ 13:00: BP 138/83, P 62, R 20, SAO2 99% VS @ 13:04: BP 123/73, P 54, SAO2 99% VS @ 13:10: BP 100/69, P 78, SAO2 98% Sitting at edge of bed without symptoms at 13:05, alert and conversing with staff and mother. EMS arrived at 13:07 - their monitor showed NSR, random blood sugar = 93. Ate a snack and drank juice, symptoms completely resolved. Mother declined transport to ED. Discharged home with mother with post-vaccination instructions, will receive 2nd dose while lying down. |

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| 1274385 | 4/30/2021 | CA | 61 | F | 3/27/2021 | 3/31/2021 | <p>~~Moderna COVID-19 Vaccine EUA" -- received 1st dose 3/27/2021 Received 1st Moderna vaccine in R arm on 3/27/21. Within first hour, she had a headache, R eye pain, and felt tired; symptoms subsided after she laid down. On 3/31 in early AM, felt sudden and more severe headache and same eye pain, and "electrical contractions down neck, back, and spine." Went to medical facility, then transferred to hospital, and transferred to another hospital via helicopter. 61-year-old female, generally very healthy, on no medications, here complaining of sudden onset right sided stabbing/electrical headache which began 30 minutes prior to arrival. She states she was standing at work when had sudden onset severe headache radiating into her right eye. Stating that it feels like my right eyeball is going to explode. She ranks the pain a 9 out of 10. She does have a history of migraine headaches which have never been evaluated with imaging or by neurology. They were normally frontal, and she has not had one in more than 2 years. She states that this headache is dramatically different than her prior migraines. Patient states associated with this sudden onset headache, she had bilateral neck pain, and substernal chest pain. Upon arrival to clinic, she points to her substernal region as the site of her chest pain. She denies associated shortness of breath, irregular heart rate/rhythm, presyncope. She does feel slightly weak. Of note, patient states she had a MODERNA COVID-19 vaccine on Saturday and subsequently had some right-sided shoulder pain. Her symptoms are on the same side. - 7:50 AM: BP 165/109 (R arm); pulse 86; no antihypertensives given, given a total of 100 mcg fentanyl over 1 hr - 9:04 AM: BP 150/92 (R arm); pulse 60; transferred to hospital and then transferred to another hospital via helicopter for SAH 3/31/2021 ED - given nicardipine IV, dexamethasone IV, levetiracetam, and antiemetics. Nero noted that no associated trauma, LOC, or seizure with the HA, Neuro assessment - day 4 (plus possible re-rupture within last 24 hours) of good clinical grade HH2 low volume aSAH due to ruptured R ICA ANR 4/1/2021 - completed successful and uncomplicated RICA oblong aneurysm coiling (successful coil elimination & preservation adjacent PcommA infundibulum). Patient was admitted to critical care for post procedure care, monitoring, and management of sodium, blood pressure, and headache.</p> |

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Levetiracetam discontinued since patient did not have any seizures. 4/7/2021 - discharged

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| 1274185 | 4/30/2021 | OR | 58 | F | 4/27/2021 | 4/29/2021 | <p>This was a 58 year old female who received her 1st dose Pfizer on 4/6/21 (Lot# EW0175) and 2nd dose Pfizer on 4/27/21 (Lot# EW0151). Of note, the patient was in a motor vehicle accident on 4/12/21 with a diagnosis of concussion and cervical/thoracic strain/sprain (see history under patient information). On 4/29/21, the patient's sister contacted the patient's primary care clinic with the following documented concern: "Pt's sister calling to report that two days ago pt got 2nd dose Pfizer vaccine and has been sick. This morning they found her passed out against the her bedroom door. Pt reports that she can't remember much other than going to the bathroom. Pt's sister states that patient totaled her car a week ago, and that it was determined she had a concussion. "She hasn't been herself since the wreck and I am very concerned." This caller recommended the Ed or UC but caller denied stating that either needs to see her today. This writer is reaching out to nurse to see if they can advise from here." A RN assessed the patient virtually with the following documentation: "RN note: Call transferred from patient's sister. Pt noted to be found on her floor this morning. Pt unsure if she hit her head. Spoke to patient. She reports body aches, and feeling weak. Pt is slow to answer questions, and had a lot of difficulty hearing me (sister did not have any difficulty hearing me). Pt is noted to have more rapid breathing, and some slight wheezing. Speech is clear when she is speaking. Sister gave patient water to drink. She drank out of bottle and was able to hold on her own (though had difficulty with this at first). Sister noted some water dripping down face, but was able to swallow okay. Sister also noted that patient's lips seem to be pursed. Plan: Given recent concussion, and patients change in behavior per sister (pt more irritable, speaking more slowly, moving slowly, breathing faster, and wheezing), recommended patient be taken to the ED today--recommended ambulance since it took 2 men to help patient back to bed this morning. Sister states patient is not agreeable to going to ED at this time. Advised to try to encourage her to drink more fluids, and continue to monitor her sx's, and if any worsening, to call for ambulance transport. Sister agreeable to plan, and will discuss with sister, and recommend ED visit today." On 4/30/21, the patient's sister contacted the clinic to inform them that the patient was found dead that</p> |

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| | | | | | | | morning. The medical examiner is completing the further investigation. If additional information is needed from the primary care physician for this patient. |
| 1275255 | 4/30/2021 | TX | 25 | M | 4/11/2021 | 4/11/2021 | Fainted following |
| 1274798 | 4/30/2021 | FL | 25 | M | 4/30/2021 | 4/30/2021 | PT appear to have a Focal Seizure and syncope ensue. PT hit his head but no abrasion. Pt awake and alert. Reported feeling tightness in chest and anxious before passing out. Rescue Team contacted ; PT refuse transfer. Vitals in all normal range; BP:120/70 HR:98 Spo2: 97-98. Pt monitor longer in observation by Nurse and Rescue Team REFUSE Transport vitals taken before leaving site. Vitals before leaving site: BP:122/77 HR:90 Spo2 97-99.Pt was able to be ambulatory and leave site |
| 1274294 | 4/30/2021 | NC | 22 | M | 4/30/2021 | 4/30/2021 | Patient fainted within 5 minutes after receiving the Janssen vaccine. He then appeared to be experiencing a seizure lasting no more than a minute. No history of fainting or seizure. EMS was called and arrived within about 10 minutes, and patient appeared to experience another seizure and he vomited. EMS then transported the patient to the hospital. |
| 1274268 | 4/30/2021 | SC | 58 | F | 4/30/2021 | 4/30/2021 | Patient fainted. Taken by EMS while conscious |
| 1274486 | 4/30/2021 | CA | 16 | M | 4/30/2021 | 4/30/2021 | Patient fainted and proceeded to feel nauseous. Patient was in chair when the mother asked for help and the patients head was slumped over. Patient was put in cot and counties to feel headache and dizzy. |
| 1274503 | 4/30/2021 | | 17 | M | 4/30/2021 | 4/30/2021 | PT 7 MINS POST VACCINE BECAME DIAPHORETIC, A/Ox0, UNRESPONSIVE TO VERBAL STIMULI, EPISODE OF SYNCOPE LASTING LESS THAN 1 MINUTE. PT LAID ON FLOOR AND STERNAL RUB PERFORMED. PT RESPONSIVE TO PAINFUL STIMULI. V/S W/IN NORMAL LIMITS WITH SPO2 PRESENTING AT 93% BUT RESOLVED ONCE PT BECAME A/Ox3. PT GIVEN WATER TO SIP ON AND DISCHARGED IN NAD. |
| 1274681 | 4/30/2021 | IL | 23 | F | 4/30/2021 | 4/30/2021 | Fainted and fell onto ground 5 min after receiving vaccine. 911 was called, I turned down the ambulance and had family take me to the hospital. |

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| 1274762 | 4/30/2021 | MN | 42 | F | 4/29/2021 | 4/29/2021 | Fainted approximately 2 minutes after injection. Woke up approximately 1 minute later and immediately vomited. |
| 1274790 | 4/30/2021 | ME | 47 | M | 4/30/2021 | 4/30/2021 | Within 5 minutes, patient was sweating, flushed, and stated that he was about to faint. Patient fainted and was unable to respond to verbal or motor commands. Patient had rapid, shallow breathing. Patient's hands/arms were twitching very slightly. Patient was moved onto the floor and rolled onto his side after he started to gag like he would vomit. Once on the floor, patient regained consciousness within 1-2 minutes and was able to sit up after another 5 minutes. Paramedics arrived and examined him. He left under his own power. |
| 1274281 | 4/30/2021 | PA | 17 | F | 4/30/2021 | 4/30/2021 | Near syncopal episode, revived with smelling salt. Water and snacks offered. Patient has history of fainting with needles. After laying down for several minutes she was able to sit up to eat and drink. Patient able to walk out, father at her side for assistance. |
| 1269744 | 4/29/2021 | MI | 33 | F | 4/13/2021 | 4/13/2021 | Fainting; Swelling of arm; no taste; headache; This is a spontaneous report from a contactable consumer (patient). A 33-year-old female patient received the first dose of BNT162B2 (Pfizer-BioNTech COVID-19 vaccine, lot number and expiry date not reported), via an unspecified route of administration, administered in the left arm on 13Apr2021 at 13:30 as a single dose for COVID-19 immunization. Medical history included narcolepsy from an unknown date and unknown if ongoing. The patient did not have COVID prior to the vaccination. The patient's concomitant medications were not reported. The patient previously took Cymbalta and experienced allergies. The patient was not tested for COVID post vaccination. On 13Apr2021 at 05:30 PM, the patient experienced fainting, swelling of arm, no taste and headache. The patient did not receive treatment for the events. The outcome of the events was not recovered. Information on the lot/batch number has been requested. |

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| 1269735 | 4/29/2021 | TX | 43 | F | 4/15/2021 | 4/16/2021 | Fainted; fell down to the ground after using restroom; I was cold; sweating; slowed heartbeat and pulse; extreme nausea; This is a spontaneous report from a contactable consumer (patient). A 43-year-old female patient received bnt162b2 (Pfizer-BioNTech COVID-19 Vaccine), dose 1 via an unspecified route of administration, administered in Arm Right on 15Apr2021 14:00 (Batch/Lot number was not reported), at the age of 43 years, as single dose for covid-19 immunization. Medical history included fibromyalgia and t5 back fracture. The patient is not pregnant. Concomitant medications included pregabalin (LYRICA); buspirone and cannabidiol (CBD OIL). On 16Apr2021 at 2 AM, the patient fainted 12 hours later and fell down to the ground after using restroom. She was cold, sweating, slowed heartbeat and pulse, extreme nausea. The patient did not receive treatment for the events. The patient had No COVID-19 prior to vaccination and had not been COVID-19 tested post vaccination. The outcome of the events fainted, fell down to the ground after using restroom, she was cold, sweating, slowed heartbeat and pulse, extreme nausea was unknown. Information about lot/batch number has been requested. |

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| 1269802 | 4/29/2021 | HI | 33 | F | 4/26/2021 | 4/26/2021 | 33 year old female with no significant past medical history presents to the ED with syncope s/p receiving first COVID-19 vaccination this evening at 1758. The patient states that she completed her 15 minutes of observation when she suddenly felt dizziness after standing and had a syncopal episode, waking up on the ground. Per the nurse at the scene, the patient hit the back of her head. The patient does not remember hitting the back of her head as she lost consciousness prior to falling. Since then, the patient has been experiencing symptoms of generalized weakness and intermittent nausea, but denies symptoms of headache, visual changes, vomiting, neck pain, back pain, shortness of breath, chest pain, or abdominal pain. The patient has had normal PO intake today. She reports that she has had three separate syncopal episodes s/p getting her blood drawn in the past, but denies syncopal episode s/p receiving vaccinations in the past. The patient is an otherwise healthy individual with no known drug allergies, taking no daily medications, and denies the use of alcohol, tobacco, or drugs. Her last normal menstrual period was completed recently and she denies any chance of pregnancy, recent pregnancies, or currently nursing. |
| 1269787 | 4/29/2021 | CA | 36 | F | 4/28/2021 | 4/28/2021 | Patient fainted and was unconscious for about 10-20 seconds. Patient also felt nauseous and vomited. Paramedics were called and patient was examined. No further treatment needed. |
| 1269789 | 4/29/2021 | CA | 16 | F | 4/27/2021 | 4/27/2021 | Patient fainted and unconscious less than 10 seconds. Patient flushed and admitted she had not eaten since the am. No further treatment required. |
| 1269795 | 4/29/2021 | CA | 17 | F | 4/28/2021 | 4/28/2021 | Patient fainted |

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| 1269828 | 4/29/2021 | CA | 26 | M | 4/28/2021 | 4/28/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Additional Details: PATIENT FAINTED WITHIN FEW MINUTES OF RECEICING THE VACCINE WHILE IN THE OBSERVATION AREA. I GRABBED THE PATIENT BEFORE HE FAINTED AND LAYED HIM ON THE FLOOR. HAD THE PATIENT SIT FOR ADDITIONAL 15 MINUTES FOR OBSERVATION, A TOTAL OF 35 MIN. HE FELT FINE AND LEFT THE STORE ON HIS OWN. PATIENT DID ADVISE THAT HE HAS A HISTORY OF FAINTING WHEN GIVING BLOOD. |

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| 1270006 | 4/29/2021 | MD | | M | 4/1/2021 | 4/1/2021 | <p>passed out at vaccination facility.was taken by ambulance to the ER; started to feel strange and tried to flag someone after 10 minutes of first dose; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of LOSS OF CONSCIOUSNESS (passed out at vaccination facility.was taken by ambulance to the ER) in a 59-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 019B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No medical history was reported by the reporter. On 01-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 01-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (passed out at vaccination facility.was taken by ambulance to the ER) (seriousness criterion medically significant) and FEELING ABNORMAL (started to feel strange and tried to flag someone after 10 minutes of first dose). At the time of the report, LOSS OF CONSCIOUSNESS (passed out at vaccination facility.was taken by ambulance to the ER) and FEELING ABNORMAL (started to feel strange and tried to flag someone after 10 minutes of first dose) had resolved. Not Provided DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Computerised tomogram: normal. On an unknown date, Electrocardiogram: normal. On an unknown date, Laboratory test: normal. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. The patient was taken to ER after the patient passed out. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. This case was linked to US-MODERNATX, INC.-MOD-2021-089511 (E2B Linked Report).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. US-MODERNATX, INC.-MOD-2021-089511:Case for patient</p> |

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| 1270010 | 4/29/2021 | SC | 38 | F | 4/6/2021 | 4/6/2021 | was in neuro ICU for 2 days where she had oxygen issues; passed out while driving her car and hit a car in front of her; passed out while driving her car and hit a car in front of her; her body felt like it was vibrating on the inside, nausea, achy pains and tired; her body felt like it was vibrating on the inside, nausea, achy pains and tired; her body felt like it was vibrating on the inside, nausea, achy pains and tired; her body felt like it was vibrating on the inside, nausea, achy pains and tired; her body felt like it was vibrating on the inside, nausea, achy pains and tired; This spontaneous case was reported by a consumer and describes the occurrence of OXYGEN SATURATION ABNORMAL (was in neuro ICU for 2 days where she had oxygen issues) and LOSS OF CONSCIOUSNESS (passed out while driving her car and hit a car in front of her) in a 38-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Brain damage (due to coming off drugs cold turkey) and Drug abuse. Concomitant products included ETHINYLESTRADIOL, LEVONORGESTREL (TRIVORA) for an unknown indication. On 06-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 06-Apr-2021, the patient experienced OXYGEN SATURATION ABNORMAL (was in neuro ICU for 2 days where she had oxygen issues) (seriousness criterion hospitalization), LOSS OF CONSCIOUSNESS (passed out while driving her car and hit a car in front of her) (seriousness criterion medically significant), ROAD TRAFFIC ACCIDENT (passed out while driving her car and hit a car in front of her), CHILLS (her body felt like it was vibrating on the inside, nausea, achy pains and tired), NAUSEA (her body felt like it was vibrating on the inside, nausea, achy pains and tired), MYALGIA (her body felt like it was vibrating on the inside, nausea, achy pains and tired) and FATIGUE (her body felt like it was vibrating on the inside, nausea, achy pains and tired). At the time of the report, OXYGEN SATURATION ABNORMAL (was in neuro ICU for 2 days where she had oxygen issues), LOSS OF CONSCIOUSNESS (passed out while driving her car and hit a car in front of her), ROAD TRAFFIC ACCIDENT (passed out while driving her car and hit a car in front of her), CHILLS (her body felt like it was vibrating on the inside, nausea, achy pains |

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and tired), NAUSEA (her body felt like it was vibrating on the inside, nausea, achy pains and tired), MYALGIA (her body felt like it was vibrating on the inside, nausea, achy pains and tired) and FATIGUE (her body felt like it was vibrating on the inside, nausea, achy pains and tired) outcome was unknown. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Treatment information was not provided. The reporter wants to know, if the patient need to get the second dose as they were going on a cruise in August. Company comment: Based on the information provided which includes a temporal association between the use of mRNA-1273 vaccine and onset of the reported events, a causal relationship cannot be excluded. Myalgia, nausea , chills and fatigue are consistent with the product safety profile.; Sender's Comments: Based on the information provided which includes a temporal association between the use of mRNA-1273 vaccine and onset of the reported events, a causal relationship cannot be excluded. Myalgia, nausea , chills and fatigue are consistent with the product safety profile.

1270034 4/29/2021 AZ 18 M 4/28/2021 4/28/2021 Systemic: Fainting / Unresponsive-Mild

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| 1269727 | 4/29/2021 | | 17 | F | 4/14/2021 | 4/14/2021 | Passed out right after vaccine; muscle aches; tired; chills; migraine; This is a spontaneous report from a non-contactable consumer (patient). A 17-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in the left arm on 14Apr2021 at 14:15 (Batch/Lot number was not reported) as single dose for covid-19 immunization, administered at the Pharmacy or Drug store. The patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) on 17Mar2021 at 14:15 in the left arm for covid-19 immunisation. The patient's medical history was not reported. There were no concomitant medications. The patient was not pregnant at the time of report and vaccination. The patient did not receive other vaccines in four weeks. The patient had no COVID prior to vaccination and was not tested for COVID post vaccination. The patient passed out right after vaccine, also experienced muscle aches, tired, chills, and migraine; all on 14Apr2021 with outcome of unknown. No follow-up attempts are possible, information about batch number cannot be obtained. No further information is expected. |

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1271161 | 4/29/2021 | NY | 17 | F | 4/29/2021 | 4/29/2021 | Recipient is a 17yo who presented for second dose of COVID-19 vaccine. She reported some anxiety related to receiving dose #2, and had some nausea after dose #1. She was alone as a driver of her own POV. Consent was obtained from the recipient and her custodial grandparent by phone, witnessed by doctor. She initially did well after the vaccine, but after approximately 5 minutes began to complain of feeling nauseated, lightheaded, and tingling extremities (hands and feet). She was noted to be hyperventilating, and was placed in a supine position but continued to feel some lightheadedness and difficulty breathing. Breath sounds were clear without wheezing noted, HR 70s with RRR. She was noted to have ongoing anxiety, nausea and symptoms progressed and although she remained normotensive to hypertensive (initial BP 128/74), she had repeated episodes of syncope. She was transferred to the ambulance and further vitals and EKG were obtained. She had some confusion after episodes of syncope and some seizure-like activity with syncope, with very brief episodes of LOC, with noted tachycardia with HR up to the 140s during episodes of syncope. BP ranged 129/86 to 140/84. IV access obtained and she was given NS and started on oxygen at 2 liters, but saturations remained in the 98-99% range. She was ultimately transferred to the local ER for further evaluation and management given ongoing symptoms, evaluated at hospital. |
| 1270032 | 4/29/2021 | AZ | 18 | M | 4/28/2021 | 4/28/2021 | Systemic: Fainting / Unresponsive-Mild |

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| 1269716 | 4/29/2021 | TX | 34 | M | 4/15/2021 | 4/15/2021 | <p>pass out; I started feeling dizzy little bit; really feel very fatigue; I start breathing hard/barely can breathe; start seeing everything turned yellow; soaking sweating; But couldn't move; sharp pain in my stomach; This is a spontaneous report from a contactable consumer (patient). A 34-year-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot/batch number and expiration date not reported), via an unspecified route of administration, administered in Left arm on 15Apr2021 at 16:30 (at the age of 34-year-old) at single dose for COVID-19 immunisation. Medical history reported as no other medical history, no known allergies. Prior to vaccination, patient was not diagnosed with COVID-19. Concomitant medications reported as none. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. After 5 min from taking the shot on 15Apr2021 at 16:35, patient started feeling dizzy little bit. He thought walking around the aisle. But he still really felt very fatigue. He wanted back and a suit and started breathing hard. He started seeing everything turned yellow and barely could breathe. Then he passed out. The stuff came and help put an alcohol by his nose. He was soaking sweating. But couldn't move. The ambulance came to check his heart, blood sugar and blood oxygen on 15Apr2021, all with unknown results. Then patient started having sharp pain in his stomach. He had lunch on 15Apr2021 at one but he had spinach broccoli and beans. Patient was healthy. He worked out four times a week. After 30 minutes of receiving care. Patient felt better but he was worry for tonight on 15Apr2021. Events resulted in Doctor or other healthcare professional office/clinic visit. Since the vaccination, patient had not been tested for COVID-19. Therapeutic measures were taken as result of event passed out included put an alcohol by his nose, treatment for the other events was unknown. The outcome of the events was unknown. Information on the lot/batch number has been requested.</p> |

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| 1269714 | 4/29/2021 | MO | 22 | F | 4/10/2021 | 4/10/2021 | passed out; fainted; migraine; feel body aches; fatigue; felt incredibly ill; nauseous; hitting head; This is a spontaneous report from a contactable consumer (patient). A 22-year-old non-pregnant female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Lot Number: EW0153), via an unspecified route of administration, administered in Right Arm on 10Apr2021 11:30 (at age of 22 years old) at single dose for COVID-19 immunisation. Medical history included Seasonal allergies, asthma, Known allergies: peanuts (mildly). Concomitant drug was Yes. The patient previously took first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Lot Number: ER8727) on 20Mar2021 11:30AM (at 22 years old) at Left arm at single dose for COVID-19 immunisation. No other vaccine in four weeks. No COVID prior vaccination. No COVID tested post vaccination. A few hours after second dose, on 10Apr2021 02:00PM, patient developed a migraine and began to feel body aches and fatigue. The next morning, patient felt incredibly ill. Shortly after rising, patient became severely nauseous and fainted, hitting head; patient became conscious and passed out again before being taken to the ER (Emergency room). All AE resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care. Treatment (IV and anti-nausea med. administered) received for all events. The outcome of the events was Recovering. Information on the lot/batch number has been requested. |

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| 1269712 | 4/29/2021 | | | F | | | heart hurts; the feeling of fainting stopped; sore throat; trouble breathing; nasal congestion and felt very hot; nasal congestion and felt very hot; had chest pain/ heart hurts; seeing stars; This is a spontaneous report from a contactable consumer (patient's parent). A female patient of an unspecified age (age 27, unit: unknown) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot number was not reported) via an unspecified route of administration on an unspecified date at 5:30 pm at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. E-transmitting possible duplicate AE as caller stated they already reported AE to previous agent. Caller reporting on behalf of her daughter. The patient got the 1st dose at 5:30 pm, woke up with a jolt at 1:00 am with trouble breathing, a sore throat, nasal congestion and felt very hot. She took a COVID test since then which was negative. 5 days after that, this Monday 12Apr2021, she had trouble breathing again, that didn't get better, while in the shower. She had chest pain which she described as 'my heart hurts' when she got out of the shower started seeing stars. She put her head down and the feeling of fainting stopped. Both times, the trouble breathing lasted 5-10 minutes. And she felt okay after just a few deep breaths. On the 2nd time she felt better after deep breaths, cold water and felt fine. She had a Tele-visit with a different doctor than her usual physician. She was told to go to urgent care, where they did an X-ray and EKG (electrocardiogram) and COVID test, as mentioned earlier. By the time she went to urgent care she had no trouble breathing though. The outcome of the events trouble breathing and felt faint was resolved on an unspecified date, of other events was unknown. Information on the lot/batch number has been requested. |

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| 1269700 | 4/29/2021 | | 16 | M | 4/11/2021 | 4/11/2021 | was sweating profusely and breathing heavy then he passed out; was sweating profusely and breathing heavy then he passed out; was sweating profusely and breathing heavy then he passed out; he started getting dizzy; felt nauseated; This is a spontaneous report from a contactable consumer (patient's parent). A 16-years-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in Arm Right on 11Apr2021 14:30 (Lot Number: EW0150) (age at vaccination: 16-year-old) as SINGLE DOSE for covid-19 immunisation. Medical history was reported as no. No COVID prior vaccination, no COVID tested post vaccination, no Known allergies. There were no concomitant medications (no other vaccine in four weeks and no other medications in two weeks). Right after the patient was administered the vaccine, he started getting dizzy and felt nauseated, was sweating profusely and breathing heavy then he passed out. They were in the car so the nurse reclined his chair. He passed out and then woke up and then passed out (twice) -They gave him water and gum to chew and remained laying flat. After about 20 or so minutes he felt better and nurse checked his pulse and heart rate during the ordeal. The adverse events start date was reported as 11Apr2021 14:30. No treatment received for the events. The outcome of the events was recovered. |

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| 1269664 | 4/29/2021 | CA | 61 | F | 4/12/2021 | 4/12/2021 | <p>passed out; tunnel vision; "jerking movements" of her upper extremities; left arm was tingling/left pinky and ring fingers felt nerve tingling sensations; then the back of her throat had a chemical taste and tingling; then the back of her throat had a chemical taste and tingling; BP was 164/94 while lying down; continued to have pain in her left arm and across the left side of her chest and left-sided back shoulder; continued to have pain in her left arm and across the left side of her chest and left-sided back shoulder; continued to have pain in her left arm and across the left side of her chest and left-sided back shoulder; tongue was tingling and felt swollen with an altered chemical taste for 2 days; tongue was tingling and felt swollen with an altered chemical taste for 2 days; This is a spontaneous report from a contactable consumer (patient). A 61-year-old female patient (not pregnant) received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), dose 1 via an unspecified route of administration, administered in Arm Left on 12Apr2021 11:00 (Lot Number: ER8734) at the age of 61 years old as single dose for covid-19 immunisation. Medical history included Low thyroid, kidney infections, skin rashes, high cholesterol, food sensitivities. Concomitant medications in two weeks included liothyronine sodium (CYTOMEL); levothyroxine; vitamin b complex (VITAMIN B); levoglutamide (L GLUTAMINE). Facility type vaccine was Pharmacy or Drug Store. No other vaccine in four weeks. On 12Apr2021 11:00, within 1st min of vaccine, the patient's left arm was tingling, then the back of her throat had a chemical taste and tingling, then tunnel vision, then that was the last thing she remembered until she heard her partner saying, "Are you ok?" The patient said to her she thought she fell asleep. She was an RN and said that the patient passed out for about 15 seconds and had "jerking movements" of her upper extremities before she woke up. The staff and medic helped the patient to the floor where she rested for 20 min with her legs elevated on chair. BP was 164/94 while lying down, pulse was 74. The patient returned home and continued to have pain in her left arm and across the left side of her chest and left-sided back shoulder for most of the day. Also her left pinky and ring fingers felt nerve tingling sensations for the rest of the day. Her tongue was tingling and felt swollen with an altered chemical taste for 2 days. No</p> |

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| | | | | | | | treatment received for the events. No covid prior vaccination and no covid tested post vaccination. The outcome of the events was recovering. |
| 1269657 | 4/29/2021 | FL | 53 | F | 4/5/2021 | 4/5/2021 | Began with rash, severe body aches, loss of smell and taste, brain fog, unsteadiness, nausea, diarrhea that eventually led to dehydration and finally colitis that resulted in ER visit for fluids; sent home; next day, passed out at home, back to ER and was admitted for the colitis. |
| 1269636 | 4/29/2021 | MN | 34 | F | 4/21/2021 | 4/21/2021 | Within five minutes of my vaccination I started to feel very dizzy and my eyesight became blurry. I told my husband who had also been vaccinated that I thought something was wrong and within a seconds I then passed out and he caught me. I vomited twice in the span of the next ten minutes and I was not alert for any of that time-no recollection of being able to see or hear. My husband stated my eyes were open and pupils very dilated. He was able to get me to the ground with the help of the pharmacist who had administered the vaccine. 911 was called and by the time they arrived I became coherent enough to talk and interact. I declined a hospital visit because I had no interest in a ambulance ride but did follow up with my primary. No history of ever fainting or medical anxiety. |

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| 1269623 | 4/29/2021 | IN | | F | 4/1/2021 | 4/1/2021 | This is a spontaneous report from a contactable consumer (patient). A 62-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 01Apr2021 (Batch/Lot number was not reported) as single dose (dose 2) for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient previously received the first dose of BNT162B2 in Mar2021 for COVID-19 immunization. The patient got her first dose in Mar2021 and had mild side effects then 3 weeks later on 01Apr2021 she got the 2nd dose. She has not been normal since then, she stated that it does not work. She signed a paper that showed all the side effects with the vaccine and the side effects she had were not on that paper. The patient thinks they were negligent. She passed out two times, it knocked her down but she didn't call the ambulance, her heart stopped for 2 minutes and came back it's been several days since she got the vaccine. She was weak, she has no energy, felt like she was going to die any moment, she can't eat food and she didn't digest for 12 to 16hours. These side effects were not mentioned on paper. The patient mentioned that she has no health issues. She was extremely healthy, she was a former athlete and mentioned that all this was because of the vaccine. It's not normal that she can't eat. She was dizzy and very weak and she felt like her heart can stop anytime. The outcome of the events was unknown. Information on the lot/batch number has been requested. |

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| 1269554 | 4/29/2021 | | 22 | M | | | <p>severe blurred vision; shortness of breath; shaking; stiffness in his jaws; patient who fainted; This is a spontaneous report from a contactable pharmacist. A 22-year-old male patient received the first dose of bnt162b2 (BNT162B2, Solution for injection, Lot number was not reported), via an unspecified route of administration on an unspecified date (received at the age of 22-years-old) as SINGLE DOSE for COVID-19 immunisation. Medical history SVT (supraventricular tachycardia) (diagnosed with SVT by his cardiologist, however it was never confirmed), palpitation, and had fainted in two different situations in the past. Concomitant medications were not reported. The patient fainted after the first dose of COVID-19 vaccine as soon as he stood up. He was unconscious for about 5 seconds. He was experiencing severe blurred vision, shortness of breath, shaking and stiffness in his jaws. He was 22 years old, 170 pounds, and 6 feet tall. He has history of palpitation. In the past he was diagnosed with SVT by his cardiologist, however it was never confirmed. In addition, he had fainted in two different situations in the past. Based on what the patient says, his health issues and why he faints was never fully understood by medical doctors. Outcome of the events was unknown. Information about Lot/batch number is requested.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on event syncope cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.</p> |

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| 1269551 | 4/29/2021 | FL | 24 | M | 4/14/2021 | 4/14/2021 | fell out completely; passed out/fell off at the store; feeling dizzy; had terrible headache; chills; weak with shilling; i started sweating; I'm still feeling very sick; This is a spontaneous report from a contactable consumer (patient). A 24-year-old male patient received first dose of bnt162b2 ((PFIZER-BIONTECH COVID-19 VACCINE; lot EW0158; Expiration Date: Jul2021), via an unspecified route of administration, administered in left arm on 14Apr2021 12:00 as single dose for COVID-19 immunisation. Medical history included eye allergy. Concomitant medication included amoxicillin sodium, clavulanate potassium (AMOXICILINA CLAV) taken for eye allergy from 12Apr2021. On 14Apr2021, he received the first dose of the vaccine about an hour ago and waited five minutes and went to the bathroom. He had a severe reaction while patient was in the bathroom, he started to feel dizzy, had a terrible headache and chills. He walked out of the bathroom at the store and fell out completely in front of the pharmacists. The patient also experienced weak with shilling (as reported) and started sweating. The pharmacists called 911 and the responders checked his vitals and blood pressure and all of that and everything was fine. Patient clarified he passed out completely for almost 5 minutes. Patient stayed there with everyone until, they were waiting to see how he was doing. He reported he was feeling much better now, still feel a bit dizzy, not 100% but not as bad as when it happened. It has improved and he definitely felt terrible at the time. He was monitoring himself at home to see if he notices something weird going on. He does not have a headache right now and was feeling much better. When he was having the effect, he was mentally sharp, and knew what was going on. He thought about letting himself walk outside the bathroom so he could be seen. He didn't lose track of what was going on and body reacted adversely. He remembered stuff and everything and he felt good. Patient stated the chills went away; however, would not say they went away completely, he was recovering. The events did not require a visit to emergency room or physician office and the paramedic said it was not necessary right now because all the vitals and everything else seemed fine. There was no therapy received for the events. There were no additional vaccines administered on same date of the vaccine and no other vaccines within 4 weeks prior |

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| 1269536 | 4/29/2021 | FL | 18 | F | 4/8/2021 | 4/8/2021 | <p>to vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient had not been tested for COVID-19. Outcome of events feeling dizzy, terrible headache, chills was recovering; still feeling very sick was unknown; outcome of the rest of events was not recovered.</p> <p>I passed out in the car.; My blood pressure was extremely low; I was pale and incoherent; I was pale and incoherent; This is a spontaneous report from a contactable consumer. An 18-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 1 via an unspecified route of administration, administered in Arm Left on 08Apr2021 13:30 (Batch/Lot Number: ER8734) as SINGLE DOSE for covid-19 immunisation. The patient's medical history was reported as none. Pfizer shot was administered at 1:30 pm. The patient's mother decided to drive her car home. 10 minutes later the patient passed out in the car. The patient's mom called (Number) and paramedics transported her to the ER. The patient's blood pressure was extremely low, She was pale and incoherent. The patient underwent lab tests and procedures which included electrocardiogram: unknown result on an unspecified date. Therapeutic measures were taken as a result of i passed out in the car, my blood pressure was extremely low, i was pale and incoherent, i was pale and incoherent: EKG, a bag of fluids and monitoring. The outcome of the events was recovered in Apr2021. The event passed out was assessed as serious (medically significant).</p> |

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| 1269502 | 4/29/2021 | MD | 35 | F | 3/29/2021 | 3/30/2021 | <p>Caller states she was not due for her monthly menstrual period for another week, so she found, passing the clot, odd.; Blot clot/Very big blood clot, that passed out of body; Fever, of 102; Sore arm; This is a spontaneous report from a contactable Other HCP (patient). A 35-years-old female patient (no pregnant) received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in Arm Right on 29Mar2021 09:00 (Lot Number: ER2613) as single dose for covid-19 immunisation. Medical history included ongoing asthma , contraception. Concomitant medication included ethinylestradiol, norgestimate (SPRINTEC) taken for contraception from an unspecified start date and ongoing. The patient previously took bactrim and experienced drug hypersensitivity. The blood clot only was for one day on 31Mar2021, and it was one blood clot. The patient went to the bathroom and it was passed, one time. The patient was not due for her monthly menstrual period for another week, so she found, passing the clot, odd. The patient menstrual period did happen on time and it was normal. The patient was not due for her menstrual period for another week, and she takes birth control. The patient contacted her Gynecologist, and it was confirmed that she was not pregnant, and states her menstrual period happened on time. The clot did not happen again. The patient had Fever, of 102 on 30Mar2021, the temperature resolved in a day. The patient took Aleve, drank a lot of water and napped, reclarifies, and the temperature improved. The patient experienced sore arm on 30Mar2021. The outcome of event Clot blood was recovered on 31Mar2021; outcome of event Fever was recovered on 30Mar2021; outcome of event Sore arm was recovered on 01Apr2021, outcome of other event was unknown. No other vaccine in four weeks; No covid prior vaccination; No covid tested post vaccination.; Sender's Comments: Based on the temporal relationship, A possible contributory role of the suspect product to the development of Thrombosis and Menstrual Disorder cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this</p> |

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| 1270078 | 4/29/2021 | NY | 18 | F | 4/28/2021 | 4/28/2021 | review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate. Systemic: Fainting / Unresponsive-Medium, Systemic: Seizure-Medium, Systemic: Shakiness-Medium |
| 1269530 | 4/29/2021 | NC | 49 | F | 4/9/2021 | 4/10/2021 | This is a spontaneous report from a contactable consumer reporting for a patient. A 49-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in Arm Left on 09Apr2021 11:00 (Batch/Lot Number: ER8737) as SINGLE DOSE for covid-19 immunisation, at 49 years old at other facility type. The patient is not pregnant at time of vaccination. Medical history included allergies to Rosemary from an unknown date. No other vaccine in four weeks were noted. Patient did not have COVID prior vaccination and was not tested for COVID post vaccination. Concomitant medications included cetirizine hydrochloride (ZYRTEC); propranolol hydrochloride (INDERAL); lorazepam (ATIVAN); hctz; quetiapine fumarate (SEROQUEL); gabapentin taken for an unspecified indication, start and stop date were not reported. The patient previously took macrobid [nitrofurantoin] and experienced allergies. The patient previously received the first dose of BNT162B2 (Lot number: ER8727) on 17Mar2021 13:00 (left arm) for COVID-19 immunisation. On 10 Apr2021, the patient experienced Itchy palms (reported as within hours), tachycardia, tightness in chest, difficulty breathing, tingling tongue and fingers, vomiting, confusion, dizzy, fainting, abdominal pain, severe pain everywhere, too fatigued to move. Patient tried to call ambulance but could not get phone or unlock the door. She stated she tried from 1 AM to 07:30 AM. After 07:30 AM she had expected effects of fever as well as fatigue and pain. The events resulted in Doctor or other healthcare professional office/clinic visit. Treatment was not given. Outcome of the events was recovered on an unspecified date. |

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| 1272335 | 4/29/2021 | FL | 18 | M | 4/29/2021 | 4/29/2021 | Patient received vaccine and stood up to go to observation when patient appeared pale and experienced an episode of syncope. Patient stated he felt the need to vomit. Patient's mom at side. She stated that in the past he has been known to have these episodes after venipuncture. Patient redirected back to seat. Staff directed to call 911. Emergency kit at side and vital signs and pulse ox taken. Assessment of patient, alert and oriented x4 and vitals within normal limits. EMS came to site and patient refused further evaluation after clearance. |
| 1270129 | 4/29/2021 | NV | 17 | M | 4/28/2021 | 4/28/2021 | Systemic: Fainting / Unresponsive-Mild |
| 1272487 | 4/29/2021 | CA | 65 | F | 3/19/2021 | 4/24/2021 | This patient was seen in the ER and hospitalized on 4/24/21 after syncope, and was found to have hypoxia and fever. NP specimen for SARS-CoV-2 was positive by PCR. Cycle Threshold was 15.4. We are trying to get whole genome sequencing done on the specimen. This appears to be a new COVID-19 case after being fully vaccinated. This is the reason for reporting. She is stable and may be discharged in the next day or two. |
| 1272327 | 4/29/2021 | OH | 18 | F | 4/29/2021 | 4/29/2021 | Shortly after administering the vaccine, some people out in the waiting area grabbed me and said patient's eyes rolled back and she passed out and fell forward. She had mentioned that she was very anxious about the shot while I gave it to her. After I came out to her, she was very pale and I gave her some water. I had her call her boyfriend to come inside. One of the technicians called the squad to come check her out. They did so, and they left shortly after. She mentioned that they told her she could either go to the hospital and be observed or go home. She said she wanted to go home. She and her boyfriend went home. |
| 1272266 | 4/29/2021 | IA | 17 | F | 4/28/2021 | 4/29/2021 | Arm pain, slight swelling in injection site area. Swollen lymph nodes on both sides of neck, overall malaise/body aches, fatigue, light-headedness resulting in fainting episode, headache |

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| 1272089 | 4/29/2021 | MA | 20 | F | 4/29/2021 | 4/29/2021 | patient was administered vaccine as per EUA/standin order. Approx 30 seconds after the vaccine was injected, the patient who was seated, stated she didnt feel well, fainted and slumped forward in chair. RPH who administered shot was able to catch her, keep her from further injury. Approx 10 seconds later, she came to and was disoriented. RPH explained where she was and what had occured. She complained of nausea, feeling hot and sweaty and numbness in fingers. 911 was called, and while waiting for EMTs to arrive she stated that she had had some similar reaction during a previous blood draw. EMT arrived and transported her to local ER |
| 1272083 | 4/29/2021 | CO | 18 | F | 4/29/2021 | 4/29/2021 | patient fainted about 5 min. after receiving the shot. Hit her head on the floor, was immediately awake, alert. Paramedics checked her out and said she was fine. |
| 1272015 | 4/29/2021 | OH | 63 | F | 4/6/2021 | 4/8/2021 | Nervous system impairment severe dizziness syncope no balance 12 days as inpatient, received solumedrol antivert and 5 doses of IVIG |
| 1271823 | 4/29/2021 | LA | 22 | F | 3/19/2021 | 3/20/2021 | I Passed out in store while grocery shopping, 08/10/2021 |
| 1271694 | 4/29/2021 | CA | 16 | M | 4/27/2021 | 4/27/2021 | Pt fainting during vaccination. Pallor at vaccination area. Vitals wnl. |
| 1271650 | 4/29/2021 | PA | 18 | F | 4/28/2021 | 4/28/2021 | PATIENT FAINTED |

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| 1271572 | 4/29/2021 | OH | 16 | M | 4/29/2021 | 4/29/2021 | Approximately 10 minutes after being administered with Pfizer COVID vaccine patient became lightheaded and almost fainted. Patient did not fall out of chair, but did slouch over in chair. The patient's father alerted pharmacy staff and the nurse administering vaccines today, and I went out to check on him. Patient was sitting up in chair at this time, but was very sweaty, pale and cloudy. Nurse instructed him to place his head down by his knees and provided him with water, Gatorade, and cold compresses. Once patient was feeling a little bit better we moved him into a private room with father and let him lay down at rest. When patient felt okay to leave he was advised to lay flat when he got home and eat. Father was also advised to stay with him until he was feeling 100%. Event lasted approximately 30 minutes. A call was placed to parents around 3pm to check on him and he was doing well. (moving around and playing video games) |
| 1271361 | 4/29/2021 | CA | 17 | M | 4/27/2021 | 4/27/2021 | Syncope. BPs 119/49 (pulse 58), 99/47 (pulse 59). O2 sats 99%. |
| 1270209 | 4/29/2021 | FL | 48 | M | 4/25/2021 | 4/25/2021 | Client fainted after receiving the COVID-19 vaccine as per the vaccinating nurse. Attending nurse administered an ammonia inhalant. The client woke up, Fire Rescue arrived to evaluate client. Showed symptoms of weakness, diaphoresis and paleness. Client presented hypotension and bradycardia. Client needed to be transported to a hospital as per Fire Rescue. Client was transferred to Clinic by Fire Rescue at 3:27pm. |
| 1272495 | 4/29/2021 | TX | 16 | M | 4/29/2021 | 4/29/2021 | Pt was in the waiting room waiting 15 mins post vaccine. He was sitting with father and felt dizzy and put his head down. Father said pt has fainted in past and was expecting this reaction. Pt was dizzy for less than a minute and we gave some orange juice and he felt better. |
| 1271277 | 4/29/2021 | SC | 22 | F | 4/29/2021 | 4/29/2021 | Patient started tearing about 3 minutes after received the vaccine. Her face and lips turned really pale and fainted on pharmacist's arms for 30 seconds. She wore up but still pretty confused. WE gave her water. She stayed in pharmacy with her mom for about 40 minutes and went home. |

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| 1270173 | 4/29/2021 | IA | 55 | M | 4/28/2021 | 4/28/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Exhaustion / Lethargy-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Additional Details: Shortly after administration pt began to sweat and fainted. Pt regained consciousness after 3 seconds and then remained under observation of the rph until pt was confident they would be able to make it home on their own. #4 benadryl was given to take home but instructed to take if symptoms came back. |
| 1270417 | 4/29/2021 | PR | 45 | F | 4/27/2021 | 4/28/2021 | Strong tachycardia, dizziness, and fainting |
| 1270542 | 4/29/2021 | CT | 18 | M | 4/29/2021 | 4/29/2021 | Patient received the J&J Covid-19 vaccine then fainted approximately 5 minutes later. Patient came to immediately and was conscious by the time the pharmacist reached the patient. Patient was ok other than having a sore head from when he fell. We provided the patient water and continued to monitor for an additional amount of time for a total of 30 minutes. Patient denied needing anything else such as juice. Patient was okay after and when asked if there was anyone that he could contact to drive with, he said he was okay to drive after. |

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| 1270761 | 4/29/2021 | | 20 | F | 3/11/2021 | 3/18/2021 | <p>After first vaccine: History: Moderna COVID vaccine on 3/11/2021. Arm soreness over the first day or two but nothing else that really struck her. A few days after she started to notice axillary pain that progressed up her right neck and down to her right hand. She saw a physician who thought she was having nerve pain brought on by the vaccine. Around the 18th she started to feel a snapping pain in her wrist. Went to ED on the 20th because she started to have arm shaking, she was given ativan, her arm shaking stopped and they discharged her home. That evening her fingers felt clenched. On the 21st she woke up in the morning, went to urinate and dropped to the floor because her legs felt like jello and felt like they kept giving out. They initially thought the ativan was just making her feel out of it. They waited until the evening but then needed to go to the ED. The concern was GBS and transverse myelitis. They ate dinner and decided to drive to ED, on the drive she was kind of falling asleep periodically. Then she suddenly couldn't lift her water bottle. She started to be completely out of it, Mom says she wasn't responding. Pt says that she felt like she knew what was going on, felt a little out of body and wasn't quite responding. Mom couldn't get her out of the car, she was carried into the ED and at that point she started to recover a little bit more. About 10 minutes later she started to feel better. She was admitted because she was still having trouble walking. In the hospital she had a normal CT head and video EEG but she didn't have any events while on the monitor. Discharged home the following day with the diagnosis of functional neurologic disorder and instructions to establish care with an adult PCP. They advised considering CBT as well. Since discharge her legs feels tired, going up the stairs feels much harder than it should. She has not had any falls and no longer feels like she is going to fall. She follows with a therapist, has had dissociative episodes and panic attacks in the past. Assessment: 20 YOF with PMH of panic attack, POTS, IDA and benign heart murmur who developed weakness of b/l LE and altered consciousness approximately 10 days after her first dose of Moderna COVID vaccine. Also had an episode of unilateral arm shaking the day prior that resolved with ativan in the ED. At this point unclear if directly related to vaccination. Differential includes mild Guillain-Barre 2/2 previous infection or vaccination,</p> |

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stress reaction/anxiety, POTS complication, myasthenia gravis, tick bite, infection, heavy metal poisoning, B12 deficiency, seizure disorder, atypical migraine. Functional Neurologic Disorder diagnosed by neurology after overnight admission for video EEG which captured no events. CT head also WNL per neurology discharge summary. Neurologic exam today WNL. After Second Vaccine: History: She had her 2nd vaccine on 4/15 (6 days ago). Had vaccine in right arm again, she did have some arm pain again. She had coffee without breakfast in the morning. Had finished her first virtual class, went to the restroom during her second class, felt strangely in the restroom, went back to her room. She then passed out. Her fall was unwitnessed. She called to her roommate when she came to but her roommate hadn't heard the fall. She thinks she was only out for a few seconds but cannot be sure. Called her Mom who advised her to eat something so she ate an orange sitting on the floor. She got up to make herself breakfast and she passed out again. Again unwitnessed but patient thinks it was very fast. She crawled over to the couch, sat on the couch for for 15 minutes then felt fine for the rest of the day. She did not feel nauseous at all. She denies palpitations, difficulty breathing and chest pain. Today in office after orthostatics and blood draw she fainted again, only out for seconds. BP elevated immediately after the event but WNL minutes later. These syncopal episodes reminded her of her syncopal episodes with IDA and POTS. They do not feel like the episode after the first vaccine when she lost feeling in her legs and was very out of it. She feels like her arm pain from the first vaccine never fully resolved. After the arm pain worsened from the 2nd shot she tried a 3 day course of aleve to see if that helped things. At this point it is mostly just her right wrist that is painful. Overall feels more localized to wrist than prior. She has since stopped the aleve, last was last night. She has not noticed redness or swelling in wrist or arm. LMP was 4/2-4/6. She went almost a year without menses so stopped her OCP, but her menses have returned recently and she has restarted OCP. Assessment: Right arm pain persisted from the first vaccination but otherwise sx had resolved. She got 2nd vaccination on 4/15, only arm pain but yesterday had 2 brief syncopal events and one today in the office. Orthostatic BPs not completely convincing for orthostatic hypotension today.

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| 1270991 | 4/29/2021 | FL | 18 | M | 4/21/2021 | 4/21/2021 | Within 15-minutes of vaccination, the patient experienced a syncopal episode. EMS evaluated the patient on-site. The patient reported taking a marijuana edible prior to vaccination and stated he was anxious about the vaccine. The patient was normotensive (121/68). EMS administered 0.5L normal saline and 4mg IV Zofran. EMS transported the patient to Emergency Department. In the ED, the patient reported taking a marijuana edible at 1200 and that after their vaccination they experienced feeling flushed, nausea, vomiting, and near-syncope. After several hours waiting in the ED, the patient noted feeling improvement. The patient's labs and tests were unremarkable. Patient was discharged with vasovagal reaction and cannabis abuse. |
| 1272544 | 4/29/2021 | CA | 16 | F | 4/29/2021 | 4/29/2021 | patient received vaccination at 9:29am. She was asked to sit down and wait for 15 minutes post vaccination. Patient and grandmother left after 5 minutes. she had a brief fainting episode at the front door of store. She came back to pharmacy and was observed for 30 more minutes, she felt fine and then left the pharmacy |
| 1271159 | 4/29/2021 | CA | 17 | F | 4/27/2021 | 4/27/2021 | Syncope. BPs 85/43 (pulse 43), 95/57 (pulse 86). Found slumped in chair and placed in Trend. Position. Given water, juice. |
| 1270928 | 4/29/2021 | OH | 16 | F | 4/29/2021 | 4/29/2021 | Patient passed out during monitoring, observation period. She was alert and oriented and EMS was contacted. She sat up and drank some water. EMS monitored her heart rate and blood pressure and she was released to her father. |
| 1271218 | 4/29/2021 | MA | 18 | F | 4/29/2021 | 4/29/2021 | Systemic: Fainting / Unresponsive-Medium |

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| 1271015 | 4/29/2021 | FL | 16 | F | 4/22/2021 | 4/22/2021 | Within 2-minutes of vaccination, the patient experienced a syncopal episode. EMS evaluated the patient on-site. The patient was hypotensive (84/44) with a FSBG of 59mg/dL. EMS administered 15g PO Glucose. IV access was attempted but not obtained. Upon re-evaluation, the patient was hypertensive (147/116) and tachycardic (117bpm). EMS transported the patient to Hospital Emergency Department. In the ED, the patient stated they became dizzy and passed out after vaccination. The patient noted that they did not eat anything all day. The patient was hypotensive (99/56). The patient's labs/tests indicated dehydration and the physician administered 1L IV normal saline. The patient was discharged with dehydration and vasovagal syncope. |
| 1266337 | 4/28/2021 | NY | 17 | F | 4/28/2021 | 4/28/2021 | Pt. had first vaccine at 14:55. Pt. walked to observation one where she fainted upon arrival. Pt. was CAOx3 after she was laid down. Pt. was transferred to the back via wheelchair where she was observed for 15 minutes without any further complications. After 15 minutes patient walked out without any obvious difficulties. |

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| 1266054 | 4/28/2021 | | | U | 4/2/2021 | 4/3/2021 | fainted/blacked out; fainted/blacked out; skin felt like had spider and ants crawling all on skin; goosebumps; farted; fell backwards and hit the elbow, and thumb and back of head on the floor; fell backwards and hit the elbow, and thumb and back of head on the floor; fell backwards and hit the elbow, and thumb and back of head on the floor; fell backwards and hit the elbow, and thumb and back of head on the floor; fell backwards and hit the elbow, and thumb and back of head on the floor; could not walk; dizzy; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 02Apr2021 (Lot Number: ER8737, unknown expiration) as a single dose for COVID-19 immunisation. Medical history included COVID-19 disease from 06Jan2021 to an unknown date. The patient's concomitant medications were not reported. The patient woke up in the middle of the night on 03Apr2021 at 02:00 AM, and the patient's skin felt like had spider and ants crawling all on skin and got goosebumps and had to get up to go to the restroom. The patient went to the restroom and urinated, and when he/she was ready to get up from the toilet he/she farted, the patient fainted/blacked out and fell backwards and hit the elbow, and thumb and back of head on the floor. The patient woke up, when that happened, it was a very hard crash. After that, the patient was unable, could not walk because when he/she tried, he/she got dizzy and had to crawl back to bed, with hands and knees back to bed. The patient asked if he/she should get the second shot. Outcome of the events was unknown. No follow-up attempts are possible. No further information is expected. |

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| 1266058 | 4/28/2021 | MD | 28 | F | 4/7/2021 | 4/7/2021 | Low grade fever; seizure; Passed out; syncope/ fainted; Blood pressure drop; Sore arm; This is a spontaneous report from a contactable consumer (patient's parent). A 28-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date were not provided) at the age of 28-years-old, via an unspecified route of administration in left arm on 07Apr2021 at single dose for COVID-19 immunization. Medical history included autism, being nervous, passed out, and anxiety. Concomitant medications included sertraline hydrochloride (ZOLOFT), quetiapine fumarate (SEROQUEL), gabapentin, bupropion hydrochloride (WELLBUTRIN), and lorazepam (ATIVAN) for being nervous. The patient received the Pfizer vaccine last Wednesday (07Apr2021) and immediately after that, at about 1:30 (unspecified), she just started having a seizure. They thought that it was more of a major response she was just having, fighting and was nervous about it, but it was kind of a different situation. The reporter has seen the patient passed out before. She did some blood test on 07Apr2021 and her sugars were fine. The reporter's concern was that they didn't know whether she should get the second one. The reporter didn't believe she got a seizure but was not sure about it. It's just that what immediately happened after she got the shot was that she passed out and they called the ambulance. After she passed out, she went to the emergency room and they did blood work on her. The reporter just did not know if they were going to let her go for the second dose because they couldn't relay if it was a seizure or a bizarre response where she just syncope and fainted. They were just thinking it was a bizarre response as it was just blood pressure drop but they were just not sure where to go from here. The patient was told to rest and intravenous fluid and something through the blood were given. The patient also experienced sore arm from 07Apr2021 for 2 days and had a low-grade fever the following day (08Apr2021). The outcome of the event sore arm was recovered on 09Apr2021 and recovered on Apr2021 for all other events. Information about the lot/batch number has been requested. |

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| 1266126 | 4/28/2021 | CA | 22 | F | 4/23/2021 | 4/24/2021 | Fainted; Thirsty; Shaking; Look pale; Hypotension; Arm soreness; Nausea; CHILLS; Fever; This spontaneous case was reported by a consumer and describes the occurrence of SYNCOPÉ (Fainted) in a 22-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 008C21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Pollen allergy (environmental allergy) and Dust allergy (environmental allergy). Concomitant products included CETIRIZINE HYDROCHLORIDE (ZYRTEC [CETIRIZINE HYDROCHLORIDE]), FEXOFENADINE HYDROCHLORIDE (ALLEGRA) and CLARITHROMYCIN (CLARITIN [CLARITHROMYCIN]) for Allergy, MONTELUKAST for Asthma, COLECALCIFEROL (VITAMIN D [COLECALCIFEROL]) for Supplementation therapy. On 23-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) at an unspecified dose. On 24-Apr-2021, the patient experienced SYNCOPÉ (Fainted) (seriousness criterion medically significant), THIRST (Thirsty), TREMOR (Shaking), PALLOR (Look pale), HYPOTENSION (Hypotension), MYALGIA (Arm soreness), NAUSEA (Nausea), CHILLS (CHILLS) and PYREXIA (Fever). On 24-Apr-2021, SYNCOPÉ (Fainted), TREMOR (Shaking), PALLOR (Look pale) and HYPOTENSION (Hypotension) had resolved. At the time of the report, THIRST (Thirsty), MYALGIA (Arm soreness), NAUSEA (Nausea), CHILLS (CHILLS) and PYREXIA (Fever) outcome was unknown. The action taken with mRNA-1273 in response to the event was not applicable. The treatment medications included Tylenol (paracetamol) and Advil (Ibuprofen). Company comment: Based on the information provided which includes a temporal association between the use of mRNA-1273 vaccine and onset of the reported events, a causal relationship cannot be excluded. Headache, nausea, myalgia, pyrexia and chills are consistent with the product safety profile.; Sender's Comments: Based on the information provided which includes a temporal association between the use of mRNA-1273 vaccine and onset of the reported events, a causal relationship cannot |

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be excluded. Headache, nausea, myalgia, pyrexia and
chills are consistent with the product safety profile

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| 1266127 | 4/28/2021 | CO | 28 | F | 4/6/2021 | 4/6/2021 | Fatigue; Brain fog; Sweating a lot; Was ghost white; severe chills,freezing; Very very high fever; Nausea; Had a seizure; Blue lips; Fainted; Was out for like 30 minutes; Something white on the patient's mouth; Little lightheaded; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of SEIZURE (Had a seizure), CYANOSIS (Blue lips), SYNCOPE (Fainted) and LOSS OF CONSCIOUSNESS (Was out for like 30 minutes) in a 28-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No medical history was provided by the reporter. Concomitant products included VITAMINS NOS for an unknown indication. On 06-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 06-Apr-2021, the patient experienced SEIZURE (Had a seizure) (seriousness criteria medically significant and life threatening), CYANOSIS (Blue lips) (seriousness criterion life threatening), SYNCOPE (Fainted) (seriousness criterion medically significant), LOSS OF CONSCIOUSNESS (Was out for like 30 minutes) (seriousness criterion medically significant), ORAL DISCHARGE (Something white on the patient's mouth), DIZZINESS (Little lightheaded), HYPERHIDROSIS (Sweating a lot), PALLOR (Was ghost white), CHILLS (severe chills,freezing), PYREXIA (Very very high fever) and NAUSEA (Nausea). On an unknown date, the patient experienced FEELING ABNORMAL (Brain fog) and FATIGUE (Fatigue). On 06-Apr-2021, SEIZURE (Had a seizure), CYANOSIS (Blue lips), SYNCOPE (Fainted), LOSS OF CONSCIOUSNESS (Was out for like 30 minutes), ORAL DISCHARGE (Something white on the patient's mouth), HYPERHIDROSIS (Sweating a lot), PALLOR (Was ghost white), CHILLS (severe chills,freezing) and PYREXIA (Very very high fever) had resolved. At the time of the report, DIZZINESS (Little lightheaded), FEELING ABNORMAL (Brain fog), FATIGUE (Fatigue) and NAUSEA (Nausea) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. The patient's concomitant medication included Adderol used for an unknown indication. The patient had received 1st dose of Moderna vaccine and was monitored |

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| 1266442 | 4/28/2021 | OR | 18 | F | 4/28/2021 | 4/28/2021 | <p>for 30 minutes at the facility where she got the vaccine , the patient went to her house and had little light headed and nausea, that evening she went to sleep and around 9 or 10 Hours after she had received the 1st dose of the Moderna vaccine she` fainted and had a seizure. She was out for like 30 minutes, she had blue lips, had something white on her mouth. The HCP told, that she should go to the hospital but it was really busy so they stabilized her at her house. The patient had never had seizures, it is a life threatening event. The patient is being seen by a neurologist and her primary care, and `they have just started with the CT scans and the studies(caller did not specify)` with pending results, so once the caller has all the test results she wouldlike to call back and give the most updated details on the patient`s case. The patient had fatigue and brain fogs, but she did not have another seizure, Caller reported that `for now, we are dealing with the symptoms she had on the 06-Apr-2021. The patient had cancelled her 2nd dose appointment. The patient treatment medication included Advil on 06-Apr-2021. Company comment: Based on the information provided which includes a temporal association between the use of mRNA-1273 vaccine and onset of the reported events, a causal relationship cannot be excluded. chills, nausea, pyrexia and fatigue are consistent with the product safety profile.; Sender's Comments: Based on the information provided which includes a temporal association between the use of mRNA-1273 vaccine and onset of the reported events, a causal relationship cannot be excluded. chills, nausea, pyrexia and fatigue are consistent with the product safety profile.</p> <p>Patient received her first Pfizer Covid vaccine, sat down for the waiting period and fainted 1-2 minutes afterwards. She states she thinks she was only out for about a minute. Came to on her own. Pulse checked by personnel at the vaccine clinic. Patient then called her PCP's office (me) to report the event.</p> |

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| 1266244 | 4/28/2021 | | | U | | | <p>FAINTED; HEAD SMACKED; WHOLE BODY HURT; This spontaneous report received from a patient concerned a 30 year old of unspecified sex. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, administered 1 total, therapy start date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, the subject experienced fainted while taking a pee 15 hours post-shot and smacked my head. Whole body hurt for 2 days. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the fainted, body pain and head smacked was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: 20210422129-COVID-19 VACCINE AD26.CO2.S- Fainted, Head smacked. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p> |

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| 1266013 | 4/28/2021 | | 21 | F | | 4/9/2021 | I have passed out three times.; arm pain; body aches; This is a spontaneous report from a non-contactable consumer (patient). A 21-year-old non-pregnant female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Batch/Lot number was not reported), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The facility type vaccine was school or student health clinic. There were no other vaccine in four weeks. On 09Apr2021 at 14:45, the patient have passed out three times. The patient also had arm pain and body aches on 09Apr2021 14:45. She had no fever, and she was well hydrated. She have not taken any medication at all since then. There was no treatment for the events. The patient had no COVID prior vaccination and has not been tested for COVID post vaccination. The outcome of the events was recovering. No follow-up attempts are possible; information about lot/batch number cannot be obtained. |

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1265953 | 4/28/2021 | MD | 26 | M | 4/12/2021 | 4/12/2021 | Passed out; felt dizzy; hit my head and injured my ankle; fallen; hit my head and injured my ankle; This is a spontaneous report from a contactable consumer (patient). A 26-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; Lot number was not reported) via an unspecified route of administration, administered in Arm Right at the age of 26-year-old, on 12Apr2021 10:30, as SINGLE DOSE for covid-19 immunisation. Medical history was not reported. The patient's concomitant medications were not reported. The patient did not receive vaccine in four weeks nor was the patient tested for COVID post vaccination. On 12Apr2021 at 11:00, the patient felt dizzy and then the patient passed out. When the patient woke 3 minutes later, he had fallen and hit his head and injured his ankle. The patient was taken by the ambulance to the local ER and was released later that day as his vitals had returned to normal. Therapeutic measures taken in response to the events included IV fluids. They advised that the patient reach out to see if he can receive my second shot on 03May202. Outcome of the events was recovering at the time of the report. Information about lot/batch number has been requested. |
| 1266453 | 4/28/2021 | TX | 26 | M | 4/28/2021 | 4/28/2021 | The patient wanted to go to the restroom after getting the vaccine. He said he felt a little nauseous and had a slight headache but felt ok to walk to the bathroom. After returning from the bathroom, the patient informed he gotten a little dizzy in the bathroom and passed out. His head was bleeding. Patient informed his head was hurting at hit sit, feeling nauseous, vision a bit blurry and did throw up a bit. He was able to state his name, address, DOB, and was cognizant. There was no signs of SOB or allergic reaction. The EMS was called and it was detected his BP was a little low. Patient did feel a little better but it was advised to go to the hospital to make sure he did not have a concussion. Patient was then escorted by EMS to the hospital. |

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| 1266158 | 4/28/2021 | NC | 29 | M | 4/27/2021 | 4/27/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Visual Changes/Disturbances-Medium, Additional Details: Gave patient water, a snack, and had him sit in pharmacy for full 30 minutes before leaving. He said he felt perfectly fine and was having no other continuing symptoms. |
| 1266010 | 4/28/2021 | FL | 22 | F | 4/13/2021 | 4/14/2021 | Fainted in the shower while shaving; This is a spontaneous report from a contactable consumer (patient). A 22-year-old non-pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot number was not reported), via an unspecified route of administration, administered in arm left on 13Apr2021 at 11:00 (at the age of 22-years-old) as a single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient fainted in the shower while shaving on 14Apr2021 at 15:30. There was no treatment received for the event. The outcome of the event was recovering. Information on the lot/batch number has been requested. |

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| 1266006 | 4/28/2021 | GA | 35 | M | 4/5/2021 | 4/9/2021 | fainted; weak; tired; dizziness, light headed; nausea; soreness and aches in upper legs; ear pain; swollen throat; joint pain; fever 101; chills; shortness of breath; elevated heart rate; sinus drainage; entire body pain; This is a spontaneous report from a contactable consumer (patient). A 35-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), dose 1 via an unspecified route of administration, administered in the right arm on 05Apr2021 at 09:00 (Batch/Lot Number: ER8734) at 35-years-old as a single dose for COVID-19 immunisation. The patient did not receive any other vaccine within four weeks of the suspect vaccine. The patient medical history was not reported. It was unknown if the patient had COVID prior to the vaccination. There were no concomitant medications. On 09Apr2021 (as reported), the patient experienced: fainted (medically significant; also reported as 4 days after vaccine), weak (non-serious; also reported as 1-2 days after vaccine), tired (non-serious; also reported as 1-2 days after vaccine), dizziness, light headed (non-serious; also reported as 4 days after vaccine/ 7 days after vaccine), nausea (non-serious; also reported as 4 days after vaccine), soreness and aches in upper legs (non-serious; also reported as 4-7 days after vaccine), sinus drainage (non-serious; also reported as 4-7 days after vaccine), ear pain (non-serious; also reported as 4-7 days after vaccine), swollen throat (non-serious; also reported as 4-7 days after vaccine), joint pain (non-serious; also reported as 4-7 days after vaccine), fever 101 (non-serious; also reported as 7 days after vaccine), chills (non-serious; also reported as 7 days after vaccine), entire body pain (non-serious; also reported as 7 days after vaccine) shortness of breath (non-serious; also reported as 7 days after vaccine), and elevated heart rate (non-serious; also reported as 7 days after vaccine). The patient underwent lab tests and procedures which included body temperature: 101 on 09Apr2021, heart rate: 118-125 beats per minute (bpm) on 09Apr2021. Therapeutic measures were not taken as a result of the events. The clinical outcome of the events was not recovered. The patient was not tested for COVID post vaccination. |

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| 1265992 | 4/28/2021 | TX | 42 | M | 4/13/2021 | 4/14/2021 | This is a spontaneous report from a contactable consumer (the patient). A 42-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number not provided), via an unspecified route of administration in the left arm on 13Apr2021 10:45 (at the age of 42-years-old) as a single dose for COVID-19 immunization. The patient's medical history included: tonsils removed at age 6 and heart rate at rest low. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient had no allergies to medications, food, or other products. Concomitant medications included: acetylsalicylic acid/ caffeine, paracetamol (EXCEDRIN EXTRA STRENGTH) and cetirizine hydrochloride (ZYRTEC), both taken for an unspecified indication, start and stop date were not reported. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number not provided), via an unspecified route of administration in the left arm on 23Mar2021 11:15 (at the age of 42-years-old) as a single dose for COVID-19 immunization. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient stated he fainted the morning after receiving the shot on 14Apr2021 06:00. No treatment was received for the event. The outcome of fainted was recovering. It was also reported that since the vaccination, the patient had not been tested for COVID-19. Information about lot/batch number has been requested. |

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| 1265989 | 4/28/2021 | LA | 26 | F | 4/3/2021 | 4/4/2021 | Fainting; Fever of 103; Vomiting Green Fluid; Nausea; Body Aches; Shortness of breath; This is a spontaneous report from a contactable consumer (patient). A 26-year-old female patient received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiration date unspecified), via an unspecified route of administration, administered in left arm on 03Apr2021 15:00 as single dose for COVID-19 immunisation. Medical history included psoriasis. The patient was not pregnant and had no known allergies. There were no concomitant medications. The patient received first dose of bnt162b2 on 13Mar2021, 14:30 for COVID-19 immunisation. On 04Apr2021 03:45, the patient experienced fainting, fever of 103, vomiting green fluid, nausea, body aches and shortness of breath that lasted 7 days after the second dose. There was no therapy for the events. There was no other vaccine in four weeks and no other medications in two weeks. The patient did not have Covid prior vaccination and was not covid tested post vaccination. Outcome of the events was recovered on an unspecified date. Information on the lot/batch number has been requested.; Sender's Comments: Based on temporal association, the causal relationship between bnt162b2 and the event syncope cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate. |

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| 1265988 | 4/28/2021 | | 32 | M | 4/13/2021 | 4/13/2021 | Woke up sweaty; was cold for about 30 minutes after; Mild tingling in left arm for about a minute after passing out; Mild numbness in lips for a few minutes after passing out; Passed out 25 mins after receiving vaccination; This is a spontaneous report from a contactable consumer (patient). A 32-years-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; Batch/Lot Number: EW0150), via an unspecified route of administration, administered in Arm Left on 13Apr2021 09:15 (32-years-old) as single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. Patient had no known allergies. Patient did not have covid prior vaccination and not tested for covid post vaccination. The patient passed out 25 mins after receiving vaccination (13Apr2021 09:40). Lasted a few seconds. Woke up sweaty (13Apr2021 09:45), was cold for about 30 minutes after (13Apr2021 09:45). Mild tingling in left arm for about a minute after passing out (13Apr2021 09:45). Mild numbness in lips for a few minutes after passing out (13Apr2021 09:45). Patient had no treatment for events. The outcome of the event passed out 25 mins after receiving vaccination and mild numbness in lips for a few minutes after passing out was recovered on 13Apr2021, woke up sweaty was recovering, was cold for about 30 minutes after was recovered on 13Apr2021 10:15, mild tingling in left arm for about a minute after passing out was recovered on 13Apr2021 09:46. |

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| 1265959 | 4/28/2021 | OH | 35 | F | 3/26/2021 | 3/30/2021 | Nearly fainting; vertigo like symptoms; lightheaded; lethargic; blurred vision; shaky; heart palpitations; limbs feel heavy; This is a spontaneous report from a contactable consumer (patient). A 35-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot number: ep 6955) via an unspecified route of administration, administered on the right arm on 26Mar2021 15:30 at a single dose for COVID-19 immunization. Medical history included anxiety, depression; and known allergies: penicillin and gluten. Concomitant medications included bupropion hydrochloride (WELLBUTRIN) and sertraline hydrochloride (ZOLOFT). The patient previously took amoxicillin and diflucan and experienced allergies. On 30Mar2021 22:00, the patient experienced nearly fainting, vertigo like symptoms, lightheaded, lethargic, blurred vision, shaky, heart palpitations and limbs feel heavy. The event resulted to a doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Hospitalization. The patient was hospitalized for the events for 1 day. Treatment was received for the events which included medication, heart monitor, MRI, MRA, MRV, CT scan. COVID test post vaccination included nasal swab on 01Apr2021: negative. Patient was not pregnant. The facility where the vaccine was administered was in a school or student health clinic. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Post vaccination, the patient has not been tested for COVID-19. Outcome of the events was not recovered. |

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| 1265925 | 4/28/2021 | | 35 | M | 4/12/2021 | 4/12/2021 | passed out; black out; tense nerve feelings/nerve twitching; tense nerve feelings/nerve twitching; typical body aches or pain; This is a spontaneous report from a contactable consumer (patient). This 35- year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE Lot number: EN6208), via an unspecified route of administration, on 12Apr2021 at 09:30 am (at the age of 35-years-old) as a single dose for COVID-19 vaccination, in left arm. The facility where COVID-19 vaccine was administered was a hospital. No known allergies. Patient has no relevant medical history. States: I live a healthy lifestyle diet, exercise, proper rest. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient did not receive any other vaccines within four weeks prior to the vaccination. On 12Apr2021 10:00 am, the patient stated: I passed out and or blacked out on my drive home from the hospital. I was careful to follow the 15minute wait period before I left the hospital and was ok at that point. I had tense nerve feelings came over me as it grew so strong, I was forced to try and get my car on an off ramp to leave the highway I was on. I thankfully did not get any real injuries to my body as I spun and landed on the side of the road in the grass area. However, this experience was horrifying to say the least. I had a delayed reaction to this vaccine, other than this one incident, I really only had the typical body aches or pain for 24 hours and a bit of nerve twitching. I will not mark this as a risk of death, because it was my driving a car that risked my safety not the vaccine, however, the vaccine did cause the black out. The clinical outcome of the events was recovered. The patient was not tested for COVID-19 after the vaccination. Information about the Lot/batch number has been requested. |

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| 1265903 | 4/28/2021 | CA | 49 | F | 4/11/2021 | 4/12/2021 | This is a spontaneous report from a contactable other healthcare professional (patient). A 49-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EW0158 and expiration date not provided), via an unspecified route of administration administered in the right arm on 11Apr2021 14:00 as a single dose for COVID-19 immunization. Medical history included Crohns Disease. The patient is not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient has no known allergies. There were no concomitant medications. The patient did not receive any other vaccine within 4 weeks prior to the COVID vaccine. On 12Apr2021 01:45, about 12 hours after the first dose, the patient passed out and then broke out in a cold sweat, multiple times. No treatment was given in response to the events. The outcome of the events was recovering. The patient has not been tested for COVID post vaccination.; Sender's Comments: Based on the plausible temporal association and product safety profile, the reported events are possibly related to the vaccine BNT162B2. administration. This case will be reassessed upon receipt of additional information. The impact of this report on the benefit/risk profile of the Pfizer drug is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate. |

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| 1265667 | 4/28/2021 | AZ | 25 | M | 4/27/2021 | 4/27/2021 | The patient reported that they were experiencing tightness in their arm and believed it swelled initially. They left the pharmacy area and went to get Tylenol that was recommended by the pharmacist. They then began to get lightheaded and had syncope, attempted to get back up and the cashier asked to if they wanted to sit, but fell again. It was not clear initially to the employee who was helping them they had received the vaccine. 911 was called and the employee helping them let the pharmacist know they had just gotten their vaccine. The immunizing pharmacist went to check on the patient. EMTs were already helping the patient and had taken his blood pressure which was normal the lightheadedness had stopped and both sitting and standing blood pressure was the same. He had an elevated heart rate per the patient but didn't know any of the numbers the EMTs had taken. His father was driving him. He was not experiencing any symptoms and the injection site had no swelling and was otherwise unremarkable. |
| 1266684 | 4/28/2021 | NC | 25 | M | 4/28/2021 | 4/28/2021 | Patient received immunization. Was sitting in chair for observation and about 5 minutes after immunization was given he passed out. Was awake immediately but said he didn't remember passing out. Knew his name, date of birth, where he was. I watched him until paramedics arrived. He said he felt fine but was sweaty. Paramedics stated all his vitals were normal and he said he felt ok but he said he got really hot. Remained at the pharmacy until his friend could come and get him. |
| 1266426 | 4/28/2021 | CA | 17 | F | 4/27/2021 | 4/27/2021 | Pt had an episode of syncope for 10 seconds after getting vaccinated . Blood pressure dropped to 90/50, Hr 48. After repositioning the pt and giving some fluid Blood pressure raised to 113/96 Hr 72. |

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| 1265984 | 4/28/2021 | WI | | F | 4/6/2021 | 4/6/2021 | Patient experienced brief (15-30 second) episode of syncope; This is a spontaneous report from a contactable pharmacist. A female patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 06Apr2021 (Lot number: EW0150) as single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. Patient was not pregnant at the time of vaccination. On 06Apr2021, immediately following injection of 1st dose of vaccine, patient experienced brief (15-30 second) episode of syncope. She was sitting in chair and slumped forward momentarily. It was unknown if patient had Covid prior vaccination and unknown if tested for Covid post vaccination. No treatment received for the event. The outcome of the event syncope was recovered. No follow up attempts are possible. No further information is expected.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the event syncope cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate. |
| 1268393 | 4/28/2021 | NY | 24 | M | 4/28/2021 | 4/28/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Mild |
| 1266247 | 4/28/2021 | | 33 | F | 4/16/2021 | 4/16/2021 | Patient received the Moderna vaccine and proceeded to the 15 minutes waiting area. After sitting down for 2-3 minutes she was noted by her husband to be feeling lightheaded. She proceeded to slump over on the chair and fainted. Emergency and 911 was called. She was placed on the stretcher and attached to the monitor, vital signs were obtained. Initial, BP 107/60, HR 80, RR 16, SpO2 98% on room air. Blood sugar obtained 77. |

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| 1266707 | 4/28/2021 | MN | 17 | F | 4/27/2021 | 4/27/2021 | Patient fainted after vaccine, had patient lay down, called 911, Fire and Rescue responded, patient left with father. |
| 1269447 | 4/28/2021 | NY | 18 | F | 4/27/2021 | 4/27/2021 | patient blacked out and passed out after receiving her first dose within the 15 min wait time. 911 was called and vitals were normal. patient refused admission to hospital |

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1269285 | 4/28/2021 | FL | 50 | F | 3/26/2021 | 3/26/2021 | Fainted 2 times; low blood pressure; dizzy; tachycardia; vertigo; nystagmus; body aches; fatigue; Felt nauseas; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of SYNCOPES (Fainted 2 times) in a 50-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 018821A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Hypothyroidism. Concurrent medical conditions included Allergy (anything cold.). Concomitant products included NSAIDS for Back pain, LEVOTHYROXINE for Hypothyroidism. On 26-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 26-Mar-2021, the patient experienced SYNCOPES (Fainted 2 times) (seriousness criterion medically significant), HYPOTENSION (low blood pressure), DIZZINESS (dizzy), TACHYCARDIA (tachycardia), VERTIGO (vertigo), NYSTAGMUS (nystagmus), MYALGIA (body aches), FATIGUE (fatigue) and NAUSEA (Felt nauseas). At the time of the report, SYNCOPES (Fainted 2 times), HYPOTENSION (low blood pressure), DIZZINESS (dizzy), TACHYCARDIA (tachycardia), VERTIGO (vertigo), NYSTAGMUS (nystagmus), MYALGIA (body aches), FATIGUE (fatigue) and NAUSEA (Felt nauseas) outcome was unknown. Not Provided DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 26-Mar-2021, Laboratory test: normal. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. Treatment information included, meclizine 25 mg and metoclopramide was provided for vertigo and nystagmus.; Sender's Comments: This case concerns a 50-year-old female with a serious unexpected event of syncope, and nonserious unexpected hypotension, dizziness, tachycardia, vertigo, nystagmus, and expected myalgia, fatigue, nausea. Event onset the same day as first dose mRNA-1273. Event outcomes unknown. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. |

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| 1269229 | 4/28/2021 | CO | 17 | M | 4/27/2021 | 4/27/2021 | Patient passed out and ended up falling off the chair hitting his forehead (left side) on the concrete flooring. Patient seemed to be doing okay after being observed by EMS for about 45 minutes. BP 110/74, denied dizziness or nausea but was complaining of headache. Patient's mother refused transport to ER. |
| 1268689 | 4/28/2021 | OK | 18 | F | 4/25/2021 | 4/25/2021 | 18 yo female requests to have injection in supine position due to previous history of passing out with injections. Mom at pts side and sts pt first passed out at the age of 4 years old when she witnessed her father having blood drawn for a health screen. She also reportedly passed out after receiving a vaccine at Pharmacy in 2017. Due to her history of injection related syncopal episodes, pt is placed in a supine position on the cot as precaution. Approximately 30 seconds after receiving the injection, the pt was witnessed becoming unresponsive by this HCP. Pt was then witnessed having her eyes roll up and back followed by a few seconds of generalized seizure activity. HCP remains at pts side. The cot has a suspended cloth and is soft, therefore, pt is safe from harm on it. Seizure ends after seconds and pt awakens. She is initially confused but orients quickly. She remains AOX4 and has no complaints. Spoke with mom extensively about pts condition and presenting symptoms. VS- HR initially 52 but quickly improves to 77, BP 107/64, RR 16, sats 98%. Pt will follow up with pts pediatrician. Mother and pt do not want pt evaluated at the ER today and do not want an ambulance. VAERS info given. |
| 1268056 | 4/28/2021 | NJ | 17 | F | 4/28/2021 | 4/28/2021 | Patient fainted after vaccine administration. |
| 1267939 | 4/28/2021 | AL | 50 | M | 4/28/2021 | 4/28/2021 | Patient passed out walking down the hall to the bathroom about 5 minutes after receiving the vaccine. When patient regained consciousness, he stated he was having a hot flash and was going to the bathroom to get something to wipe off his face. |
| 1267908 | 4/28/2021 | ME | 41 | F | 4/27/2021 | 4/27/2021 | 5pm started with chills, followed by headache and rapid heart rate and fever. Syncope upon standing. Heart rate stayed elevated for over 5 hours. Fever came down with Tylenol amd Motrin. |

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| 1267618 | 4/28/2021 | FL | 21 | F | 4/6/2021 | 4/6/2021 | Passed out for a few minutes. Chest pains 2 weeks later. |

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| 1267320 | 4/28/2021 | CA | 41 | M | 3/26/2021 | 4/4/2021 | <p>3/26 @ 3:15pm ? Got the first dose of Pfizer COVID-19 vaccine for the 1:10pm appointment. However actual time received was around 3:15pm. No vaccine reaction was observed and drove back home. However did not eat or drink much from morning till 4:30pm due to the long line at the vaccination center</p> <p>4/4 @ 9:00pm ? Experienced first sign of near-syncope at the dinner table upon picking up a glass of milk</p> <p>4/6 @ 8:45am ? Experienced brain fog, to be exact head felt like it was filled with cotton candy, at the back and top of the head. Felt this way the entire day. Went to work as usual. Logged out at around 5:30pm</p> <p>4/7 @ 9:00am ? dizziness started getting worse. Started feeling imbalance and started losing depth perception which climbing down staircase</p> <p>4/8 @ 10:00am ? started to get easily startled by any unexpected trigger. Whole body would ?twitch? or ?startle? upon slightest unexpected event. For e.g., sound, touch, taste (hot/cold)</p> <p>4/10 @ 12:00pm ? Went to ER. ER ordered series of blood tests, EKG, chest x-ray. Everything came out normal. ER doctor said to wait it out and after a week symptom may go away. ER doctor felt body?s immune response was over-working due to the vaccine immune response and possibly pollen allergy I may have experienced right after getting the vaccine. No prescription meds give. Advised to take Meclizine 25mg and Zyrtec. Below are the symptoms experienced on 4/10: ? Lightheadedness/Sudden Jerking body movements when triggered/passing out momentarily for a second when taking strain/not in my elements ? Feeling extremely fatigued. Did not sleep well at night on 4/8 and 4/9 ? Head feels Intoxicated, foggy, lightheaded, as if stuffed with cotton candy. Startled when unexpected things happen like a sudden jerking movement along with momentary passing out while anything unexpected happens. E.g., when I am pushing myself on the sofa to re-position, I feel my whole body is turning off for a second. Simply does not feel normal ? Rubbery legs ? Worsens after shower. I feel like I need to lay down as the foggy feeling worsens after shower ? Lightheadedness. Losing control sometimes. ? I am easily startled when climbing down the stairs - no Depth perception. ? Don?t have the strength to blow nose or cough. Feels like momentary fainting when doing these activities ? Dis-equilibrium. Whole body is twitching when something unexpected happens to my senses. ? Unable</p> |

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to control while laughing feels like momentary faint. I have felt like this when I was down with a fever. Ticked easily ? Difficulty pulling myself out of bed. Felt like muscle was giving away ? Tingling feeling in the right abdomen area ? Difficulty staying alert or focused and random rather unpleasant thoughts constantly coming to mind. Felt a bit of panic attack. 4/11 ? Went to PCP. Body weakness and fatigue got worse. PCP did blood sugar test and flushed out the left ear. Ordered Brain MRI to see if structurally anything was wrong. Brain MRI came out OK as well however noticed minor sinusitis. Prescribed Amoxicillin antibiotics and nasal spray. Referred me to Neurologist and Head and Neck Specialist. 4/11 ? 4/15 - Above symptoms progressively got worse. Especially weakness in the arms and shoulders. Arms quivered every time trying to stand up and felt like fainting. Hand-eye coordination progressively got worse. For e.g., could not pick up water bottle, hands were quivering badly 4/15 ? Neurologist conducted certain diagnostic tests and concluded that there are no neurological issues. Said with rest and plenty of fluids it should get better. Spinal tap was not recommended and said if symptoms got worse a spinal tap can be done during the next visit. Follow up visit with neurologist scheduled on 4/27 4/15 ? 4/27 ? Weakness in arms got better. Arm strength and coordination has improved however it?s still not back to normal. Brain fog and dizziness still persists with no improvement. Left limb and arms are stronger than the left. Difficulty climbing up and down stairs. Dizziness worsens after shower. Not feeling myself. In addition, not able to multitask - getting startled and need to be deliberate about having to do everyday chores need to just focus on one task 100% completely and if something else comes up then my body just goes into a momentary shock. Mostly I can feel my head feeling heavy and my eyelids shutting down when something shocking happens ? a feeling like body is ?turning off?, almost a fainting or passing out feeling. Sometimes when I turn to one side and sleep, I can feel a flickering sensation in the ear. Still always feeling woozy and as if there is something in my head ? a medicated or intoxicated feeling in the head 4/27 ? Neurologist said she sees a lot of improvement and reiterated again that I don?t have any neurological issues. She said I can go back to work starting 5/1. She said I may have

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| | | | | | | | Conversion Disorder / Disequilibrium. It?s hard for me to fathom why she would diagnose me with Conversion Disorder when so many people are reporting very similar symptoms that I am facing on the below forum: https://www.drugdiscoverytrends.com/dizziness-among-common-covid-19-vaccine-side-effects/ 4/30 ? Next appointment with Head and Neck / Audiology |
| 1267281 | 4/28/2021 | NJ | 35 | M | 4/28/2021 | 4/28/2021 | Pt felt lightheadedness after getting vaccine. For about 15 seconds pt passed out. I was about to give epipen and he came back as felt better. So did not need epipen. Called 911 and EMS came and took over. Pt felt better afterwards only little lightheadedness and nauseated. Pt waited about an hour at pharmacy and then brother took him home. |
| 1266809 | 4/28/2021 | MI | 63 | M | 4/8/2021 | 4/22/2021 | Presented to emergency department on 4/22/21 after having an unwitnessed syncope episode at home. Was found to be in atrial fibrillation with RVR. He denies any COVID-19 exposure, but was found to be positive upon screening for admission. No COVID-19 symptoms were reported during admission. |
| 1266929 | 4/28/2021 | CA | 18 | F | 4/27/2021 | 4/27/2021 | PATIENT RECEIVED FIRST DOSE MODERNA VACCINE AFTER FEW MINUTES SHE IS FAINTED AND FELT ON FLOOR AT PHARMACY WAITING ROOM.PATIENT PASSED OUT FOR FEW SECONDS. STORE ASSOCIATE CALLED 911. EMERGENCY TEAM ARRIVED AND CHECK HER VITAL SIGNS. HER BLOOD PRESSURE DROPPED TO UNDER 100. PATIENT HAD SOME SNACKS AND DRUNK GATORATE . AFTER FEW MINUTES PATIENT WAS BACK TO NORMAL SHE WAITED FOR ANOTHER 30 MINUTES AND WALKED HOME WITH MOM. |
| 1266906 | 4/28/2021 | CT | 30 | F | 4/28/2021 | 4/28/2021 | at 4/28/21 patient was vaccinated w/ Jessen vaccine and soon became pale and observed to become flaccid and pass out. pt's HR was 50, satO2 99% and BP 70/40. Pt soon observed with BLUE contracting and BLLE adducting followed by urine incontinence. Pt did not fall and was sitting in her chair the entire episode that lasted for approximately 40-60sec. Pt awake and continued to have hypotension, dizziness reported. EMS contacted and pt transferred to local ER for evaluation of suspected syncope and seizure s/p vaccination. |

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| 1266854 | 4/28/2021 | PA | 17 | M | 4/27/2021 | 4/27/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Additional Details: Patient fainted after receiving his first dose of the shot. He was very pale and sweating but responsive to questions. Monitored his blood pressure and had him sit and drink water. After 15 minutes his color had returned, stopped sweating and was totally alert/oriented. Per patients mother he had just come from school and had not eaten much that day which she belived to be a contributing factor |
| 1266829 | 4/28/2021 | TX | 28 | M | 4/27/2021 | 4/27/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Nausea-Mild, Systemic: Numbness (specify: facial area, extremities)-Mild, Systemic: Shakiness-Mild, Systemic: Tingling (specify: facial area, extremities)-Mild, Additional Details: pt experienced syncopal episode in store, resolved and left after 30 minute stay |
| 1266824 | 4/28/2021 | TX | 37 | M | 4/27/2021 | 4/27/2021 | Systemic: Allergic: Difficulty Breathing-Severe, Systemic: Chills-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Severe, Systemic: Headache-Medium, Systemic: Hyperventilation-Severe, Systemic: Shakiness-Severe, Systemic: Tingling (specify: facial area, extremities)-Severe, Additional Details: epipen given. called 911. but the patient was ok before they get to the store after giving epipen. |
| 1266819 | 4/28/2021 | IL | 27 | F | 4/27/2021 | 4/27/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Nausea-Severe, Systemic: Visual Changes/Disturbances-Medium |
| 1266758 | 4/28/2021 | WA | 18 | F | 4/28/2021 | 4/28/2021 | event: patient passed out shortly after vaccine (in store) treatment: patient was instructed to remain seated on the floor. Patient was sweating and pale in the face. She was given water, BP was taken and within range. Patient remained sitting in store for 20 min. Patient left with an alternative driver and stated she was okay and felt much better. |

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| 1266798 | 4/28/2021 | MD | 20 | M | 4/27/2021 | 4/27/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Shakiness-Mild, Systemic: Weakness-Mild |
| 1268977 | 4/28/2021 | IL | 16 | F | 4/1/2021 | 4/1/2021 | Patient fainted while seated minutes after vaccine was given. Mother was next to her to prevent her from falling to floor. She complained of nausea and blurred vision. She was given water and Gatorade and began feeling better 5-10 minutes after fainting. |
| 1266803 | 4/28/2021 | DC | 32 | M | 4/27/2021 | 4/27/2021 | Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Tingling (specify: facial area, extremities)-Severe, Systemic: Visual Changes/Disturbances-Mild, Systemic: Weakness-Mild, Additional Details: Numbness, tingling in hands/ mouth/ tongue. History of similar reactions with other vaccinations per patient. Patient has a phobia with needles. |
| 1267116 | 4/28/2021 | IN | 48 | F | 4/26/2021 | 4/27/2021 | Received shot in upper right arm and it was painful. My arm grew more painful throughout the day. I became very tired as the day went on. Went to bed for the evening, Monday 4/26/2021 and woke up at 1:50am on Tuesday morning, 4/27/2021 in full body sweats, dripping with sweat. So weak I couldn't get up or lift my head. My husband took my temperature which was 103. Massive headaches, full body aches and pains, chills which made my body shake uncontrollably. My whole body hurt. Could not get up to use the restroom, tried and fainted back into the bed. Heart felt like it was beating out of my chest. My husband wanted to call 911 but I didn't want to. Felt like I had COVID again. |

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| 1261790 | 4/27/2021 | OK | 74 | F | 3/24/2021 | 3/24/2021 | troponin: high troponin levels; pain on the back of her head and her back; pain on the back of her head and her back; Chills; fever; She was shaking badly; Fainted; This is a spontaneous report from a contactable consumer. A 74-year-old female patient received her second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in Arm Right on 24Mar2021 11:15 (Lot Number: ER8727; Expiration Date: 31Jul2021) as SINGLE DOSE for covid-19 immunisation (Age at vaccination: 74 years). Medical history included ongoing rheumatoid arthritis, melanoma, depression, heart attack (had a heart attack 7 or 8 years ago) and covid (covid in the first week of January). Concomitant medications included levothyroxine sodium (SYNTHROID) and escitalopram oxalate (LEXAPRO) for depression. The patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 03Mar2021 for covid-19 immunisation and experienced rash with itching and a lump and swelling (74 years). The patient fainted on 24Mar2021, chills and fever on 24Mar2021 20:00, pain on the back of her head and her back and a couple of places like anyone would get when they fall on 25Mar2021 and she was shaking badly on 24Mar2021. The patient underwent lab tests and procedures which included blood work: unknown results and troponin: high troponin levels on an unspecified date. Therapeutic measures were taken as a result of tremor included Aleve. Outcome of the events chills and pyrexia was recovered on 25Mar2021 (four hours) while outcome of the events head pain and back pain was recovering. Outcome of the remaining events was unknown. |

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| 1261789 | 4/27/2021 | NY | | F | | 2/26/2021 | Fainted; Sudden light nausea; Full body chills; Muscle weakness in legs; Lightheadedness; This is a spontaneous report from a contactable consumer (the patient). A 70-year-old female patient received the first dose and second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), on 26Feb2021 12:15 (lot number EN6203) and on 19Mar2021 12:00 (lot number EN6208), respectively, both via an unspecified route of administration in the right arm (age at vaccination unknown), as a single dose for COVID-19 immunization. The patient's medical history was not reported. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications included: fluoxetine hydrochloride (PROZAC), lorazepam, and pantoprazole. The patient had an allergy to contrast dye. The patient did not receive any other vaccines within four weeks prior to the vaccination. On an unspecified date, the patient experienced sudden light nausea, then full body chills, followed by muscle weakness in legs, and lightheadedness, then she fainted. Then she was fine. This whole reaction progression took place within 60 seconds, plus about 2 minutes for full leg muscle strength to return. No treatment was received for the events. The patient had a negative nasal swab COVID test on 04Mar2021. The outcome of the events was recovered on an unspecified date. |

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| 1261795 | 4/27/2021 | NY | 78 | F | 4/5/2021 | 4/6/2021 | she just felt dizzy so fast and passed out; passed out; She hurt her ankle from it; This is a spontaneous report from a contactable consumer. A 78-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 2 via an unspecified route of administration, administered in Arm Left on 05Apr2021 08:45 (Batch/Lot Number: EP7534) as SINGLE DOSE for covid-19 immunisation. Medical history included ongoing hypertension, atrial fibrillation from Aug2020 and ongoing , cystitis. Concomitant medications included sulfamethoxazole, trimethoprim taken for cystitis from 27Mar2021 to 02Apr2021; apixaban (ELIQUIS) taken for atrial fibrillation from an unspecified start date and ongoing; atenolol (ATENOLOL) taken for Blood pressure from an unspecified start date and ongoing. The patient received first dose of bnt162b2 for COVID-19 immunization on 15Mar2021 lot number: EN6202, Expiry date: 30Jun2021. The patient received the second dose of the Covid vaccine around 8:45 a.m. and states that she "felt fabulous." On 06Apr2021 she felt fabulous. She said that she had a doctors appointment at 1200 06Apr2021 and her blood pressure was good. She said that she was also taking an antibiotic prior to that week. She asked the doctors about taking vaccines after taking the antibiotic since the medication said that you should avoid vaccines while taking the antibiotic, and they all said that it was fine. She came home about 1330 06Apr2021 and she passed out while making her lunch. She hurt her ankle from it and she is not a happy camper. She said that all her vitals were good and her blood was good. That was all taken 2 hours before she passed out. The weird thing was she never felt better that day after she passed out. She said that she had no reaction after the first shot. Prior to this she felt good and there was no warning, she just felt dizzy so fast and passed out. Caller said that her ankle is getting better and she hurt her toe too, but it is getting better. She treated the ankle with ice. She said that it could have been worse. She said that she did not understand this and had no side effects previously. The event passed out was assessed as serious (medically significant). The patient underwent lab tests and procedures which included blood test: good on an unspecified date her blood was good. Therapeutic measures were taken as a result of she hurt her ankle |

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| | | | | | | from it (arthralgia). The outcome of the event passed out was recovered with sequel on 06Apr2021, unknown for the other events. | |
| 1261752 | 4/27/2021 | FL | 60 | F | 3/27/2021 | 3/27/2021 | This is a spontaneous report from a contactable consumer. A 60-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 1 via an unspecified route of administration, administered in Arm Left on 27Mar2021 12:30 (at the age of 60-years-old) (Batch/Lot Number: ER-8730) as SINGLE DOSE for covid-19 immunization. Medical history included Hypothyroid, High Blood Pressure. Concomitant medications included levothyroxine sodium (SYNTHROID); losartan potassium (LOSARTIN); amlodipine; hydrochlorothiazide; all taken for unspecified indications, start and stop dates were not reported. On 27Mar2021 13:30, the patient experienced Bleeding at the site, fainting and vomiting while passed out for 5 minutes. The patient believes the injection was too high and she hit a vein. It was further reported that the patient is not a squeamish person and have never had reactions to any shots or blood draws in the past. The event fainting and passed out was assessed as serious (medically significant). Therapeutic measures were taken as a result of bleeding at the site. The patient did not receive treatment for the events fainting, passed out, and vomiting. The outcome of the events was recovered. |
| 1262113 | 4/27/2021 | AL | 40 | F | 4/26/2021 | 4/27/2021 | Fainted twice and couldn't maintain consciousness. I woke to urinate and went from feeling a little ill to burning up and unable to move off the ground or move my limbs. I became nauseous and dizzy. I fainted on the bathroom floor and again a little while later when I tried to crawl to my purse for the thermometer. After I laid on the floor for a while, I regained enough energy and to make it back to the bathroom with an intense urge to defecate. (I almost pooped my pants while passed out.) But, it wasn't diarrhea consistency. It was blackish, but normal consistency. At some point I took 2 Tylenol and fell asleep in the floor. By 2:30am, I was feeling strong enough to climb back into bed. I felt like I was dying but then it was over pretty quickly and I was back to feeling normal flu symptoms; 102 fever, body aches, etc. |

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| 1261731 | 4/27/2021 | IL | 39 | F | 3/12/2021 | 3/12/2021 | Fainted; extreme dizziness and disorientation since; extreme dizziness and disorientation since; metallic taste in mouth; smell metal coming out of pores; This is a spontaneous report from a contactable other healthcare professional (patient). A 39-year-old female patient (not pregnant, age at vaccination 39-year-old) received the second dose of bnt162b2 (BNT162B2 also reported as COVID 19 brand=Pfizer, Batch/Lot number was not reported), via an unspecified route of administration in the left arm, on 12Mar2021 09:00 as SINGLE DOSE for Covid-19 immunisation. Medical history included allergy to contrast dyes. She reported of Covid prior vaccination. She had her first dose of bnt162b2, 09am (lot unknown), left arm on 19Feb2021. Concomitant medications was antibiotics (unspecified) in two weeks. On 12Mar2021 09:15, the patient experienced faint/fainted, extreme dizziness and disorientation, metallic taste in mouth and had a smell metal coming out of pores (no treatment for the events). She had a clinic visit and Emergency room/department visit. The patient was hospitalized for 2 days due to the events. The patient underwent laboratory test Sars-cov-2 test: negative on 01Apr2021. The outcome of events was recovering. Information about lot/batch number has been requested. |

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| 1261712 | 4/27/2021 | PA | 53 | F | 4/9/2021 | 4/10/2021 | pass out; Vasovagal syncope; passed out again; This is a spontaneous report from a contactable consumer (Patient). A 53-year-old female patient (Non-pregnant) received second dose of BNT162B2 (Pfizer Covid-19 vaccine, Lot number ER8729 expiry date: unknown) via an unspecified route of administration at right arm as a single dose on 09Apr2021 03:00 PM, for Covid-19 immunization. Medical history included Hypothyroid, She had known allergies to Anti-Inflammatory, aspirin, penicillin, codein, ginger and horse radish. Concomitant medications were not reported. The patient received first dose of BNT162B2 (Pfizer Covid-19 vaccine, Lot number: EP7534 expiry date: unknown) via an unspecified route of administration at right arm as a single dose on 19Mar2021 04:00 PM, for Covid-19 immunization. On 10Apr2021 at 03:00 am, she woke to go to the bathroom feeling fine, after getting up from the toilet she saw stars and felt and had a Vasovagal syncope. When she woke up, she tried to get and pass out again. She woke up and was able to walk to my bed and passed out again when she reached the bed. She did not receive treatment for the events. She did not have any other vaccine in four weeks prior to suspect. She did not have Covid prior vaccination nor was she tested for Covid post vaccination. The patient had recovered from the events of pass out, vasovagal syncope and passed out again. No further information was available. |

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| 1261759 | 4/27/2021 | CT | 53 | F | 4/11/2021 | 4/11/2021 | This is a spontaneous report from a contactable consumer. A 53-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in Deltoid Left on 11Apr2021 09:15 (Lot Number: EP7533; Expiration Date: 31Jul2021) as SINGLE DOSE for covid-19 immunisation (Age at vaccination: 53 years). Medical history included asthma, Blood pressure high, acid reflux , allergies: Sulfa, Lactose intolerant and allergies: Latex. The patient's concomitant medications were not reported. The patient had a historical vaccine of Flu shot (INFLUENZA) on an unspecified date for immunisation and experienced bad side effects. The patient previously took bactrim, minocycline, doxycycline, ciprofloxacin, Moxifloxacin, demerol, avelox, nitrofurantoin, naprosyn, motrin, perocet, tramadol and aleve and experienced allergies. The patient experienced anaphylaxis on 11Apr2021. It was also reported that she had an appointment for COVID Vaccine at 9:15AM. Received COVID Vaccine and was told to wait for 30 minutes. Within 10 minutes her chest starting getting tight with difficulty of breathing. Her throat was closing up, and she was light headed. She explained this to the administrator who asked if caller could get up to see the paramedic. As caller tried to stand up, she almost passed out. Had to sit there for a second and the second time was able to get up and made it in to the room. Was going in and out of consciousness. Had to stab her with an Epi Pen. She couldn't breathe. Her throat was closing up. Her tongue was swollen. She was in and out of consciousness. First Epi Pen didn't work. An IV was put in and was given something through it. She was jabbed with a second Epi Pen. Was still in and out of consciousness but she was starting to come back. Was given oxygen and a nebulizer. She does have asthma. Ambulance was called. Was told she was worked on for 20 minutes. When ambulance arrived she was able to get up and get on the cart. She was taken to the hospital. Was given medicine through her IV. Had to be kept at hospital because she had two Epi Pens and medication at the vaccine facility. Hospital wanted to make sure when the Epi Pens wore off she didn't go back into anaphylaxis. Was kept in ER for over four hours. Was given IV fluids. Her oxygen, heart rate, and blood pressure dropped at |

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vaccination facility. Oxygen was 81. Blood pressure was 94. At hospital, her levels started to get better. Once she was given the second Epi Pen and whatever else she was given, the medication started to work and she had come through. At the hospital, someone came in and did bloodwork for research to see why this happened. Was prescribed Epi Pens by the doctor in the hospital and was advised to carry Epi Pens with her at all times. If she has another anaphylaxis, was advised to jab herself with Epi Pen and call right away. Was told her tongue was swelling. Attempted to obtain the outcome of the anaphylaxis. At the hospital, she was so out of breath walking to the bathroom. Was told at hospital now she is having side effects from the COVID Vaccine including the tiredness and headache she is experiences. Was told to take Tylenol and Benadryl, lay down and rest, and to make sure she drinks so she does not get dehydrated. Today, she feels nauseous, lightheaded and tired with a little headache. She feels better from yesterday. Is getting better and is having a little chills maybe an hour ago. She checked her temperature and does not have a temperature, but her insides feel warm . The patient was hospitalized for the event anaphylaxis on an unspecified date. Therapeutic measures were taken as a result of was going in and out of consciousness. Events for anaphylaxis, consciousness fluctuating, chest discomfort. dyspnea, throat tightness, presyncope and swollen tongue occurred on 11Apr2021 while the remaining events occurred on an unspecified date. The patient underwent lab tests and procedures which included blood pressure: dropped and 94, blood work: unknown results, heart rate: dropped, oxygen saturation: 81 and dropped on an unspecified date. Therapeutic measures were taken as a result of all the events. Outcome of the events was unknown.

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| 1261803 | 4/27/2021 | | | F | 4/1/2021 | 4/1/2021 | she passed out after taking her second dose yesterday; This is a spontaneous report from Pfizer-sponsored program. A non-contactable female consumer (patient) of unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), second dose via an unspecified route of administration on Apr2021, single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. Patient passed out after taking her second dose yesterday (Apr2021). The outcome of the event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained. |
| 1261937 | 4/27/2021 | PA | 32 | M | 4/13/2021 | 4/13/2021 | passed out; sweating profusely; This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 23-Apr-2021 and was forwarded to Moderna on 23-Apr-2021. This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (passed out) in a 32-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No relevant medical history provided. Concomitant products included VITAMINS NOS for an unknown indication. On 13-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 13-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (passed out) (seriousness criterion medically significant) and HYPERHIDROSIS (sweating profusely). On 13-Apr-2021, LOSS OF CONSCIOUSNESS (passed out) and HYPERHIDROSIS (sweating profusely) had resolved. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No treatment information was provided.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |

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| 1261943 | 4/27/2021 | AL | 68 | M | 3/23/2021 | 3/23/2021 | He was faint; Shortness of breathe; Rapid heart beat; Hungry; This spontaneous case was reported by a consumer and describes the occurrence of SYNCOPE (He was faint) in a 68-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 04021a) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 23-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 23-Mar-2021, the patient experienced SYNCOPE (He was faint) (seriousness criterion medically significant), DYSPNOEA (Shortness of breathe), HEART RATE INCREASED (Rapid heart beat) and HUNGER (Hungry). At the time of the report, SYNCOPE (He was faint), DYSPNOEA (Shortness of breathe), HEART RATE INCREASED (Rapid heart beat) and HUNGER (Hungry) outcome was unknown. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Concomitant medications reported were blood pressure medications. No further information regarding names of the medications was provided. No treatment information for the events was reported.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |
| 1261966 | 4/27/2021 | CT | 28 | F | 4/23/2021 | 4/23/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient has a history of fainting upon receiving vaccinations. |
| 1262139 | 4/27/2021 | WA | 16 | F | 4/27/2021 | 4/27/2021 | Pt felt "near syncope" event, with a feeling like she was going to vomit. The sensations relived themselves with several minutes of observation from the EMTs on site. |

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| 1261711 | 4/27/2021 | NY | 50 | F | 3/31/2021 | 4/1/2021 | fainted; slammed my face on the bathroom floor and broke my nose (among other cuts & bruises); nausea/mild queasiness; dizziness; heat; slammed my face on the bathroom floor and broke my nose (among other cuts & bruises); slammed my face on the bathroom floor and broke my nose (among other cuts & bruises); slight fever/mild queasiness; slammed my face on the bathroom floor; This is a spontaneous report from a contactable consumer, the patient. This 50 year-old patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number: ER8733), dose 1 , single dose via an unspecified route of administration in the left arm on 31Mar2021 at 02:30 PM (at the age of 50 years-old) for COVID-19 vaccination. Medical history included Grave's disease under control with medication. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications included desogestrel, ethinylestradiol (KARIVA), methimazole, lansoprazole and atorvastatin. The patient had no known allergies. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. On 01Apr2021 at 12:30 AM, 10 hours after vaccination administration, the patient experienced a sudden wave of severe nausea, dizziness, and heat and fainted. She slammed her face on the bathroom floor and broke her nose (among other cuts & bruises). Afterwards, her only symptoms were fainting injuries, slight fever/mild queasiness for 2 days. The events required a doctor or other healthcare professional office/clinic visit. Laboratory tests included a nose X-ray. Treatment was received for nausea, dizziness, heat and fainted, fever, slammed face, broke her nose (among other cuts & bruises). The clinical outcome of nausea, dizziness, heat and fainted, fever, slammed face, broke her nose (among other cuts & bruises) was unknown. It was also reported that since the vaccination, the patient had not been tested for COVID-19. |

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| 1262133 | 4/27/2021 | WI | | M | | 4/1/2021 | <p>COLD SORES ON THE EDGE OF LIPS; SORES ON OUTSIDE OF THE BRIDGE OF HIS NOSE; LOST APPETITE; PAIN IN SPINE (BACK) FROM TOP TO BOTTOM; FELT TIRED; HEADACHE; ARM FELT SORE/ACHY FOREARM; FAINTING; STRANGE DREAMS; BLUISH-GREEN MARK AT THE INJECTION SITE; FELT SLEEPY; ENERGY WAS LOW; ACHY ELBOW; This spontaneous report received from a patient concerned a male of unspecified age. The patient's height, and weight were not reported. The patient's past medical history included sick, fatigue, mood swings, depressive symptoms, headache, and joint pain, and concurrent conditions included allergies, shingles, Lyme's disease, brain fog, loss of smell, irritability, and sense of taste improved but not 100%. On DEC-2020, Laboratory data included: COVID-19 antibody test (NR: not provided) Negative. On MAR-2021, Laboratory data included: COVID-19 antibody test (NR: not provided) Negative. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, 1 in total administered on 06-APR-2021 to right arm for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On 06-APR-2021, the subject experienced fainting (dizziness) and dizziness at the vaccination facility. He drank juice and his blood pressure was checked. On the same day, his arm felt sore/achy forearm and during night he had strange dreams. On 07-APR-2021, the subject experienced pain in spine (back) from top to bottom, lost appetite, felt tired and headache. On an unspecified date in APR-2021, the subject experienced felt sleepy, energy was low, achy elbow, bluish-green mark at the injection site. On 11-APR-2021, the subject experienced sores on outside of the bridge of his nose (they were small, red, not leaky and tender to touch - felt like a skin eruption), cold sores on the edge of lips. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from fainting, and dizziness on 06-APR-2021, and the outcome of strange dreams, arm felt sore/achy forearm, headache, felt tired, lost appetite, sores on outside of the bridge of his nose, achy elbow, felt sleepy, energy was low, cold sores on the edge of lips, bluish-green mark at the</p> |

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| 1261180 | 4/27/2021 | FL | 32 | F | 4/12/2021 | | <p>injection site and pain in spine (back) from top to bottom was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210428769-covid-19 vaccine ad26.cov2.s -fainting. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p> <p>SYNCOPE EPISODE; NECK PAIN; LOSS OF APPETITE; BODY ACHE; DIZZINESS; VOMITING; CHILLS; HEADACHE; NAUSEA; This spontaneous report received from a health care professional concerned a 32 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included penicillin allergy, hepatitis C, HIV, opioid dependence, polysubstance abuse, and depression. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 1805025, and expiry: UNKNOWN) dose was not reported, administered on 12-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On 12-APR-2021 about one hour after the vaccination, the patient experienced neck pain, loss of appetite, body ache, dizziness, vomiting, chills, headache, and nausea. On 13-APR-2021, the patient experienced syncope episode and other symptoms got worsened. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from syncope episode, chills, neck pain, loss of appetite, headache, nausea, vomiting, body ache, and dizziness. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked.; Sender's Comments: V0- covid-19 vaccine ad26.cov2.s-syncope. This event(s) is considered not related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: MEDICAL HISTORY, UNDERLYING DISEASE</p> |

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| 1261952 | 4/27/2021 | NJ | | M | 3/19/2021 | 4/18/2021 | Fever; Fainting (15h post injection); Increased HR; This spontaneous case was reported by a consumer and describes the occurrence of SYNCOPE (Fainting (15h post injection)) in a 35-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 018B21A and 039A21B) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concomitant products included ADALIMUMAB (HUMIRA) for an unknown indication. On 19-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 18-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 18-Apr-2021, the patient experienced SYNCOPE (Fainting (15h post injection)) (seriousness criterion medically significant). 18-Apr-2021, the patient experienced HEART RATE INCREASED (Increased HR). On 19-Apr-2021, the patient experienced PYREXIA (Fever). At the time of the report, SYNCOPE (Fainting (15h post injection)) had resolved and HEART RATE INCREASED (Increased HR) and PYREXIA (Fever) outcome was unknown. Treatment received in response to the event was acetaminophen. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |

| <u>VAERS_ID</u> | <u>RECVDATE</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1261329 | 4/27/2021 | | 31 | F | | | <p>THROMBOSIS; Dizziness; Pass Out; Weakness in the all side of the body; This spontaneous report received from a patient. The patient's height, and weight were not reported. The patient's concurrent conditions included sea food allergy, and other pre-existing medical conditions included the patient did not had any other illness at the time of vaccination and to one month prior and chronic or long standing health condition. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin, and batch number were not reported) dose was not reported, administered on 02-APR-2021 11:25 for prophylactic vaccination. The batch number was not reported. As per procedure, no follow-up will be requested for this case. Concomitant medications included metformin for drug used for unknown indication. On an unspecified date, the subject experienced thrombosis, dizziness, pass out, and weakness in the all side of the body, and was hospitalized (date unspecified). Laboratory data (dates unspecified) included: X-ray (NR: not provided) heart, head and lungs. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from thrombosis, dizziness, pass out, and weakness in the all side of the body. This report was serious (Hospitalization Caused / Prolonged, and Life Threatening).; Sender's Comments: V0: This is a report of a patient, who was noted to have thrombosis on unspecified time after receiving the covid-19 vaccine ad26.cov.2. Patient's height and weight were not reported. Patient medical history was not reported. Concomitant medications included metformin for unknown indication. Patient is allergic to seafoods. On an unspecified date, the subject experienced dizziness and passed out. She also had weakness on the left side of the body. Patient was noted to have thrombosis. Patient was hospitalized, where laboratory and diagnostic tests were done. Results were not reported. The information provided precludes a meaningful medical assessment. Additional information requested.</p> |

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| 1261751 | 4/27/2021 | TX | 35 | F | 4/11/2021 | 4/11/2021 | syncope two hours after the vaccine.; This is a spontaneous report from a contactable other hcp (patient). A 35-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; Batch/Lot Number: ew0151), via an unspecified route of administration, administered in Arm Right on 11Apr2021 13:00 (at 35-year-old) as single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. Patient was not pregnant. Vaccination facility type was Pharmacy or Drug Store. Patient had no covid prior vaccination. Patient was not tested for covid post vaccination. Patient had no known allergies. The patient experienced syncope two hours after the vaccine on 11Apr2021 15:00, she never had any history of syncope before. No treatment was received. The outcome of the event was recovered in Apr2021. |
| 1262158 | 4/27/2021 | NV | 34 | M | 4/27/2021 | 4/27/2021 | THE INTERN PHARMACIST PROVIDED THE VACCINE IN DESIGNATED VACCINE ROOM. VACCINE WAS ADMINISTERED AT 12:20 PM. AS INTERN WAS CLEANING ROOM, KNOCKING WAS HEARD AT VACCINE ROOM DOOR AND PATIENT'S FRIEND/SIGNIFICANT OTHER STATED THAT PATIENT HAD FAINTED IN A CHAIR AROUND 12:22 PM. WHILE 911 WAS BEING CALLED AT 12:24 PM PATIENT WAS ALREADY CONSCIOUS. ACCORDING TO PATIENT'S FRIEND/SIGNIFICANT OTHER, PATIENT SAT DOWN IN CHAIR AND THEN PASSED OUT FOR APPROXIMATELY 20-30 SECONDS BEFORE BECOMING CONSCIOUS AND WAS CONSCIOUS WHEN PARAMEDICS ARRIVED. PATIENT LOOKED PALE AND STATED TO FEEL WEAK. PATIENT WAS PROVIDED WATER WHILE WAITING FOR PARAMEDICS TO ARRIVE AND STATED TO FEEL BETTER. WHEN PARAMEDICS ARRIVED, VITALS WERE CHECKED AND BP WAS LOW. PATIENT WAS THEN TAKEN TO HOSPITAL DUE TO PROGRESSIVELY FEELING WORSE (WEAK). |

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| 1261081 | 4/27/2021 | | | F | 1/19/2021 | 1/20/2021 | <p>Syncope x2; This case was received via United States FDA VAERS (Reference number: 0958516) on 20-Apr-2021 and was forwarded to Moderna on 20-Apr-2021. This regulatory authority case was reported by an other health care professional (subsequently medically confirmed) and describes the occurrence of SYNCOPE (Syncope x2) in an 888-month-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 immunisation. No Medical History information was reported. On 19-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 20-Jan-2021, the patient experienced SYNCOPE (Syncope x2) (seriousness criterion medically significant). At the time of the report, SYNCOPE (Syncope x2) had resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No Concomitant medications reported by the investigator. Treatment of these events were not reported.</p> |

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| 1261153 | 4/27/2021 | CA | 30 | F | 4/5/2021 | | <p>FAINTED; WEAKNESS; This spontaneous report received from a patient concerned a 30 year old female. The patient's height, and weight were not reported. The patient's past medical history included lightheadedness from injections. The patient had no history of any reaction to vaccines before. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: GL12A21A, expiry: UNKNOWN) dose was not reported, 1 total, administered on left arm on 05-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On 05-APR-2021, the patient was fainted after receiving the vaccine and treated with emergency medical services. On the same day, the patient felt dizzy and experienced weakness. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from fainted, and weakness on 05-APR-2021. This report was serious (Other Medically Important Condition).;</p> <p>Sender's Comments: V0: -JANSSEN COVID-19 VACCINE Ad26.CO2.S-Fainted. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.</p> |

| <u>VAERS_ID</u> | <u>RECVDATE</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1261165 | 4/27/2021 | | | U | | 4/1/2021 | RIGHT NOSTRIL BLEED; FLU LIKE SYMPTOMS; ON THE WAY TO FAINTING; SERUM FELT LIKE FIRE; DIZZINESS; HAVE NOT FELT LIKE MYSELF; This spontaneous report received from a patient concerned a patient of unspecified age and sex. The patient's height, and weight were not reported. The patient's concurrent conditions included thyroid disorder, and other pre-existing medical conditions included take a thyroid pill daily. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin, and batch number were not reported) dose was not reported, administered on 06-APR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On APR-2021, the subject experienced have not felt like myself. On 06-APR-2021, the subject experienced on the way to fainting. On 06-APR-2021, the subject experienced serum felt like fire. On 06-APR-2021, the subject experienced dizziness. On 09-APR-2021, the subject experienced flu like symptoms. On 12-APR-2021, the subject experienced right nostril bleed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from on the way to fainting on 06-APR-2021, had not recovered from dizziness, and the outcome of right nostril bleed, serum felt like fire, flu like symptoms and have not felt like myself was not reported. This report was non-serious.; Sender's Comments: V0:Medical assessment comment not required as per standard operating procedures, as the case was assessed as non-serious. |

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| 1261231 | 4/27/2021 | NY | 54 | F | 3/30/2021 | PASSED OUT; VERY HOT FEELING; SKIN WAS BURNING LIKE SEVERE SUNBURN (ON WAIST, SHOULDER, ARM, HAND, BELLY, NECK, BREAST, AND FACE); BODY DRAINED; SKIN REDNESS; GOOSE BUMPS; FEELING COLD; SCRATCHED BODY; HEADACHE; FELT LIKE FAINTING BUT DID NOT FAINT; This spontaneous report received from a patient concerned a 54 year old female. The patient's weight was 165 pounds, and height was 154.94 centimeters. The patient's concurrent conditions included high blood pressure, diabetes, penicillin allergy, nonsmoker, and non-alcohol user. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1808980,expiry: 20-JUN-2021) .5 ml, administered on 30-MAR-2021 to the left arm for prophylactic vaccination. No concomitant medications were reported. On 30-MAR-2021, the patient experienced dizziness (felt like fainting but did not faint). Then 15 minutes later, she was fine. On 31-MAR-2021, the patient experienced headache. On 03-APR-2021, three hours into the work, she felt very very hot and her skin was burning like severe sunburn. It was waist, shoulder, arm, hand, belly, neck, breast, and face were hot and red. She scratched the body and was really warm and skin was really red. After 40 min, the patient's body went to back to normal. After 5 min, patient started feeling really cold and goose bumps on her arms that lasted for 30 minutes. After that episode she went home and felt her body was drained and passed out. The patient felt better on 04-APR-2021. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from passed out on 04-APR-2021, very hot feeling, skin was burning like severe sunburn (on waist, shoulder, arm, hand, belly, neck, breast, and face), body drained, skin redness, goose bumps, feeling cold, and scratched body on 03-APR-2021, and felt like fainting but did not faint on 30-MAR-2021, and was recovering from headache. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210430845-covid-19 vaccine ad26.cov2.s-Passed out. -This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s). | |

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| 1261262 | 4/27/2021 | VA | 35 | M | 4/7/2021 | | <p> FAINTED; HEARTRATE SLOWED; LOW BP; SHORTNESS OF BREATH; SWEATING FROM HEAD TO TOE; FATIGUE/TIREDNESS; This spontaneous report received from a patient concerned a 35 year old male. The patient's height, and weight were not reported. The patient's concurrent conditions included food allergy-poultry. The patient had no known allergies. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 1808978 expiry: UNKNOWN) dose was not reported, 1 total, administered on 07-APR-2021 13:30 to left arm for prophylactic vaccination. No concomitant medications were reported. On 07-APR-2021, the patient experienced dizziness, light headedness and fainted 10 minutes after at vaccination centre. It was not allergy reaction, he had low blood pressure (BP) and his heartrate slowed. The nurses elevated his legs, other nurse took vitals. He was covered in sweats from head to toe, they gave him Gatorade. He kept his head down and legs up and was monitored for his vitals. It was reported that he came around in 10 minutes, after fainting until BP and heart rate returned to normal. The nurses kept checking vital, at vaccination centre, then sent home, asked him to eat and drink. He also had shortness of breath on and off lasting for 3 hours at a time and also fatigue/tiredness. He had never fainted before so unusual behaviour. Laboratory data included: Blood pressure (NR: not provided) normal, Low, and Heart rate (NR: not provided) Normal, Slowed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from fainted, heartrate slowed, low BP, and sweating from head to toe on 07-APR-2021, and was recovering from shortness of breath, and fatigue/tiredness. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210432065-covid-19 vaccine ad26.cov2.s-Fainted. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s). </p> |

| <u>VAERS_ID</u> | <u>RECVDATE</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1261278 | 4/27/2021 | | | U | 3/28/2021 | | <p>PASSED OUT; BOTH ARMS WENT COMPLETELY NUMB; LEGS CRUMBLED/COULDN'T STAND UP; VOMITED; THE DAY GOT THE VACCINE IT BLED AND A BLOOD CLOT CAME ON MY ARM; This spontaneous self-report concerned a patient of unspecified age and sex. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin, and batch number were not reported) dose was not reported, administered on 28-MAR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 28-MAR-2021, the day the patient got the vaccine it bled and a 'blood clot' came on my arm (coded to injection site bleeding). On 01-APR-2021, the patient passed out in a store, both arms went completely numb, legs crumbled/couldn't stand up, and vomited. The patient believed this was a side effect of the vaccine. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of events (passed out, both arms went completely numb, legs crumbled/couldn't stand up, vomited, and the day got the vaccine it bled/blood clot came on my arm) was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: This patient of unknown age and gender passed out 3 days after receiving the Janssen Covid-19 vaccine. The patient was in a store when when both arms became numb, legs "crumbled" and could not stand; the patient also vomited. No other information regarding the serious loss of consciousness was provided. Additionally, on the day of vaccination, the patient experienced bleeding at the injection site and a clot formed. Considering the missing information (e.g., age, sex, medical history, concomitant medications, clinical details leading up the event, corrective treatment, event outcome), the serious loss of consciousness is considered unclassifiable. The nonserious injection site reaction is consistent with a causal association with vaccination.</p> |

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| 1261535 | 4/27/2021 | TX | 41 | M | 3/21/2021 | 4/21/2021 | <p>Passed out; Sweaty; Slightly feverish; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out) in a 41-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 045B21A and 045A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 21-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 21-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 21-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (Passed out) (seriousness criterion medically significant), HYPERHIDROSIS (Sweaty) and PYREXIA (Slightly feverish). At the time of the report, LOSS OF CONSCIOUSNESS (Passed out), HYPERHIDROSIS (Sweaty) and PYREXIA (Slightly feverish) had resolved. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications were not reported. Description: The patient felt sweaty and slightly feverish all night on 21 April 2021. When he got up to urinate he actually passed out (medically significant) and was on the floor for a few seconds. Later last night, on the same day, he went to drink some water, and passed out again for a few seconds. The patient did not seek any medical attention, and stated that he felt fine now. No treatment information provided. The patient received both scheduled doses of mRNA-1273 prior to the event, therefore action taken with the drug in response to the event is not applicable. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.</p> |

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| 1261488 | 4/27/2021 | IN | | F | 3/11/2021 | 4/16/2021 | chills to the bone; couldn't crawl herself to bed; slept for 18 hours; headache was worst than a migraine; vomiting; passed out; arm sun brunt; swollen; arm red; she wish she was dead,brutal; four good days of life, not a happy camper, lost three days of existing; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (passed out) and SUICIDAL IDEATION (she wish she was dead,brutal) in a 65-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No reported medical history). On 11-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 15-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 16-Apr-2021, the patient experienced CHILLS (chills to the bone), HYPOKINESIA (couldn't crawl herself to bed), SOMNOLENCE (slept for 18 hours), HEADACHE (headache was worst than a migraine), VOMITING (vomiting), LOSS OF CONSCIOUSNESS (passed out) (seriousness criterion medically significant), SUNBURN (arm sun brunt), PERIPHERAL SWELLING (swollen), ERYTHEMA (arm red), SUICIDAL IDEATION (she wish she was dead,brutal) (seriousness criterion medically significant) and DEPRESSED MOOD (four good days of life, not a happy camper, lost three days of existing). At the time of the report, CHILLS (chills to the bone), HYPOKINESIA (couldn't crawl herself to bed), SOMNOLENCE (slept for 18 hours), HEADACHE (headache was worst than a migraine), VOMITING (vomiting), LOSS OF CONSCIOUSNESS (passed out), SUNBURN (arm sun brunt), PERIPHERAL SWELLING (swollen), ERYTHEMA (arm red), SUICIDAL IDEATION (she wish she was dead,brutal) and DEPRESSED MOOD (four good days of life, not a happy camper, lost three days of existing) outcome was unknown. No concomitant medication were not provided patient underwent treatment medication of Tylenol Very limited information regarding these events has been provided at this time. No follow up is possible.; Sender's Comments: Very limited information regarding these events has been |

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| 1261501 | 4/27/2021 | FL | 28 | F | 4/17/2021 | 4/17/2021 | <p>provided at this time. No follow up is possible.</p> <p>hard section on her left breast; whole left side of her chest and breast is red till her arm; had a "mini" anxiety; light headed, passed out and fell cold flat on the floor; Blood pressure dropped; fever; passed out and fell cold flat on the floor; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of LOSS OF CONSCIOUSNESS (passed out and fell cold flat on the floor) in a 28-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 037B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 17-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 17-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (passed out and fell cold flat on the floor) (seriousness criterion medically significant), ANXIETY (had a "mini" anxiety), DIZZINESS (light headed, passed out and fell cold flat on the floor), BLOOD PRESSURE DECREASED (Blood pressure dropped) and PYREXIA (fever). On 20-Apr-2021, the patient experienced BREAST INDURATION (hard section on her left breast) and ERYTHEMA (whole left side of her chest and breast is red till her arm). On 17-Apr-2021, LOSS OF CONSCIOUSNESS (passed out and fell cold flat on the floor) outcome was unknown. At the time of the report, BREAST INDURATION (hard section on her left breast), ERYTHEMA (whole left side of her chest and breast is red till her arm), ANXIETY (had a "mini" anxiety), DIZZINESS (light headed, passed out and fell cold flat on the floor), BLOOD PRESSURE DECREASED (Blood pressure dropped) and PYREXIA (fever) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 17-Apr-2021, Blood pressure measurement: low blood pressure dropped. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications were not provided. Treatment included acetaminophen.</p> |
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| 1261508 | 4/27/2021 | PA | | M | | | Faintness; Eyes are yellow; Stomach cramps; Diarrhea; Can't sleep; Feeling unwell; Dizzy; Chills; Light headache; Nausea; Tiredness; This spontaneous case was reported by a consumer and describes the occurrence of SYNCOP (Faintness) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 immunisation. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Asthma. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced SYNCOP (Faintness) (seriousness criterion medically significant), OCULAR ICTERUS (Eyes are yellow), ABDOMINAL PAIN UPPER (Stomach cramps), DIARRHOEA (Diarrhea), SLEEP DISORDER (Can't sleep), MALAISE (Feeling unwell), DIZZINESS (Dizzy), CHILLS (Chills), HEADACHE (Light headache), NAUSEA (Nausea) and FATIGUE (Tiredness). At the time of the report, SYNCOP (Faintness), OCULAR ICTERUS (Eyes are yellow), ABDOMINAL PAIN UPPER (Stomach cramps), DIARRHOEA (Diarrhea), SLEEP DISORDER (Can't sleep), MALAISE (Feeling unwell), DIZZINESS (Dizzy), CHILLS (Chills), HEADACHE (Light headache), NAUSEA (Nausea) and FATIGUE (Tiredness) had not resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. |

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| 1261514 | 4/27/2021 | PA | 44 | F | 4/16/2021 | 4/16/2021 | Fainted; Concussion; Dizziness / Light-headed; Vertigo; Loss of taste; Lost sense of smell; Soreness in the arm; This spontaneous case was reported by a physician assistant and describes the occurrence of SYNCOPE (Fainted) and CONCUSSION (Concussion) in a 44-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 046B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Thyroid activity decreased and Allergy (Undefined allergies). Concomitant products included CLARITHROMYCIN (CLARITRON) for Allergy, THYROID for Thyroid activity decreased. On 16-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 16-Apr-2021, the patient experienced PAIN IN EXTREMITY (Soreness in the arm). On 17-Apr-2021, the patient experienced VERTIGO CNS ORIGIN (Vertigo), AGEUSIA (Loss of taste) and ANOSMIA (Lost sense of smell). On 18-Apr-2021, the patient experienced SYNCOPE (Fainted) (seriousness criterion medically significant), CONCUSSION (Concussion) (seriousness criterion medically significant) and DIZZINESS (Dizziness / Light-headed). On 18-Apr-2021, SYNCOPE (Fainted) had resolved. At the time of the report, CONCUSSION (Concussion), AGEUSIA (Loss of taste) and ANOSMIA (Lost sense of smell) outcome was unknown and DIZZINESS (Dizziness / Light-headed), PAIN IN EXTREMITY (Soreness in the arm) and VERTIGO CNS ORIGIN (Vertigo) had not resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. The patient received her first dose of the Moderna COVID-19 vaccine on Friday (16-Apr-2021) morning in the left arm and had very minimal symptoms, just soreness in the arm. On Saturday evening, she experienced dizziness, was light-headed and fainted. She had a concussion because she fell on the floor in her home. She is currently experiencing vertigo and still feels dizzy and light-headed, probably as a result of the concussion. She lost her sense of taste and smell more than likely as a consequence of the concussion. Her arm is still a little bit sore. Treatment for the events: Tylenol |

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(acetaminophen) and Benadryl (diphenhydramine) to sleep at night. company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded

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| 1261520 | 4/27/2021 | TX | 55 | F | 3/23/2021 | 4/20/2021 | <p>Feels dizzy while walking; Can not get up; Bad chills in night and Teeth chattering; Passed out for couple of hours; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out for couple of hours) in a 55-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Dysautonomia, Neurocardiogenic syncope and Orthostatic hypotension. On 23-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 20-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 20-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (Passed out for couple of hours) (seriousness criterion medically significant) and CHILLS (Bad chills in night and Teeth chattering). On 21-Apr-2021, the patient experienced DIZZINESS (Feels dizzy while walking) and ASTHENIA (Can not get up). At the time of the report, LOSS OF CONSCIOUSNESS (Passed out for couple of hours) and DIZZINESS (Feels dizzy while walking) had not resolved and ASTHENIA (Can not get up) and CHILLS (Bad chills in night and Teeth chattering) outcome was unknown. There was no treatment information provided. Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded. However, her concurrent medical conditions of Dysautonomia, Neurocardiogenic syncope and Orthostatic hypotension are cofounders.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded. However, her concurrent medical conditions of Dysautonomia, Neurocardiogenic syncope and Orthostatic hypotension are cofounders.</p> |

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1261523 4/27/2021 MT

M

super dizzy, gets really really light headed; He passed out once, and very close to passing out the other times; his extremities get tingly; delayed speech, and he feels like he's going to say something but it doesn't come out; gets really bad headaches, The lightheaded comes and goes but the headaches is persistent; he feels like he's going to vomit; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of DIZZINESS (super dizzy, gets really really light headed), LOSS OF CONSCIOUSNESS (He passed out once, and very close to passing out the other times), PARAESTHESIA (his extremities get tingly), SPEECH DISORDER (delayed speech, and he feels like he's going to say something but it doesn't come out), HEADACHE (gets really bad headaches, The lightheaded comes and goes but the headaches is persistent) and NAUSEA (he feels like he's going to vomit) in a 20-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included No adverse event (No medical history reported.). On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced DIZZINESS (super dizzy, gets really really light headed) (seriousness criterion medically significant), LOSS OF CONSCIOUSNESS (He passed out once, and very close to passing out the other times) (seriousness criterion medically significant), PARAESTHESIA (his extremities get tingly) (seriousness criterion medically significant), SPEECH DISORDER (delayed speech, and he feels like he's going to say something but it doesn't come out) (seriousness criterion medically significant), HEADACHE (gets really bad headaches, The lightheaded comes and goes but the headaches is persistent) (seriousness criterion medically significant) and NAUSEA (he feels like he's going to vomit) (seriousness criterion medically significant). At the time of the report, DIZZINESS (super dizzy, gets really really light headed), LOSS OF CONSCIOUSNESS (He passed out once, and very close to passing out the other times), PARAESTHESIA (his extremities get tingly), SPEECH DISORDER (delayed speech, and he feels like he's going to say something but it doesn't come out), HEADACHE (gets really bad headaches, The

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lightheaded comes and goes but the headaches is persistent) and NAUSEA (he feels like he's going to vomit) had not resolved. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown Route) was unknown. Patient received Moderna vaccine almost 5-6 weeks ago, the exact date was not reported. Patient started having events 2 days after the administration of mRNA-1273. Since then, patient has been rushed to ER (Emergency Room) 4 time already. Patient has seen a neurologist, nephrologist, cardiologist but they cant find anything. Several tests and procedure including " all the blood work, CT, MRI. Spinal tap, ECHO Cardiogram" have performed, and the results of this tests/procedure reported as "shows nothing"; Sender's Comments: Based on the information provided which includes a temporal association between the use of mRNA-1273 vaccine and onset of the reported events, and excluding other etiologies, a causal relationship with the product use cannot be excluded.

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| 1261533 | 4/27/2021 | | | M | 4/7/2021 | 4/7/2021 | passed out in his car; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of LOSS OF CONSCIOUSNESS (passed out in his car) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 07-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 07-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (passed out in his car) (seriousness criteria hospitalization and medically significant). The patient was hospitalized from 07-Apr-2021 to 08-Apr-2021 due to LOSS OF CONSCIOUSNESS. At the time of the report, LOSS OF CONSCIOUSNESS (passed out in his car) outcome was unknown. Concomitant medications were not provided. Treatment information was not reported. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. This case was linked to MOD-2021-085853 (Patient Link).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. |

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| 1261268 | 4/27/2021 | NJ | | F | | 4/1/2021 | <p>FAINTING; NUMBNESS; SORENESS; FEELING EXTREMELY HOT; SOAKING WET; HEADACHE ON THE RIGHT SIDE; This spontaneous report received from a patient unspecified age. The patient's height, and weight were not reported. The patient's past medical history included miscarriage, and concurrent conditions included anxiety, fainting, hazelnut allergy, Cefitin allergy, Alcoholic (drinks once a week), and non-smoker. The patient has no history of drug abuse or illicit drug usage. The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1808980, and expiry: UNKNOWN) dose was not reported, one total, administered on 08-APR-2021 to the left arm for prophylactic vaccination. No concomitant medications were reported. She fainted on occasion per her history. She felt numbness and felt hot and fainted 5 minutes after she received the vaccine. She experienced headaches on the right side, soreness, and soaking wet. She took ibuprofen and switch to aspirin yesterday. She still has the headaches come and go. She spoke with her doctor and was advised to go to the emergency room (ER) if symptoms continued. On 14-APR-2021, treatment medications included: Acetylsalicylic acid (Aspirin). Additional treatment medications (dates unspecified) included: Ibuprofen. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from fainting, numbness, soreness, feeling extremely hot, and soaking wet, and had not recovered from headache on the right side. This report was serious (Other Medically Important Condition).; Sender's Comments: V0-20210432537-Covid-19 vaccine ad26.cov2.s -Fainting. This event(s) is considered not related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: MEDICAL HISTORY, UNDERLYING DISEASE</p> |
| 1263945 | 4/27/2021 | | 52 | M | 3/17/2021 | 3/17/2021 | <p>Patient had a syncope episode. Fluids and food were given. EMTs called to the scene. Patient is a type 2 diabetic. Blood glucose was 274 when checked by EMTs. EMT cleared patient after normal EKG and vital signs. Watched patient for an additional 1.</p> |

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| 1262516 | 4/27/2021 | | 24 | F | 4/27/2021 | 4/27/2021 | Dizzy and passed out. Amonia applied,feet up and head supported. Ambulance called and patient transported in stretcher. Five mins later patient awake and stable . Patient discharge home with significant other. |
| 1262574 | 4/27/2021 | | 25 | F | 4/27/2021 | 4/27/2021 | Patient received Pfizer Covid Vaccine Dose 2 (LOT EW0175 EXP 08/2021). Patient was in post-vaccination observation area sitting in char when she began to feel dizzy and lightheaded. She fell from chair to floor. Both HMs assigned to observation area stated they heard impact to the floor and other patient sitting in area witnessed patient hitting head on the floor. Nurse was notified at 0743 by HM and nurse responded. When nurse arrived, patient had eyes closed but immediately opened eyes with contact. Nurse was notified of fall and that she lost consciousness for about 30 seconds upon syncope episode. Code was called at 0745. Vitals taken (BP 94/65, HR 80, RR 16, 92 BG). Patient continued talk and stated she had nothing to eat this morning and has a known history of syncope/vasovagal with vaccinations and blood work. Code team arrived at 0747 and Code secured at 0751. Patient was escorted by code Team to Emergency Department for further evaluation. |
| 1262617 | 4/27/2021 | MA | 24 | M | 4/18/2021 | 4/18/2021 | SYNCOPE +LOC, -FALLS, +NAUSEA, +DIZZINESS ALL SYMPTOMS RESOLVED W/I 10 MINS OF SYNCOPE |
| 1262696 | 4/27/2021 | NJ | 61 | M | 4/7/2021 | 4/12/2021 | since getting the COVID 19 vaccine on April 7, I had at least 6 times "heart beat stopped" feeling, two times I almost passed out. I never had that kind of feeling before. |

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| 1262761 | 4/27/2021 | | 30 | F | 4/27/2021 | 4/27/2021 | Patient presented to Immunizations clinic for Covid Vaccine (Pfizer LOT EW0175 EXP 08/2021) Dose 2. Patient received vaccine and moved to post-vaccination observation area. After 15 minutes, patient went to leave clinic. Shortly after patient returned and informed lobby staff that she was not feeling well. Nurse on staff went to escort patient back to observation area when patient complained of feeling weak. Nurse held patient and patient had syncope episode. Nurse was able to guide patient to floor without impact to floor. Patient was alert and oriented when placed on floor. Patient denies history of syncope and/or vasovagal after injections. Patient returned to baseline and stayed for additional 20 minutes for further observation then released. |
| 1263077 | 4/27/2021 | CA | 16 | M | 4/2/2021 | 4/3/2021 | Fever 100.6 - given tylenol Near fainting - mother called medical facility and spoke and was advised by a Triage nurse |
| 1262497 | 4/27/2021 | HI | 22 | M | 4/26/2021 | 4/26/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Seizure-Mild, Additional Details: Less than 5 mins after injection, patient blacked out and fainted to the ground and hit his head in the process. patient experienced mild seizure/movement after fall and regained consciousness after about 10-15 seconds later after pharmacist rolled patient to his side. patient reported similar events after having his blood drawn. ambulance was called and EMT team came to check out patient. patient reportedly felt fine, but after advise from EMT, patient drove himself to ER to get checked out. |
| 1263332 | 4/27/2021 | UT | 17 | M | 4/3/2021 | 4/3/2021 | Patient fainted 25 minutes after receiving the vaccine. He was seated at the time, and fell forward out of his chair. He hit his head on the hard floor. The medical staff on site treated him and called for EMS. He was taken by ambulance to the hospital because of a continued low blood pressure and to rule out any problems due to hitting his head. |

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| 1262924 | 4/27/2021 | FL | 76 | M | 3/30/2021 | 4/21/2021 | Patient received J&J vaccine 3/30/21 4/21/21 Presented to hospital with syncope and collapse, work-up for NSTEMI and placed on heparin infusion Patient found to have RLE DVT and bilateral PE with right heart strain. Platelet decreased and patient started on argatroban infusion. HIT negative, platelets remained stable. Discharged 4/25/21 on apixaban |
| 1264175 | 4/27/2021 | | 32 | M | 4/27/2021 | 4/27/2021 | vasovagal syncope |
| 1264396 | 4/27/2021 | VA | | M | | | FAINTED; LOSS OF CONSCIOUSNESS; CRASHED VEHICLE; This spontaneous report received from a patient concerned an adult (In between 18 to 65 years) male. The patient's weight, height, and medical history were not reported. The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot number. No concomitant medications were reported. On an unspecified date, the patient fainted while driving on the interstate after vaccination. He crashed his vehicle (road traffic accident) and experienced loss of consciousness, Currently under the care of a neurologist. The action taken with Covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the fainted, loss of consciousness and crashed vehicle was not reported. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to 20210436363.; Sender's Comments: - 20210436318-Covid-19 vaccine ad26.cov2.s-Fainted, Loss of consciousness. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s). |
| 1264611 | 4/27/2021 | NY | 26 | F | 4/27/2021 | 4/27/2021 | PATIENT FAINTED |

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| 1264694 | 4/27/2021 | CA | 46 | F | 3/10/2021 | 4/6/2021 | <p>almost passed out/Felt like she was going to pass out; her blood pressure was low; Really bad stomach cramps; she was so dizzy; urge to have bowel movement, such cramps, pain all the way into the uterine area; shaky legs; weak legs; nausea; as soon as it went in it hurt really bad/arm soreness; felt like throwing up; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PRESYNCOPE (almost passed out/Felt like she was going to pass out) and HYPOTENSION (her blood pressure was low) in a 46-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 028A21A and 013A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Gallbladder disorder on 29-Jan-2021 and Gallbladder removal on 19-Apr-2021. Concurrent medical conditions included Indigestion. Concomitant products included FAMOTIDINE (PEPCID AC) for Indigestion, IRON, ASCORBIC ACID (VITAMIN C ACID), PROBIOTICS NOS and VITAMIN D3 for an unknown indication. On 10-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 06-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 06-Apr-2021, the patient experienced PRESYNCOPE (almost passed out/Felt like she was going to pass out) (seriousness criterion medically significant), HYPOTENSION (her blood pressure was low) (seriousness criterion medically significant), ABDOMINAL PAIN UPPER (Really bad stomach cramps), DIZZINESS (she was so dizzy), PAIN (urge to have bowel movement, such cramps, pain all the way into the uterine area), TREMOR (shaky legs), MUSCULAR WEAKNESS (weak legs), NAUSEA (nausea), VACCINATION SITE PAIN (as soon as it went in it hurt really bad/arm soreness) and VOMITING (felt like throwing up). On 06-Apr-2021, PRESYNCOPE (almost passed out/Felt like she was going to pass out), HYPOTENSION (her blood pressure was low), ABDOMINAL PAIN UPPER (Really bad stomach cramps), DIZZINESS (she was so dizzy), PAIN (urge to have bowel movement, such cramps, pain all the way into the uterine area), TREMOR (shaky legs),</p> |

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MUSCULAR WEAKNESS (weak legs), NAUSEA (nausea), VACCINATION SITE PAIN (as soon as it went in it hurt really bad/arm soreness) and VOMITING (felt like throwing up) had resolved. Treatment includes Zofran and IV medications. On 06-Apr-2021 at 7.30 PM, the patient got the second dose of vaccine and as soon as it went in it hurt really bad. After the medication was pushed the patient had instant nausea, almost passed out, really bad stomach cramps. The pharmacist did not want her driving home because she was so dizzy. At 7:50pm the patient had urge to have bowel movement, such cramps, pain all the way into the uterine area, felt like throwing up, felt like going to pass out so she got off the toilet and was crawling on the floor because the patient had super shaky legs and weak legs. The patient's husband said get dressed and we're going to the ER. He ended up calling the ambulance which took her to the ER. In the ambulance, they started IV, the patient's blood pressure was low, and gave Zofran under the tongue. The patient said Zofran helped so much that within 15 minutes it took the extreme nausea away. At the ER, around 8:40, the patient was feeling a lot better. The doctor in the ER said that people with inflamed GI were having the same problems with the Moderna vaccine. The patient experienced these symptoms from 7:30-9:20 pm and by 9:30pm the patient was completely fine. She went home and even had a snack. The patient did not have an ounce of arm soreness or any other symptoms after that. The patient's first gall bladder attack was on 29-Jan-2021. On 06-Apr-2021 at 4.30 PM the patient had a gall bladder scan. On 19-Apr-2021, the patient had a gall bladder removal. Patient could not eat or drink for 6 hours prior to scan. She said she did hydrate before the shot. Action taken with mRNA-1273 in response to the event was not applicable. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. This case was linked to MOD21-079818, MOD21-079820, MOD21-079821, -MOD-2021-083836; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. MOD21-079818: MOD21-079820: MOD21-079821: -MOD-2021-083836:DOSE 1

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| 1264703 | 4/27/2021 | MI | | U | 4/8/2021 | | Passed out; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out) in a patient of an unknown age and gender who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 08-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced LOSS OF CONSCIOUSNESS (Passed out) (seriousness criterion medically significant). At the time of the report, LOSS OF CONSCIOUSNESS (Passed out) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Concomitant product use was not provided. Treatment information was unknown. Based on current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded. Reporter did not allow further contact; Sender's Comments: Based on current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded. |
| 1264840 | 4/27/2021 | WI | 28 | F | 4/27/2021 | 4/27/2021 | PATIENT WAS PANICKINK BEFORE GETTING THE VACCINE.WAS VERY NERVOUS AND AFTER GOT THE SHOT HAD LITTLE SEIZURES AND FAINTED FOR FEW SECONDS.REGAINED CONSCIOUSNESS WITHIN FEW SECONDS.WAS TALKING AFTERWARDS.DID NOT WANT TO LIE DOWN SO MADE HER KEEP HER HEAD BETWEEN THE LEGS FOR PROPER BLOOD FLOW.DID COLD COMPRESS FOR SOME TIME.PATIENT STARTED FEELING BETTER AFTERWARDS.PARAMEDICS HAD ARRIVED BY THAT TIME AND TOOK HER VITALS HIGH SEEMED GOOD PER PARAMEDICS.PATIENT SIGNDE A WAIVER AND PARAMEDICS LEFT AFTREWARDS. WE GAVE PATIENT GATORADE TO DRINK AND HAVE ONE OF THE PHARMACY ASSOCIATE BE BY PATIENTS SIDE .AFTER STAYING IN THE PHARMACY FOR ABOUT AND HOUR PATIENT LEFT ALONG WITH HeR HUSBAND |

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| 1262160 | 4/27/2021 | WA | 18 | F | 4/23/2021 | 4/23/2021 | syncope |
| 1263158 | 4/27/2021 | NY | 42 | M | 4/27/2021 | 4/27/2021 | THE PATIENT RECEIVED JANSSEN COVID 19 VACCINE IN THE LEFT ARM. I RECOMMENDED TO SIT FOR 15 MINUTES TO OBSERVE THE PATIENT. PATIENT REQUESTED TO USE THE BATHROOM IN THE PHARMACY RIGHT AFTER VACCINE. PATIENT CAME BACK FROM THE BATHROOM SAYING THAT HE FAINTED AND FELL IN THE BATHROOM AND SLASH OPEN THE LEFT SIDE OF HIS CHEEK WAS BLEEDING A LOT AND HE FELT DIZZY AND NAUSEA. HE FAINTED THE SECOND TIME ON THE FLOOR. 911 WAS CALLED PROMPTLY. POLICE AND AMBULANCE CAME TO GO TO THE HOSPITAL. |
| 1262254 | 4/27/2021 | OH | 38 | M | 4/26/2021 | 4/26/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Shakiness-Medium, Additional Details: At the 15 minute mark of the observation period, patient dropped cell phone and slid to the floor. Pharmacist and Pharmacy Student went over to see if he was okay, patient was unresponsive for 30 seconds. Patient was breathing throughout. 911 was called and the paramedics arrived in under 5 minutes to do a full workup. All vitals were normal when they got there. Patient reports feeling "blacked out", but felt fine after about 5 minutes. Paramedics walked with the patient outside. |

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| 1262189 | 4/27/2021 | FL | | F | | 3/23/2021 | PASSED OUT; TIGHTNESS IN CHEST; SWELLING IN RIGHT LEG AND RIGHT CALF; DIZZINESS; NAUSEA; STOMACH PAIN; LEG CRAMPS; FOOT PINS AND NEEDLES; LEG PAIN; CHILLS; FEVER; NIGHT SWEATS; This spontaneous report received from a patient concerned a female of unspecified age. The patient's weight, height, and medical history were not reported. The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1802070, expiry: UNKNOWN) dose was not reported, one total, administered to the left arm on 23-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 23-MAR-2021, the subject experienced night sweats, chills, fever and leg pain. On 30-MAR-2021, the patient experienced leg cramps, stomach pain and foot pins and needles. On 08-APR-2021, the patient experienced swelling in right leg and right calf, tightness in chest, dizziness, nausea and patient passed out The action taken with Covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from passed out on 08-APR-2021, and night sweats, chills, and fever on 26-MAR-2021, and had not recovered from leg pain, stomach pain, foot pins and needles, swelling in right leg and right calf, tightness in chest, dizziness, nausea, and leg cramps. This report was serious (Other Medically Important Condition).; Sender's Comments: V0- covid-19 vaccine ad26.cov2.s - Passed out. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s). |
| 1263091 | 4/27/2021 | OH | 17 | F | 4/27/2021 | 4/27/2021 | Patient felt dizzy and fell over. Possible Vasovagal syncope |
| 1262245 | 4/27/2021 | MA | 19 | F | 4/24/2021 | 4/24/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Nausea-Mild, Additional Details: Patient fainted shortly after receiving the first dose of Moderna. |
| 1262475 | 4/27/2021 | WA | 17 | M | 4/27/2021 | 4/27/2021 | Fainted immediately after administration. Came too shortly after by utilizing cold pack and drank cold water. Patient left feeling well after 30 minutes. |

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| 1262282 | 4/27/2021 | FL | 23 | F | 4/26/2021 | 4/26/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Seizure-Mild, Systemic: Shakiness-Mild, Systemic: Weakness-Medium, Additional Details: pt passed out after reporting not feeling well, 911 had been called, pt taken to hospital and released today, severe muscle twitching possible seizure like |
| 1262289 | 4/27/2021 | FL | 40 | M | 4/26/2021 | 4/26/2021 | Systemic: Allergic: Difficulty Breathing-Severe, Systemic: Confusion-Severe, Systemic: Fainting / Unresponsive-Medium |
| 1262294 | 4/27/2021 | CT | 16 | F | 4/26/2021 | 4/26/2021 | Systemic: Flushed / Sweating-Mild, Systemic: Shakiness-Mild, Additional Details: Patient has been fasting and did not mention to immunizer that she passed out twice today because she is not eating anything only water. Paramedics came and check on her and patient was stable and recovered at the time. |
| 1262296 | 4/27/2021 | NY | 80 | M | 4/26/2021 | 4/26/2021 | Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Mild, Systemic: Nausea-Mild |
| 1262303 | 4/27/2021 | OH | 18 | F | 4/27/2021 | 4/27/2021 | After receiving the vaccine the patient became clammy and fainted. Patient faints every time she gets a vaccine. We let the patient lay down to regain consciousness and she did after about 30 seconds. After patient sat for a few minutes she was feeling well again |
| 1262324 | 4/27/2021 | CA | 27 | M | 4/26/2021 | 4/26/2021 | Systemic: Fainting / Unresponsive-Medium |
| 1262375 | 4/27/2021 | MA | 18 | F | 4/27/2021 | 4/27/2021 | Patient received the Moderna COVID-19 vaccine today at our pharmacy and on the way to the waiting chair she came up to the pharmacy counter and started to say that she felt a little nauseous. She then fainted and I rushed up to the counter and she was already sitting up, very pale. When she was ready we helped her up to the waiting chair and gave her a bottle of water. Her mother was with her to care for her. She waited almost a half hour and felt fine so they both left. She did mention that she was afraid of needles so potentially she could've been thinking about that when she fainted. |

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| 1262462 | 4/27/2021 | | 19 | F | 4/13/2021 | 4/13/2021 | Dizziness for 5 minutes after vaccination. Passed out for less than 30 seconds. Patient stable, released from vaccination site. |
| 1265583 | 4/27/2021 | MN | 18 | F | 4/21/2021 | 4/21/2021 | Patient was sitting in a chair after the vaccine was administered, stated she was feeling well then fainted onto the floor. Assistance provided by nursing staff, noted to be pale, given water and stayed sitting on the floor (declined transfer to cot). She then felt intermittent nausea, had numerous emesis when attempting to stand 30" after initial fainting. Able to stand at 2015 and tolerated well. Able to ambulate to car, stated she felt better, accompanied by her father. Mother reported intermittent nausea and vomiting continued until 4/26 when seen in the ER, given IV fluids and antiemetics |
| 1262463 | 4/27/2021 | CA | 29 | M | 4/27/2021 | 4/27/2021 | After receiving Moderna vaccine in left arm, client passed out in chair, and fell to the floor. He was aroused with the assistance of staff. Client presented diaphoretic and extremely anxious. Emergency Services were notified, and arrived, client's vitals were 120/80, 68 (sitting), and 120/80, 62 (standing), blood sugar was 112. Client denied any medical problems, but admitted he had similar episode when receiving a steroid shot for an injury in a doctor's office. Client stated he always gets extremely anxious and blacks |

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| 1261713 | 4/27/2021 | CA | 62 | F | 1/19/2021 | 1/20/2021 | <p>on the verge of fainting; blood pressure was was 82/48/blood pressure remained low; felt faint/extremely light-headed; This is a spontaneous report from a contactable nurse (patient). A 62-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 2 via an unspecified route of administration, administered in left arm on 19Jan2021 06:45 (Batch/Lot Number: EL3248) as single dose for COVID-19 immunisation. Medical history included hypertension, diabetes (well controlled), and fatty liver disease. The patient was not pregnant at the time of vaccination. The patient was not diagnosed with COVID-19 prior to vaccination and had not been tested for COVID-19 since the vaccination. Concomitant medications included hydrochlorothiazide; olmesartan medoxomil (BENICAR); and omeprazole (PRILOSEC); and vitamin B complex. The patient previously took the bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 1 via an unspecified route of administration, administered in left arm on 28Dec2020 06:30 (Batch/Lot Number: EL1284) at the age of 62 years old as single dose for COVID-19 immunisation. On 20Jan2021 09:15, the patient experienced felt faint and extremely light-headed and on the verge of fainting. The patient laid down and then took her blood pressure. It was 82/48. Her blood pressure remained low throughout the day and did not return completely to normal until 3 days later. No treatment was received for the events. Outcome of the blood pressure was 82/48/blood pressure remained low was recovered on 23Jan2021 while of the remaining events was recovered on 2021.; Sender's Comments: Based on the information currently available, there is a reasonable possibility of an association of the suspect drug administration with the reported events, due to a plausible temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p> |

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| 1262312 | 4/27/2021 | FL | 40 | M | 4/26/2021 | 4/26/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: Fell from chair and hit head on floor - small gash on bridge of nose-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Headache-Medium, Systemic: Hypotension-Medium, Systemic: Weakness-Medium, Additional Details: Within 5 minutes of vaccination, pt fell from sitting position in chair to the ground. Pt hit his head and had small gash on bridge of nose. When I got to him, his eyes opened and he knew what happened. Called 911. He laid on ground while we had NP check blood pressure, pulse, and O2 levels. Pt was stable and walked out with EMS to be checked out. |
| 1262196 | 4/27/2021 | WA | 57 | F | 3/14/2021 | 3/18/2021 | I had a rash from the shot and an immediate headache in my temple right above my eye. I started to get Migraines which became very painful four days after the vaccine. I had to go to the ER because the pain was so bad one day that I almost passed out. It is a much different pain than my normal Migraines my left arm and leg were numb. I have been getting Migraines daily for five weeks now. I have been trying to control my diet and switched medication in an effort to control the Migraines. The medication helps a little if I take it early. I also still get a little of the numbness in the left side of my body. All services provided by insurance company. |
| 1257421 | 4/26/2021 | | 28 | F | 4/23/2021 | 4/23/2021 | Pt fainted for 10-15 seconds at vaccination station. PHN CM and RNs came to assist. Diaphoretic but alert upon awakening. PT on oral BCP, fluoxetine and took 10mg of adderall this morning w/ coffee at 7:38 AM. +anxiety with needles and shots. She had first vaccination w/o fainting. C/O of sore arm and tired after first vaccination. VS taken times 4. Sat her up at 11:23 AM and she felt better. Provided her with granola bar and Powerade. Friends came to pick her up from clinic at 12:13pm; able to ambulate independently and felt better |
| 1257954 | 4/26/2021 | | 17 | M | 4/19/2021 | 4/19/2021 | Patient became very nervous five minutes after having vaccination, fainted to the floor with body tremors, BP 81/38 P45, Resp. 18, EMT at side with nursing staff, was put on stretcher, and complained of dizziness, nausea and lightheadedness, Later BP 114/55, P67 Resp.17. Patient transferred to ER. Recovered, no medications administered. |

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| 1257914 | 4/26/2021 | NJ | 53 | F | 4/24/2021 | 4/24/2021 | 12:51pm post vaccination vasovagal episode w/brief syncope; reports feeling shaky and seeing spots, appears flushed, skin clammy. Medical monitoring w/ rest, po hydration/ juice; vital assessment: BP 98/62 P60 O2 sat 98% RA During monitoring reports symptom resolve w/no additional complaints; released from facility w/ husband |
| 1257770 | 4/26/2021 | TN | 24 | F | 4/23/2021 | 4/23/2021 | The patient experienced presyncope, nausea, and blacked out for about 20 minutes 2 hours after receiving the vaccine. |
| 1257679 | 4/26/2021 | CA | 17 | M | 4/25/2021 | 4/25/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Pt fainted about 5 min after admin. Had pt on the floor about 1/2 hour. He responded in a few seconds, but on multiple blood pressure checks he bp was low. Gave crackers and water. Took pulse which was normal. Had pt sit for additional 15 minutes. Eventually he was ok to lewave but mom was monitoring bp. Called pt at end of day and he was fine. Said he had fainted before with blood drawn in past. |
| 1257648 | 4/26/2021 | FL | 21 | M | 4/25/2021 | 4/25/2021 | Site: Pain at Injection Site-Mild, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Additional Details: pt was fasting from past 2 days before getting vaccine |
| 1257642 | 4/26/2021 | AZ | 18 | M | 4/25/2021 | 4/25/2021 | Systemic: Fainting / Unresponsive-Medium, Additional Details: bp 159/75 hr51 |
| 1257474 | 4/26/2021 | MA | 21 | F | 4/25/2021 | 4/25/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: called 911. fire and EMT/rescue checked patient. patient declined to go to hospital. Brother was nearby and drove her home. |
| 1257471 | 4/26/2021 | NY | 28 | F | 4/19/2021 | 4/19/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Pt has history of fainting with vaccinations. She fainted immediately following injection and was moved to the floor by her boyfriend. She was fully recovered approximately 20 minutes later. |

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| 1257467 | 4/26/2021 | CA | 31 | F | 4/25/2021 | 4/25/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: vasovagal syncope-Mild, Systemic: Flushed / Sweating-Mild, Additional Details: Patient has a history of vasovagal syncope. Patient fainted a couple minutes after immunization and regained consciousness after 10-20 seconds. Patient BP reading was 102/70 and HR 75 at 10:40am about 40 minutes after administration. |
| 1257394 | 4/26/2021 | NY | 39 | F | 4/24/2021 | 4/25/2021 | Woke up at 0700 with fever that fluctuated between 103-106 and would not come down with Tylenol, tepid shower, and cold compress. Nausea, dizziness, headache and could not sit up without vomiting. Could not hold down liquids 0700 to 1030. Passed out at 1030 and woke up at 1400 with fever holding at 100.1-100.2. Called Urgent care for advise on treating. Got it to dip for an hour (1830-1930) to 98.9 with increased Tylenol. Slept and woke at 2000 with fever of 100.2 that is holding steady at time of writing. No nausea and can hold down fluids. Reported symptoms through online Covid symptom tracker. Will go in once clinics open at 0800 if still running fever to have this checked out. |
| 1258616 | 4/26/2021 | IN | 29 | M | 4/24/2021 | 4/24/2021 | Fainted 10 minutes after administration. High fever (102.4 measured t+2 hours after 1000MG of tylenol), aches, severe muscular cramps, chills, diarrhea, nausea lasting in varying severity for 40 hours after injection. |
| 1258090 | 4/26/2021 | | 54 | F | 4/21/2021 | 4/21/2021 | Admitted to hospital after syncopal event after COVID-19 vaccination. Patient with prior history of syncope. Evaluated in hospital with low potassium (3.1). Possible history of orthostatic hypotension. Referred for further outpatient cardiology work-up for syncope. |
| 1257469 | 4/26/2021 | NV | 29 | M | 4/25/2021 | 4/25/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: patient had a seizure that lasted a few seconds-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Seizure-Mild |
| 1259688 | 4/26/2021 | OR | 17 | M | 4/20/2021 | 4/20/2021 | bp 128/76 pt w syncope 5 mins into monitoring. hit head on front left. monitored for s/sx of concussion. denies blurred vision head ache. monitored for 15mins post fall 09:07 am pt c/o blurring in right eye peripheral vision pt to check with pcp if symptoms continue or worsen. |

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| 1260022 | 4/26/2021 | OR | 16 | M | 4/23/2021 | 4/23/2021 | Patient presents with a potential reaction to the COVID19 vaccine. I was called to the patient's vehicle just outside the vaccination area. The patient appeared to having a moderate to severe vasovagal episode without total syncope. There did appear to be slight pseudoseizure activity present, however, there was no LOC or loss of bowel or bladder tone. The patient was placed in a supine position and moved to the monitoring area. With positional changes and aggressive hydration, he rapidly improved to baseline. He did endorse that he has had similar episodes with blood draws, etc. He was returned home with his mother as the driver and with preventative instructions for his second dose. |
| 1258113 | 4/26/2021 | TX | 16 | F | 4/24/2021 | 4/24/2021 | Received first dose of Pfizer , within 1 minute father noted she "passed out". Called staff to car and observed pt with clonic/tonic movement of hands, eyes closed, respirations slowed but even pulse approx 58/min. Responded to verbal Stimuli. Said she felt faint, lips pale, skin clammy. 911 called had additional same incident 9 minutes later. Transferred pt to medical facility by EMS after 2nd episode . |
| 1258399 | 4/26/2021 | | 17 | M | 4/18/2021 | 4/18/2021 | Patient had syncope (BP 100/59 -- > 97/63), flushing/sweating, dizziness, nausea. Stable -- released from vaccination site. |
| 1259981 | 4/26/2021 | NV | 16 | M | 4/26/2021 | 4/26/2021 | 5 minutes after dose while standing and watching sister receive dose of vaccine, patient experienced presyncope. Patient started to sway and lost muscle control. I helped to the floor and laid him out. Patient conscious whole time and never stopped breathing. Did not lose cognizance. Had momentary feeling of nausea that immediately passed. Did not believe necessary to call 9-1-1 as patient did not exhibit any allergy symptoms of any distress during the whole episode. Allowed to lay on floor for about 5-10 min. Supplied patient with bottle of water to help with dry mouth and he drank and felt better. After another 10 minutes patient was up on feet and felt much better. Mother called an hour and a half later (about 5 min ago as I prepare this form) to inform me that he was back to 100%. |

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| 1259706 | 4/26/2021 | IL | 17 | F | 4/26/2021 | 4/26/2021 | pt has a history of fainting almost every time she has a needle stick , she did again. Patient was faint and light headed for 20-30 minutes at 30 minutes her bp was 96/69 63 pulse. she left on her own feet with mother at her side. |
| 1259686 | 4/26/2021 | MA | 17 | M | 4/26/2021 | 4/26/2021 | pt got lightheaded and passed out. pt informed us he had not eaten all day so we are not sure if the lightheadness is from that or the vaccine |
| 1259609 | 4/26/2021 | CA | 17 | F | 4/25/2021 | | FAINTED D/T FEAR OF NEEDLES, RESOLVED, NO TRANSPORT |
| 1259464 | 4/26/2021 | FL | 35 | M | 4/26/2021 | 4/26/2021 | Patient had a syncope episode and failed sitting. While trying to stand patient had another episode and was slid down on the floor by the nurses. Paramedic came and attended to patient. Patient recovered after few minutes and family member pick patient to home. |
| 1259075 | 4/26/2021 | MN | 16 | F | 4/26/2021 | 4/26/2021 | Patient was with her mother and she fainted while walking down the aisle. We got her water and a chair to sit in. She stared feeling nauseous and seeing "dark". 911 was called and she was assessed. was found to have low blood pressure (patient reported not having food or drink yet). Ambulance advised she go to the ER , She did with her mom. |
| 1258631 | 4/26/2021 | TX | 16 | M | 4/24/2021 | 4/24/2021 | Patient received his first dose and fainted in the chair immediately after, when he saw a drop of blood trickle down his arm. Patient regained consciousness right after. Patient was monitored closely in observation and left the vaccination site in stable condition. |
| 1258563 | 4/26/2021 | | 16 | F | 4/25/2021 | 4/25/2021 | Patient had syncope (BP 85/52 -- > 106/68, RR 14 -- > 14), flushing/sweating, not alert for 9 minutes. BP dropped after passing out, put patient in Trendenbug position, gave orange juice. Patient alert & ate crackers. Advised to give second dose lying down. Patient stable, released from vaccination site. |

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| 1259719 | 4/26/2021 | IN | 16 | F | 4/26/2021 | 4/26/2021 | After RN administered vaccine she spoke to my daughter for some time afterwards 5-6 minutes and my daughter was fine answering her questions and just visiting with her. She directed us to the table to schedule her second vaccine which was directly in front of us. We went to this table and spoke with two other ladies choosing a date and time and she was also fine talking with them and answering questions of eat time offered and then suddenly she went straight back with warning passed completely out and struck the back of her head on the concrete floor. EMS and RN?s who were there went to her aid immediately and she was unconscious for a little over a minute. They initially couldn?t get her to respond and finally she came to and had no idea what happened and no recollection of falling. She had blurred vision and bleeding a bit from the back of her head and they wanted her to have CT of her head after hitting it that hard. They took her by ambulance to hospital and they assessed her and ordered a CT. The CT thankfully came back clear and she has follow up appointment with concussion doctor first thing in the morning. On discharge she was describing her pain from hitting head a 7/10 It was very scary and everyone around us was visibly upset as well. She has never fainted or had a reaction to any other shot, vaccine or needle before today so that was a very unusual reaction. |

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| 1254611 | 4/25/2021 | MO | | M | 4/6/2021 | 4/6/2021 | fainted/passed out; Fainted/passed out; This is a spontaneous report received from a contactable pharmacist via a medical information team. This report is in reference to one of the patients the caller states passed out. A male patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, Lot number: ER8729, Expiration date: 20Jul2021), via an unspecified route of administration on 06Apr2021 as a single dose for COVID-19 immunization, sodium chloride (SALINE, Formulation: Unknown, Batch number: 6023228), via an unspecified route of administration on an unspecified date at an unknown dose and frequency for an unknown indication. The patient's medical history and concomitant medications were not reported. The patient had fainted/passed out on 06Apr2021. It was reported that, vaccine coordinator said that they use the same lot number for all three of their facilities. An hour ago, at one of their facilities, he said 3 people fainted and 1 had seizure after receiving the 1st dose of the Pfizer-BioNTech Covid-19 Vaccine. HCP wants to know if there have been any reports of having these reactions associated with the specific lot number: ER8729. He said he already has 56 vials of the vaccine mixed up with the same lot and wants to know if he should still continue using it. HCP also added that out of 3,200 vaccines that they have out of the same lot, they only had 4 incidences. Pharmacist told the HCP that there was no information available about fainting and having seizures associated with the lot: ER8729. However, pharmacist told him that I would forward his concern to someone from our team for further research. Escalating to second line for further research and handling. Caller was a pharmacist who was heavily involved in the COVID-19 vaccine. He manages 3 locations and more than 1500 COVID-19 vaccine doses. Today he's reporting that at one of his other locations, administering the COVID-19 vaccine within about 20 minutes there were 4 patients with reactions. One patient had a seizure and 3 patients passed out. These patient's had just received the COVID-19 vaccine and were still being watched within the 15-minute post vaccination time. All 4 patients received the COVID-19 vaccine from the same lot number but not from the same vial. One of the patient's that passed out said that she has had some |

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issues with vaccines in the past. Caller reports that his COVID-19 vaccine facilities are busy today giving COVID-19 vaccines and about half the people receiving the vaccine are waiting inside and about half are waiting outside. It's about 84F outside and he's reporting that he's not seeing anything to eat or drink in these individuals waiting for the COVID-19 vaccine. He believes the NDC number for the COVID-19 vaccine ends in "02". Caller did not have any information on the patients involved. The outcome of the events was unknown. Information on Lot/Batch number was available. No further information is provided or obtained. Additional information has been requested.; Sender's Comments: As there is limited information in the case provided, the causal association between the events of syncope, loss of consciousness and the suspect vaccine BNT162B2 cannot be excluded. The case will be reassessed once new information is available. The impact of this report on the benefit/risk profile of the Pfizer drug is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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| 1254579 | 4/25/2021 | MO | | M | 4/6/2021 | 4/6/2021 | seizure; This is a spontaneous report received from a contactable pharmacist (patient) via medical information team. Follow-up (06Apr2021) was received from same reporter and processed together with initial information. A male patient of an unspecified age received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Lot Number: ER8729; Expiration Date: 20Jul2021), via an unspecified route of administration on 06Apr2021 as SINGLE DOSE for covid-19 immunization. Other suspect medications included: saline [sodium chloride], via an unspecified route of administration from an unspecified date (Lot Number: 6023228), at unspecified dose for an unspecified indication. The patient medical history and concomitant medications were not reported. The patient reported that after administering the Covid 19 vaccine on 06Apr2021, within about 20 minutes there were 4 patients with reactions. One patient had a seizure and 3 patients passed out. These patients had just received the Covid 19 vaccine and were still being watched within the 15-minute post vaccination time. All 4 patients received the Covid 19 vaccine from the same lot number but not from the same vial. Seriousness of event was medically significant. The outcome of event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information in the case report and strong temporal relationship, A possible causal relationship between event Seizure and suspect drug bnt162b2 cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate. |

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| 1255250 | 4/25/2021 | OH | 30 | F | 4/8/2021 | 4/8/2021 | passed out/stared to black out; got really hot; had trouble breathing; This is a spontaneous report from a contactable consumer. A 30-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EW0158), via an unspecified route of administration, administered in Arm Left on 08Apr2021 13:00 as SINGLE DOSE for covid-19 immunisation (Age at vaccination: 30 years). Medical history included anxiety, depression. Concomitant medications included trazodone; phentermine (ADIPEX [PHENTERMINE]); omeprazole; citalopram; alprazolam (XANAX). The patient previously took lmitrex and experienced allergies. On 08Apr2020 (13:00), the patient stated that she felt fine and was texting. Then all of a sudden she got really hot, had trouble breathing, and stared to black out. She was blacking out. She could hear someone asking if she was okay and if she needed help. She dropped all her things and passed out. The patient was not pregnant. The patient did not received any treatment for the events. Outcome of the events was recovered on an unspecified date. |

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| 1255194 | 4/25/2021 | FL | 17 | F | 4/7/2021 | 4/8/2021 | Fainted; This is a spontaneous report from a contactable consumer (patient). A 17-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot number was not reported), dose 1 via an unspecified route of administration, administered in Arm Left on 07Apr2021 15:30 (at the age of 17years) as single dose for Covid-19 immunization. The patient is not pregnant at the time of vaccination. Medical history included asthma, pediatric Kawasaki disease from 2006 to an unknown date, known allergies: Sulfa drugs, and Covid-19 from an unknown date and unknown if ongoing (Covid prior vaccination: Yes). Concomitant medications included sertraline hydrochloride (ZOLOFT) and ethinylestradiol, ferrous fumarate, norethisterone acetate (BLISOVI FE 1/20), both taken for an unspecified indication, start and stop date were not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. It was reported that the patient fainted the following morning on 08Apr2021 10:00. There was no treatment received for the adverse event. The patient has not been tested for COVID-19 since the vaccination. The outcome of event was recovering. Information on the lot/batch number has been requested. |

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| 1254965 | 4/25/2021 | TX | 35 | F | 4/6/2021 | 4/6/2021 | <p>passed out; dizzy; nauseous; hit her head/huge bump on head; My left eye is half swollen shut; eyelid and under eye are black; very swollen all over head and eye; in lots of pain; breastfeeding; breastfeeding; This is a spontaneous report received from a contactable consumer (who is also the patient). This consumer reported events for mother (self) and child. This is the maternal report. A 35-year-old female patient received the first dose of BNT162B2 PFIZER-BIONTECH COVID-19 VACCINE, lot number: ER8733), via an unspecified route of administration in the left arm, on 06Apr2021 12:15, as single dose, for COVID-19 immunisation, at a drug store. The patient medical history was not reported. The patient had no known allergies. The patient was not pregnant at the time of vaccination. The patient had no prior COVID-19 and was not tested for COVID-19 post vaccination. Concomitant medication included minerals nos, vitamins nos (PRENATAL VITAMINS). The patient did not received other vaccines in four weeks. On 07Apr2021 at 03:00, the patient went to the bathroom and felt fine. She sat on the toilet and all of a sudden felt dizzy and nauseous. Next thing she knew, she woke up on the floor and had a huge bump on her head near her left eye. She passed out and hit her head on the tile in the bathroom. Her left eye was half swollen shut, her eyelid and under eye were black, was very swollen all over her head and eye and was in lots of pain. She went to the emergency room around 04:30. All tests, CT scan and blood work came back normal. She was told that it was most likely caused by the vaccine. Treatment for the events included "CT scan, bloodwork, IV fluids" (as reported). She was hoping that Pfizer will pay for her ER visit since the events were vaccine reactions. She reported that she was still in lots of pain and was not taking pain meds because she was breastfeeding. The events resulted to emergency room and physician office visits. The outcome of pain was not recovered. The patient was recovering from the remaining events.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021442302 Baby case</p> |

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| 1255105 | 4/25/2021 | MA | 74 | F | 3/20/2021 | 3/21/2021 | I fainted and hit my head.; I fainted and hit my head.; passing out; stomach cramps; diarrhea; chills; This is a spontaneous report from a contactable consumer. A 74-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 2 via an unspecified route of administration, administered in Arm Left on 20Mar2021 12:45 (Batch/Lot Number: EN6208) as SINGLE DOSE for covid-19 immunisation. Medical history included Thyroidectomy. Concomitant medications included pravastatin sodium (PRAVASTATIN SODIUM); levothyroxine sodium (SYNTHROID); aspirin [acetylsalicylic acid] (ASPIRIN [ACETYLSALICYLIC ACID]). The patient received first dose of BNT162B2 on 27Feb2021 at 74-years-old for COVID-19 immunization: lot number=EN6203, lot unknown=False, administration date=27Feb2021, vaccine location=Left arm, dose number=1. On 22Mar2021 16:00, the patient fainted and hit her head. On 21Mar2021, the patient had stomach cramps, diarrhea and chills. I was wondering if passing out was an uncommon side effect. The outcome of the events was recovered. The patient received treatment for the events. |

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| 1254962 | 4/25/2021 | CA | 30 | F | 4/1/2021 | 4/1/2021 | fainted or got disoriented; fainted or got disoriented; I was in a car accident; This is a spontaneous report from a contactable consumer (patient). A 30-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: ER8737), via an unspecified route of administration in the left arm, on 01Apr2021 14:30, as single dose, for COVID-19 immunisation. There was no medical history, no known allergies. The patient was not pregnant at the time of vaccination. The patient did not have COVID-19 prior to vaccination and was not tested for COVID-19 post vaccination. Concomitant medication included "digestion herbs" (as reported). Historical vaccine included the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN6199) received at age 30 years, via an unspecified route of administration in the left arm, on 04Mar2021 10:30, for COVID-19 immunisation. The patient did not receive other vaccines in four weeks. After the patient received the second dose on 01Apr2021, the patient waited the full 15 minutes in the waiting area before leaving. The patient did not notice any adverse effects while waiting. However, it was reported that about 100 feet from the exit, at 14:45, "I was in a car accident. I believe I fainted or got disoriented because I do not remember anything for a short period from the time I left the parking lot until the moment of impact with an oncoming truck." The events resulted to emergency room, physician's office, and acupuncture visits. Treatment for the events was reported as "emergency room visit, acupuncture visit". The patient was recovering from the events. |

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| 1255114 | 4/25/2021 | FL | 35 | M | 4/8/2021 | 4/8/2021 | I had blacked out or passed out while driving; Shortly afterwards while driving I suddenly started to not feel well.; Horrible dry, metallic taste in my mouth; Horrible dry, metallic taste in my mouth; VERY dizzy; My whole body started to tingle and I knew I needed to pull over as fast as possible; I feel very "off/extremely upset; This is a spontaneous report from a contactable consumer. This 35-year-old male consumer (patient) reported for himself. A 35-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number: ER8729) via an unspecified route of administration in left arm on 08Apr2021 11:00 as SINGLE DOSE for COVID-19 immunization. Medical history was not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient had no allergy to medications, food or other product. The patient receives other medication in two weeks include probiotics. After patient received first dose and waited 15 minutes as directed before leaving. He felt fine at this point. Shortly afterwards while driving I suddenly started to not feel well. Horrible dry, metallic taste in my mouth and started getting VERY dizzy. My whole body started to tingle and I knew I needed to pull over as fast as possible. I turned my signal on to turn right onto a side road and the next thing I know, I woke up in the woods. I had blacked out or passed out while driving and trying to pull off to safety. I was blacked out for at least 15 minutes. Now I feel very "off" and not myself. My car is damaged, and I don't have the means to get it fixed. I'm extremely upset. Adverse events start time: 01:30 AM. Patient didn't received treatment for the events. The clinical outcome is not recovering. |

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| 1254958 | 4/25/2021 | FL | 64 | F | 3/30/2021 | 3/30/2021 | passed out two times; Left arm shoulder and neck completely numb; Left lower section of my head severe pain; dizziness; vertigo; nauseous; heavy sweats; my head feels very foggy; Having spots of memory issues; This is a spontaneous report from a contactable consumer. A 64-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), via an unspecified route of administration, administered in left arm on 30Mar2021 11:30 (Batch/Lot Number: EM9810) as single dose for covid-19 immunization. Medical history included asthma, neuropathy, high cholesterol, and several allergies from an unknown date. The patient has no history of COVID prior vaccination. She was not COVID tested post vaccination. Concomitant medications included duloxetine hydrochloride (CYMBALTA) taken for an unspecified indication. The patient previously received the first dose of BNT162B2 (Lot number=EN6200) on 09Mar2021 12:15, on left arm for COVID-19 immunization. The patient experienced having left arm, shoulder and neck completely numb for four days since 30Mar2021, 19:00. Left lower section of her head with severe pain; she had dizziness, vertigo and was nauseous. She started having heavy sweats and passed out two times. She reported it has been a week since she had the shot and she was still dizzy and her head feels very foggy. She was also having spots of memory issues. The events were experienced on 30Mar2021, 19:00. No treatment was received for the events. The outcome of the events was not recovered from dizziness, and recovered with sequela from "Left arm shoulder and neck completely numb" on 03Apr2021, and recovered with sequelae on an unspecified date for other events.. |

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| 1255213 | 4/25/2021 | PA | 54 | M | 4/9/2021 | 4/9/2021 | <p>passed out/continued to drift in and out of conscientiousness; BP was very low; chest tightness; This is a spontaneous report from a non-contactable consumer (patient). A 54-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EP6955), via intramuscular route of administration on 09Apr2021 at 17:45 (at the age of 54 years) at a single dose in the left arm for COVID-19 immunization. Medical history included stroke/heart attack from 2014 to an unknown date. Concomitant medications included omeprazole (PROTONIX [OMEPRAZOLE]); atorvastatin calcium (LIPITOR [ATORVASTATIN CALCIUM]); levothyroxine sodium (LEVOTHYROXINE [LEVOTHYROXINE SODIUM]); amlodipine besilate, benazepril hydrochloride (AMLODIPINE BENAZEPRIL); citalopram; and clopidogrel. The patient previously took the first dose of BNT162B2 (lot number: EP6955) on 19Mar2021 (age: 54 years) in the left arm for COVID-19 immunization. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. It was unknown if patient was diagnosed with COVID-19 prior to vaccination. Patient had no known allergies. On 09Apr2021 at 18:00, after second vaccine was given, patient passed out. His wife was with him. He came to but continued to drift in and out of conscientiousness. His BP was very low, pulse ox 99. He also had chest tightness. Ambulance was called. He was stable till ambulance came and took him to hospital. The events resulted in emergency room/department or urgent care and hospitalization. Therapeutic measures were taken as a result of the events which included IV fluids, Tylenol and something was placed under his tongue for chest tightness. The patient had COVID test on an unspecified date with unknown results. The outcome of the events was recovering. No follow-up attempts are possible. No further information is expected.</p> |

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| 1255215 | 4/25/2021 | IL | 57 | F | 4/8/2021 | 4/8/2021 | possible seizure; fainting; chills; headache; joint and long bone pain; dizziness; Right abdominal pain; temperature spike at 101; unquenchable thirst; sweating; This is a spontaneous report from a contactable consumer (patient) reported for herself that the 57-year-old female patient received second dose of bnt162b2 (BNT162B2), intramuscular, administered in Arm Right on 08Apr2021 04:00 PM (Lot Number: EW0151) at single dose for covid-19 immunization. Medical history included multiple allergies from an unknown date and unknown if ongoing, asthma from an unknown date and unknown if ongoing, chronic obstructive pulmonary disease from an unknown date and unknown if ongoing, orthostatic hypotension from an unknown date and unknown if ongoing, traumatic lung injury from an unknown date and unknown if ongoing, metaplasia from an unknown date and unknown if ongoing, hiatus hernia from an unknown date and unknown if ongoing, polyp from an unknown date and unknown if ongoing, diverticulum intestinal from an unknown date and unknown if ongoing, exposure to toxic agent from an unknown date and unknown if ongoing. Concomitant medications included pantoprazole taken for an unspecified indication, start and stop date were not reported; famotidine taken for an unspecified indication, start and stop date were not reported; cyclobenzaprine taken for an unspecified indication, start and stop date were not reported; calcium carbonate;soya isoflavones;vitamin d nos taken for an unspecified indication, start and stop date were not reported; ibuprofen;phenylephrine hydrochloride taken for an unspecified indication, start and stop date were not reported. The patient previously took firs dose of bnt162b2 (BNT162B2) intramuscular, administered in Arm Right on 18Mar2021 04:15 PM(Batch/Lot Number: ER2613) at single dose for covid-19 immunisation. The patient experienced possible seizure on 08Apr2021 20:00 with outcome of recovering, chills on 08Apr2021 with outcome of recovering, headache on 08Apr2021 with outcome of recovering, joint and long bone pain on 08Apr2021 with outcome of recovering, dizziness on 08Apr2021 with outcome of recovering, fainting on 08Apr2021 with outcome of recovering, right abdominal pain on 08Apr2021 with outcome of recovering, temperature spike at 101 on 08Apr2021 with outcome of recovering, unquenchable thirst on 08Apr2021 with |

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outcome of recovering , sweating on 08Apr2021 with outcome of recovering. The patient underwent lab tests and procedures which included body temperature: temperature spike at 101 on 08Apr2021. Therapeutic measures were taken as a result of possible seizure. She is not pregnant at the time of vaccination. Facility where the most recent COVID-19 vaccine was administered was other. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The clinical course was reported as follows: 4 hrs post vax: chills, sub normal temperature drop >96 f oral, eat, and airmpit , sub normal low BP, headache, joint and long bone pain, dizziness, 2 episodes of warned fainting (vasovagal); followed by temperature spike at 101 F oral onset @21 hrs. post vax rigors and falls, with warned loss of consciousness & possible seizure, followed by lower right abdominal pain w/rebound tenderness, sweating, unquenchable thirst, until fever broke 30 hrs post onset. At febrile onset 400 mg ibuprofen, followed by 200 mg every 8 hrs until symptom resolution. The adverse event result in any of the following Doctor or other healthcare professional office/clinic visit. Treatment was received for the adverse event included Public Health RN telephone consult, ibuprofen see. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. Allergies to medications, food, or other products:Yes a long list that does not include PG. Other diagnosed illnesses/medical history/chronic health conditions:IMMUNE SYSTEM: multiple allergies including anaphylaxis; R.A., reactive asthma; CARDIOPULMONARY: reactive asthma, chemical exposure lung injury scaring, COPD, orthostatic hypotension; GI: Barrets esophagial metaplasia, hiatal hernia, colonic polyps adenocarcinoma, diverticula. Follow-up (20APR2021): Follow-up attempts completed. No further information expected.

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| 1255218 | 4/25/2021 | | | F | 3/24/2021 | 3/28/2021 | BP 190/110; fainted; shortness of breath; severe pain to upper back; severe pain to upper back and shoulder; chest pain; Pain to sternum; This is a spontaneous report from a contactable consumer (patient) via Medical information team. A 57-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 24Mar2021 (Batch/Lot number was not reported) as SINGLE DOSE for COVID-19 immunization. Medical history included hypertension from an unknown date and unknown if ongoing. The patient's concomitant medications were not reported. The patient had pain began on 28Mar2021. This is severe pain to upper back and shoulder and chest pain causing shortness of breath and the patient fainted went to the emergency department and was ruled out stroke. 2 weeks later, the patient was still taking Ibuprofen for pain. The patient had pain to sternum on 28Mar2021. The patient has a history of hypertension and had BP 190/110 resolved only after taking Ibuprofen 800mg 3 times a day, otherwise the pain prolongs. The patient underwent laboratory tests and procedures which includes CT, blood work, EKG, Chest X-ray of chest of lung; all negative on unspecified date. The patient was reported to be hospitalized due to the events. The events were treated with Ibuprofen. The outcome of the events was unknown. Information about the lot/batch number has been requested. |
| 1254945 | 4/25/2021 | DC | 38 | M | 4/8/2021 | 4/8/2021 | Convulsion; Syncope; This is a spontaneous report from a contactable consumer (patient). A 38-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), first dose via an unspecified route of administration, administered in Arm Left on 08Apr2021 14:15 (2:15 PM) (Batch/Lot Number: ER8729) as SINGLE DOSE for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient had no covid prior vaccination and not covid tested post vaccination. There were no other vaccines in four weeks. It was reported that the patient experienced Syncope and Convulsion on 08Apr2021 at 14:30 (2:30 PM). The outcome of the events was recovered in Apr2021. No treatment for the reported events. The event resulted in Emergency room/department or emergent treatment. |

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| 1255234 | 4/25/2021 | NY | 65 | M | 4/10/2021 | 4/10/2021 | <p>vasovagal syncope; This is a spontaneous report from a non-contactable consumer (patient). A 65-year-old male patient received the second dose of bnt162b2 (BNT162B2, Solution for injection, lot number: EP6955), intramuscular, administered in Arm Right on 10Apr2021 11:00 (received at 65-years-old) as SINGLE DOSE for COVID-19 immunization. The vaccine was administered at a clinic. It was unknown if patient received any other vaccines within four weeks prior to receiving bnt162b2. Medical history included always gets nervous. Concomitant medications were not reported. The patient had no known allergies and denied having other medical history. The patient previously received the first dose of bnt162b2 (BNT162B2, Solution for injection, lot number: EP6955), intramuscular, administered in Arm Right on 20Mar2021 (received at 65-years-old) as SINGLE DOSE for COVID-19 immunization. On 10Apr2021 11:00 AM, 1-2 (unspecified) after receiving vaccine #2, the patient became pale and diaphoretic and then lost consciousness. He was taken out of car and medics evaluated person and family stated he had not eaten or drank anything and glucose stick was 130. When patient became conscious, he stated he had a similar episode when he was a child and received a vaccine. States he was very anxious receiving both vaccines and always gets nervous. The reported adverse event resulted in doctor or other healthcare professional office/clinic visit and emergency room/department or urgent care. The patient was evaluated in emergency and diagnosed with vasovagal syncope. Therapeutic measures were taken as a result of the event. Outcome of the event was recovered on an unspecified date. No follow-up attempts are possible. No further information is expected.</p> |

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| 1254758 | 4/25/2021 | CA | 33 | M | 4/6/2021 | 4/6/2021 | Felt like was fainting; Five to ten minutes after receiving the first dose I started feeling dizzy; numb (tingling) in my fingers.; numb (tingling) in my fingers.; I also started to sweat; my BP fell when the nurse checked.; This is a spontaneous report from a contactable consumer (patient). A 33-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration, administered in Arm Left on 06Apr2021 12:45 (Lot Number: ER8737) as single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. There was no other vaccine in four weeks or in two weeks. There was no known allergies. The patient has no Covid prior vaccination and has no Covid tested post vaccination. After receiving the first dose, on 06Apr2021 13:00, the patient started feeling dizzy and numb (tingling) in his fingers. Felt like him was fainting. He also started to sweat and his BP fell when the nurse checked. The patient did not have a full breakfast or lunch before getting the dose. The patient had coffee in the morning with some dates and later had two oranges and a Kind Nut Bar. Drank some water and juice after the dizziness subsided. The events did not result in emergency room visit or physician office visit. Therapeutic measures were taken as a result of all the events. The outcome of events was resolved on unknown date. |
| 1255287 | 4/25/2021 | CA | 41 | F | 4/8/2021 | 4/8/2021 | Fainting; Nausea; Dizziness; Fatigue; This is a spontaneous report from a contactable consumer (Patient). A 41-year-old non-pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE Formulation: Solution for injection, Lot number: EW0162) via unspecified route of administration on arm left at a single dose on 08Apr2021 17:00 for COVID-19 immunization. The patient medical history. Concomitant medication was not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 08Apr2021 at 17:15 patient experienced nausea, fainting, dizziness and fatigue. The outcome of the events was recovered on an unspecified 2021. No follow-up attempts are possible; information about lot/batch number cannot be obtained. |

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| 1255291 | 4/25/2021 | TX | 28 | M | 4/9/2021 | 4/9/2021 | fainted; unconscious for a few minutes; This is a spontaneous report received from a contactable consumer (reporting on himself). A 28-years-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Formulation: solution for injection, Lot Number and Expiration Date was not reported), via an un-specified route of administration in in Arm Left on 09Apr2021 10:45 as single dose for COVID-19 immunization. The patient medical history was not reported and known allergies included Codeine, Abilify. The patient's concomitant medications were not reported. Patient did not receive any other vaccine in four weeks. Patient did not have COVID prior vaccination. Not tested COVID post vaccination. It was reported that 09Apr2021 11:00 patient fainted about a hour after getting home. Then the next day at approximately 2:45 she fainted again both times hitting the floor and laying unconscious for a few minutes. Patient had to go Emergency room and hospitalization for a few hours. The outcome of the events was recovered on an unspecified date. Information on the lot/ batch number has been requested. |

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| 1255224 | 4/25/2021 | IL | 46 | F | 3/27/2021 | 3/27/2021 | fainted/fainting; felt weak and dizzy/weakness; felt weak and dizzy/dizziness; blood pressure was very high; fast heartbeat; This is a spontaneous report from a Pfizer-sponsored program. A contactable consumer (patient) reported that a 46-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: ER8733), via an unspecified route of administration, administered in arm left on 27Mar2021 18:15 (at the age of 46-years-old) as a single dose for covid-19 immunisation. The patient was not pregnant at the time of vaccination. The patient's medical history and concomitant medications were not reported. The patient had no known allergies. The patient had no covid prior vaccination. No other medication in two weeks. No other vaccine in four weeks. On 27Mar2021 18:45, the patient felt weak and dizzy a few minutes after getting the vaccine and then she fainted. The paramedics took her to the ambulance to check her vitals. EKG, blood sugar and blood oxygen was good, but her blood pressure was very high. Clinical course details was reported as she received the first dose of the Pfizer COVID vaccine on 27Mar2021 and she experienced fainting, dizziness, weakness and a fast heartbeat. The patient would like to know if fainting was considered an allergic reaction. The patient would like to know if she should receive the second dose of the vaccine. She received the 1st dose last 27Mar2021 and 2nd dose will be on 17Apr2021. The reported events resulted in doctor or other healthcare professional office/clinic visit. The patient did not received any treatment for the events. The outcome of the events was recovering. The patient did not covid tested post vaccination. |

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| 1254681 | 4/25/2021 | KS | 18 | M | 4/7/2021 | 4/7/2021 | <p>Passed Out; feeling light headed/lightheadedness/being lightheaded; Fell Down Stairs/falling; hit his head and his knee; hit his head and his knee; This is a spontaneous report from a contactable consumer (patient's father). An 18-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), dose 1 via an unspecified route of administration, administered in right arm at the age of 18-year-old on 07Apr2021 09:50 (Batch/Lot number was not reported) as single dose for COVID-19 immunisation. Medical history included ongoing congenital diaphragmatic hernia (that prevented his lungs from developing before he was born). There were no concomitant medications. The patient previously took influenza vaccine (FLU) for immunization and without a reaction. Caller is a consumer, calling about his 18 years son who received the covid vaccine this morning and had an adverse event afterwards. Caller reported that his 18 years son had his first covid vaccine dose this morning. He has had all of his vaccinations, even the flu shot every year without a reaction. After having his covid vaccination, on the way home he said he started feeling light headed. He was supposed to go back to school once they got home but the caller noticed that his son hadn't left yet because he drives himself. He reported that his son's room is downstairs and when he looked his son was laying down at the bottom of the stairs and appears to have passed out. He reports that now he is fine and he has eaten. Calling now because he was concerned and "wanted to make sure there was nothing else I should do in this situation". Caller stated that he took his two kids to get their vaccines. His son is 18 years old and his daughter will be 18 next Tuesday. Stated that they stayed at the site in case of a reaction to the vaccine and nothing happened. On the way back home the son became lightheaded. Caller thought maybe he needed to eat even though he had eaten a light breakfast before they went to get the vaccines. Stated his son got home and passed out. Caller had never seen his son pass out before. Said his son fell down the stairs while going to the basement where his room is located. Caller was concerned this could've been a reaction and is calling to see if there is anything further they should be concerned about. The son's vaccine, lightheadedness, passing out, and falling all took place today 07Apr2021. Caller said</p> |

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he nor his son are certain if he was injured during the fall. His son thinks he hit his head and his knee and noticed that his shorts where ripped behind the leg on 07Apr2021. Caller states his son says he is feeling back to normal and fine. The son was supposed to go to school after the vaccine but the caller had him stay home so he could keep an eye on him. Caller stated it was scary. The caller opened the door and saw his son lying on the floor with the gum he had bought at the drug store strewn out everywhere. Caller stated they are believers in vaccines. Stated his son used to have a part time job at the grocery store bagging groceries for customers and was wanting to go back to work. Caller also said that his son was born with a congenital diaphragmatic hernia that prevented his lungs from developing before he was born. Caller stated that due to this him and his wife felt it was best for the son to get the vaccine since if he got the Covid virus it could have been really bad for him. Caller denies any medications, labs, testing or treatments that are relevant to these events. Caller stated his son is healthy. Stated when his son mentioned being lightheaded in the car, the caller didn't think much of it. The outcome of events was recovered on 07Apr2021. Information on the lot/batch number has been requested.

fainting; seizure; Tachycardia; dizziness; This is a spontaneous report from a contactable consumer. This 24-year-old non-pregnant female consumer (Patient) reported that she received the first dose of BNT162B2 (Pfizer-BioNTech COVID-19 Vaccine; Solution for injection; Lot number: unknown; Expiry date: Unknown) via an unspecified route of administration in the right arm on 07Apr2021 at 12:45 PM. The patients past medical history included Postural orthostatic tachycardia syndrome. The patient was allergic to Phenergan and Zofran. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since vaccination, patient had not tested for COVID-19. Concomitant medication was not reported. On 10Apr2021, at 12:00PM the patient developed Tachycardia, dizziness, fainting and seizure. The patient did not receive any treatment for the events. The outcome for the events was recovering. Information about Lot/batch number is requested.

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| 1256950 | 4/25/2021 | WA | 18 | M | 4/25/2021 | 4/25/2021 | Patient fainted after waiting for 10 minutes. He did not lose consciousness. He responded to RPH commands. He did not have shortness of breath, rash, inflammation. He urinated himself after falling. He remained laying on the ground for 20 minutes, after which he stood up and had recovered from the dizziness/nausea. Patient and parents did not wish for 911 to be called or to go the hospital. They agreed to call 911 if patient has any further symptoms. |
| 1254535 | 4/25/2021 | | | F | 4/1/2021 | 4/1/2021 | had a "protein thing" around her heart; BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE) subcutaneously; blood pressure to go "sky high"; This is a spontaneous report from a contactable consumer (patient). A 64-year-old female patient received the first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE) subcutaneously on 01Apr2021 at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. The patient would like to know the percentage of BNT162b2 that was in her system after one dose. She spoke with one physician who told her that she was 50% covered and another who told her it was 80%. The first dose of the vaccine caused her blood pressure to go "sky high" in Apr2021 and reported she almost passed out. She was taken to the emergency room where it was found that she had a "protein thing" around her heart that the doctors were not sure came from the vaccine or not. Due to this reaction, the patient was unsure if she would be able to get the second dose and would like to know how protected she was with just the first dose. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained. |

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| 1254572 | 4/25/2021 | NY | 28 | M | 3/28/2021 | 3/28/2021 | afraid to take second dose of Pfizer COVID-19 vaccine due to the events; brain fog every single day; kind of off and uneasy; body aches; slight dizziness not like he was going to fall over, but cant stand still without lean a little/felt immediate rush to the head and feeling of fainting; very weird like an out of body experience this was almost like an anxiety attack/anxiety attacks for every 30 minutes or so; tension headaches; Chills; tunnel vision/tunneled, it was like tunnel vision and a very very weird like an out of body experience this was almost like an anxiety attack; it was extremely intense; pain at the injection; insane rush from the bottom of his feet to the top of head, felt like he was going to pass out; weakness; This is a spontaneous report from a contactable consumer (Patient). A 28-year-old male patient received first dose of BNT162B2 (Pfizer COVID Vaccine, solution for injection, Lot Number: ER8733; Expiration Date: 31Jul2021), via an unspecified route of administration, administered in left arm on 28Mar2021 at 17:00 (at the age of 28 years-old) as single dose for COVID-19 immunization. Medical history included ongoing asthma, anxiety experienced years and years ago when he was about 19-20 years old and it has been under control, he hasn't had this happen in years. The patient mother suffers from slight anxiety at times; dad currently has high blood pressure. Concomitant medication included albuterol sulfate taken for asthma (in inhalation (90mcg per actuation 200 metered inhalations: 2 puffs as needed) and liquid form (0.083% 2.5 mg out of 3ml as needed) for nebulizer since he was born). Patient did not have COVID prior vaccination. Patient did not want to contract COVID-19 because he has asthma. On 28Mar2021 at 17:00 (within 5 minutes of vaccination), patient experienced Tunnel Vision, chills, weakness, insane rush from the bottom of his feet to the top of head, felt like he was going to pass out (which was recovered same day with lasting effects), weakness, hasn't felt the same; feels like something is off every day; not himself, very weird like an out of body experience this was almost like an anxiety attack/anxiety attacks for every 30 minutes or so, tension headaches, dizziness and felt immediate rush to the head and feeling of fainting, at 8PM or 9PM, he felt pain at the injection and body aches. The patient visited physician room as a result of Insane tension headaches, and anxiety. On 29Mar2021, he |

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didn't really feel too anxious, but he felt out of place, kind of off and uneasy. The chills and body aches, kind of off and uneasy were disappeared on 30Mar2021. On 31Mar2021, brain fog and slight dizziness does not like he was going to fall over but cant stand still without lean a little/felt immediate rush to the head and feeling of fainting. On 02Apr2021, injection site pain was gradually faded away. The patient states that these events started after the Pfizer COVID 19 vaccine. Therapeutic measures were taken as a result of events included Tylenol. The patient underwent lab tests and procedures which included SARS-CoV-2 test (Nasal swab): Pending on 06Apr2021. The patient did not take any other vaccinations four weeks prior to vaccination. The patient was afraid to take second dose of Pfizer COVID-19 vaccine due to the events. Patient felt very hard to work with these symptoms and to get through everyday life, it is very tough. Patient knows plenty of people that died from COVID-19 and he does not want to have to make changes and fix things in his life that he did not cause and worries this will stick around for the rest of his life all because he took a vaccine. The patient had physician office and Emergency room visit. The outcome of the events insane rush from the bottom of his feet to the top of head, felt like he was going to pass out, pain at the injection, chills and body aches were recovered, while for tension headaches, anxiety attacks, dizziness, weakness, brain fog, hasn't felt the same; feels like something is off every day; not himself was not recovered, and for tunnel vision it was unknown. Information on the lot/batch number has been requested.

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| 1254579 | 4/25/2021 | MO | | M | 4/6/2021 | 4/6/2021 | seizure; This is a spontaneous report received from a contactable pharmacist (patient) via medical information team. Follow-up (06Apr2021) was received from same reporter and processed together with initial information. A male patient of an unspecified age received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Lot Number: ER8729; Expiration Date: 20Jul2021), via an unspecified route of administration on 06Apr2021 as SINGLE DOSE for covid-19 immunization. Other suspect medications included: saline [sodium chloride], via an unspecified route of administration from an unspecified date (Lot Number: 6023228), at unspecified dose for an unspecified indication. The patient medical history and concomitant medications were not reported. The patient reported that after administering the Covid 19 vaccine on 06Apr2021, within about 20 minutes there were 4 patients with reactions. One patient had a seizure and 3 patients passed out. These patients had just received the Covid 19 vaccine and were still being watched within the 15-minute post vaccination time. All 4 patients received the Covid 19 vaccine from the same lot number but not from the same vial. Seriousness of event was medically significant. The outcome of event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information in the case report and strong temporal relationship, A possible causal relationship between event Seizure and suspect drug bnt162b2 cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate. |

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| 1254796 | 4/25/2021 | CT | 53 | M | 3/21/2021 | 3/22/2021 | Blood clots in right leg below knee; he passed out from pain; pain in his right knee; he couldn't bend his knee at all; knee was swollen; couldn't walk/limping around; his knee more stiff; This is a spontaneous report from a contactable consumer (patient). A 53-year-old male patient received the first dose of BNT162B2 (Pfizer-BioNTech COVID-19 vaccine, lot number: EN6206), via an unspecified route of administration, administered in the right arm on 21Mar2021 at 10:00 as a single dose for COVID-19 immunization. Medical history included ongoing Factor V Leiden heterozygous, allergies to mushrooms from an unknown date and unknown if ongoing and a torn meniscus in his right knee and he had surgery 3 to 4 years ago. The patient's concomitant medications were not reported. The patient previously took Cephalexin and Percocet and experienced allergies. The patient did not have COVID prior to vaccination and has not been tested post vaccination. On 22Mar2021 at night around 2:30AM, the patient woke up and started walking to the bathroom and he passed out from pain. He had pain in his right knee. He thought he had torn his knee again. He had surgery 3 or 4 years ago for a torn meniscus in his right knee and he thought he had torn his meniscus again. He passed out, his wife found him and he went back to bed. In the morning, his knee was still very very sore, he couldn't bend his knee at all. He took an Advil between 6:30AM and 8:00AM. He hadn't taken any medications prior to the COVID-19 vaccine. His knee was swollen but the pain was manageable. He couldn't walk, he was on crutches for about 24 hours then the swelling started coming down and he put a brace on his knee. He could then walk without the crutches but it was still painful. The next day he had pain in the back of his knee. He thought the pain was caused because he had put the brace on and had been using the crutches. Like he had made his knee more stiff from not using it. He was limping around and the pain was bearable. At that point, the pain was maybe a 4 on a scale of 1-10 where his pain had been a 9 on a scale of 1-10. He took another Advil and he realized the pain in the back of his knee wasn't going away. He went to see his family doctor and his doctor was able to get him in that same day for an ultrasound. The ultrasound showed 2 blood clots behind his right knee. The patient had blood clots in right leg below knee. The week of the report, he got an |

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appointment with a hematologist. The hematologist reviewed his case and the doctor isn't 100% sure the blood clots were from the Pfizer COVID-19 vaccine but the doctor isn't ruling it out either because it happened within 24 hours of receiving his first COVID-19 dose. He hadn't done anything strenuous before getting the COVID-19 vaccine, nothing that he thinks would have caused the blood clots. He would like to add, what he thinks is relevant, is that he is positive for Factor V. He reports he has one copy and Factor V only impacts about 3% of the population. The hematologist thought that he might be prone to developing blood clots. The hematologist reports that he has had patients who have had the COVID-19 virus who have developed blood clots. Maybe it's possible that the COVID-19 antibodies were trying to build up his immune system to COVID-19 and it created something similar to having the COVID-19 virus. If he is predisposed to blood clots then the COVID-19 vaccine may have precipitated the blood clots. His second COVID-19 vaccine is scheduled for Sunday, 11Apr2021. He had talked to both his family doctor and his hematologist and they both thought he should be ok in getting the second COVID-19 vaccine. He was prescribed blood thinners. If the second COVID-19 vaccine caused more blood clots the blood thinners would help him. He was asking if there is any additional information or guidance on receiving the second COVID-19 vaccine after his reaction. The pharmacist told him that the COVID-19 vaccine trials were all done in the left arm. He received his vaccine in his right arm and his right knee was affected. If he gets the second COVID-19 vaccine he's getting it in his left arm. He was prescribed Eliquis 5mg take one tablet twice daily. The outcome of the event blood clots in right leg below knee was recovering while the outcome of the other events was unknown.

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| 1254611 | 4/25/2021 | MO | | M | 4/6/2021 | 4/6/2021 | fainted/passed out; Fainted/passed out; This is a spontaneous report received from a contactable pharmacist via a medical information team. This report is in reference to one of the patients the caller states passed out. A male patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, Lot number: ER8729, Expiration date: 20Jul2021), via an unspecified route of administration on 06Apr2021 as a single dose for COVID-19 immunization, sodium chloride (SALINE, Formulation: Unknown, Batch number: 6023228), via an unspecified route of administration on an unspecified date at an unknown dose and frequency for an unknown indication. The patient's medical history and concomitant medications were not reported. The patient had fainted/passed out on 06Apr2021. It was reported that, vaccine coordinator said that they use the same lot number for all three of their facilities. An hour ago, at one of their facilities, he said 3 people fainted and 1 had seizure after receiving the 1st dose of the Pfizer-BioNTech Covid-19 Vaccine. HCP wants to know if there have been any reports of having these reactions associated with the specific lot number: ER8729. He said he already has 56 vials of the vaccine mixed up with the same lot and wants to know if he should still continue using it. HCP also added that out of 3,200 vaccines that they have out of the same lot, they only had 4 incidences. Pharmacist told the HCP that there was no information available about fainting and having seizures associated with the lot: ER8729. However, pharmacist told him that I would forward his concern to someone from our team for further research. Escalating to second line for further research and handling. Caller was a pharmacist who was heavily involved in the COVID-19 vaccine. He manages 3 locations and more than 1500 COVID-19 vaccine doses. Today he's reporting that at one of his other locations, administering the COVID-19 vaccine within about 20 minutes there were 4 patients with reactions. One patient had a seizure and 3 patients passed out. These patient's had just received the COVID-19 vaccine and were still being watched within the 15-minute post vaccination time. All 4 patients received the COVID-19 vaccine from the same lot number but not from the same vial. One of the patient's that passed out said that she has had some |

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issues with vaccines in the past. Caller reports that his COVID-19 vaccine facilities are busy today giving COVID-19 vaccines and about half the people receiving the vaccine are waiting inside and about half are waiting outside. It's about 84F outside and he's reporting that he's not seeing anything to eat or drink in these individuals waiting for the COVID-19 vaccine. He believes the NDC number for the COVID-19 vaccine ends in "02". Caller did not have any information on the patients involved. The outcome of the events was unknown. Information on Lot/Batch number was available. No further information is provided or obtained. Additional information has been requested.; Sender's Comments: As there is limited information in the case provided, the causal association between the events of syncope, loss of consciousness and the suspect vaccine BNT162B2 cannot be excluded. The case will be reassessed once new information is available. The impact of this report on the benefit/risk profile of the Pfizer drug is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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| 1254922 | 4/25/2021 | PA | 50 | F | 3/3/2021 | 3/1/2021 | Dizziness/ extreme dizziness/ Some degree of dizziness every day/ Varies from daily light headedness to extreme dizziness; had extreme fatigue; Almost fainted once; This is a spontaneous report from a contactable consumer (patient). A 50-year-old non-pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EN6199), via an unspecified route of administration, administered in right arm on 03Mar2021 19:30 at single dose for COVID-19 immunisation. The patient's medical history included Hashimoto's autoimmune, and known allergies to penicillin. The patient's concomitant medications included liothyronine, and levothyroxine, both taken for an unspecified indication, start and stop date were not reported. The patient had no other vaccine in four weeks. The patient had no COVID prior to vaccination and was tested for COVID post vaccination. The facility type vaccine was Pharmacy or Drug Store. The patient experienced dizziness on 10Mar2021 at 12:00 and has not ceased. It varies from daily light headedness to extreme dizziness. The patient almost fainted once on an unspecified date in Mar2021. The patient had some degree of dizziness every day. The patient also had extreme fatigue since 09Mar2021. The patient was completely normal and physically active before the first dose, and she have not felt normal since. Events resulted in doctor or other healthcare professional office/clinic visit. The patient underwent lab tests and procedures which included nasal swab, with both negative test results on 17Mar2021 and on 31Mar2021. No treatment was received for the events. The outcome of the events were not recovered. |

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| 1254422 | 4/25/2021 | PA | 36 | F | 1/17/2021 | 1/1/2021 | having discoloration on her toes; she was having numbness and tingling; she was having numbness and tingling; her extremities, from the knee down and both her hands and feet were cold,ice cold; Tachycardia; palpitation/palpitation complications without doing anything straight away; Pulse keeps raising, elevating to 148-157/Pulse went to 209; shortness of breath and basically blasting of air; Difficulty breathing; Dizziness; Weakness; Syncope episodes; Costochondritis; chest pain; The initial case was missing the following minimum criteria: suspect product was not reported or specified. Upon receipt of follow-up information on 06Apr2021, this case now contains all required information to be considered valid. This is a spontaneous report from a contactable nurse (patient). A 36-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 17Jan2021 (Batch/Lot Number: EL3246) (at the age of 36-year-old) as single dose for COVID-19 immunisation. Medical history included migraine from an unknown date and unknown if ongoing. Concomitant medication included topiramate (TOPAMAX) at 250 mg, daily (2 DF 100mg and 1 DF 50mg at bedtime) taken for migraine, start and stop date were not reported. The patient previously received fist dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 27Dec2020 (Lot Number: EK5730) for COVID-19 immunization. The patient reported that since the second vaccination experienced tachycardia, palpitation, shortness of breath and basically blasting of air, difficulty breathing, dizziness and weakness, all on 18Jan2021. She reported pulse keeps raising, elevating to 148-157, she had palpitation complications without doing anything straight away. Elevated pulse and tachycardia, that all started and that was very concerning, pulse went to 209 and that was when she got transported to the emergency room. The patient reported also syncope episodes, costochondritis and chest pain on Jan2021. On 26Mar2021 the patient experienced having discoloration on her toes, numbness and tingling and that her extremities, from the knee down and both her hands and feet were cold, ice cold. The patient was transported to the hospital by ambulance three times due to the events (hospitalizations on 22Jan2021, 30Jan2021 and 25Mar2021). The patient underwent lab tests and |

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procedures which included Troponin, D dimer, electrocardiogram (EKG), Chest X ray, Full blood count (CBC), exercise electrocardiogram (TMT) all resulted: normal, nuclear stress test: unknown results and pulse 148-157, 209, all on unspecified date. The patient outcome of the events was unknown.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the tachycardia and other reported events due to temporal relationship. However, the reported events may possibly represent intercurrent medical conditions in this patient. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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| 1254768 | 4/25/2021 | VA | 34 | F | 3/2/2021 | 3/6/2021 | <p>Syncope and collapse 3 times; This is a spontaneous report from a contactable consumer (patient). A 34-year-old female patient received bnt162b2 (BNT162B2), dose 1 via an unspecified route of administration, administered in right arm on 02Mar2021 (Batch/Lot Number: EN6199) as single dose for covid-19 immunization. Medical history included allergy to penicillin. Concomitant medication included amlodipine accept in two weeks. There was no other vaccine in four weeks. The patient experienced syncope and collapse 3 times on 06Mar2021, resulted in Emergency room/department or urgent care, Hospitalization. The patient was hospitalized for syncope and collapse 3 times for 3 days. The patient has not covid prior vaccination, tested covid post vaccination. covid test type post vaccination was Nasal Swab, covid test date on 31Mar2021 with negative result. Therapeutic measures included potassium replenishment, rest and monitor were taken as a result of syncope and collapse 3 times. The outcome was recovered. No follow-up attempts are needed. No further information is expected.</p> |
| 1254797 | 4/25/2021 | CA | 22 | F | 2/26/2021 | 2/26/2021 | <p>fainting; hot flashes; Fatigue; arm pain; diarrhea; This is a spontaneous report from a contactable consumer (patient). A 22-year-old female patient (not pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration, administered in left arm on 26Feb2021 10:00 at single dose for COVID-19 immunisation. Medical history included Narcolepsy, dysautonomia and POTS (Postural orthostatic tachycardia syndrome). No known allergies. Concomitant medication included modafinil. No other vaccine in four weeks. The patient experienced fainting, hot flashes, fatigue, arm pain, diarrhea, all on 26Feb2021. No treatment received for the events. No COVID prior vaccination. No COVID tested post vaccination. The outcome of the events was recovered. Information on the lot/batch number has been requested.</p> |

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| 1254799 | 4/25/2021 | CA | 22 | F | | | 2 episodes of fainting with shaking; 2 episodes of fainting with shaking; foaming at mouth; Fatigue; Body aches; Headache; This is a spontaneous report from a contactable consumer (patient). A 22-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at age of 22-years, on an unspecified date (Lot number was not reported), as single dose for covid-19 immunisation. Medical history included narcolepsy, dysautonomia and Postural orthostatic tachycardia syndrome (POTS). The patient was not pregnant. Concomitant medications included modafinil. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at age of 22-years, as single dose in left arm, on 26Feb2021 at 10:00 for covid-19 immunisation and she experienced fatigue, arm pain, fainting, diarrhea, hot flashes after first dose all within 48 hours. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced 2 episodes of fainting with shaking, foaming at mouth, fatigue, body aches and headaches after second dose all within 48 hours. Events outcome was unknown. Information about lot/batch number has been requested. |

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| 1254858 | 4/25/2021 | VA | 80 | F | 3/20/2021 | 3/21/2021 | 24 hours after second shot fainted; This is a spontaneous report from a contactable consumer (patient). An 80-year-old non-pregnant female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: ER2613), via an unspecified route of administration, administered in left arm on 20Mar2021 12:00 at single dose for COVID-19 immunization. The patient's medical history included glaucoma, and underactive thyroid. The patient had no known allergies. The patient's concomitant medications included levothyroxine sodium (SYNTHROID), and latanoprost (XALATAN), both taken for an unspecified indication, start and stop date were not reported. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EN6198), in the left arm on 27Feb2021 12:00PM for COVID-19 immunization. Facility vaccine type was Physician's Office (reported as Doctor's office/urgent care). The patient had no other vaccine in four weeks. The patient had no COVID prior vaccination and was tested for COVID post vaccination. It was reported that 24 hours after second shot, the patient fainted on 21Mar2021 07:00. The event resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, hospitalization. The patient was hospitalized from 21Mar2021 to an unknown date for 1 day. The patient underwent lab tests and procedures which included nasal swab: negative on 21Mar2021. Therapeutic measures were taken as a result of 24 hours after second shot fainted and included stitches on bridge of nose and lip. The outcome of the event was recovered on Mar2021. |

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| 1254904 | 4/25/2021 | IN | 58 | M | 3/4/2021 | 3/4/2021 | Four hours later he passed out/ Four hours after getting vaccine he was on the floor and out like a light; Sore right arm; goofy; This is a spontaneous report from a contactable consumer. A 58-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), first dose at the age of 58-years-old intramuscular, administered in Arm Right on 04Mar2021 09:30 (Batch/Lot Number: EN6200) as single dose for covid-19 immunisation and prophylaxis. Medical history included high cholesterol, allergy (When pollen is heavy, it is worse) from an unknown date and unknown if ongoing, fractured his shoulder in 05Feb2021, sinus jacked up from an unknown date and unknown if ongoing, covid-19 from Nov2020 to an unknown date, anemic from Dec2020 to an unknown date, nasal surgery on an unknown date, fever blisters from an unknown date and unknown if ongoing, immune system disorder from an unknown date and unknown if ongoing. Concomitant medications included zolpidem tartrate (AMBIEN) taken to help sleep; atorvastatin (LIPITOR) taken for high cholesterol; loratadine taken for allergy; cetirizine hydrochloride (ZYRTEC) taken for allergy; mometasone furoate (FLONASE) taken for allergy; start and stop date were not reported for all; fish oil (OMEGA 3) and selenium (SELENIUM) taken for an unspecified indication, start and stop date were not reported; colecalciferol (VITAMIN D3 1000) taken for immune system disorder; iron (IRON) taken for anaemia; lysine taken for fever blisters ; zinc taken for immune system disorder, start and stop date were not reported for all and multivitamin. It was reported that four hours after getting vaccine on 04Mar2021, he was on the floor and out like a light. This is the first one he received and his doctor said not to get second one. He had the first one and about 4 hours later, he was on the kitchen floor and out like a light. He doesn't know if it was connected to shot or not. He never had problems before. He got the vaccine around 09:30 and around 13:30, his friend came in for lunch and found him on the floor. She freaked out. She said she liked to never got him awake and said he was goofy for a good half hour. He does not know how long he was on the floor. His arm was sore on 04Mar2021 09:30 for about 4 days. The patient underwent lab tests and procedures which included blood iron: so low on an unspecified date. The patient was recovering from |

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passed out and sore arm while recovered from goofy on
04Mar2021.

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| 1254609 | 4/25/2021 | PA | 54 | F | 3/7/2021 | 3/1/2021 | <p>passed out; trouble flexing her right hand open and closed; not feeling well, she feels very bad; sores in her mouth and nose; sores in her mouth and nose; anal hemorrhoid sores; had difficulty speaking, with her words; has been dropping things, she has broken glass; her eye felt heavy and her eye was drooping; Dizzy; Fall; Slight fever; Fatigue; extreme pain through right side (right side means her shoulders, neck, torso, arm, and entire leg); first dose given 14Jan2021, and second dose given 07Mar2021; first dose given 14Jan2021, and second dose given 07Mar2021; Shortness of breath; severe nerve pain; Vomiting; had a feeling of urination, like she had to urinate when she didn't, that feeling of urination; Disorientated; eye pain like pins and needles; skin is burning and painful to the touch; Headache; joint and muscle pain; joint and muscle pain; Nausea; horrible lack of appetite/couldn't eat anything other than soup; This is a spontaneous report received from a contactable consumer (patient) via a Pfizer-sponsored program called COVAX US Support. A 54-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in Arm Right on 07Mar2021 (Lot Number: EN6204) as single dose for covid-19 immunization. The patient's medical history included history of three spinal surgeries (takes no pain meds, she is not on pain meds, she has never been on or kept taking them); and has "neuropathy and nerve related issues" that were not this bad since ten years ago in 2011, clarified that what she has is not actually neuropathy, something with the peripheral nerve, she says she doesn't remember actual verbiage), since ten years ago in 2011, and the only difference was this vaccination, it was not this bad until this vaccination. She doesn't react well to pharmaceuticals anyway (unspecified). Her medications are that she takes the minimum amount of medications, very minimal (unspecified). There were no concomitant medications. There was no other products. Also, she has not had any other recent vaccinations or started any new medications. For past drug, she didn't take anything other than 5mg of zolpidem tartrate (AMBIEN) to sleep at night because of her spine. Patient previously also took pregabalin (LYRICA) and was off it, was also on gabapentin or neurontin (patient did not have those</p> |

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medications to provide NDC/LOT/EXP for either of them because she took them back to the pharmacy or turned them in to the police station because she doesn't keep medications in her house if she isn't taking them, and she couldn't take that medication). Historical vaccine included first dose of bnt162b2 on 14Jan2021 (at the age of 54-year-old; Lot Number: EN5318) in Arm Right for covid-19 immunization, and for her first dose the only thing was a sore arm, it was very sore, and she only experienced a slight bit of fatigue after her first dose. She received both doses of vaccine. Her first dose was LOT: EN5318 and was given 14Jan2021, and her second dose was LOT: EN6204 given 07Mar2021. The patient was reporting for Pfizer COVID-19 vaccine, for she was having a horrible reaction to it "45 days" (as reported) after taking 2nd dose, and had been in the ER, and her temperature still hasn't gone back down to her normal, her oral temp is still raised and her rectal is raised even more. She was not feeling well, she felt very bad, she would never get a vaccine again, that is how bad it was. Since "45 days" later she was still having significant pain and trouble flexing her right hand open and closed. For events treatment, she took over the counter Tylenol for fever and pain, strength unknown. Patient said she had not had this kind of disabling symptoms or anything before this vaccination. She had a slight fever almost the whole "45 days". On 08Mar2021, her oral temp was over 98 degrees Fahrenheit when her norm temp being 97.2 or 97.3degrees Fahrenheit. Her rectal temp stayed at 100 degrees Fahrenheit. The next day, actually on the 09Mar2021 (which was two days after her second dose), she had the slight fever, fatigue, and extreme pain through her right side. She said her right side means her shoulders, neck, torso, arm, and entire leg. She also had shortness of breath, and severe nerve pain. She called her primary care provider who said to wait 5 days to be seen. On day 5, or actually the whole five days (reported as in Mar2021), she was in bed and didn't leave her apartment because she was in bed and she was vomiting. On day 2 or within 6 hours of vaccination, she had a feeling of urination, like she had to urinate when she didn't, that feeling of urination was equivalent of having contrast dye (NDC/LOT/EXP: Unknown) put in her IV which makes her feel like she is peeing her pants but she did not, and that feeling has not gone away. On day

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5 (11Mar2021), she was dizzy and fell. In Mar2021, she was disorientated and vomiting, she couldn't eat anything other than soup. On day two (Mar2021) she had some kind of eye pain that is still there "45 days later", it feels like pins and needles. Her skin was burning and painful to the touch, she couldn't keep an IV in her when she was in the ER. She was not admitted to the hospital. She was having headaches, and joint and muscle pain. She had nausea and vomiting at different times. She continued to have shortness of breath. She had a horrible lack of appetite. She had sores in her mouth and nose. She had anal hemorrhoid sores. Last night (05Apr2021)she had a headache that was severe like someone put a knife behind her right eye, and when she got up (06Apr2021) her eye felt heavy and her eye was drooping. She also had difficulty speaking, with her words. She says she had passed out, and had been dropping things, she had broken glass. She has been to a neurologist and a gastroenterologist. She clarified that all of these events were after her second dose, for her first dose the only thing was a sore arm, it was very sore, and she only experienced a slight bit of fatigue after her first dose. None of her doctors know what to do, her gastro doctor was giving her an anti inflammatory suppository and was going to do some tests. She had blood done from neurologist and at the ER and no one knows what to do, they keep referring her to other doctors. She wished someone could explain to her, but no one know and they said it was uncharted territory, they didn't know what to do. She is now back on Lyrica which she was off of but the ER prescribed her 300mg three times a day. She wanted to know what the hell is going on with this vaccine, and that she doesn't think having these side effects "45 days" out is normal. She wanted to be transferred to speak with someone about what to do because her doctor's don't know anything. The outcome of the events was unknown. No follow-up attempts are needed. No further information is expected.

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| 1256766 | 4/25/2021 | IA | 18 | M | 4/18/2021 | 4/18/2021 | patient fainted about 2-3 minutes after receiving the vaccine--lasted only seconds--patient was shaking and pale after recovering--patient was did state they probably should have eaten breakfast that morning and did not-- his mom got him some orange juice and a popart -- we also got him a cool/wet compress for the back of his neck--within 10 minutes his color improved-his shaking subsided and he began feeling much better. he was able to leave with his mother under his own power after 15 - 20 minutes. |
| 1255882 | 4/25/2021 | PA | 17 | M | 4/25/2021 | 4/25/2021 | Pt fainted after vaccine given . C/o of not eating prior to arrival. PT ambulate to stretcher w/o assistance. Water and crackers given. No c/o dizziness or S.O.B. Pt released at 8:18am. |
| 1256043 | 4/25/2021 | FL | 18 | F | 4/25/2021 | 4/25/2021 | Immediately following pt receiving Pfizer vaccine, she fainted in chair. Symptoms lasted approx 3-4 mins. Medic placed on stretcher and observed for over 30minutes. VS WNLs. Pt diaphoretic and provided juice, water and peanut butter crackers. Pt's mother reported no PMH. |
| 1256154 | 4/25/2021 | PA | 26 | F | 4/2/2021 | 4/2/2021 | Fainting about 5 minutes after vaccination, we gave patient water, let her rest and put her feet up. She recovered fully after 10 minutes. |
| 1256415 | 4/25/2021 | CA | 16 | F | 4/23/2021 | 4/23/2021 | Syncope, flushing/sweating, vitals wnl. Given apple juice, graham crackers. |

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| 1255323 | 4/25/2021 | VA | 35 | F | 4/10/2021 | 4/11/2021 | went to go lay back down/fainted; went to go lay back down; felt nauseous; Went to lay in bed and was sweating a lot; Before I fainted I had taken some ibuprofen for the headache; This is a spontaneous report from a contactable consumer patient(herself) reported. A 35-years-old female patient received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Solution for injection, Lot number: EM9810, Expiration date: unknown), via an unspecified route of administration in arm left on 10Apr2021 at 12:00 PM as single dose for covid-19 immunization. The patient historical vaccine included first dose BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, formulation: Solution for injection, lot number: EM9810, Expiration date: unknown), via an unspecified route of administration in left arm on 20Mar2021 at12:00 PM as single dose Covid-19 immunization. Patient medical history included fatty liver disease. Patient had known to allergies sulfa medication. Patient concomitant medication in two weeks included escitalopram oxalate (LEXAPRO), allergy medicine, allergy nasal spray. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient was not diagnosed with COVID-19 prior to vaccination. The patient was not tested for COVID-19 since the post vaccination. Patient experienced about 16 hours after the vaccine went to go lay back down, felt nauseous and fainted, got back up and fainted again. Went to lay in bed and was sweating a lot 11Apr2021 at 05:15 AM. Before fainted, patient had taken some ibuprofen for the headache. Patient not received treatment for the events. The outcome of the event was unknown. |
| 1255871 | 4/25/2021 | CA | 18 | F | 4/24/2021 | 4/24/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Headache-Mild, Additional Details: patient experienced lightheadness flushing and paramedics were called. blood pressure 114/88 and hr 76. patient responsive by the time ambulance came and was alert and oriented. patient rested and recovered. patient left clinic with mom and will follow up with pcp. |

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| 1256775 | 4/25/2021 | MD | 18 | F | 4/25/2021 | 4/25/2021 | Feels like she's going to pass out Pt. passed out then placed in wheelchair Pt.taken to ER via ambulance BP=89/43 Pulse= 82 Po2 =97% FS=149 Recorded by: RN and EMT |
| 1256556 | 4/25/2021 | CA | 16 | F | 4/23/2021 | 4/23/2021 | Syncope, 102/62 (pulse 72), 98/64 (pulse 70). O2 sat 100%. Feeling dizzy post-vaccination and syncope. |
| 1256874 | 4/25/2021 | CA | 17 | M | 4/25/2021 | 4/25/2021 | Tingly, Dizzy, nausea , fainted |
| 1256955 | 4/25/2021 | IL | 16 | M | 4/25/2021 | 4/25/2021 | Patient received the vaccine and sat down for 15 minutes. After the 15 minute wait patient got up to schedule their second dose appointment. While waiting in line, patient fainted and fell to the floor. Patient stated had blurred vision, was not showing signs of difficulty breathing , denied a soar itchy throat. Had patient lay down, feet were elevated. ambulance removed patient from pharmacy area via stretcher. |
| 1256960 | 4/25/2021 | CA | 44 | F | 4/10/2021 | 4/10/2021 | Within 24hours pt with fever, myalgia, chills, rigors, weakness and extreme dizziness with headache and episode of syncope. Had waves of flushing in body with central abdominal pain and redness and pale extremities. Abdominal pain "burning" recurrent for 6 days with diarrhea, nausea and vomiting and stools pale. In clinic 4/16/2021 pt appeared greenish/yellowish on day 6 and had weight loss from baseline 4lbs in 9 days when she was last seen. Pt labs done and normal. Night of 4/16/2021 started with palpitations racing heart. 4/17/2021 presented to ER for worsening palpitations with flushing and diaphoresis. Labs CXR normal. send home. Anxiety like symptoms fluctuating. Was given diazepam. 4/21/2021 seen in clinic again feeling slightly better. Still with nausea and also now dysgeusia. EKG normal. palpitations better. 4/23/2021 seen on video appt doing better. able to keep food down but still tired and weak. no longer needing diazepam. Taste improving. |

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| 1257061 | 4/25/2021 | KS | 30 | M | 3/31/2021 | 3/31/2021 | Patient stated he passed out while driving and ended up crashing into a tree. He stated he was treated at a hospital where it was determined he had a concussion. He was later released and did not say he had sustained any other injuries. He informed me at the time of his second dose. He stated he wanted to get the second shot but the doctor who treated him advised him not too. I told him to delay until further consultation with same doctor or a 2nd consultation with another doctor. |
| 1257174 | 4/25/2021 | CA | 18 | F | 4/21/2021 | 4/21/2021 | Medical alert called. arrived to patient on floor unconscious. LVN who first visualized stated patient fainted. Aroused after 1-2minutes. vitals taken 1025 92/56 73 bpm 99%O2sat FSBG 105 MD present assessing pt. 1030 vitals repeated 119/72 82bpm 99% O2Sat patient Alert and oriented, stated dizziness. after initial eval, seated patient upright, provided water and juice. then moved patient to chair. cracker provided. pt states dizziness resolved. vitals 1040 108/72 78bpm 100%O2 saturation. pt states she feels stable. refuses wheelchair to car. stable to walk, accompanied by mother. reviewed vaccination patient instructions. advised to call 911 if symptoms worsen or any of the listed severe reactions occur. mother of pt stated understanding. pt stable and stated she feels much better. released. |
| 1257240 | 4/25/2021 | NY | 30 | F | 4/13/2021 | 4/14/2021 | Vasovagal syncope and acute pulmonary embolism |
| 1256579 | 4/25/2021 | CA | 17 | F | 4/25/2021 | 4/25/2021 | C/O dizzy, syncope x1, less than 5 seconds, patient reports similar problem with all other vaccinations and injections. Father reports daughter ate dinner last night . Did not eat breakfast before coming to site. Patient alert and oriented x4 after incident. |

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| 1255350 | 4/25/2021 | NY | 45 | F | 3/26/2021 | 3/26/2021 | is passing out at 7PM; had two antibody tests and she's been negative; Patient verifies she is not dizzy, she just feels like yuck; Patient states she has pain; she felt like she couldn't breathe; she felt like, not herself, like un-well. Patient states she is feeling unwell since; zapping, basically like a electric shock; nausea and vomiting; nausea and vomiting; extreme fatigue/that night she was exhausted, she couldn't pick up her head; head just doesn't feel right/she couldn't pick up her head; fever; closing of her throat; heat coursing through her body, felt heat in her vessels/she was a bloody, hot mess; chills; This is a spontaneous report from a contactable other health professional. A 45-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in Arm Left on 26Mar2021 at 10:00 (Batch/Lot Number: ER8733) as single dose for COVID-19 immunization. Patient states she had chronic strep throat, she was sick four times a year for the first 12 years of her life. Patient stated she has no allergies, she was a healthy woman. Concomitant medication included simvastatin taken for an unspecified indication from 2020 and ongoing. On 26Mar2021, the patient experienced nausea/vomiting happened almost immediately, soon after the injection. The patient stated she wasn't feeling well, she had to go home from work, but the symptoms started that day almost immediately and persisted for a few days later. She has this zapping. The patient stated it was actually a term, it's basically like an electric shock that she was feeling throughout her body, like from head to toe on 08Apr2021. The patient stated and her head just doesn't feel right, just like dizziness. The patient stated she has pain and was uncomfortable. Patient stated she was concerned about what to do moving forward. Patient stated the day she got the shot, within three minutes, she felt like she couldn't breathe. Patient stated it was not emotional, she's very self aware, she was a psychologist. Patient stated it was a closing of her throat, but that has turned on and off as well. Patient stated then she had heat coursing through her body, felt heat in her vessels, down the center of her throat down in to her throat into the center chest and down into legs. Patient stated that night she was exhausted, she couldn't pick up her head. Patient stated she threw up and had chills, she felt like, not herself, like un-well. Patient states |

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she was feeling unwell since. Patient states she did travel that Monday after, which she doesn't know if it made it worse, but was gone only for an hour, then got sick again that night with fever and throwing up. Patient states then yesterday, she started getting these zaps in her body, it felt like someone had put a taser to her all over her body. Patient stated she was just not herself, she wasn't at her normal. Patient stated she passed out at 7PM at night. Patient verified she was not dizzy, she just felt like yuck. Patient stated she also experienced chills and fever, that happened later that day on 26Mar2021. Patient stated she came back to work and she just felt like she needed to go home. She was instantly not well. Patient stated she has had two antibody tests and she's been negative. Patient stated she checked after that, she made sure she had no antibodies. Patient clarified she checked her antibodies twice before getting the vaccine. Patient stated her resting heart rate was at 55, she was in athletic shape, she was healthy. Patient stated when she had the both, she was on the toilet and throwing up at the same time, she was a bloody, hot mess. Patient states she ripped her clothes off, she was hot. The outcome of the event nausea, vomiting, fatigue, "head just doesn't feel right" was recovered with sequel on 03Apr2021; fever was recovered with sequel on 07Apr2021; chill was recovered on 03Apr2021; electric shock was not recovered and unknown for the other events. The patient did not received any recent vaccines for SARS-COV2 other than Pfizer- BioNtech COVID-19 Vaccine prior to the event being report and has not received any other vaccines around the time of Pfizer- BioNTech Vaccine Vaccination.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

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| 1256622 | 4/25/2021 | GA | 17 | M | 4/25/2021 | 4/25/2021 | Patient fainted. Patient also stated that they have not eaten all day. BP was normal when it was checked after the event |

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| 1255324 | 4/25/2021 | OH | 38 | M | 3/30/2021 | 3/31/2021 | <p>passing out/ passed out; fainted; Vomited all over self; Blood pressure: Low, experiencing hypotension; Lethargy; Pains in legs; Pain in lymph nodes on left side; Migraine headache/ headache; Felt unwell; This is a spontaneous report from a contactable consumer (patient). A 38-year-old male patient received the first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE Lot Number: ER8732, expiration date: 31Jul2021) via an unspecified route of administration, administered on the left arm on 30Mar2021 09:00 at a single dose for COVID-19 immunisation. Medical history included ongoing asthma, thyroid cancer, thyroid removed, rhinitis, allergic to eggs (ongoing). Concomitant medications included calcium since they took out part of parathyroid, levothyroxine for Thyroid removed and calcitriol taken for Better absorption of calcium; and all were ongoing. The patient previously received Tetanus shot on an unspecified date in 2021 (3 weeks to a month prior to getting the first dose of the Covid-19 vaccine) with no adverse events. Patient was calling to report adverse side effects that he experienced 2 days ago on 07Apr2021 after having the first dose of the Pfizer Covid-19 vaccine. He said that on 07Apr2021, he was taken ill in an ambulance after passing out and vomiting all over himself and his wife. His wife may have saved his life by keeping him from falling down when he fainted. He was taken in an ambulance to the emergency room after he passed out. He said that it was an unpleasant experience as he had to strip down all of his clothes because they had vomit all over them and change in front of the paramedics before being placed on a stretcher and taken to the emergency room. While in the emergency room, he had a CT scan, bloodwork, and checked body movement by having him follow a finger and various other regular tests. He mentioned that the emergency room physician determined that in likelihood, the reason that he passed out and vomited on himself was a side effect from the Pfizer vaccination. He talked to his physician yesterday. His physician explained to him that because of his health background, what happened following the first dose of the Covid-19 vaccine, and due to the severity of things, the physician believed that it wouldn't be a good idea for the caller to get the second dose of the Covid-19 vaccine given his reaction. The physician stated that it was up to him whether or not he</p> |

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1255860 4/25/2021 VA

17 M

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got the second dose of the Covid-19 vaccine. He had his first dose of the Covid-19 vaccine on 30Mar2021. He began to feel unwell the following day of the Covid-19 vaccine (31Mar2021), experiencing lethargy, pains in his legs and migraine headache. He reported that he got progressively worse and thought he was having a thyroid issue. He reported that the physicians in the emergency room couldn't really determine what the cause of the fainting episode could be as all lab work and the CT scan came back normal. The emergency room physician thought that the caller experienced the fainting episode and vomiting due to the Covid-19 vaccine. He experienced a headache and pain in his lymph nodes on the left side. He took Tylenol and was ok. The next day, 31Mar2021, he didn't feel too well but was ok. He reported that for a few more days following 01Apr2021, he felt not too bad. He didn't have a temperature or a fever and didn't think he was suffering from any specific flu like symptoms. The facility where the vaccine was administered was in a Medical Facility, outpatient hospital like a walk-in center. The event passing out resulted in Emergency room visit. The patient underwent lab tests and procedures on 07Apr2021 which included, potassium levels: normal, blood pressure: low, experiencing hypotension, thyroid levels were normal, CT scan normal and checked for diabetes: negative. Outcome of the events lethargy, pain in legs and migraine headache was recovering, pain in lymph nodes on left side recovered on 31Mar2021 while unknown for the other events.

Systemic: Chills-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Exhaustion / Lethargy-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Shakiness-Mild, Systemic: Visual Changes/Disturbances-Mild, Systemic: Weakness-Mild, Additional Details: Family History: Both parents had seizures after being immunized in the past and this was their son's first immunization. Otherwise, the patient was calm and healthy.

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| 1255362 | 4/25/2021 | OR | 44 | F | 3/30/2021 | 3/30/2021 | <p>PMS symptoms; nipples became very hard and sore.; swollen breast tissue; Menses late and hasn't started; symmetrical lumps on the distal sides of my breasts; faint; slight injection site soreness; intense tingly whole body sensations; Sense of pressure and tingling on eyeballs; Increased sensitivity to touch; This is a spontaneous report from a contactable healthcare professional (patient). A 44-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in arm left on 30Mar2021 16:00 (Batch/Lot number was not reported) as single dose for covid-19 immunisation. Medical history included Mild/moderate TBI in Oct1999 with herniated disk in lower lumbar region from auto accident (patient was a pedestrian and a car ran into her); fractured tibia/fibula from occurrence; low blood pressure which she had occasionally fainted from at blood draws (started after being active athletically during recovery from 1999 injury). Patient was not pregnant. There were no concomitant medications (no vaccine in 4 weeks and no other medication in two weeks). Patient did faint 15 minutes after receiving Pfizer Covid vaccine on 30Mar2021. Medical people at vaccination site made a vasovagal note on record. Patient reported that there were no body aches or fatigue or fever, only slight injection site soreness for a couple of days which was hard to notice through intense tingly whole body sensations that started after receiving vaccine on 30Mar2021 16:15. Still continuing to feel a week and a half later. It was very uncomfortable but not painful. Patient also experienced sense of pressure and tingling on eyeballs and increased sensitivity to touch. Menses were due one week after vaccination but 4.5 days after vaccination on 03Apr2021, nipples became very hard and sore. After a few days on nipples slightly sore still but mostly swollen breast tissue with soreness on Apr2021. Patient had not had this as PMS symptom since becoming pregnant almost 9 years ago and it never lasted 7.5 days with it still ongoing as of time of report. Her menses was late on Apr2021 and hasn't started but she was not pregnant. Patient's usual PMS symptoms have kind of started yesterday on 09Apr2021. It quickly formed bilaterally symmetrical lumps on the distal sides of her breasts which was also unusual on Apr2021. No</p> |

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treatment was received and events results in doctor's clinic visit. Outcome of the events was not recovered. Patient was not diagnosed with covid prior to vaccination and had not been tested post vaccination. Information on the lot/batch number has been requested.; Sender's Comments: Based on known drug safety profile, there is reasonable possibility of causal association between the event syncope and the suspect suspect vaccine BNT162B2. The impact of this report on the benefit/risk profile of the Pfizer drug is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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| 1255445 | 4/25/2021 | OH | 53 | F | 4/7/2021 | 4/8/2021 | rash covering most of torso; Passed out; unable to hold urine; diarrhea; extremely weak; sweating profusely; temp of 101; trembling uncontrollable; freezing; terrible headache; lethargic; This is a spontaneous report from a contactable consumer (who is also the patient). A 53-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: ER8732), via an unspecified route of administration in the left arm, on 07Apr2021 10:30, as single dose, for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient had no known allergies and was not pregnant at the time of vaccination. The patient did not have COVID-19 prior to vaccination and was not tested for COVID-19 post vaccination. Historical vaccine included the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN6207) received at age 53 years, via an unspecified route of administration in the left arm, on 16Mar2021 11:00, for COVID-19 immunisation. The patient did not receive other vaccines in four weeks. On 08Apr2021 at 03:30, the patient woke up trembling uncontrollable and was freezing. She had a terrible headache. At about 04:30, the patient got out of bed to get some Advil and go to the bathroom. She almost got to the bathroom but was unable to hold her urine and had sudden diarrhea as soon as she sat down. She then became extremely weak and passed out. She was sweating profusely and had a temp of 101. She took Tylenol and Advil and her temp broke an hour or two later. She then had a headache and was lethargic all day on 08Apr2021. On 09Apr2021, the patient felt much better but reported she was still weak, she also had a rash covering most of her torso. Treatment for the events trembling uncontrollable, freezing, terrible headache and temp of 101 included Tylenol and Advil. No treatment was taken for the remaining events. The outcome of extremely weak was not recovered; and the outcome of the remaining events was recovering. |

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| 1255475 | 4/25/2021 | FL | 80 | F | 2/23/2021 | 2/1/2021 | <p>very ill and had to be taken to hospital; terrible pains all over; dehydrated; headache; feeling like something was choking her in mouth; coughing real hard; it was breathing and it was like somebody has cranky paper in hand which screaming up that's what breath sounded like; joint pain; patient was like fainting; panicked; allergic reaction/face swollen up; and lymph node was swelling up; white lumps on lip; some white patches on face/couple of patches around mouth; white lips; Short of breath; sore around mouth; face swollen up; pneumonia; This is a spontaneous report from a contactable consumer (patient). An 80-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration on 23Feb2021 (Batch/Lot Number: EN6200; Expiration Date: 06May2021) as single dose for covid-19 immunisation. Medical history included insomnia from an unknown date and unknown if ongoing. Patient weight was 155 now. Patient was overweight because this eating and eating. Feeling inactive, not going out so patient gained a lot of weight. Patient took blood pressure medication and for heart some basically and patient didn't sleep well, so patient took Alprazolam to relax to sleep, but patient was an insomniac but that was basically problem. The patient's concomitant medication included isosorbide. Patient had the first Pfizer shot and wasn't even sore or anything, patient was so happy but that about 4 or 5 hours later about maybe 5 o'Clock, patient had allergic reaction and started to feel a sensation in lip and when she looked in the mirror, what was all that on lip and one side on lip it had turned white and it had lump was extended along lip line, lymph node was swelling up and patient had white lumps on lip which still had but it was going down and some white patches on face. Nothing happened on the 24Feb2021. Patient thought it was the 25Feb2021 that was when all trouble started. Patient felt like nightmare because she started feeling like something was choking her in mouth and next minute patient started coughing, coughing real hard and that was terrible cough then after this strange voice and patient realized it was breathing and it was like somebody has cranky paper in hand which screaming up that's what breath sounded like. Patient start to get out of bed and then waken to kitchen, patient had terrible headache, joint pain, pain all over from head to foot and</p> |

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patient was certainly dehydrated. She had no water in at all, she was like don't know something come over and felt like she was sort of leaving the world, patient was like fainting, and panicked. Patient had terrible pains all over and felt like patient was dying, patient was going to die. Patient said she need an ambulance, patient was very ill and had to be taken to hospital. They came within a few minutes, they started questioning about what was happening and they put patient to the emergency room and well they test patient for Covid as well naturally. It was negative, they did it 2 times and it was negative. When they took patient to one of the room in fact patient was frightened because they didn't told patient it was negative. Patient said she got the virus, they said not but patient had to take the oxygen as it's surge to scan on lungs. They said patient had allergic reaction to the vaccine. Patient was supposed to have it but at the same time there was the variant, doctor said patient was 70% covered, didn't have it but patient want to just check the status was with a person like her was allergic. Patient had shots in face and patient did tell them that she had all sorts of things on face. Now patient still had the white lips and couple of patches around mouth and naturally patient was worried like what to do. The patient didn't take the second shot because she was too nervous. Patient went hospitalization on the 25Feb2021 very early, and was relieved on 27Feb2021 (not sure). Reason of Hospitalization: On the University hospital. They put down to the Pfizer injection but that was older happens to patient, they infused patient with antibiotic they gave pills. Patient said she won't be able breath with them and that was what they did, they 'reflect' her, they said patient had pneumonia which she did not have (Further clarification was unknown). Early the next morning they put patient down 2' o'clock in the morning. Patient wanted to go home, they said patient can't as she had very bad infection in lungs which was completely untrue. The next morning (the same morning early), patient was okay because the pains and everything was gone but she believe the medication they put patient on that caused to short of breath and patient said please don't give her the medication and they did. They only give generic medicine in the hospital and patient took brand name. On 26Feb2021 patient actually called the doctor for all results and she told nothing, patient didn't get the result.

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Anyway they took patient off one medication, they didn't give it to her and this medication you can not get off of it and through that patient had a headache the whole of the day and the whole day on the 26Feb2021 patient was suffering with very bad headache and kept asking for the medication they said they would give to the patient. Finally the doctor gave only to the aspirin and paracetamol (TYLENOL) that both the same and in the end patient husband have to go and get the pill because they still hadn't given it to patient all day long. Patient said to doctor because she was breathing hard and she said the doctor did this to her by giving these pills that don't agree with her. She told she can not take this medication, anyway the doctor said to patient husband go home and get her medication, and he said so now you are medicating yourself. By the next day patient was ready, she was breathing normally and was ready to go home but late afternoon they said patient should go home but she still had those white patches but they were not as prominent as what they were. Patient whole lip turn white, whatever they did, whatever they gave, patient had sore around mouth and face swollen up. Patient didn't know whether she was allergic to the medicine or what but her face, it looked like she had, patient was fine anyway couldn't get an appointment with GP to the Wednesday (unspecified week) but it free appointment on the Tuesday and patient went in and showed him what it looked like. He said it should return to normal within 2 weeks and it but still face like normally excepted lips. Outcome of events pain, short of breath was recovered in 2021, and outcome of other events was unknown. Date of second shot was 17Mar2021, it was reported patient had got the both shot of covid vaccine.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021404239 similar report from same reporter

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| 1255492 | 4/25/2021 | | | F | | | she also fainted; her blood pressure drops drastically on Sunday morning; This is a spontaneous report from a non-contactable consumer. A consumer reported that a 94-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: unknown) on an unknown date at a single dose for COVID-19 immunization. Medical history and concomitant drugs were not reported. The consumer reported that the patient had the vaccine on 'Saturday' and on Sunday morning her blood pressure drops drastically, they called the doctor, she was under in doctor's hand, she called the doctor again today, she also fainted. The consumer was questioning if it can in very extreme cases cause the blood pressure to go havoc. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained |

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| 1255577 | 4/25/2021 | IN | 22 | M | 4/8/2021 | 4/1/2021 | <p>Passed out; pounding headache/headache symptoms are getting worst; body ache; tiredness; This is a spontaneous report from a contactable consumer. A 22-years-old male patient (Son) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), dose 1 via an unspecified route of administration on 08Apr2021 (Batch/Lot number UNKNOWN) as single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. My son is having a tough time with the vaccine. Everyday he has a couple of side effects. He started with body ache and tiredness on unspecified date Apr2021. He had a pounding headache. His headache was moderate today. However, the headache symptoms are getting worst. Generally, the symptoms last a day his have been getting worst for 7 days. He has been taking Tylenol and Advil. But the Advil doesn't even seem to hep anymore." headache is a common side effect reported with the vaccine. If the symptoms persists or get worst please consult your HCP. Please note blood clot has not been associated with the vaccine. Patient is been experiencing what I considered to be pretty severe, I guess reaction in term of aches and headache. This morning he woke up with the pounding headache, he kid described it as pounding and I just I guess I want to ask because everywhere I read, it says mild headaches are common and aches and I understand that but I guess understanding why this, this is considered somewhat as severe reaction or is there anything he can do to alleviate the symptom and should he, I guess my question is actually I guess my question also is should he not possibly get the second dose if he is experiencing such bad headaches with the first dose. When paraphrased the concern, reporter stated, Yes, basically we are thinking if can do to alleviate it and then he could not get the second dose, if you have any advice, I guess and just let you know he went to his health center in the college he went to get a COVID test and a flu test just to make sure he doesn't have actual Covid or flu and those report I got yesterday and so they told him that it's most likely still vaccine reaction. When probed for event start date, reporter stated, I would say a day after, I would say 09Apr2021, I guess it's phantom (not clarified) with symptom, the first day he was just tired, as far as the headache that started on the 09Apr2021. He (son) also</p> |

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passed out after the vaccine, which I also did that I didn't have Pfizer I (reporter) had Moderna and I had that same reaction, so I think that sometimes happens to some people but that's it happens also. When probed for vaccination anatomical site, reporter stated, Outside of the body I guess, I don't know that for sure. Patient still having the problem (event), and out event outcome, reporter stated, Yes, I think persisting, I think it varies. Patient has been taking Advil (Ibuprofen) and Tylenol (treatment). The patient underwent lab tests and procedures which included influenza virus test: negative on 12Apr2021, sars-cov-2 test: negative on 12Apr2021. They told him that it's most likely still vaccine reaction. Therapeutic measures were taken as a result of body ache (pain), tiredness (fatigue), pounding headache/headache symptoms are getting worst (headache). The outcome of the events was reported as unknown. QR Comment: Call handler not filed split case. Might have been split case. Information about the lot/batch number has been requested.

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| 1255594 | 4/25/2021 | | | F | | | <p>Passed out on the floor; nausea; every limb hurt; 103 fever chills; 103 fever chills; severe headache; This is a spontaneous report received from a contactable consumer. A female patient in her 40s received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; solution for injection) via an unspecified route of administration on an unspecified date as a single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; solution for injection) via an unspecified route of administration on an unspecified date as a single dose for COVID-19 immunisation. On an unspecified date the patient experienced passed out on the floor, severe headache, nausea, 103 fever chills and every limb hurt. The clinical course was reported as follows: "after the 2nd dose, every limb hurt, severe headache for 48hrs, nausea, 103 fever chills for 2days. She crawled downstairs to get water and passed out on the floor. Woke up and crawled back to bed." The clinical outcomes of the events passed out on the floor, severe headache and 103 fever chills were all recovered/resolved on unspecified dates and the clinical outcomes of the events nausea and every limb hurt were unknown. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.</p> |

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| 1255642 | 4/25/2021 | PA | 78 | F | 3/26/2021 | 3/26/2021 | Blood clots in Lungs; No longer able to do activities of daily living; Almost fell to floor from sitting position; short of breath; total body exhaustion/fatigue; sleepy throughout the day; unstable, weak; debilitating symptoms bedridden/unstable, weak; debilitating symptoms bedridden; passed out completely while sitting; Unable to complete daily 1 mile walk at park/Unable to take stairs; Lightheaded/dizzy; This is a spontaneous report from a contactable consumer. A 78-years-old female patient received bnt162b2 (BNT162B2), dose 1 via an unspecified route of administration, administered in Arm Right on 26Mar2021 15:00 (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunisation. Medical history included patient had COVID-19 Dec2021 and recovered completely in 2 weeks. Symptoms: fever, sleepy. Went back to daily walk after 2 weeks. No loss of smell, no loss of taste, no mental changes- was very happy with my complete recovery. Took vaccine 26Mar2021 at recommendation of doctor to be safe from variants. Regret deeply, still hospitalized as of this writing. Concomitant medications included ramipril; rosuvastatin calcium 40mg; levothyroxine, all taken for an unspecified indication, start and stop date were not reported. The patient previously took sulphur and experienced allergies. The patient experienced unable to complete daily 1 mile walk at park/unable to take stairs on 27Mar2021, lightheaded/dizzy on 27Mar2021, passed out completely while sitting on 28Mar2021, unstable, weak on 30Mar2021, short of breath on 31Mar2021, total body exhaustion/fatigue on 31Mar2021, sleepy throughout the day on 31Mar2021, almost fell to floor from sitting position on 09Apr2021, debilitating symptoms bedridden/unstable, weak on 26Mar2021, debilitating symptoms bedridden on 26Mar2021, no longer able to do activities of daily living on 13Apr2021, blood clots in lungs on 14Apr2021, all with outcome of not recovered. Reported adverse event: 27Mar2021 - Unable to complete daily 1 mile walk at park. Lightheaded, dizzy 28Mar2021 Dizzy, passed out completely while sitting. Revived and taken to hospital by ambulance 28Mar2021 Admitted to (hospital name withheld) 30Mar2021 Discharge from hospital - unstable, weak 31Mar-08Apr2021 - short of breath easily. Unable to take stairs. Discontinued daily walk, weak, total body exhaustion, |

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sleepy throughout the day 09Apr2021 - Almost fell to floor from sitting position. Patient's daughter lowered patient gently to the floor. Revived shortly 13Apr2021 Saw primary doctor Dr (name withheld). Shared her debilitating symptoms bedridden since Covid-19 vaccine on 26Mar. BP taken from lying down, sitting and standing was markedly different and explained caused passing out and lightheaded. No longer able to do activities of daily living 14Apr2021 - Exhaustion and fatigue, her daughter to her back to the hospital 14Apr2021 - Passed out in Emergency Room @ (hospital name withheld). Admitted. Blood clots in LUNGS. The events resulted in: Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Hospitalization, Life threatening illness (immediate risk of death from the event), Disability or permanent damage. The patient was hospitalized for unable to complete daily 1 mile walk at park/unable to take stairs, lightheaded/dizzy, passed out completely while sitting, all from 28Mar2021 to 30Mar2021. The patient underwent lab tests which included blood pressure measurement: markedly different on unknown date. Patient was not pregnant. No other vaccine in four weeks. Patient had covid prior vaccination. No covid tested post vaccination. The treatment received for events included Heparin administered, still hospitalized as of now. Information about Lot/ Batch number has been requested.

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| 1255700 | 4/25/2021 | OR | 54 | M | 3/26/2021 | 4/6/2021 | Felt something in my leg like a cramp / did a scan of my leg and found the clot; dizzy; nearly passed out; This is a spontaneous report from a contactable consumer (patient). A 54-year-old male consumer received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 26Mar2021 at 16:30 at single dose in right arm for COVID-19 immunisation at the age of 54-year-old. Lot number was ER8732. Medical history included Human papilloma virus (HPV) positive tonsil cancer, ankylosing spondylitis, tinnitus, neuropathy, decreased memory from chemo and radiation. The patient did not have Covid prior to vaccination. Concomitant medications were unknown. The patient felt something in leg like a cramp for a week since 06Apr2021 before ER visit. On 06Apr2021, the patient got dizzy at home nearly passed out, and he went to ER. On 14Apr2021, Doctor did a scan of leg and found the clot. The patient was hospitalized due to the events and they were considered life-threatening. The patient was treated with heparin and ELIQUIS. On 14Apr2021, Rapid Covid test was negative. The patient was recovering from the events. |
| 1255701 | 4/25/2021 | | | M | | | Syncopal episode; This is a spontaneous report from a Pfizer Sponsored program. A non-contactable male patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as SINGLE DOSE for COVID-19 immunization. Medical history and concomitant medications were not reported. The patient had syncopal episode after receiving his shot on an unknown date. The patient was then transported to the emergency department (ED) as 911 was activated. Then, the patient was discharged from the ED with diagnosis of syncope. Outcome of the event was unknown. No follow-up attempts are possible. Information on lot/batch cannot be obtained. |

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| 1255746 | 4/25/2021 | FL | 81 | F | 2/2/2021 | 2/18/2021 | heart arrhythmia; cardiac arrest; This is a spontaneous report from a contactable consumer who reported for his wife. An 81-year old female patient received her second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Batch/Lot number EM9810) via unspecified route of administration on 02Feb2021 (at the age of 81-year old) at single dose for COVID-19 immunization. Relevant medical history was not reported. Concomitant medication included metoprolol from Jan2021 for congestive heart failure. The patient received the first dose of the same vaccine BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Batch/Lot number) on 12Jan2021 and on 15Jan2021, she had such trouble breathing diagnosed in the Urgent care as congestive heart failure with enlarged heart and fluid in her lungs because of her heart being enlarged. She had not had any previous heart problems. On 18Feb2021 she collapsed, went limp and went into the hospital and she was neurologically unresponsive. They tried to revive her and did bring her back with 5 epi shots, he was told that they did bring her back. When she got to the ER she went pulseless again and they gave her two more epi shots and got her back but she never did come out of a coma-like state. They admitted her to ICU. She stayed there until she passed away on the 22Feb2021. CT scans, X-rays, images of her heart, echocardiograms were performed. She was tested for COVID in Feb2021 and it was negative. They did a brain scan and there was no activity because she had been too long without oxygen. The consumer reported that the week before the cardiac arrest, she was feeling faint but she never passed out. Death certificate stated cause of death was heart arrhythmia and cardiac arrest. No autopsy was done.; Reported Cause(s) of Death: heart arrhythmia; cardiac arrest |
| 1255843 | 4/25/2021 | NC | 30 | M | 4/23/2021 | 4/24/2021 | Woke up feeling funny next morning. Stood up and collapsed/passed out. Paramedics were called. Blood pressure very low. Went to hospital for tests. Severe headache, aches, and chills. |

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| 1255542 | 4/25/2021 | | | F | | | patient fainted while driving the car; This is a spontaneous report from a non-contactable consumer reporting for a patient. A female patient of an unspecified age received bnt162b2 (BNT162B2), dose 2 via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunisation, age at vaccination unknown. The patient medical history and patient's concomitant medications were not reported. 40 minutes after the application, patient fainted while driving the car. Outcome of the event was unknown. No follow-up attempts are possible; information about batch/ lot number cannot be obtained. |

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| 1249679 | 4/24/2021 | NJ | 95 | F | 3/17/2021 | 4/17/2021 | <p>Almost blacks out/when the patient bends down to tie their shoe their dizziness get to the point where the patient almost blacks out; Dizziness/when the patient bends down to tie their shoe their dizziness get to the point where the patient almost blacks out; This spontaneous case was reported by a consumer and describes the occurrence of PRESYNCOPE (Almost blacks out/when the patient bends down to tie their shoe their dizziness get to the point where the patient almost blacks out) in a 95-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 040A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No medical history was reported). On 17-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 14-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 17-Apr-2021, the patient experienced PRESYNCOPE (Almost blacks out/when the patient bends down to tie their shoe their dizziness get to the point where the patient almost blacks out) (seriousness criterion medically significant) and DIZZINESS (Dizziness/when the patient bends down to tie their shoe their dizziness get to the point where the patient almost blacks out). At the time of the report, PRESYNCOPE (Almost blacks out/when the patient bends down to tie their shoe their dizziness get to the point where the patient almost blacks out) and DIZZINESS (Dizziness/when the patient bends down to tie their shoe their dizziness get to the point where the patient almost blacks out) outcome was unknown. The action taken with mRNA-1273 in response to the events was not applicable. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p> |
| 1251737 | 4/24/2021 | NY | 16 | F | 4/24/2021 | 4/24/2021 | FAINTING, LIGHTHEADED |

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| 1251669 | 4/24/2021 | IL | 16 | M | 4/24/2021 | 4/24/2021 | after vaccination patient start feeling dizziness and fainting. Pharmacist on duty helped the patient by checking blood pressure and pulse rate. Patient was give orange juice, after 10 minutes patient starts feeling better left pharmacy |
| 1251584 | 4/24/2021 | IL | 17 | M | 4/24/2021 | 4/24/2021 | 3 min after receiving the vaccine pt verbalized feeling faint. Staff offered pt a cool pack for his neck. Patient accepted. Pt reported not having had breakfast and leaned back into the chair and became pale. PTA eyes were noted to be rolled into his head. Pts body became rigid. Staff assisted pt to the floor to a supine position. Staff obtained baseline vitals (127/75, HR 66) while simultaneously dialing EMS. Pt a color returned within approx 2 min and pt was talkative. Dad reports pt with fear of needles with hex of syncope in past. Pt reported feeling fine upon EMS arrival. Pt declined EMS transport. Tolerated water and muffin without difficulty. Pt without injury. Self ambulated out of clinic after additional 15 min observation period. |
| 1251439 | 4/24/2021 | | 17 | M | 4/24/2021 | 4/24/2021 | Passed out, vomited once |
| 1251277 | 4/24/2021 | IL | 17 | M | 4/24/2021 | 4/24/2021 | Pt felt dizzy after receiving his vaccine. While walking towards the observation room accompanied by father and vaccinator nurse patient had a fainting episode. He was lowered to the ground by nurse/father and an assessment performed. VS within normal limits Fainting episode lasted a few seconds. Pt reported no medical conditions or hx of fainting . Pt also mentioned he hadn't eaten anything before receiving his vaccine. Vitals signs as follows: BP at 0830 110/55, HR 60, O2: 96%, at 0837: BP 107/58, HR 69, O2 97%. Pt observed for approximately 25 minutes and discharged home in stable condition accompanied by his father. |

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| 1250827 | 4/24/2021 | OH | 19 | F | 4/15/2021 | 4/15/2021 | After receiving my second dose, I started to develop mouth ulcers covering the entire inside of my mouth. Throughout the weekend, they continued to develop. I went to the ER to receive pain medication, as the ulcers were so bad that I could not talk or eat. The following morning, I passed out going to pick up my medication at CVS, where I was taken back to the hospital in an ambulance and had a 103 degree fever. I was given IV fluids and was sent on my way. I was on strict bedrest for 4 days, until on Thursday 04/22/2021, I was readmitted to the ER due to worsening of the sores and lack of nutrition. For 3 days since then, I have been on IV fluids, pain medication, and taking a steroid solution to help the ulcers in my mouth lessen. The doctors here believe that it is an extremely strong reaction to the COVID-19 vaccine second dose. |
| 1250823 | 4/24/2021 | RI | 16 | F | 4/23/2021 | 4/23/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Additional Details: patient briefly fainted post vaccination, was accompanied by mother, immunizing pharmacist assisted with care, provided ice pack for head, laid patient on back with feet elevated, patient returned to consciousness, after returning to seated position patient complained of nausea so we returned patient to laying on back feet elevated. Patient was observed by immunizing pharmacist and mother prior to leaving under own ability. BP 123/81 HR 87 at 555pm, injection was at 517pm. |
| 1251893 | 4/24/2021 | CO | 23 | F | 4/7/2021 | 4/7/2021 | Per EMS observation staff: "Patient experienced throat tightness, feeling funny, and had syncope after receiving the vaccine. Patient had a syncopal episode with convulsions for approximately 30 seconds. Patient was given 50mg of IM Benadryl at 11:18 and 911 was called. After administering IM Benadryl patient seemed to improve. Patient was transported by Fire Department at 11:26 and transported to Hospital." VS per obs staff: 11:18: BP 80/palp, HR 54, resp 24 labored, oxygen 94% on RA. 11:23: BP 80/40, HR 56, resp 20 semi labored, oxygen 92% on RA. Per roommate pt received dose of epi upon arrival in ED. Attempted to make FU phone call. No answer at this time. Will continue to call and verify patients condition. |

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| 1249683 | 4/24/2021 | | 68 | F | 2/11/2021 | 3/12/2021 | <p>Passed out; she does not remember passing out; did not wake up till 3 in the afternoon that day; she was nauseous and in the morning when she got up she was extremely nauseous; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out) in a 68-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 048A21A and 006M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No medical history reported). On 11-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 11-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 12-Mar-2021, the patient experienced LOSS OF CONSCIOUSNESS (Passed out) (seriousness criterion medically significant), AMNESIA (she does not remember passing out), SOMNOLENCE (did not wake up till 3 in the afternoon that day) and NAUSEA (she was nauseous and in the morning when she got up she was extremely nauseous). On 12-Mar-2021, LOSS OF CONSCIOUSNESS (Passed out), AMNESIA (she does not remember passing out), SOMNOLENCE (did not wake up till 3 in the afternoon that day) and NAUSEA (she was nauseous and in the morning when she got up she was extremely nauseous) had resolved. Concomitant medications were not provided. The patient did not remember passing out but found herself on the bathroom floor. Treatment information included bismuth subsalicylate. This case was linked to MOD-2021-081743 (Patient Link).;</p> <p>Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p> |

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| 1249682 | 4/24/2021 | FL | 41 | M | 3/22/2021 | 4/19/2021 | <p>head spinning; dizzy; tired; pain at injection site; nauseas; cold sweats; really weak; could barely stand up; sick to his stomach; Passed out to sleep at 745 pm; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out to sleep at 745 pm) in a 41-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 037B21A and 044A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Asthma and Hyperthyroidism. Concomitant products included FLUTICASONE PROPIONATE (FLOVENT) for an unknown indication. On 22-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 19-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 19-Apr-2021, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced LOSS OF CONSCIOUSNESS (Passed out to sleep at 745 pm) (seriousness criterion medically significant). On 19-Apr-2021 at 11:30 PM, the patient experienced COLD SWEAT (cold sweats), ASTHENIA (really weak), DYSSTASIA (could barely stand up) and ILLNESS (sick to his stomach). On 20-Apr-2021, the patient experienced VERTIGO (head spinning), DIZZINESS (dizzy), FATIGUE (tired), VACCINATION SITE PAIN (pain at injection site) and NAUSEA (nauseas). At the time of the report, LOSS OF CONSCIOUSNESS (Passed out to sleep at 745 pm), COLD SWEAT (cold sweats), ASTHENIA (really weak), DYSSTASIA (could barely stand up), ILLNESS (sick to his stomach), VERTIGO (head spinning), DIZZINESS (dizzy), FATIGUE (tired), VACCINATION SITE PAIN (pain at injection site) and NAUSEA (nauseas) had not resolved. Not Provided Products known to have been used by the patient, within two weeks prior to the event, included thyroid medication. Treatment information was not provided. The patient received both scheduled doses of mRNA-1273 prior to the event; therefore, action taken with the drug in response to the event is not applicable. Based on the information provided which includes a temporal association between the use of mRNA-1273 vaccine and onset of the reported</p> |

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events, a causal relationship cannot be excluded. Nausea, fatigue, and vaccination site pain are consistent with the known safety profile of the vaccine. This case was linked to US-MODERNATX, INC.-MOD-2021-081679 (E2B Linked Report).; Sender's Comments: Based on the information provided which includes a temporal association between the use of mRNA-1273 vaccine and onset of the reported events, a causal relationship cannot be excluded. Nausea, fatigue, and vaccination site pain are consistent with the known safety profile of the vaccine, US-MODERNATX, INC.-MOD-2021-081679:cross link Dose 1

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| 1249691 | 4/24/2021 | NC | 43 | F | 4/15/2021 | 4/15/2021 | she almost passed out; dizzy; fast hearth beats; sick; high fever; throwing up; nausea; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (she almost passed out) in a 43-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Asthma, COPD, Cholesterol, Hypertension and Cyst of kidney (Cyst in left kidney). On 15-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 15-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (she almost passed out) (seriousness criterion medically significant), DIZZINESS (dizzy), HEART RATE INCREASED (fast hearth beats), ILLNESS (sick), PYREXIA (high fever), VOMITING (throwing up) and NAUSEA (nausea). At the time of the report, LOSS OF CONSCIOUSNESS (she almost passed out) had resolved and DIZZINESS (dizzy), HEART RATE INCREASED (fast hearth beats), ILLNESS (sick), PYREXIA (high fever), VOMITING (throwing up) and NAUSEA (nausea) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No treatments were reported. No concomitant medications were reported. Patient asked if she can receive another company's vaccine as a second dose.; Sender's Comments: This case concerns a 43-year-old female with a serious unexpected event of loss of consciousness, nonserious unexpected dizziness, heart rate increased, illness, and expected pyrexia, nausea, vomiting. Event onset the same day as first dose mRNA-1273. Events resolved. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. |

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| 1249670 | 4/24/2021 | FL | 72 | F | 3/24/2021 | 4/2/2021 | fell on 2april at a local Walmart; started itching last night in my hands after I took Oxycodone/Every time I take opioids, I have itching; woke up with hives on my torso, knees, and my arms/hives are most likely related to oxycodone; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of SYNCOPE (tripped over a pallet and fell) and FALL (fell on 2april at a local) in a 72-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 046A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Surgery (surgery to repair my elbow) on 08-Apr-2021. Concurrent medical conditions included Allergy. Concomitant products included CITALOPRAM and MULTIVITAMINS & MINERALS PLUS LUTEIN for an unknown indication. On 24-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 02-Apr-2021, the patient experienced SYNCOPE (tripped over a pallet and fell) (seriousness criterion medically significant) and FALL (fell on 2april at a local) (seriousness criterion hospitalization). On an unknown date, the patient experienced PRURITUS (started itching last night in my hands after I took Oxycodone/Every time I take opioids, I have itching) and URTICARIA (woke up with hives on my torso, knees, and my arms/hives are most likely related to oxycodone). The patient was treated with Surgery for Fall. At the time of the report, SYNCOPE (tripped over a pallet and fell), PRURITUS (started itching last night in my hands after I took Oxycodone/Every time I take opioids, I have itching) and URTICARIA (woke up with hives on my torso, knees, and my arms/hives are most likely related to oxycodone) outcome was unknown and FALL (fell on 2april at a local was resolving. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Treatment drugs included, Oxycodone , Zyrtec, Benadryl. Patient went to see doctor and they put on a new brace called T-form. It was reported that these hives are most likely related to oxycodone.; Sender's Comments: Based on reporter's causality (Tripped over a pallet and fell) the event is |

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| | | | | | | | assessed as unlikely related to mRNA-1273. |
| 1252055 | 4/24/2021 | AZ | 16 | M | 4/19/2021 | 4/21/2021 | Diffuse urticarial reaction leading to mild distributive shock and syncope |
| 1253026 | 4/24/2021 | MI | 35 | F | | 3/13/2021 | ALMOST PASSED OUT; BODY ACHE; REALLY TIRED; CHILLS; FEVER; This spontaneous report received from a patient concerned a 35 year old female. The patient's weight was 145 pounds, and height was 157.48 centimeters. The patient's past medical history included back issue, and covid-19 infection, and other pre-existing medical conditions included the patient had no known allergies. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1802068 and expiry: UNKNOWN) dose was not reported, administered on 12-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 13-MAR-2021, the subject experienced almost passed out. On 13-MAR-2021, the subject experienced body ache. On 13-MAR-2021, the subject experienced really tired. On 13-MAR-2021, the subject experienced chills. On 13-MAR-2021, the subject experienced fever. Laboratory data included: Body temperature (NR: not provided) 102 F. On 14-MAR-2021, Laboratory data included: Body temperature (NR: not provided) 101.7 F. Treatment medications (dates unspecified) included: ibuprofen. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from almost passed out on 13-MAR-2021, body ache, and chills on 14-MAR-2021, and fever on MAR-2021, and had not recovered from really tired. This report was non-serious. Additional information was received from patient on 24-03-2021 following information was updated and incorporated into case narrative: Patient demographic details (height, weight, patient age and age group), pre-existing condition, event outcome and end date (fever), medical history added (covid-19 infection, back issues); Sender's Comments: Medical assessment comment not required as per standard procedure as case assessed as non-serious. |
| 1253784 | 4/24/2021 | CO | 17 | F | 4/24/2021 | 4/24/2021 | Patient felt lightheaded and dizzy after receiving the vaccine, and then passed out. |

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| 1252940 | 4/24/2021 | CA | | F | | 3/15/2021 | HEADACHE; NAUSEAS; FATIGUE; ALMOST FAINTING SENSATION; SWEATING; BLURRY VISION; COLD ARMS; This spontaneous report received from a patient concerned a 50 year old female. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unk) dose was not reported, administered on 15-MAR-2021 for prophylactic vaccination on right deltoid. The batch number was not reported and has been requested. No concomitant medications were reported. On 15-MAR-2021, the subject experienced cold arms. On 16-MAR-2021, the subject experienced almost fainting sensation. On 16-MAR-2021, the subject experienced blurry vision. On 16-MAR-2021, the subject experienced sweating. On 16-MAR-2021, the subject experienced nauseas. On 16-MAR-2021, the subject experienced fatigue. On 17-MAR-2021, the subject experienced headache. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from headache on 17-MAR-2021, and had not recovered from almost fainting sensation, cold arms, blurry vision, sweating, nauseas, and fatigue. This report was non-serious. |
| 1252671 | 4/24/2021 | TN | 17 | M | 4/24/2021 | 4/24/2021 | Patient received vaccine and came and sat down next to his father in the waiting area. Approximately 5 minutes after sitting down he fainted and fell out of chair. His father guided his fall. It took 2-3 minutes for patient to gain conscientiousness. He was disoriented, pale, groggy. 911 was called and arrived approximately 20 minutes after event. After the paramedics examined patient, he regained his bearings and color. The family decided to go home at approximately 10am. I spoke with mother at 7pm tonight and patient has been fine all day. |

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| 1252652 | 4/24/2021 | CA | 18 | F | 4/24/2021 | 4/24/2021 | Patient is a 18-year-old, female. No known medical history. No known allergies. At 3:18 pm, the patient received her first dose of Pfizer vaccine (lot number EW0179, expires on 08/2021) on left deltoid, given by RN. Patient informed RN that she has a history of fainting after vaccines. RN recommended the patient wait in the zero-gravity chair. Patient continued to be A&Ox3, walked herself over to the EMT waiting area with a steady, balanced, and sat down in zero-gravity chair. At 3:20 pm, patient checked in with EMT and stated she feels "fine". At 3:27 pm, while waiting in observation area, patient stated "I don't feel good" and went unconscious. EMT reclined patient into supine position. Patient remained unconscious for approximately 10 seconds. RN called 9-1-1 at 3:28 pm. Patient regained consciousness at 3:28 pm and stated "I need something sweet". At 3:30 pm, the patient's BP 69/44, RR 8/min, HR 63 bpm and weak, skin dry and cold to touch, lips pale and cyanotic. At 3:33 pm, the patient's BP was 87/60. Fire Department arrived on site at 3:34 pm. Patient was transferred to gurney by FD. Patient left facility at 3:34 pm . |

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| 1252422 | 4/24/2021 | IL | 16 | M | 4/24/2021 | 4/24/2021 | Pt was seated in the waiting area after receiving his first dose of covid 19. His parents who also received the vaccine were waiting with him. I was preparing another dose for patients waiting for their covid vaccination. I heard pounding on the clinic room and ran to check. The mom had knocked on the door because her son had fallen out of his chair.. when I arrived he was on the floor and his parents said he was regaining consciousness and moved him in to a seated position. At this point another customer was calling 911. I had my technician call management. I observed the patient and asked if he was doing ok. His parents asked him if he was hurt and he responded in the negative. The patient was feeling cold and his hands were "cold and clammy" according to his mom so I held off on the cold compress. He wanted water but was also nauseous so I told the parents that I do not want to risk aspiration. We gave him a bag to throw up. I recommended that they take him to get seen when the paramedics arrived as I was concerned about him shaking before fainting. At this point the paramedics arrived and he was taken to the hospital as he was not feeling well. I followed up with the patient's mom and she said all his tests came back normal (EKG, et) and that the doctors may think it could have been due to anxiety from getting the vaccine. She was really appreciative of the call. |
| 1252372 | 4/24/2021 | WA | 25 | M | 4/6/2021 | 4/6/2021 | 25 you M with vasovagal syncope after injection. Patient recovered. He had a companion drive home. He was evaluated by EMS on scene. |

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| 1252197 | 4/24/2021 | TN | 24 | F | 3/10/2021 | | NECK PAIN; BODY ACHES; BURNING SKIN; POSSIBLE SINUS INFECTION; POSSIBLE DOUBLE EAR INFECTION; FAST HEART RATE; SHORTNESS OF BREATH; SPLITTING HEADACHE; FATIGUE; DIZZINESS; VISION CHANGES; POOR SLEEP; This spontaneous report received from a patient concerned a 24 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included vasovagal syncope, postural orthostatic tachycardia syndrome, atypical asthma, ehlers-danlos syndrome, attention deficit hyperactivity disorder, hallucinations, and no allergies or reactions to previous vaccination. The patient experienced drug allergy when treated with hydrocodone for drug used for unknown indication, and drug allergy when treated with salbutamol. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805020, expiry: UNKNOWN) dose was not reported, administered on 10-MAR-2021 13:30 to Left Arm for prophylactic vaccination. No concomitant medications were reported. On MAR-2021, treatment medications included: levosalbutamol. On 10-MAR-2021, the subject experienced dizziness. On 10-MAR-2021, the subject experienced vision changes. On 10-MAR-2021, the subject experienced poor sleep. Laboratory data included: Blood pressure (NR: not provided) 102/60 mmHg, and Pulse rate (NR: not provided) 72 pm. Treatment medications included: paracetamol. On 10-MAR-2021 22:00, the subject experienced splitting headache. On 10-MAR-2021 22:00, the subject experienced fatigue. On 10-MAR-2021 23:30, the subject experienced fast heart rate. On 10-MAR-2021 23:30, the subject experienced shortness of breath. On 11-MAR-2021, the subject experienced possible sinus infection. On 11-MAR-2021, the subject experienced possible double ear infection. On 11-MAR-2021, the subject experienced burning skin. On 11-MAR-2021 03:00, the subject experienced neck pain. On 11-MAR-2021 03:00, the subject experienced body aches. On 11-MAR-2021 07:45, treatment medications included: atenolol. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from shortness of breath, and splitting headache on 11-MAR-2021, and dizziness, and vision changes on 10-MAR-2021, was recovering from fatigue, burning skin, and possible |

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| | | | | | | double ear infection, had not recovered from fast heart rate, possible sinus infection, body aches, and neck pain, and the outcome of poor sleep was not reported. This report was non-serious.; Sender's Comments: V0 Medical assessment comment not required as per standard operating procedure as the case assessed as non-serious. | |
| 1252129 | 4/24/2021 | NY | 63 | F | 4/14/2021 | 4/21/2021 | Presented to the ER on 4/21/21 with c/o syncope and abdominal pain and nausea and vomiting. pt wasn't feeling good earlier in the day and became unresponsive falling back onto her bed and son called 911. she arrived in hemorrhagic shock, abd imaging showed a large splenic subcapsular hematoma of unclear etiology (no hx of trauma) with hemoperitoneum and was transferred to a higher level of care for IR .intervention for embolization. She ultimately required splenectomy and mx units of blood. (did get embolization but progressed to further bleeding) and ultimately needed splenectomy 4/24. She is sp 7 units prbc total, 2ffp, 1 plt, 1 cryo. She remains hospitalized as of 4/24 on critical condition |
| 1252099 | 4/24/2021 | MD | 25 | F | 4/3/2021 | 4/3/2021 | About 7 minutes of receiving my J&J vaccine, I started to feel nauseous while sitting down and waiting for my fifteen minutes of monitoring. I experienced pain in my left arm and my heart was beating fast. My vision was in and out, started seeing black and white spots. I then got up from my chair and I went to the counter and as I was talking to the clerk telling her I did not feel good, I just went down and fainted. I had fainted and when I came back, woke up a nurse was trying t put an epi-pen on me but I told her I did not need it. They called the ambulance and they monitored me there. The EMT said to me that my blood pressure had dropped and I had had a "vasovagal syncope" and that my body probably went into shock. I did not go to the hospital and went home. For the rest of the day I felt ill, and out of it. I also felt pain, an aching pain to the right buttocks region. The next day I still felt not good. Also I have noticed since the J&J vaccine, I had my menstrual cycle but normally my menstrual cycle lasts 5 days now this month it only lasted about 4 hours and I this concerns me. Before this vaccine, I did not have experience these symptoms. |

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| 1252082 | 4/24/2021 | | 18 | F | 4/23/2021 | 4/23/2021 | Right after vaccination syncope occurred with loss of vision, pale complexion, sweating, light headed ness, etc. for about 10 minutes after |
| 1252426 | 4/24/2021 | TN | 16 | M | 4/24/2021 | 4/24/2021 | PATIENT PASSED OUT AND EXPERIENCED CONVULSIONS APPROXIMATELY 1-2 MINUTES POST VACCINATION. HE WAS UNRESPONSIVE FOR 5 - 10 SECONDS AND THEN BECAME ALERT COMPLAINING OF "FEELING HOT" AND HAD TROUBLE BREATHING. EMS WAS CALLED AND PATIENT WAS TRANSPORTED TO LOCAL HOSPITAL. |
| 1247338 | 4/23/2021 | MA | 66 | F | 3/20/2021 | 3/29/2021 | Diaphoresis, abdominal cramping, loose stools, syncope x2 Lactic acidosis, descending colitis on CT felt to be ischemic colitis. |
| 1246097 | 4/23/2021 | CA | 24 | F | 4/21/2021 | 4/21/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: PATIENT HAD HISTORY OF VASOVAGAL SYNCOPE -Medium, Systemic: Nausea-Medium, Systemic: Weakness-Medium, Additional Details: PATIENT FAINTED AFTER RECIEVING HER 1ST DOSE OF MODERNA VACCINE. PATIENT'S MOTHER WAS WITH HER AND NOTIFIED US THAT PATIENT HAS A HISTORY OF VASOVAGAL EPISODES AFTER GETTING VACCINATION. PATIENT REFUSED FOR US TO CALL 911 AND AFTER LAYING ON THE FLOOR FOR 40 MIN LEFT THE PHARMACY WITH HER MOM. SHE WAS GIVEN WATER AND APPLE JUICE AND HER BLOOD PRESSURE WAS CHECKED 110/86. |

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| 1246099 | 4/23/2021 | CA | 25 | M | 4/22/2021 | 4/22/2021 | Systemic: Allergic: Anaphylaxis-Medium, Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Hyperventilation-Medium, Systemic: Hypotension-Medium, Systemic: Shakiness-Medium, Systemic: Weakness-Medium, Additional Details: immediately after first dose pt head started to lower, eyes closed, slid down in chair. respiratory rate decreased for several seconds then panic breathing occurred thereafter. pt was sweating profusely and skin was cold and clammy. could not verbally respond for 30-45 seconds. after a minute pt could talk and answer question. blood pressure was taken 3 different times 5 minutes apart 75/43, 87/46, 93/52. Pt was feeling fine a half hour later and was called 4 hours later to follow up. |
| 1246117 | 4/23/2021 | NJ | 15 | M | 4/22/2021 | 4/22/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Vomiting-Mild, Additional Details: Patient had fading consciousness 5 minutes after vaccine administration. When patient became unresponsive to questions and care, EpiPen was administered. Patient recovered quickly, ambulance was called. Patient went with ambulance. |
| 1246121 | 4/23/2021 | GA | 47 | M | 4/22/2021 | 4/22/2021 | Site: Pain at Injection Site-Mild, Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Hypertension-Mild, Additional Details: Patient reported that he had difficulty hearing. Patient sat in the chair and then lost consciousness. He was laid down on the ground, vitals were checked, and water was given. Noted high blood pressure. Patient regained consciousness within 3-5 minutes. Vitals were rechecked and returned to normal. |
| 1246173 | 4/23/2021 | WI | 61 | F | 3/1/2021 | 4/16/2021 | Headache, chills, shaking, nausea, vomiting, diarrhea, lightheadedness, through 4/16/2021. Low BP, Lightheadedness, diarrhea, fainting. Till 4/22/2021. Still have light headedness as of today. |

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| 1246269 | 4/23/2021 | CA | 46 | F | 4/5/2021 | 4/5/2021 | I'm writing this as a former, trained healthcare professional (physical therapist). 30sec-after injection I raised my left (injected) arm and my deltoid/bicep had a sudden hard spasm. I told my husband (who was in the middle of getting his shot) and the administrator that I was passing out. I blacked out. They ran over. They said 5 minutes passed in which my eyes were wide open and dilated. I suddenly began profuse sweating and convulsions/ severe full body shaking. They could not keep me lucid, and called 911. Paramedics came and got a systolic BP of 36 (I'm unaware of the diastolic BP) with blood sugar at 111 ish. I could not form words and kept going in and out of consciousness. I was transported by ambulance to the ER. A few minutes into the ambulance ride I was able to form words, and vitals started to return. I've passed out a few times and this WAS NOT a normal episode of syncope. |
| 1246431 | 4/23/2021 | CT | 21 | F | 4/8/2021 | 4/8/2021 | Upon receiving the vaccine, I immediately fainted (vasovagal syncope). I was unconscious for ~15-20 seconds. My apartment-mate who came with me for the shot laid me down on the floor until I could sit up again without feeling dizzy (~15 min). I also had pretty serious bruising at the injection site for ~9 days following the injection and my arm was swollen and painful (although this is a pretty normal side-effect). |

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| 1246638 | 4/23/2021 | PA | 18 | F | 4/14/2021 | 4/14/2021 | She received the shot walked a couple steps had a blank stare on face sat her in a chair where she sat for a couple seconds and just stared at me then head jerked and right hand curled and eyes rolled back into head. tried shaking her to respond she passed out .She came to opened eyes wasn't speaking but followed my command to spit out gum then again went limp with head shaking and hands twitching. Got her to the ground with help and called 911. She laid on ground then came to . She did not remember incident but was responding appropriately to questions. drank orange juice and placed ice bag under neck while laying. By the time paramedics arrived she was awake and appropriate. Pulse ox, blood sugar and EKG normal. Blood pressure was low but not unusual for her. Prior to shot she was well hydrated and had eaten. After being checked out by paramedics we denied need to go to hospital and she did walk out on her own. Observed her closely over night and had no further symptoms. |
| 1247396 | 4/23/2021 | NC | 16 | M | 4/23/2021 | 4/23/2021 | Syncope occurred 10-15 seconds after getting COVID vaccine. Was sitting in the car with mother at a drive-through clinic and no injury was noted. He was not driving vehicle. He was immediately aroused and was oriented to person, place and time. He did not seek medical help after leaving clinic due to feeling well. Symptoms resolved immediately. Upon speaking to patient(Mother with him), he continues to have no symptoms and advice was given about future vaccines and hydration. Patient stated that he will seek medical help if having any new/worsening symptoms. |

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| 1247226 | 4/23/2021 | IN | 17 | M | 4/23/2021 | 4/23/2021 | Pt arrived to facility accompanied by his father to receive 1st dose of pfizer vaccine. Prior to receiving the vaccine pt denied any illness, allergies, or previous reactions to other vaccines. Pt appeared nervous. Received 1st dose on 4/23/2021 at 1000 in right deltoid. Pt and father then walked to front of the room to schedule appointment for 2nd dose of pfizer vaccine. While standing at the table making his appointment, pt experienced a vasovagal syncope episode where he fainted hitting his head on the ground. Pt regained consciousness about 10sec later. Pt then assisted to a chair. On assessment pt diaphoretic/pale, HR bradycardic 42, RR 14, O2 96%, POCT glucose 81, alert/oriented x3. Pt assisted to wheelchair, transported to ED accompanied by father and 2 MAs for further evaluation. |
| 1247355 | 4/23/2021 | AR | 22 | F | 3/8/2021 | 3/8/2021 | 03/08 AT 4PM BEGAN TO HAVE SYMPTOMS. AT 5PM AN EPIPEN .3 WAS GIVEN FOLLOWED BY A EMERGENCY VISIT. GIVEN IV STEROIDS AND BENADRYL. BP WAS NORMAL. ON 03/10, WAS TAKEN BY AMBULANCE FOR FAINTING / LOW BLOOD PRESSURE, CONCUSSION, AND VOMITING. (FAINTING SPELL HAD CAUSED THE CONCUSSION). SPENT 5 DAYS IN HOSPITAL WITH LOW BLOOD PRESSURE UNTIL RESOLVED. CONTINUES TO HAVE BLURRED VISION IN LEFT EYE. |
| 1246094 | 4/23/2021 | CT | 34 | F | 4/22/2021 | 4/22/2021 | Systemic: Allergic: Difficulty Breathing-Mild, Systemic: Abdominal Pain-Mild, Systemic: Dizziness / Lightheadedness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Shakiness-Mild. |

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1245404 | 4/23/2021 | OK | | F | 4/1/2021 | 4/1/2021 | dementia; incontinency; passed out; 1 hour at home she was grabbing her head; She was responsive and was administered oxygen and taken to the Hospital; She was diagnosed as having low potassium; This spontaneous case was reported by an other caregiver (subsequently medically confirmed) and describes the occurrence of LOSS OF CONSCIOUSNESS (passed out), HEADACHE (1 hour at home she was grabbing her head), OXYGEN CONSUMPTION (She was responsive and was administered oxygen and taken to the Hospital), BLOOD POTASSIUM DECREASED (She was diagnosed as having low potassium), DEMENTIA (dementia) and INCONTINENCE (incontinency) in a 76-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 046A21A) for COVID-19 vaccination. The patient's past medical history included No adverse event (No medical history reported). Concomitant products included CARVEDILOL, AMLODIPINE, METOPROLOL, CLONIDINE and ATORVASTATIN for an unknown indication. On 01-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 01-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (passed out) (seriousness criteria hospitalization and medically significant), HEADACHE (1 hour at home she was grabbing her head) (seriousness criterion hospitalization), OXYGEN CONSUMPTION (She was responsive and was administered oxygen and taken to the Hospital) (seriousness criterion hospitalization) and BLOOD POTASSIUM DECREASED (She was diagnosed as having low potassium) (seriousness criterion hospitalization). On an unknown date, the patient experienced DEMENTIA (dementia) (seriousness criterion hospitalization) and INCONTINENCE (incontinency) (seriousness criterion hospitalization). The patient was hospitalized on 01-Apr-2021 due to BLOOD POTASSIUM DECREASED, DEMENTIA, HEADACHE, INCONTINENCE, LOSS OF CONSCIOUSNESS and OXYGEN CONSUMPTION. At the time of the report, LOSS OF CONSCIOUSNESS (passed out), HEADACHE (1 hour at home she was grabbing her head), OXYGEN CONSUMPTION (She was responsive and was administered oxygen and taken to the Hospital), BLOOD POTASSIUM DECREASED (She was diagnosed as |

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having low potassium), DEMENTIA (dementia) and INCONTINENCE (incontinency) had not resolved. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Patient was administered Oxygen by EMA, and taken to the ER (Emergency Room). Patient stayed over night at the Hospital. Patient is now admitted to a Nursing home.; Sender's Comments: Based on the information provided which includes a strong temporal association between the use of mRNA-1273 vaccine and onset of the reported events, causal relationship cannot be excluded

1247048 4/23/2021 CA 16 F 4/19/2021 4/19/2021 syncope

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| 1245409 | 4/23/2021 | MN | 36 | F | 4/11/2021 | 4/12/2021 | seizure; passed out due to extreme vomiting as per doctor in ER; vomiting every 40 minutes; stomachaches; body pain; Sweating; Headache; This case was received via an unknown source no reference has been entered for a health authority or license partner on 15-Apr-2021 and was forwarded to Moderna on 15-Apr-2021. This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of SEIZURE (seizure) and LOSS OF CONSCIOUSNESS (passed out due to extreme vomiting as per doctor in ER) in a 36-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 027B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No medical history provided.). On 11-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 12-Apr-2021, the patient experienced SEIZURE (seizure) (seriousness criterion medically significant), LOSS OF CONSCIOUSNESS (passed out due to extreme vomiting as per doctor in ER) (seriousness criterion medically significant), HEADACHE (Headache), ABDOMINAL PAIN UPPER (stomachaches), VOMITING (vomiting every 40 minutes), PAIN (body pain) and HYPERHIDROSIS (Sweating). The patient was treated with IBUPROFEN at an unspecified dose and frequency. At the time of the report, SEIZURE (seizure), LOSS OF CONSCIOUSNESS (passed out due to extreme vomiting as per doctor in ER), HEADACHE (Headache), ABDOMINAL PAIN UPPER (stomachaches), VOMITING (vomiting every 40 minutes), PAIN (body pain) and HYPERHIDROSIS (Sweating) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No medical history or concomitant medications provided. Patient used ibuprofen for treatment of headache. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |

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| 1245266 | 4/23/2021 | CO | 42 | F | 4/22/2021 | 4/22/2021 | OS 42 Y.o. Female AAox4, anaphylactic reaction. translator was used. Pt complained of extreme difficulty breathing, swollen tongue, difficulty swallowing. Pt was out side of vehicle pacing back and forth in distress. Prior to epi admin pt. Was having near syncope also. Pt. Appeared pale in color and distressed, pacing back and forth with anxious look on her face. Pt pulse rate also was approx 110 prior to administration, and strong. RR was approximately 20. Bp 186/92 post administration. Tx. Pt was examined and verbal interview conducted through interpreter. EMS summonsed. Pt advised tongue was starting to swell significantly, and increase in SOB, nausea and. Near syncope. Pt administered 0.3 mg epinephrine through autoinjector to r thigh @ 1128. Pt advised after approx 6 min post injection that tongue swelling was decreasing and she was able to breath again and was not having near syncopal episodes. Pt care transfers to hospital with a non-emergent transfer to hospital. |

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| 1245358 | 4/23/2021 | NJ | | M | 3/10/2021 | 3/10/2021 | passed out; seizure; fever; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (passed out) and SEIZURE (seizure) in a 39-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 040A21A and 045A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No relevant medical history provided.). On 10-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 07-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 10-Mar-2021, the patient experienced LOSS OF CONSCIOUSNESS (passed out) (seriousness criterion medically significant), SEIZURE (seizure) (seriousness criterion medically significant) and PYREXIA (fever). On 10-Mar-2021, LOSS OF CONSCIOUSNESS (passed out) and SEIZURE (seizure) had resolved. At the time of the report, PYREXIA (fever) outcome was unknown. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Treatment information was not provided. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested This case was linked to US-MODERNATX, INC.-MOD-2021-072687 (E2B Linked Report).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested US-MODERNATX, INC.-MOD-2021-072687:1st dose vaccine |

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| 1245361 | 4/23/2021 | TX | 22 | F | 4/7/2021 | 4/9/2021 | Fainted; Vomiting; Nausea; This spontaneous case was reported by a consumer and describes the occurrence of SYNCOPE (Fainted) in a 22-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 036B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No Reported Medical event). On 07-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 09-Apr-2021, the patient experienced SYNCOPE (Fainted) (seriousness criterion medically significant), VOMITING (Vomiting) and NAUSEA (Nausea). At the time of the report, SYNCOPE (Fainted), VOMITING (Vomiting) and NAUSEA (Nausea) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Treatment information was not provided.; Sender's Comments: This case concerns a 22-year-old female with a serious unexpected event of syncope and nonserious expected nausea and vomiting. Event onset 3 days after first dose mRNA-1273. Event outcomes unknown. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. |

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| 1245364 | 4/23/2021 | CT | 56 | F | 4/7/2021 | 4/8/2021 | <p>Patient fainted / 3 episodes of fainting attack; Feeling bad; Headache; High fever; Vomiting episodes; slept for more than 3 hours after the fainting attack; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of SYNCOPÉ (Patient fainted / 3 episodes of fainting attack) in a 56-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 57A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No reported medical history). On 07-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 2 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 08-Apr-2021, the patient experienced SYNCOPÉ (Patient fainted / 3 episodes of fainting attack) (seriousness criterion medically significant), FEELING ABNORMAL (Feeling bad), HEADACHE (Headache), PYREXIA (High fever), VOMITING (Vomiting episodes) and HYPERSOMNIA (slept for more than 3 hours after the fainting attack). At the time of the report, SYNCOPÉ (Patient fainted / 3 episodes of fainting attack), FEELING ABNORMAL (Feeling bad), HEADACHE (Headache), PYREXIA (High fever), VOMITING (Vomiting episodes) and HYPERSOMNIA (slept for more than 3 hours after the fainting attack) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. This case was linked to US-MODERNATX, INC.-MOD-2021-073768 (E2B Linked Report).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. US-MODERNATX, INC.-MOD-2021-073768:linked case</p> |

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| 1245378 | 4/23/2021 | NY | 61 | F | 4/13/2021 | 4/14/2021 | <p>She also passed out going to the bathroom twice.; Felt hot; Clammy; Feels very weak; Pain in left arm.; Difficulty moving left arm; Fever; chills; Nauseous; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (She also passed out going to the bathroom twice.) in a 61-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 031B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No reported medical history). On 13-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 14-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (She also passed out going to the bathroom twice.) (seriousness criterion medically significant), FEELING HOT (Felt hot), COLD SWEAT (Clammy), ASTHENIA (Feels very weak), PAIN IN EXTREMITY (Pain in left arm.), MOBILITY DECREASED (Difficulty moving left arm), PYREXIA (Fever), CHILLS (chills) and NAUSEA (Nauseous). At the time of the report, LOSS OF CONSCIOUSNESS (She also passed out going to the bathroom twice.), FEELING HOT (Felt hot), COLD SWEAT (Clammy), ASTHENIA (Feels very weak), PAIN IN EXTREMITY (Pain in left arm.), MOBILITY DECREASED (Difficulty moving left arm), PYREXIA (Fever), CHILLS (chills) and NAUSEA (Nauseous) outcome was unknown. Treatment medication included acetaminophen. Action taken with m-RNA1273 in response to events is consider as not applicable. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p> |

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| 1245436 | 4/23/2021 | OH | 24 | F | 4/2/2021 | 4/2/2021 | couldn't sleep; Felt sick; Fell; Body went stiff; Hit head on the wall; Vomiting; Fainted; Had seizures twice; Back pain; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of SYNCOPE (Fainted) and SEIZURE (Had seizures twice) in a 24-year-old female patient who received mRNA-1273 for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included COVID-19 in October 2020. On 02-Apr-2021, the patient received first dose of mRNA-1273 (Intramuscular) 1 dosage form. On 02-Apr-2021, the patient experienced BACK PAIN (Back pain). On 03-Apr-2021, the patient experienced SYNCOPE (Fainted) (seriousness criterion medically significant), SEIZURE (Had seizures twice) (seriousness criterion medically significant), INSOMNIA (couldn't sleep), MALAISE (Felt sick), FALL (Fell), MUSCULOSKELETAL STIFFNESS (Body went stiff), HEAD INJURY (Hit head on the wall) and VOMITING (Vomiting). At the time of the report, SYNCOPE (Fainted), SEIZURE (Had seizures twice), BACK PAIN (Back pain), INSOMNIA (couldn't sleep), MALAISE (Felt sick), FALL (Fell), MUSCULOSKELETAL STIFFNESS (Body went stiff), HEAD INJURY (Hit head on the wall) and VOMITING (Vomiting) outcome was unknown. The action taken with mRNA-1273 (Intramuscular) was unknown. For mRNA-1273 (Intramuscular), the reporter did not provide any causality assessments. Labs included Electrocardiogram: and Urine analysis, no test results provided. Treatment information not provided. Company comment: Very limited information regarding these events has been provided at this time. Further information has been requested.; Sender's Comments: Very limited information regarding these events has been provided at this time. Further information has been requested. |

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| 1247073 | 4/23/2021 | IL | 55 | F | 4/1/2021 | 4/1/2021 | Patient experienced two episodes of syncope 5 minutes after receiving immunization and approximately 2 minutes apart from each other. Patient fell out of chair as result and reportedly hit head. Blood pressure upon initial evaluation was 88/50. EMS was called. Upon arrival and assessment by EMS, vital signs were WNL. Patient was transported to local hospital. Patient was not evaluated at hospital. Patient has since been to E.R. 2 times after incident and to PCP 1 time since incident. Patient continues to feel "flushed, faint, and dizzy" at times. |
| 1246091 | 4/23/2021 | NJ | 26 | F | 4/22/2021 | 4/22/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Medium, Systemic: Seizure-Mild, Additional Details: Pt fell face flat on her face within 5 minutes of her injection and scratched her left cheekbone. Look like she was having a seizure but she was already conscious when we flipped her over. She felt fatigue from working a night shift yesterday, and a morning shift today. She ate a couple hours before the appointment. FS associate, monitored her for an extra 15 minutes before she walked home. I followed up with her at 4:40pm and 7:30pm on 4/22. Recommended that she report this to her PCP. |
| 1247491 | 4/23/2021 | VA | 30 | M | 4/11/2021 | 4/11/2021 | Client was leaving the parking lot post vaccination waiting period when he felt lightheaded. Wife indicates that client passed out twice in the car. Client reports feeling dizzy and hot and he looks pale and sweaty. His BP is 60/40. Client does not have any other medical history and is not taking any medications currently. He is allergic to sulfa. EMS on site evaluated client and was determined that 911 needed to be called. EMS responded and client was transported to the hospital. |

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| 1245456 | 4/23/2021 | FL | 84 | F | 2/26/2021 | | <p>Double pneumonia; Urinary tract infection; Silent heart attack; Delirious; Passed out; Very weak; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of DELIRIUM (Delirious), LOSS OF CONSCIOUSNESS (Passed out), PNEUMONIA (Double pneumonia), URINARY TRACT INFECTION (Urinary tract infection) and MYOCARDIAL INFARCTION (Silent heart attack) in an 84-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 001AZIA) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (no medical history was reported). On 26-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced DELIRIUM (Delirious) (seriousness criterion hospitalization), LOSS OF CONSCIOUSNESS (Passed out) (seriousness criterion hospitalization), PNEUMONIA (Double pneumonia) (seriousness criterion hospitalization), URINARY TRACT INFECTION (Urinary tract infection) (seriousness criterion hospitalization), MYOCARDIAL INFARCTION (Silent heart attack) (seriousness criterion hospitalization) and ASTHENIA (Very weak). At the time of the report, DELIRIUM (Delirious), PNEUMONIA (Double pneumonia), URINARY TRACT INFECTION (Urinary tract infection), MYOCARDIAL INFARCTION (Silent heart attack) and ASTHENIA (Very weak) outcome was unknown and LOSS OF CONSCIOUSNESS (Passed out) had resolved. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Concomitant medications and medical history were not reported. The treatment received in response to the events was unknown. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p> |

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| 1245458 | 4/23/2021 | | | F | 4/15/2021 | | <p>Patient passed out and hit head on the ground; Felt horrible when she got up; Shake; Keep getting cold and had chills; Get hot; Hit head on the ground; Patient scrapped knee and knee is burning; Move was excruciating/didn't even roll over and hurt to move; Patient scrapped knee and knee is burning; Felt like she was going to throw up; Hurt real bad, body was very very sore; Keep getting cold and had chills; Joint Sore; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (Patient passed out and hit head on the ground) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No relevant medical history provided). On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 15-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (Patient passed out and hit head on the ground) (seriousness criterion medically significant), FEELING ABNORMAL (Felt horrible when she got up), TREMOR (Shake), FEELING COLD (Keep getting cold and had chills), FEELING HOT (Get hot), HEAD INJURY (Hit head on the ground), BURNING SENSATION (Patient scrapped knee and knee is burning), PAIN (Move was excruciating/didn't even roll over and hurt to move), JOINT INJURY (Patient scrapped knee and knee is burning), NAUSEA (Felt like she was going to throw up), MYALGIA (Hurt real bad, body was very very sore), CHILLS (Keep getting cold and had chills) and ARTHRALGIA (Joint Sore). At the time of the report, LOSS OF CONSCIOUSNESS (Patient passed out and hit head on the ground), FEELING ABNORMAL (Felt horrible when she got up), TREMOR (Shake), FEELING COLD (Keep getting cold and had chills), FEELING HOT (Get hot), HEAD INJURY (Hit head on the ground), BURNING SENSATION (Patient scrapped knee and knee is burning), PAIN (Move was excruciating/didn't even roll over and hurt to move), JOINT INJURY (Patient scrapped knee and knee is burning), NAUSEA (Felt like she was going to throw up), MYALGIA (Hurt real bad, body was very very sore), CHILLS (Keep getting cold and had chills) and ARTHRALGIA (Joint Sore) was</p> |

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resolving. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. The patient got extremely hot when using the bathroom. Felt like she was going to throw up. Patient passed out and hit head on the ground. Patient didn't remember doing this. Patient scrapped knee and knee is burning. Patient feels concerned. Happened within a 24 hour period. Starting to feel better. The concomitant medications and treatment details were not provided. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. This case was linked to MOD21-075794 (E2B Linked Report).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded MOD21-075794:

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| 1245474 | 4/23/2021 | NC | 71 | F | 3/22/2021 | 3/22/2021 | a few episodes of a-fib; felt like she might black out; felt like her heart was palpitating; stress; headache; could not sleep; burning in her arm, up through her neck and to her chest.; worry; This spontaneous case was reported by a consumer and describes the occurrence of ATRIAL FIBRILLATION (a few episodes of a-fib) in a 72-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 037a21a) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Heart valve replacement (two artificial heart valves.) since 2004. Concomitant products included WARFARIN SODIUM (COUMADIN) for Heart valve replacement. On 22-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 22-Mar-2021, the patient experienced VACCINATION SITE PAIN (burning in her arm, up through her neck and to her chest.). On 18-Apr-2021, the patient experienced SLEEP DISORDER (could not sleep). On an unknown date, the patient experienced ATRIAL FIBRILLATION (a few episodes of a-fib) (seriousness criterion medically significant), PRESYNCOPE (felt like she might black out), PALPITATIONS (felt like her heart was palpitating), ANXIETY (worry), STRESS (stress) and HEADACHE (headache). On 23-Mar-2021, VACCINATION SITE PAIN (burning in her arm, up through her neck and to her chest.) outcome was unknown. At the time of the report, ATRIAL FIBRILLATION (a few episodes of a-fib), PRESYNCOPE (felt like she might black out), PALPITATIONS (felt like her heart was palpitating), SLEEP DISORDER (could not sleep), ANXIETY (worry), STRESS (stress) and HEADACHE (headache) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Treatment for the events included Acetaminophen. Echogram scheduled on 05 May 21. Company comment: Very limited information regarding these events has been provided at this time. The events are probably related to the patient's comorbidities; Sender's Comments: Very limited information regarding these events has been provided at this time. The events are probably related to the patient's comorbidities |

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| 1245980 | 4/23/2021 | MO | 23 | M | 4/22/2021 | 4/22/2021 | Site: Pain at Injection Site-Mild, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Additional Details: Patient recieved the vaccine (sitting) and was instructed to sit for 15 minutes post vaccination.After about 5 minutes, patient stated that he was feeling light headed. Patient was seated when he fainted and was out for about 12-15 seconds. Patient came back and was able to speak with us.We provided him some water and called the EMT's. EMT's looked after patient/checked vitals and everything was okay. Patient states he has a fear of needles. Called patient a few hours after the incident to check |
| 1245983 | 4/23/2021 | CA | 28 | F | 4/22/2021 | 4/22/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Mild, Systemic: Shakiness-Mild, Systemic: Visual Changes/Disturbances-Mild |

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1245401 | 4/23/2021 | TX | 24 | M | 4/3/2021 | 4/3/2021 | 30 seconds after receiving the Moderna Vaccine patient passed out; Fell to floor after passing out; Body was stiff when fell to floor; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (30 seconds after receiving the Moderna Vaccine patient passed out) in a 24-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 013A221A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Drug allergy (Cephalexin). Concomitant products included VITAMIN B COMPLEX (VITAMIN B CO) for an unknown indication. On 03-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 03-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (30 seconds after receiving the Moderna Vaccine patient passed out) (seriousness criterion medically significant). 03-Apr-2021, the patient experienced FALL (Fell to floor after passing out) and MUSCULOSKELETAL STIFFNESS (Body was stiff when fell to floor). On 03-Apr-2021, LOSS OF CONSCIOUSNESS (30 seconds after receiving the Moderna Vaccine patient passed out), FALL (Fell to floor after passing out) and MUSCULOSKELETAL STIFFNESS (Body was stiff when fell to floor) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Reported mentioned that ambulance was called after the events and paramedics monitored the patient in the ambulance, patient had stable vital signs and it was offered it take him to the emergency room, but patient declined.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
|-----------------|--------------|--------------|----------------|------------|-----------------|-------------------|---|
| 1249478 | 4/23/2021 | NC | | M | | 4/1/2021 | <p>SYNCOPE; HYPOTENSION; This spontaneous report received from an other health care professional (nurse) concerned a 45 year old white not Hispanic male. This report was received from news/social media. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 207A21A, and expiry: unknown) dose was not reported, 1 total administered on 08-APR-2021 for prophylactic vaccination. The patient was administered vaccine from an outdoor vaccination site with outdoor temperature around 70-80 degrees. No concomitant medications were reported. On an unspecified date APR-2021, the patient experienced syncope and hypotension, and was hospitalized (date unspecified). The patient was treated with unspecified fluid. The patient was discharged on an unknown date. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from syncope, and hypotension on APR-2021. This report was serious (Hospitalization Caused/Prolonged). This case, from the same reporter is linked to 20210415566 (master case); Sender's Comments: V0: 20210441626-covid-19 vaccine ad26.cov2.s-syncope, hypotension. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p> |

| <i>VAERS_ID</i> | <i>RECVD</i> | <i>STATE</i> | <i>AGE_YRS</i> | <i>SEX</i> | <i>VAX_DATE</i> | <i>ONSET_DATE</i> | <i>SYMPTOM_TEXT</i> |
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| 1249169 | 4/23/2021 | NC | 27 | M | 4/11/2021 | | <p>PASSED OUT; FALL OVER; COLD; CHILLS; FEVER; HEADACHE; This spontaneous report received from a patient concerned a 27 year old white, not Hispanic or Latino male. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, and batch number: 203A21A expiry: UNKNOWN) dose was not reported, 1 total administered on 10-APR-2021 at 16:00 to left arm for prophylactic vaccination. No concomitant medications were reported. It was reported that day after vaccination on 11-APR-2021 in early morning, the patient had chills and fever. The patient went down to get some unspecified medications and he passed out for roughly 5 minutes and fell over. The patient had headache at the time of this report. Treatment medications (dates unspecified) included: paracetamol. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from passed out, cold, chills, and fever on 11-APR-2021, had not recovered from headache, and the outcome of fall over was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0:20210421495 - covid-19 vaccine ad26.cov2.s- Passed out. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p> |

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1249170 | 4/23/2021 | MO | | F | | 4/9/2021 | <p>PASSED OUT; EXTREMELY COLD; LIGHT HEADED; SWEATING; CHANGES IN BODY TEMPERATURE; This spontaneous report received from a patient concerned a female of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported batch number: 207A21A expiry: UNKNOWN) dose was not reported, 1 total administered on 09-APR-2021 to left arm for prophylactic vaccination. No concomitant medications were reported. On 09-APR-2021, the patient experienced passed out, extremely cold, light headed, sweating and changes in body temperature. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from passed out on 09-APR-2021, was recovering from light headed, and had not recovered from extremely cold, sweating, and changes in body temperature. This report was serious (Other Medically Important Condition).; Sender's Comments: V0:20210421673- covid-19 vaccine ad26.cov2.s-Passed out. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p> |

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1249180 | 4/23/2021 | NY | | F | | 4/9/2021 | <p>DIZZINESS; NO APPETITE; HARD TO WALK; WEAK; FREQUENT HEADACHE; TIREDNESS; NAUSEA; FELL; PASSED OUT, BLACKED OUT; TROUBLE BREATHING; MEMORY LOSS; FAST HEARTBEAT; HEAD INJURY; FACIAL INJURIES; DEEP CUT ON UPPER LIPS; FACE BLEEDING; REDNESS ON RIGHT SIDE OF FACE; INSIDE OF THE EYE WAS RED; BLACK EYE; SWEATING; SHAKING; This spontaneous report received from a patient concerned a female of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported) dose was not reported, administered on 08-APR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 09-APR-2021, the patient woke up all wet from sweating, shaking, trouble breathing, heartbeat was fast, and was nauseous. Patient went to the bathroom and on the way back from the bathroom, patient passed out. Patient had no memory of this or how she ended up on the floor or how she fell. Patient blacked out and woke up about 20 minutes later. She found that there was blood everywhere because she had hit her face. There was deep cut on patients upper lip, had a black eye, and the inside of the eye was red all on the right side of her face. Patient cleaned her face carefully and then got back in the bed because patient was very weak and extremely nauseous. Patient went back to sleep and anytime she tried to get up patient was very dizzy and nauseous. Patient was able to walk with help but it was hard. The next day patient experienced dizziness, tiredness, no appetite, frequent headaches, her face was swollen, and was bleeding a lot. She thought her face needs stitches. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the sweating, shaking, trouble breathing, fast heartbeat, nausea, passed out, blacked out, memory loss, head injury, weak, dizziness, tiredness, no appetite, frequent headache, hard to walk, fell, deep cut on upper lips, black eye, inside of the eye was red, redness on right side of face, face bleeding and facial injuries was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0.20210422314-covid-19 vaccine ad26.cov2.s -passed</p> |

VAERS_ID RECVDATE STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

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| 1249216 | 4/23/2021 TX | 31 F | <p>out, blacked out. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p> <p>4/11/2021 FELT LIKE FAINTING; BODY ACHE; CHILLS; SEVERE HEADACHE; FEVER OF 102 F; This spontaneous report received from a patient concerned a 31 year old female. The patient's height, and weight were not reported. The patient's pre-existing medical conditions included the patient was not pregnant at the time of reporting. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 203A21A, and expiry: UNKNOWN) dose was not reported, administered on 11-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On 11-APR-2021, the subject experienced body ache. On 11-APR-2021, the subject experienced chills. On 11-APR-2021, the subject experienced severe headache. On 11-APR-2021, the subject experienced fever of 102 f. Laboratory data included: Body temperature (NR: not provided) 102 F. On 12-APR-2021, the subject experienced felt like fainting. Treatment medications (dates unspecified) included: paracetamol. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from felt like fainting on 12-APR-2021, chills on 13-APR-2021, and fever of 102 f on APR-2021, and had not recovered from severe headache, and body ache. This report was non-serious.; Sender's Comments: V0: Medical assessment comments not required as per standard procedure as the case is considered non serious.</p> |
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| <i>VAERS_ID</i> | <i>RECVDATE</i> | <i>STATE</i> | <i>AGE_YRS</i> | <i>SEX</i> | <i>VAX_DATE</i> | <i>ONSET_DATE</i> | <i>SYMPTOM_TEXT</i> |
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| 1249234 | 4/23/2021 | GA | | U | | | <p>FAINTING; NAUSEA; This spontaneous report received from a consumer concerned multiple patients of unspecified age and sex. The patient's weight, height, and medical history were not reported. The patient's received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose,1 total start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up would be requested for this case. No concomitant medications were reported. On an unspecified date, the patient's experienced dizziness, nausea and fainting. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the nausea and fainting was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: -covid-19 vaccine ad26.cov2.s-fainting. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p> |

| <u>VAERS_ID</u> | <u>RECVDATE</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1249245 | 4/23/2021 | | | M | | 3/26/2021 | <p>PASSED OUT; COULD HARDLY GET UP; TROUBLE WITH LEFT HIP OR KNEE; LIGHT HEADED; NOT FEELING UP TO PAR; This spontaneous report received from a patient concerned an 85 year old male. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown, expiry: unknown) dose was not reported, 1 total administered on 26-MAR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 26-MAR-2021,(on the night of vaccination) patient could hardly get up while he was putting some beer in refrigerator. Since then patient had trouble with his left hip or knee. Few days before 10-APR-2021, patient was light headed and not felt up to par. On 10-APR-2021, the patient was passed out which he never experienced before. On the same day, the patient was hospitalized and checked everything including blood clots in his leg. They did not find anything that could be causing problem. The patient was admitted to the hospital for 3 days. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the could hardly get up, trouble with left hip or knee, not feeling up to par, light headed, passed out was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: This 85-year-old male patient of unknown ethnicity was admitted in a hospital after "passing out" 15 days after receiving Janssen COVID-19 vaccine for the prevention of symptomatic SARS-CoV-2 virus infection. The patient noted difficulty standing up on h the day of vaccination but attributed it to his hip or knee "trouble". On the day of hospitalization, the patient complained of light headedness and was rushed to the hospital when he was found passed out. The patient reported that the hospital checked everything including clots in his leg but did not find anything that could cause the problem. No laboratory/diagnostic test results were reported; the treatment and outcome was not reported. Based on the information that is available, the event is assessed as indeterminate with the causal association to immunization, per WHO causality classification of adverse events following immunization based on a lack of a definitive plausible biological mechanism. However,</p> |

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3/30/2021

considering the temporal relationship and recently evolving theories in the literature about COVID infections and vaccinations, potential vaccine contribution cannot be excluded. Additional information will be requested for further assessment once contact information is available.

DIZZY/LIGHTHEADED; RUBBER LEGS; HEART RACING; LOOKED WHITE; NEAR SYNCOPAL EPISODE/NEARLY PASSED OUT; INTERMITTENTLY FEELING HOT; FLUSH; FOGGY; NOT FEELING WELL; BLURRY VISION; This spontaneous report received from a patient concerned a 59 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included seasonal allergy. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1808980, and expiry: 20-JUN-2021) dose was not reported, administered on 30-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 30-MAR-2021, the subject experienced blurry vision. On 01-APR-2021, the subject experienced intermittently feeling hot. On 01-APR-2021, the subject experienced flush. On 01-APR-2021, the subject experienced foggy. On 01-APR-2021, the subject experienced not feeling well. On 02-APR-2021, the subject experienced near syncopal episode/nearly passed out. On 02-APR-2021, the subject experienced heart racing. On 02-APR-2021, the subject experienced looked white. On 03-APR-2021, the subject experienced dizzy/lightheaded. On 03-APR-2021, the subject experienced rubber legs. On 05-APR-2021, Laboratory data included: ECG (NR: not provided) UNKNOWN (units unspecified). The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from near syncopal episode/nearly passed out on 02-APR-2021, heart racing on 04-APR-2021, and blurry vision on 30-MAR-2021, was recovering from intermittently feeling hot, flush, foggy, not feeling well, dizzy/lightheaded, and rubber legs, and the outcome of looked white was not reported. This report was non-serious.; Sender's Comments: V0: Medical assessment comments not required as per standard procedure as the case is considered non serious.

| <u>VAERS_ID</u> | <u>RECVDATE</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1249325 | 4/23/2021 | MN | 22 | F | 4/11/2021 | 4/11/2021 | Fainted for 30 seconds after standing up and walking. Ambulance came to the house and recommended a trip to the ER where I received an IV. |
| 1249489 | 4/23/2021 | NC | | F | | 4/8/2021 | SYNCOPE; This spontaneous report received from a other health professional (Nurse) via social media/news concerned a 37 year old white, not Hispanic female. The patient's height, and weight were not reported. The patient's concurrent conditions included depression, and other pre-existing medical conditions included patient had no known allergies. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 207A21A, and expiry: unknown) dose was not reported, administered, 1 total, on 08-APR-2021 for prophylactic vaccination. The vaccination site had outdoor temperatures around 78-80 degrees. No concomitant medications were reported. On 08-APR-2021, at 12:57, the patient experienced syncope, hypotension and bradycardia. The patient was evaluated by emergency medical services (EMS) and sent to hospital for further observation. The patient was discharged in good health. The patient recovered from syncope on APR-2021. This report was serious (Hospitalization Caused / Prolonged). This case, from the same reporter is linked to 20210415566.; Sender's Comments: V0: 20210441898-COVID-19 VACCINE AD26.COVS - Syncope. This event is considered Unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event. |
| 1247598 | 4/23/2021 | IL | 27 | F | 4/11/2021 | | while walking to the waiting area she was feeling sick and she lay down on the floor before passed out. Never pass out. BP and pulse were stable. Able to sit on a chair and observed for 10 minutes client voices feeling fine and sign the observation release form and went home in accompany of her mother. |

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1249619 | 4/23/2021 | MO | 60 | M | 4/9/2021 | 4/9/2021 | Passed Out; Suspecting Seizures pending EEG Results; Sore Arm; This spontaneous case was reported by a pharmacist and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed Out) and SEIZURE (Suspecting Seizures pending EEG Results) in a 60-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (medication history was not reported) and Pacemaker insertion (cardiac) since an unknown date. On 09-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 09-Apr-2021, the patient experienced VACCINATION SITE PAIN (Sore Arm). On 13-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (Passed Out) (seriousness criteria hospitalization and medically significant) and SEIZURE (Suspecting Seizures pending EEG Results) (seriousness criterion hospitalization). On 10-Apr-2021, VACCINATION SITE PAIN (Sore Arm) had resolved. At the time of the report, LOSS OF CONSCIOUSNESS (Passed Out) and SEIZURE (Suspecting Seizures pending EEG Results) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Treatment information was not reported. diagnosis yet to be determent Suspecting Seizures pending EEG results Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. However, Very limited information is available at this time. Further information is requested; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.However, Very limited information is available at this time. Further information is requested. |
| 1246724 | 4/23/2021 | MI | 26 | M | 4/23/2021 | 4/23/2021 | Pt fainted to the floor. Woke up was fine after sitting 15 more minutes. Ems came and checked him out. Pt left with wife |

| <u>VAERS_ID</u> | <u>RECVDATE</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1249625 | 4/23/2021 | KY | | M | 4/14/2021 | 4/14/2021 | migraine; Dizziness and lightheadedness; passed out; started developing itch; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (passed out) in a 58-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 021B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (no relevant medical history reported). On 14-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 14-Apr-2021, the patient experienced PRURITUS (started developing itch). On 16-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (passed out) (seriousness criterion medically significant) and DIZZINESS (Dizziness and lightheadedness). On 19-Apr-2021, the patient experienced MIGRAINE (migraine). On 16-Apr-2021, LOSS OF CONSCIOUSNESS (passed out) had resolved. At the time of the report, PRURITUS (started developing itch) and DIZZINESS (Dizziness and lightheadedness) outcome was unknown and MIGRAINE (migraine) had not resolved. No concomitant medications were reported. Treatment of these events included Excedrin migraine. Action taken with mRNA-1273 in response to the event was not applicable. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1249634 | 4/23/2021 | NH | 51 | F | 1/6/2021 | 2/3/2021 | dry heaving; hot; sweaty; passed out on the bathroom floor; weak; feverish; tired; not much of an appetite; achy; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of LOSS OF CONSCIOUSNESS (passed out on the bathroom floor) in a 51-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 039K20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No reported adverse event.). Concomitant products included LEVOTHYROXINE SODIUM (SYNTHROID), MULTI VITAMIN [ASCORBIC ACID;COLECALCIFEROL;NICOTINAMIDE;PANTHENOL ;PYRIDOXINE HYDROCHLORIDE;RETINOL PALMITATE;RIBOFLAVIN;THIAMINE HYDROCHLORIDE;TOCOPHERYL ACETATE], VITAMIN D [VITAMIN D NOS], AIRBORNE BERRY and IBUPROFEN (MOTRIN [IBUPROFEN]) for an unknown indication. On 06-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 03-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 03-Feb-2021, the patient experienced DECREASED APPETITE (not much of an appetite), MYALGIA (achy) and FATIGUE (tired). On 04-Feb-2021, the patient experienced LOSS OF CONSCIOUSNESS (passed out on the bathroom floor) (seriousness criterion medically significant), RETCHING (dry heaving), FEELING HOT (hot), HYPERHIDROSIS (sweaty), ASTHENIA (weak) and PYREXIA (feverish). On 06-Feb-2021, LOSS OF CONSCIOUSNESS (passed out on the bathroom floor), RETCHING (dry heaving), HYPERHIDROSIS (sweaty) and PYREXIA (feverish) had resolved, FEELING HOT (hot) and ASTHENIA (weak) outcome was unknown. At the time of the report, DECREASED APPETITE (not much of an appetite), MYALGIA (achy) and FATIGUE (tired) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Company Comment Based on the current available information and temporal |

VAERS_ID RECVD STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

1249654 4/23/2021 FL

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3/24/2021

3/25/2021

association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

Vaso-Vagal syncope in the 1st dose; This spontaneous case was reported by a consumer and describes the occurrence of SYNCOP (Vaso-Vagal syncope in the 1st dose) in a 66-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included No adverse event (No medical history was provided.). On 24-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 25-Mar-2021, the patient experienced SYNCOP (Vaso-Vagal syncope in the 1st dose) (seriousness criterion medically significant). At the time of the report, SYNCOP (Vaso-Vagal syncope in the 1st dose) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No concomitant medications were reported. No treatment information for the event was provided. Patient decided not to get 2nd shot due to syncope with first dose. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.

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| 1248215 | 4/23/2021 | PA | 17 | F | 4/23/2021 | 4/23/2021 | After receiving vaccine, patient became light headed and passed out sitting in chair. diaphoretic and clammy. Heartrate 60, BP 60/29, SPO2 100%. Medical response called, patient taken to ER, accompanied by mother |

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| 1249622 | 4/23/2021 | MN | | M | 3/23/2021 | 4/10/2021 | Negative COVID test; nausea; passed out; chest pain; shortness of breath; Tested positive for COVID; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of SYNCOPE (passed out) in a 77-year-old male patient who received mRNA-1273 for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Heart disease, unspecified and Atherosclerosis (blockage of artery was noted.). Concurrent medical conditions included Drug therapy (patient was on heart medications) and Drug therapy (patient was on antibiotic). Concomitant products included ATORVASTATIN CALCIUM (STATIN [ATORVASTATIN CALCIUM]), CLOPIDOGREL BISULFATE (PLAVIX) and MULTIVITAMIN [VITAMINS NOS] for an unknown indication. On 23-Mar-2021, the patient received first dose of mRNA-1273 (unknown route) 1 dosage form. On 10-Apr-2021, the patient experienced SYNCOPE (passed out) (seriousness criterion medically significant), CHEST PAIN (chest pain), DYSPNOEA (shortness of breath), SARS-COV-2 TEST POSITIVE (Tested positive for COVID) and NAUSEA (nausea). On an unknown date, the patient experienced SARS-COV-2 TEST NEGATIVE (Negative COVID test). At the time of the report, SYNCOPE (passed out), CHEST PAIN (chest pain), DYSPNOEA (shortness of breath), SARS-COV-2 TEST POSITIVE (Tested positive for COVID), SARS-COV-2 TEST NEGATIVE (Negative COVID test) and NAUSEA (nausea) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 10-Apr-2021, SARS-CoV-2 test: positive Positive. On 14-Apr-2021, SARS-CoV-2 test: negative Negative. The action taken with mRNA-1273 (Unknown Route) was unknown. This case concerns a 77-year-old male with a serious unexpected event of syncope, and nonserious unexpected chest pain, dyspnea, and expected nausea. SARS-CoV-2 test positive. Treatment with Regeneron antibodies. Event onset 19 days after first dose mRNA-1273. Event outcomes unknown. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.; Sender's Comments: This case concerns a 77-year-old male with |

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| 1249136 | 4/23/2021 | CA | 18 | M | 4/23/2021 | 4/23/2021 | a serious unexpected event of syncope, and nonserious unexpected chest pain, dyspnea, and expected nausea. SARS-CoV-2 test positive. Treatment with Regeneron antibodies. Event onset 19 days after first dose mRNA-1273. Event outcomes unknown. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. |
| 1247968 | 4/23/2021 | CO | 16 | M | 4/22/2021 | 4/22/2021 | Patient received Moderna Covid-19 vaccine and fainted approximately 5 minutes later. Patient reported feeling dizzy, hot and nauseous. Patient's blood pressure 81/41mmHg, heart rate 58 bpm, oxygen level 96% (taken by paramedics) approximately 10 minutes post-vaccination. Paramedics took patient to emergency department to be monitored. Patient was given IV fluids and discharged from the hospital a few hours later. Patient reported that he has a needle phobia and had fainting incident post-vaccination years ago. |
| 1248202 | 4/23/2021 | CA | 18 | F | 4/23/2021 | 4/23/2021 | PATIENT PASSED OUT AFTER RECEIVING HIS FIRST DOSE OF VACCINE. PATIENT STATED THAT HE HAD NOT EATEN ALL DAY. HE ONLY PASSED OUT FOR A FEW SECONDS, AND THEN FELT DIZZY FOR THE NEXT 5-10 MINUTES. |
| | | | | | | | At 12:30pm, ?When patient arrived at the tent, Patient received 1st dose Moderna Vaccine at 12:25pm. While leaving the building patient stated she felt lightheaded at 12:30pm and was immediately seated, placed in a wheelchair. At 12:32pm BP 128/66, HR 78, RR 20, O2 Sat 98%. Patient provided water for hydration and stated she has ?severe anxiety to needles?. Patient at 12:40pm stated she felt nauseas and tried to stand up to go to the bathroom and had a near syncope episode (did not fall). VS at 12:43pm, BP 56/27, HR 59, RR 25, O2 sat 98%, repeat VS at 12:40pm, BP 58/25, HR 58, RR 25, O2 sat 93%, patient also was diaphoretic?. |

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| 1248233 | 4/23/2021 | IL | 16 | F | 4/23/2021 | 4/23/2021 | Patient stated that she sometimes gets a little lightheaded after a vaccine and would like to wait her 15 minutes after the vaccine in the room instead of the waiting area. After the administration of the vaccine she stated she was going to pass out and lost consciousness. She had a normal pulse and was breathing normally. Her mother stated that she has passed out after injections in the past. Once for close to an hour. Her mother indicated that she did not want an ambulance called. I watched her closely for about 30 to 40 minutes and made sure she was not disoriented until she felt steady enough to stand up and walk. Upon leaving the pharmacy the patient felt fine and ready to get on with her day. |
| 1248429 | 4/23/2021 | CA | 75 | F | 4/12/2021 | 4/22/2021 | Patient came to ED with complaints of syncopal episode. passed out, hit her head, felt mildly short of breath with ambulation. |
| 1248436 | 4/23/2021 | IL | 17 | M | 4/23/2021 | 4/23/2021 | A few minutes after getting vaccine, while still sitting in chair, pt fainted. Never left chair. Came to quickly, and was helped to a cot. VS: P=76 BP 120/72 P. Ox=98% He was given a juice box, declined crackers. Was initially very pale, but pinked up nicely once he was prone. After 5-10 minutes, he sat up, with VS: P=80 BP 128/70 P. Ox=99% After 5 minutes, he stood up, felt fine. VS: P=80 BP=136/82 P. Ox=99%. Per mom and pt, this has happened with other vaccines in past, most recently earlier this year with a Men B vaccine. We advised giving next COVID vaccine (and others) while laying down. VAERS form completed. Pt left without further incident. |
| 1248605 | 4/23/2021 | NC | 18 | M | 4/21/2021 | 4/21/2021 | 10 Minutes after injection, passed out Headache for 2 days Fatigue for 2 days Vomiting for 1 day Hearing loss left ear currently Loss of appetite currently shortness of breath currently |
| 1248712 | 4/23/2021 | CA | 16 | F | 4/19/2021 | 4/19/2021 | Syncope |
| 1248780 | 4/23/2021 | CA | 18 | F | 4/23/2021 | 4/23/2021 | lightheaded; BP was taken 3 times: 70/40 @1535; 105/61 @ 1540; 104/77 @1548. Client has hx of syncope with sight of needles, and client stated she ate a light breakfast and lunch. |

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| 1248988 | 4/23/2021 | NY | 47 | F | | 3/9/2021 | FELT LIKE FAINTING; BODY ACHES; BILATERAL HIP PAIN; LIMPING; CHILLS; This spontaneous report received from a patient concerned an 47 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included non alcohol user, and non smoker, and other pre-existing medical conditions included the patient had no known allergies and no drug abuse/illicit drug use. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 1805022, expiry: UNKNOWN) dose was not reported, administered on 08-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 09-MAR-2021, the subject experienced felt like fainting. On 09-MAR-2021, the subject experienced body aches. On 09-MAR-2021, the subject experienced bilateral hip pain. On 09-MAR-2021, the subject experienced limping. On 09-MAR-2021, the subject experienced chills. The action taken with covid-19 vaccine ad26.cov2.s was not reported. The patient was recovering from chills, body aches, bilateral hip pain, limping, and felt like fainting. This report was non-serious.; Sender's Comments: V0: Medical assessment comment is not required as per standard procedure as case assessed as non-serious. |
| 1248591 | 4/23/2021 | RI | 89 | F | 3/9/2021 | 3/30/2021 | On 3/24/21, pain in right leg. On 3/30/21, pulse dropped to 37 and she passed out and was unable to recover, so called 911 |
| 1248099 | 4/23/2021 | CA | 17 | F | 4/22/2021 | 4/22/2021 | Fainted, BP 89/59, O2 sat 99%. Patient fell and hit her head under the chin. Patient has a history of low BP with shots. Sent to ED. |

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| 1248998 | 4/23/2021 | | | M | | | <p>BODY ACHES; SLIGHT NASAL DRIP; SWOLLEN FINGERS; SORENESS IN JOINTS; ELEVATED DIASTOLIC BLOOD PRESSURE; SORENESS AT INJECTION SITE; This spontaneous report received from a patient via a company representative concerned a 64 year old male. The patient's height, and weight were not reported. The patient's concurrent conditions included neurocardiogenic syncope, junctional rhythm bradycardia, hypothyroidism, cirrhosis, and aphasia from a lacunar infarction of my left thalamus. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, and batch number: UNKNOWN expiry: UNKNOWN) dose was not reported, administered on 06-MAR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the subject experienced body aches, slight nasal drip, swollen fingers, soreness in joints, elevated diastolic blood pressure, and soreness at injection site. Laboratory data (dates unspecified) included: Diastolic blood pressure (NR: not provided) Elevated. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the body aches, slight nasal drip, soreness at injection site, swollen fingers, soreness in joints and elevated diastolic blood pressure was not reported. This report was non-serious.; Sender's Comments: V0: Medical assessment comment not required as per standard procedure as case assessed as non-serious.</p> |

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| 1249019 | 4/23/2021 | VA | | F | | 3/6/2021 | TIRED; ALMOST PASSED OUT; MIGRAINE HEADACHE; NAUSEA; SHIVERS/CHILLS; SHAKING; WAS UP ALL NIGHT; SORE ARM; FEVER; This spontaneous report received from a patient concerned a female of unspecified age. The patient's height, and weight were not reported. The patient's concurrent conditions included strong reaction to vaccine such as the flu vaccine., and other pre-existing medical conditions included unknown. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805029 expiry: UNKNOWN) dose was not reported, administered on 06-MAR-2021 08:00 for prophylactic vaccination. No concomitant medications were reported. On 06-MAR-2021, the subject experienced was up all night. On 06-MAR-2021, the subject experienced sore arm. On 06-MAR-2021, the subject experienced fever. Laboratory data included: Body temperature (NR: not provided) 104 F. On 06-MAR-2021 15:00, the subject experienced shaking. On 06-MAR-2021 15:00, the subject experienced shivers/chills. On 06-MAR-2021 23:00, the subject experienced migraine headache. On 06-MAR-2021 23:00, the subject experienced nausea. On 07-MAR-2021 05:00, the subject experienced almost passed out. On 08-MAR-2021, the subject experienced tired. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from migraine headache, shaking, almost passed out, shivers/chills, fever, and nausea on 07-MAR-2021, and tired on MAR-2021, was recovering from sore arm, and the outcome of was up all night was not reported. This report was non-serious. Version created to amend previously reported information on 17-Mar-2021. Upon review the following information was amended: reporter causality (WAS UP ALL NIGHT); Sender's Comments: V0. medical assessment comment not required as per standard procedure as the case was assessed as non-serious. |
| 1241730 | 4/22/2021 | IL | 27 | F | 4/9/2021 | 4/9/2021 | Patient experienced syncope and hypotension, recovered and released |

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| 1240923 | 4/22/2021 | AZ | | F | | | PRE-SYNCOPE; 3 NOSE BLEEDS; HIGH BLOOD PRESSURE; This spontaneous report received from a patient concerned a female of unspecified age. The patient's height, and weight were not reported. The patient's pre-existing medical conditions included the patient was not pregnant at the time of reporting. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, administered on 13-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 2021, the subject experienced pre-syncope. On 2021, the subject experienced 3 nose bleeds. On 2021, the subject experienced high blood pressure. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from pre-syncope, and the outcome of 3 nose bleeds and high blood pressure was not reported. This report was non-serious.; Sender's Comments: V0 : Medical assessment comment not required as per standard procedure as the case was assessed as non-serious. |
| 1241341 | 4/22/2021 | MA | 34 | M | 4/9/2021 | 4/14/2021 | On day 5 started not feeling well began to run a low grade fever lasted several days. On day 3 after symptoms started patient woke up in the middle Of the night to use the restroom something that is done every night. Patient passed out and hit his head and started having a seizure |

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| 1241364 | 4/22/2021 | | | F | 1/26/2021 | 1/26/2021 | <p>Nauseated; Felt feverish; Fainting/Came to on the floor at the bottom of the stairs; Fainting/Came to on the floor at the bottom of the stairs; A little confusing at first; Shaking and clammy and too weak to get up; Shaking and clammy and too weak to get up; Slightly dizzy when I tried to get up; Wasn't hungry at all; Possible that I was dehydrated; Achy/Woke with such achiness that I couldn't sleep; Shaking, clammy and chills; Overall just really tired; Arm seriously sore and tight; This spontaneous case was reported by an other and describes the occurrence of SYNCOPE (Fainting/Came to on the floor at the bottom of the stairs) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 immunisation. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Drug allergy (Codeine type meds). On 26-Jan-2021 at 7:15 AM, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 26-Jan-2021 at 10:00 AM, the patient experienced VACCINATION SITE PAIN (Arm seriously sore and tight). On 26-Jan-2021 at 4:00 PM, the patient experienced PAIN (Achy/Woke with such achiness that I couldn't sleep), CHILLS (Shaking, clammy and chills) and FATIGUE (Overall just really tired). On 27-Jan-2021, the patient experienced SYNCOPE (Fainting/Came to on the floor at the bottom of the stairs) (seriousness criterion medically significant), FALL (Fainting/Came to on the floor at the bottom of the stairs), CONFUSIONAL STATE (A little confusing at first), COLD SWEAT (Shaking and clammy and too weak to get up), ASTHENIA (Shaking and clammy and too weak to get up), DIZZINESS POSTURAL (Slightly dizzy when I tried to get up), DECREASED APPETITE (Wasn't hungry at all) and DEHYDRATION (Possible that I was dehydrated). On 27-Jan-2021 at 2:00 AM, the patient experienced NAUSEA (Nauseated) and PYREXIA (Felt feverish). On 27-Jan-2021, SYNCOPE (Fainting/Came to on the floor at the bottom of the stairs), FALL (Fainting/Came to on the floor at the bottom of the stairs) and CONFUSIONAL STATE (A little confusing at first) had resolved. On 28-Jan-2021, PAIN (Achy/Woke with</p> |

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such achiness that I couldn't sleep), COLD SWEAT (Shaking and clammy and too weak to get up), ASTHENIA (Shaking and clammy and too weak to get up), DIZZINESS POSTURAL (Slightly dizzy when I tried to get up), DECREASED APPETITE (Wasn't hungry at all), DEHYDRATION (Possible that I was dehydrated), CHILLS (Shaking, clammy and chills), NAUSEA (Nauseated), FATIGUE (Overall just really tired) and PYREXIA (Felt feverish) had resolved. At the time of the report, VACCINATION SITE PAIN (Arm seriously sore and tight) was resolving. This case concerns an adult female with serious unexpected syncope, and nonserious unexpected postural dizziness, fall, confusion state, asthenia, pain, decreased appetite, dehydration, cold sweat, and expected pyrexia, chills, fatigue, nausea, and vaccination site pain. Event onset 2 days after second dose mRNA-1273. Events resolving. Based on current available information and temporal association between use of the product and start date of the event, a causal relationship cannot be excluded.; Sender's Comments: This case concerns an adult female with serious unexpected syncope, and nonserious unexpected postural dizziness, fall, confusion state, asthenia, pain, decreased appetite, dehydration, cold sweat, and expected pyrexia, chills, fatigue, nausea, and vaccination site pain. Event onset 2 days after second dose mRNA-1273. Events resolving. Based on current available information and temporal association between use of the product and start date of the event, a causal relationship cannot be excluded.

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| 1241379 | 4/22/2021 | MN | 43 | F | 2/27/2021 | 2/27/2021 | left neck spasm; felt uneasy; slight pain under sternum; fatigue; pain in her left knee; trembling in her upper body; face became a bright red; heat in her body; weakness in arms and hands; bed bound; pain in her lower back over kidney area; her body would be drenched in sweat mostly around heart and sternum area, she could splash; injection site started having pain; her injection site started having pain, it swelled up; Had skin eruptions like a boil on her right uper buttock; the boil was thought to be cellulitis and she was given a topical antibiotic; vomiting; racing heart; facial numbness and tingling; nausea; hard time breathing; shortness of breath; hives were on her upper back and under hips; she was covered in hives from, they covered her chest in a "Vshape; cough; burning sensation in her mouth; mouth was dry, tongue was thick and full, no salivation; Disoriented; began to feel very very thirsty; drinking 1 liter of water; felt pins and needles down her arms; numbness like pins and needles on injection site and neck; and while laying in bed, she felt like she was driving a race card; could not sleep; was going to pass out; high blood pressure; "She had a spot appear on her right leg and a ultrasound of her leg was performed to verify if a blood clot had developed (clot was not diagnosed)"; twitches in her abdomen, where her abdomen would cramp up; fallen down a short flight of stairs; felt like she could not move her limbs (elbow to fingers, knees to toes),limbs felt like they were frozen and paralyzed; dizzy; vertigo; migraine, lightheadedness, ringing ears, cloudy vision and headache; felt like as if someone was sitting on her chest; had a crawling sensation; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PRESYNCOPE (was going to pass out), CELLULITIS (Had skin eruptions like a boil on her right uper buttock; the boil was thought to be cellulitis and she was given a topical antibiotic), PERIPHERAL PARALYSIS (felt like she could not move her limbs (elbow to fingers, knees to toes),limbs felt like they were frozen and paralyzed) and DYSPNOEA (hard time breathing; shortness of breath) in a 43-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 025A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Bradycardia and Hives (Patient recalls |

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20 years ago; she had hives.) in 2001. Concurrent medical conditions included Migraine. Concomitant products included RIZATRIPTAN for Migraine. On 27-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 27-Feb-2021, the patient experienced PERIPHERAL PARALYSIS (felt like she could not move her limbs (elbow to fingers, knees to toes),limbs felt like they were frozen and paralyzed) (seriousness criterion disability), DIZZINESS (dizzy), VERTIGO (vertigo), MIGRAINE (migraine, lightheadedness, ringing ears, cloudy vision and headache) and CHEST DISCOMFORT (felt like as if someone was sitting on her chest; had a crawling sensation). On 01-Mar-2021, the patient experienced ABDOMINAL PAIN (twitches in her abdomen, where her abdomen would cramp up) and FALL (fallen down a short flight of stairs). On 02-Mar-2021, the patient experienced PRESYNCOPE (was going to pass out) (seriousness criterion medically significant), RASH MACULAR ("She had a spot appear on her right leg and a ultrasound of her leg was performed to verify if a blood clot had developed (clot was not diagnosed)'), HYPERTENSION (high blood pressure), INSOMNIA (could not sleep), PARAESTHESIA (felt pins and needles down her arms; numbness like pins and needles on injection site and neck) and RESTLESSNESS (and while laying in bed, she felt like she was driving a race card). On 03-Mar-2021, the patient experienced DISORIENTATION (Disoriented) and THIRST (began to feel very very thirsty; drinking 1 liter of water). On 04-Mar-2021, the patient experienced ORAL DISCOMFORT (burning sensation in her mouth; mouth was dry, tongue was thick and full, no salivation). On 05-Mar-2021, the patient experienced DYSPNOEA (hard time breathing; shortness of breath) (seriousness criterion medically significant), URTICARIA (hives were on her upper back and under hips; she was covered in hives from, they covered her chest in a "Vshape), COUGH (cough), HYPOAESTHESIA (facial numbness and tingling) and NAUSEA (nausea). On 07-Mar-2021, the patient experienced PALPITATIONS (racing heart). On 10-Mar-2021, the patient experienced VOMITING (vomiting). On 11-Mar-2021, the patient experienced CELLULITIS (Had skin eruptions like a boil on her right upper buttock; the

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boil was thought to be cellulitis and she was given a topical antibiotic) (seriousness criterion medically significant). On 12-Mar-2021, the patient experienced HYPERHIDROSIS (her body would be drenched in sweat mostly around heart and sternum area, she could splash), VACCINATION SITE PAIN (injection site started having pain) and VACCINATION SITE SWELLING (her injection site started having pain, it swelled up). On 13-Mar-2021, the patient experienced BACK PAIN (pain in her lower back over kidney area) and BEDRIDDEN (bed bound). On 15-Mar-2021, the patient experienced MUSCULAR WEAKNESS (weakness in arms and hands). On 17-Mar-2021, the patient experienced PYREXIA (heat in her body). On 21-Mar-2021, the patient experienced ERYTHEMA (face became a bright red) and TREMOR (trembling in her upper body). On 30-Mar-2021, the patient experienced FATIGUE (fatigue) and ARTHRALGIA (pain in her left knee). On 01-Apr-2021, the patient experienced CHEST PAIN (slight pain under sternum). On 02-Apr-2021, the patient experienced MUSCLE SPASMS (left neck spasm) and MALAISE (felt uneasy). At the time of the report, PRESYNCOPE (was going to pass out), CELLULITIS (Had skin eruptions like a boil on her right upper buttock; the boil was thought to be cellulitis and she was given a topical antibiotic), PERIPHERAL PARALYSIS (felt like she could not move her limbs (elbow to fingers, knees to toes), limbs felt like they were frozen and paralyzed), DYSPNOEA (hard time breathing; shortness of breath), RASH MACULAR ("She had a spot appear on her right leg and a ultrasound of her leg was performed to verify if a blood clot had developed (clot was not diagnosed)", DIZZINESS (dizzy), VERTIGO (vertigo), MIGRAINE (migraine, lightheadedness, ringing ears, cloudy vision and headache), CHEST DISCOMFORT (felt like as if someone was sitting on her chest; had a crawling sensation), ABDOMINAL PAIN (twitches in her abdomen, where her abdomen would cramp up), FALL (fallen down a short flight of stairs), HYPERTENSION (high blood pressure), DISORIENTATION (Disoriented), ORAL DISCOMFORT (burning sensation in her mouth; mouth was dry, tongue was thick and full, no salivation), URTICARIA (hives were on her upper back and under hips; she was covered in hives from, they covered her chest in a "Vshape), COUGH (cough), HYPERHIDROSIS

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(her body would be drenched in sweat mostly around heart and sternum area, she could splash), BACK PAIN (pain in her lower back over kidney area), MUSCULAR WEAKNESS (weakness in arms and hands), ERYTHEMA (face became a bright red), MUSCLE SPASMS (left neck spasm), INSOMNIA (could not sleep), BEDRIDDEN (bed bound), PARAESTHESIA (felt pins and needles down her arms; numbness like pins and needles on injection site and neck), RESTLESSNESS (and while laying in bed, she felt like she was driving a race car), THIRST (began to feel very very thirsty; drinking 1 liter of water), PALPITATIONS (racing heart), TREMOR (trembling in her upper body), CHEST PAIN (slight pain under sternum), MALAISE (felt uneasy), VACCINATION SITE PAIN (injection site started having pain), VACCINATION SITE SWELLING (her injection site started having pain, it swelled up), FATIGUE (fatigue), VOMITING (vomiting), PYREXIA (heat in her body), ARTHRALGIA (pain in her left knee) and NAUSEA (nausea) outcome was unknown and HYPOAESTHESIA (facial numbness and tingling) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 02-Mar-2021, Blood pressure measurement: increased (High) increased. On 02-Mar-2021, Electrocardiogram: unknown (Inconclusive) unknown. On 02-Mar-2021, Heart rate: increased (High) increased. On 02-Mar-2021, Ultrasound Doppler: unknown (Inconclusive) result unknown. On 06-Mar-2021, Blood pressure measurement: increased (High) increased. On 06-Mar-2021, Electrocardiogram: normal (normal) Tests came back fine. On 06-Mar-2021, Heart rate: 110 (High) increased. On 06-Mar-2021, Oxygen saturation: 90 (Low) decreased. On 06-Mar-2021, Ultrasound scan: normal (normal) The tests came back fine. On 07-Mar-2021, SARS-CoV-2 test: negative (Negative) negative. On 18-Mar-2021, Blood pressure measurement: normal (normal) normal. On 18-Mar-2021, Electrocardiogram: unknown (Inconclusive) unknown. On 18-Mar-2021, Heart rate: 85 (High) Pulse was a bit higher than her normal.. On 01-Apr-2021, Fibrin D dimer: unknown (Inconclusive) result unknown. On 01-Apr-2021, Ultrasound Doppler: unknown (Inconclusive) result unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown.

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| 1241599 | 4/22/2021 | CA | 17 | F | 4/21/2021 | 4/21/2021 | Per report, the patient had a skin eruption which was thought to be cellulitis at the clinic. Treatment included intravenous infusion with epinephrine, naltrexone, diphenhydramine, rizatriptan, naproxen sodium, TEA, a nerve supplement, and topical antibiotics. She was discharged home with EpiPen, prednisone, and famotidine. On 01 April 2021, the patient felt like she had a blood clot and received an EKG, D-dimer test, and ultrasound of the heart and lower limbs. On 07 April 2021, the patient reported feeling energetic. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |
| 1241656 | 4/22/2021 | GA | 32 | M | 4/21/2021 | 4/21/2021 | Systemic: Allergic: Difficulty Breathing-Medium, Systemic: Chest Tightness / Heaviness / Pain-Mild, Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Severe, Systemic: Exhaustion / Lethargy-Mild, Systemic: Fainting / Unresponsive-Severe, Systemic: Headache-Mild, Systemic: Hyperventilation-Medium, Systemic: Nausea-Severe, Systemic: Shakiness-Medium, Systemic: Tachycardia-Mild, Systemic: Visual Changes/Disturbances-Severe, Systemic: Weakness-Mild Patient with a history of syncope after injections of any kind. Afraid of needles. Approximately 7 minutes post injection patient passed out in observation. LOC less than 20 seconds. Awake and oriented x3 and VS stable and within normal limits. Dr. , medical director, consulted. No further orders. Observed for 30 minutes and wife called. Patient released to self. He will bring a driver for dose 2 and let staff know he has syncope with injections. |

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| 1241721 | 4/22/2021 | TX | 16 | M | 4/15/2021 | 4/15/2021 | 5:24pm Pt called staff over and sad he felt faint and then fainted. Parent in car, layed pt back in car, talking to him to help orient him. Vitals obtained, temp, 96.2 temporal, 62HR, 100 %spo2, 116/60 Bp. 116/60. 5:32 Pt awake enough, stable to be observed for another 10 minutes. Pt stated he is fasting ad thats probably why i fainted/ 5:47 pt awake and stable enough to leave. Mother is ok with Pts condition. |
| 1240920 | 4/22/2021 | WA | | M | | | PASSED OUT; This spontaneous report received from a consumer concerned a male of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported) dose, 1 total, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient passed out immediately upon receiving the vaccine. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of passed out was not reported. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to 20210428755.; Sender's Comments: V0: 20210429067-covid-19 vaccine ad26.cov2.s-passed out. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event. |

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| 1240509 | 4/22/2021 | FL | 63 | F | 3/1/2021 | | <p>FAINTING; ABNORMAL HEART BEAT; DIZZINESS; BLADDER CONTROL LOST/URINATED ON HERSELF; COULDN'T STAND UP; NAUSEA; CHILLS; DIDN'T HAVE APPETITE; This spontaneous report received from a patient concerned a 63 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included little asthma, cardiac resynchronization therapy (CRTS), and allergic to red tide. The patient was previously treated with gabapentin. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805029 and expiry: unknown) dose was not reported, administered on 13-MAR-2021 to left arm for prophylactic vaccination. No concomitant medications were reported. On an unspecified date in 2020, Laboratory data included: COVID-19 antigen test (NR: not provided) negative (units unspecified). On an unspecified date in MAR-2021, the subject didn't have appetite. On 13-MAR-2021, the patient experienced chills at night. On 14-MAR-2021, morning the patient experienced dizziness, nausea, she couldn't stand up and fainted (dead weight) and she reported that she was a dead weight and she didn't have control of bladder and urinated on herself (she was lying in a pool of urine. Also her heart rate went up to 84 b/p per min after she fainted and lasted for the whole day, next day it came down to 74 b/p. Her normal heart beat were 64 b/m. She was nauseous and dizzy for the past 3 weeks. Laboratory data included: Heart rate (NR: not provided) 84 (units unspecified). On 15-MAR-2021, Laboratory data included: Heart rate (NR: not provided) 72 (units unspecified). Laboratory data (dates unspecified) included: Heart rate (NR: not provided) 64 b/p. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from abnormal heart beat on MAR-2021, and bladder control lost/urinated on herself, chills, and nausea, and the outcome of dizziness, fainting, didn't have appetite and couldn't stand up was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0 20210420179-COVID-19 VACCINE AD26.CO2.S- Fainted. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially</p> |

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| | | | | | | | associated with the event. |
| 1241789 | 4/22/2021 | TX | 18 | M | 4/6/2021 | 4/6/2021 | Received Pfizer dose 1, pts father requested help, the son almost passed out. Upon assessment pt very lethargic, and pale. Father stated that his son passes easily. Pt was alert and oriented x4. Nuero checks WNL, VS WNL (106/68, 98% SPO2 and 60HR. EMT notified and onsite. Within 10 minutes pt was alert and oriented x4 and refused need to go to ER. |
| 1241908 | 4/22/2021 | VA | 16 | F | 4/21/2021 | 4/21/2021 | pt started feeling really dizzy and nauseated immediately after taking the vax. she started having a seizure and made a growling type of noise and urinated on herself. The nurse at the vax site helped bring her back and was told to take her to a doctor. She was monitored and released from the vax clinic when her BP was 107/76. She was taken to medical center where she saw. She was told she had Syncope due to the stress of the situation of getting the vaccination. She is resting today and seems to have some fatigue. |
| 1241691 | 4/22/2021 | IL | 45 | M | 4/9/2021 | 4/9/2021 | Patient experienced syncope, hypotension, recovered and released |

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| 1240882 | 4/22/2021 | CA | 51 | F | 4/7/2021 | | DIZZY; INJECTION SITE PAIN RADIATING TO NECK; ALMOST FAINTED; EXCESSIVE SWEATING AROUND ABDOMEN; FINGERS TINGLING AND JUMPING; CHILLS; SORE ARM AT INJECTION SITE; NAUSEA; FEVER; HEADACHE; This spontaneous report received from a patient concerned a 51 year old female. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 201A21A, and expiry: UNKNOWN) dose was not reported, administered on 07-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On 07-APR-2021, the subject experienced injection site pain radiating to neck. On 07-APR-2021, the subject experienced dizzy. On 07-APR-2021, the subject experienced almost fainted. On 07-APR-2021, the subject experienced excessive sweating around abdomen. On 07-APR-2021, the subject experienced fingers tingling and jumping. On 07-APR-2021, the subject experienced chills. On 07-APR-2021, the subject experienced sore arm at injection site. On 07-APR-2021, the subject experienced nausea. On 07-APR-2021, the subject experienced fever. On 07-APR-2021, the subject experienced headache. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from dizzy, almost fainted, fingers tingling and jumping, chills, nausea, and fever on 08-APR-2021, and had not recovered from headache, sore arm at injection site, excessive sweating around abdomen, and injection site pain radiating to neck. This report was non-serious.; Sender's Comments: V0:MAC comment is not required for nonserious case as per standard protocol. |

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| 1240648 | 4/22/2021 | TX | | U | | 4/10/2021 | <p>FAINTING SPELLS/ SYNCOPE; DIZZINESS/ LIGHTHEADEDNESS; NAUSEA; This spontaneous report received from a health care professional concerned multiple patients of unspecified age and sex. The patients' heights and weights were not reported. The patients had no known drug allergies. The patients received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 201A21A, expiry: Unknown) frequency one total, dose was not reported, administered on 10-APR-2021 in left arm for prophylactic vaccination. No concomitant medications were reported. The reporter stated that, on 10-APR-2021, the patients experienced side effects which included fainting spells/syncope, dizziness/lightheadedness and nausea within 15 minutes or so after vaccination at a mass vaccination clinic. The events were reported as serious by the reporter. The patients visited a healthcare professional office for fainting spells/syncope, dizziness/lightheadedness and nausea. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the fainting spells/syncope, dizziness/lightheadedness and nausea were not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: v0 This spontaneous report from a health care professional concerns multiple adult patients of unspecified age and gender from a mass vaccination site who experienced fainting spells/syncope, dizziness/lightheadedness and nausea within 15 minutes or so after the Janssen COVID-19 Vaccine Ad26.COV2 had been administered. Given the close temporal relationship and the nature of the events, the events are considered possibly related to the vaccination.</p> |

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| 1240560 | 4/22/2021 | NY | | F | | 4/11/2021 | <p>FAINTED; BLOOD PRESSURE WAS LOW; This spontaneous report received from a consumer concerned a 31-year-old female patient. Initial information was received on 13-APR-2021 and processed with additional information received on 20-APR-2021 via telephone log. The patient's height, and weight were not reported. The patient's medical history included flu shot in OCT-2020 without any side effects, gestational diabetes during pregnancy 6 years ago, and gave normal birth. The patient is a non-smoker and does not consumer alcohol. No surgery or injuries were reported. The patient did not have any prior clotting disorder or family history of clotting disorders. The patient did not have varicose veins. No allergies were reported. The patient received vaccination with JANSSEN COVID-19 VACCINE (covid-19 vaccine ad26.cov2.s) (suspension for injection, route of admin not reported, batch number: 206A217, expiry: UNKNOWN) dose was not reported, 1 total, administered on right deltoid muscle on 11-APR-2021 for prophylactic vaccination. No concomitant medications were reported as it was reported that patient did not take any medications. On 11-APR-2021, the patient received the vaccine and within 3 minutes, she felt dizzy and fainted and was taken by Emergency Medical Services to a hospital. Her vital signs were taken (pulse rate, blood pressure, and oxygen saturation) and patient was found to be hypotensive (the husband did not recall blood pressure level). When blood sugar was being tested using a needle for a prick, the blood was not coming out. Her blood sugar was normal at 129 and electrocardiogram was normal. The patient was given intravenous fluids and released home after 6 hours without any other treatment. The patient has been doing well since the release from the hospital ED and no further complaints were reported. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from fainted and blood pressure was low on 11-APR-2021. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: The case concerns a 31-year -old female who experienced low blood pressure 3-4 minutes after Janssen Covid-19 vaccine was administered intramuscularly for prevention of symptomatic SARS-CoV-2 virus infection. Patient's height and weight were not reported. Medical history included resolved gestational diabetes. The patient had</p> |

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no history of allergic reactions or reactions to a flu vaccine (last one received OCT-2020). No concomitant medications. Post vaccination the patient felt dizzy, could not sit on the chair and fainted and was taken to Emergency Room. Her blood pressure was low and she experienced hot flashes and watery eyes. Her blood sugar was 129 and electrocardiogram was normal. The subject was given IV infusion and was released from the ED without any medication. Symptoms of low blood pressure and fainting are known anxiety related reactions to immunization and given temporal relationship are considered likely related to Janssen vaccine administration.

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| 1240532 | 4/22/2021 | CA | | M | | 4/8/2021 | TIGHT MUSCLES; RIGHT HIP JOINT PAIN; FAINTED; NUMB LEG; TINGLY FOOT; FLUSHED; HIT HIS HEAD; INSOMNIA; CHILLS; This spontaneous report received from a patient concerned a male of unspecified age. The patient's weight was 185 pounds, and height was 69 inches. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1808982) dose was not reported, administered 1 total on 08-APR-2021 13:00 at Left Deltoid for prophylactic vaccination. No concomitant medications were reported. On 08-APR-2021, the patient experienced insomnia and chills at night. On 09-APR-2021, patient was doing physical activity (walking around the store). Patient experienced really sharp and stabbing right hip joint pain, right leg numbness and his right foot felt tingly like it had fallen asleep. That got worse over 5 minutes. Patient experienced very hot and flushed and proceeded to go outside where he fainted (his vision was blurry and in a confused state of mind and experienced hot and nausea) and hit his head. He tried to get up again. He fainted again and eventually came to. He was given stiches. On 11-APR-2021, he was having pain in right joint hip and tight muscles. He visited hospital where an EKG (electrocardiogram) was performed and results was normal. Laboratory data included: EKG: electrocardiogram (NR: not provided) as Normal. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from fainted (nausea/hot/blurry vision/confused state of mind), insomnia, flushed, and chills on APR-2021, was recovering from right hip joint pain, and the outcome of numb leg, tingly foot, hit his head and tight muscles was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210422158-JANSSEN COVID-19 VACCINE Ad26.COVID2.S- Fainted. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event. |

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| 1240525 | 4/22/2021 | CA | | U | | | <p>FAINTING; DIZZINESS; This spontaneous report received from a patient via a company representative concerned multiple patients of unspecified age and sex. The patient's weight, height, and medical history were not reported. The patients received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) 1 total dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The company is unable to perform follow up to request batch no/Lot numbers. No concomitant medications were reported. On an unspecified date, the patients experienced dizziness and fainted, they came back to consciousness. There was no information about the patients who experienced these symptoms. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the fainting and dizziness was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210420968-covid-19 vaccine ad26.cov2.s-Fainting. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.</p> |

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| 1240524 | 4/22/2021 | NJ | | F | | 4/10/2021 | <p>FEVER; PASSED OUT/ 'FELT REALLY BAD/TERRIBLE/HORRIBLE, VITALS VERY LOW, FELT WARM, SWEAT, CHILLS, FELT WEAK, FEELING TIRED/EXHAUSTION; CRASHING TO THE FLOOR; LEFT BUTT CHEEK HURTS; This spontaneous report received from a patient concerned a 40 year old female.. The patient's height, and weight were not reported. The patient's past medical history included passed out, and other pre-existing medical conditions included the patient had passed out when getting blood work done previously. The patient was previously treated with influenza vaccine for prophylactic vaccination. The patient was not pregnant at the time of reporting. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 205A21A, and expiry: UNKNOWN) dose was not reported, 1 total dose administered on 09-APR-2021 13:15 in left deltoid for prophylactic vaccination. No concomitant medications were reported. On APR-2021, Laboratory data included: Vital signs measurement (NR: not provided) Not reported. On 10-APR-2021, the patient experienced passed out/ felt really bad/terrible/horrible, vitals very low, felt warm, sweat, chills, felt weak, feeling tired/exhaustion. On 10-APR-2021, the patient experienced crashing to the floor. On 10-APR-2021, the subject experienced left butt cheek hurts. On 11-APR-2021, the subject experienced fever. the patient woke up in the morning, and while washing her hands in the bathroom, she began to feel really bad and started to lower herself down and she passed out, then she ended up crashing to the floor, she did not hit her head, and her left butt cheek got hurt. Her husband called emergency medical services (EMS) who treated her until she regained consciousness. Patient also stated that she felt terrible and horrible. Emergency medical services recommended that she be taken to the hospital for further evaluation, but she declined. She had a history of passing out after bloodwork, but had never had this delayed of a reaction with bloodwork or any reaction to the flu shot. EMS called and her vitals were all very low. She did not go to the hospital. She felt improved and had been taking it easy at the time of this report. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from crashing to the floor on 10-APR-2021, and was recovering from passed</p> |

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| 1240518 | 4/22/2021 | NJ | 56 | M | 4/8/2021 | | <p>out/ felt really bad/terrible/horrible, vitals very low, felt warm, sweat, chills, felt weak, feeling tired/exhaustion, left butt cheek hurts, and fever. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210420904-covid-19 vaccine ad26.cov2.s-Passed out. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p> <p>PRODUCT LOT WAS VERY SLOPPY AND HARD TO READ (PRODUCT LABEL ISSUE); DIZZY AND FELT LIKE FAINTING; This spontaneous report received from a patient concerned a 56 year old male. The patient's height, and weight were not reported. The patient's past medical history included feeling faint. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: OU1A71A, and expiry: UNKNOWN) dose was not reported, administered on 08-APR-2021 15:00 for prophylactic vaccination. No concomitant medications were reported. On 08-APR-2021 15:03, the subject experienced dizzy and felt like fainting. On an unspecified date, the subject experienced product lot was very sloppy and hard to read (product label issue). The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from dizzy and felt like fainting on 08-APR-2021, and the outcome of product lot was very sloppy and hard to read (product label issue) was not reported. This report was non-serious.; Sender's Comments: V0: Medical assessment comment was not required as per standard procedure as case assessed as non-serious.</p> |

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| 1240500 | 4/22/2021 | CA | 52 | F | 4/2/2021 | | ANAPHYLACTIC REACTION; LIGHT HEADED; SYNCOPE/LOST CONSCIOUSNESS; STOPPED BREATHING; VOMITING/PERSISTENT EMESIS; This spontaneous report received from a patient concerned a 52 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included hypertension, and anaphylaxis to peanuts. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, 1 total administered on 02-APR-2021 to right arm for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 02-APR-2021, after vaccination patient experienced an anaphylactic reaction. The patient was at her local pharmacy and was waiting in chairs as instructed; then she walked to her vehicle and began to feel light-headed and lost consciousness. Her husband was with her and was able to administer life saving measures, the local pharmacist was able to administer an epi-pen to her right thigh. On 02-APR-2021, the patient stopped breathing and was then transported to the local ER(emergency room) where she was treated. She regained consciousness and had persistent emesis and the patient was kept in hospital for 24 hours before being discharged. The patient was hospitalized for one day. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from syncope/lost consciousness, and was recovering from light headed, vomiting/persistent emesis, and anaphylactic reaction, stopped breathing. This report was serious (Hospitalization Caused/ Prolonged, and Life Threatening).; Sender's Comments: v0 A 52-year-old female patient with the past medical history remarkable for anaphylaxis to peanuts experienced anaphylactic reaction the same day the Janssen COVID-19 Vaccine Ad26.COVID2 was administered. The patient began to feel light-headed and lost consciousness, an epi-pen was administered. The next day the patient stopped breathing and was treated in the local ER (emergency room). Later she had persistent emesis. Given the close temporal relationship and history of anaphylaxis to peanuts the events are considered related. |

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| 1240495 | 4/22/2021 | WA | 35 | F | 4/18/2021 | 4/18/2021 | PT MENTIONED SHE WAS NERVOUS ABOUT GETTING THE SHOT. AFTER SHE RECEIVED THE SHOT, SHE WENT INTO THE WAITING ROOM AND A FEW MINS LATER, FELT LIKE SHE WAS GOING TO PASS OUT. WE HAD HER LAY ON THE FLOOR AND ELEVATED HER FEET. SHE PROCEEDED TO PASS OUT. WE ADMINISTERED THE SMELLING SALTS, SHE WAS SLIGHTLY AWAKE BUT OUT OF IT AND SAID SHE DIDN'T SMELL ANYTHING. WE LIFTED HER MASK AND DID ANOTHER SMELLING SALT AND SHE "WOKE UP" BUT STILL REMAINED ON THE FLOOR. SHE FELT WEIRD, EYES REMAINED CLOSED AND SHE WAS SLIGHTLY CRYING AN SCARED. WE ASKED HER PARTNER IF THIS HAS EVERY HAPPENED BEFORE AND HE SAID SHE HAS ONLY PASSED OUT B/C OF PAIN NOT ANXIETY. WE TOOK HER PRESSURE/HEART RATE EVERY 5 MIN FOR 15 MIN. IT WAS ELEVATED 165/110 (HR 69) AND STAYED AROUND THAT EACH READING. WE ASKED HER IF SHE WANTED US TO CALL EMT AFTER THE FIRST 5-10 MIN AND SHE WASN'T SURE. 15-20 MIN LATER WE CALLED EMT AND THEY CAME TO ASSIST. THEY TOOK HER VITALS AND THEN EVENTUALLY HELPED HER SIT UP AND EVENTUALLY SHE WALKED OUT ON HER OWN. |
| 1240234 | 4/22/2021 | NM | 53 | M | 4/21/2021 | 4/21/2021 | He felt nauseous, got up to go to kitchen sink and passed out for a few seconds. When I got to him, he was on the ground, eyes open, but seriously disoriented. He got up to the couch. He was very, very clammy and his heart rate was 44 bpm. I held three fingers for him to identify, he correctly answered. He has a small gash on his forehead. His heart rate came up to 70, 20 minutes after episode. Refused to go to urgent care. |
| 1243919 | 4/22/2021 | IN | 66 | F | 3/29/2021 | 4/1/2021 | Patient presented one week pos vaccination with 2 days of easy bruising and petechiae. Platelets were 4K. Seen by doctor of hematology. Started on steroids with improvement to 21K and discharged. Came back a week later with presyncope and chest tightness. Platelets again 4K. Treated with IVIG |

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| 1241913 | 4/22/2021 | MN | 16 | F | 4/19/2021 | 4/19/2021 | Within a minute of receiving the vaccine, my daughter fainted and had a short seizure. She did not hit her head because I was able to help her on her way down - it was a ver small room with 3 people in it. The pharmacist was there and he said it was a seizure, she just jerked her chin up, sharply 3 or 4 times. She laid on the ground for about five minutes, then sat on the ground, then sat in a chair for a total of about 20 minutes. She felt dizzy and nauseated for about 15 minutes after. She drank a juice and felt better so we drove home, no other symptoms since. |

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| 1240520 | 4/22/2021 | NY | | U | | | <p>FAINTING; DIZZINESS/LIGHTHEADEDNESS; This spontaneous report received from a pharmacist concerned multiple patients of unspecified age and gender (specific number of patients unknown, reported as handful/bunch of patients). The patients' weight, height, and medical history were not reported. The patients received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration was not reported, batch number and expiry date were unknown) dose, start therapy date was not reported, 1 total, for prophylactic vaccination. The batch number was not reported and will not be requested because the pharmacist does not have the lot number of the vaccine used. No concomitant medications were reported. On an unspecified date, the patients fainted and experienced lightheadedness/dizziness. It was reported that the patients experienced these side-effects not only during vaccination which were from the anxiety or stress of the injection itself but, also during the 15 minutes that the patients were kept for surveillance. The patients did not require any hospitalization or any additional medical care. They just got monitored by a nurse and some of them became better after drinking water and taking rest on the chair for 15 minutes or a bit longer than that. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the fainting and lightheadedness/dizziness was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210420689-Covid-19 vaccine ad26.cov2.s-Fainting. This event is considered unassessable. The event has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.</p> |
| 1244764 | 4/22/2021 | | 16 | M | 4/20/2021 | 4/20/2021 | <p>Syncope, dizziness, fainted. Crackers, water, apple juice given. Vitals wnl.</p> |

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| 1243741 | 4/22/2021 | CA | 16 | M | 4/22/2021 | 4/22/2021 | 16 year old received Pfizer dose #1 (Lot # EW0158) @ 1155 am. While in the recovery area @1156 began feeling dizzy and faint. Was lowered to the floor and placed in Trendelenburg position. First set of vital done at 1158am. 138/62, 18, 92, @ 96% O2 sat. Mom stated that this is not a new event, has a history of syncope with injections. Second set of vitals @ 1158, 118/60, 84, 99% O2 sat. Returned to chair. Had a second episode, and was once again lowered to the floor, and positioned with head between knees and did deep breathing exercises. Next set of vitals at 1209 am, 118/62, 77, 18, 98% O2 sats. Returned to chair when stating he felt better. Discharged from Recovery with Mother to home at 1233 am with final set of vitals of 110/70, 64, 18. |
| 1241948 | 4/22/2021 | CA | 43 | F | 3/17/2021 | 3/17/2021 | The night after I received the Johnson and Johnson vaccine I had 101.7 fever, chills, shaking. The next two days my hands got really dry and the skin peeled off them. 3 days later I fainted. |

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| 1245064 | 4/22/2021 | MD | 65 | U | 3/23/2021 | | FELT DIZZY/FELT FAINTING; HEAD SPINNING; HANDS SHAKING; DROWSY; VISION BLURRED; MOUTH DRY; ONE SIDE OF TONGUE WAS HEAVY; WEAKNESS; This spontaneous report received from a patient concerned a 65 year old of unspecified sex. The patient's height, and weight were not reported. The patient's concurrent conditions included non-smoker, and non-alcoholic, and other pre-existing medical conditions included the patient had no known allergies and no drug abuse or illicit drug usage. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, administered on 23-MAR-2021 for prophylactic vaccination. The batch number was not reported. The company is unable to perform follow-up to request batch/lot number. Concomitant medications included influenza vaccine for prophylactic vaccination, and acetylsalicylic acid. On 23-MAR-2021, the subject experienced felt dizzy/felt fainting. On 23-MAR-2021, the subject experienced head spinning. On 23-MAR-2021, the subject experienced hands shaking. On 23-MAR-2021, the subject experienced drowsy. On 23-MAR-2021, the subject experienced vision blurred. On 23-MAR-2021, the subject experienced mouth dry. On 23-MAR-2021, the subject experienced one side of tongue was heavy. On 23-MAR-2021, the subject experienced weakness. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from felt dizzy/felt fainting, drowsy, vision blurred, mouth dry, one side of tongue was heavy, hands shaking, head spinning, and weakness. This report was non-serious.; Sender's Comments: V0: Medical assessment comments not required as per standard procedure as the case is considered non serious. |

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| 1244964 | 4/22/2021 | OH | 57 | F | | 4/1/2021 | LETHARGIC; EYE FLOATERS; ALMOST PASSED OUT; MIGRAINE TYPE OF HEADACHE; FELT NAUSEOUS; LOSS OF EFFECT; This spontaneous report received from a patient concerned a 57 year old female. The patient's concurrent conditions included sulfa allergy, non alcohol user, and non smoker, and other pre-existing medical conditions included the patient did not have any drug abuse/illicit drug. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 1808978, and expiry: UNKNOWN) dose was not reported, administered on 07-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On APR-2021, the subject experienced loss of effect. On 08-APR-2021, the subject experienced lethargic. On 08-APR-2021, the subject experienced eye floaters. On 08-APR-2021, the subject experienced almost passed out. On 08-APR-2021, the subject experienced migraine type of headache. On 08-APR-2021, the subject experienced felt nauseous. Treatment medications (dates unspecified) included: paracetamol. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from eye floaters, and felt nauseous on 09-APR-2021, had not recovered from migraine type of headache, and lethargic, and the outcome of almost passed out and loss of effect was not reported. This report was non-serious. |
| 1244067 | 4/22/2021 | IL | 45 | F | | 4/9/2021 | 4/9/2021 Patient experienced syncope and hypotension, transported to hospital via ambulance |
| 1244001 | 4/22/2021 | IL | 32 | M | | 4/9/2021 | 4/9/2021 Patient experienced syncope, hypotension, recovered and released |

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| 1243829 | 4/22/2021 | NY | 78 | F | 2/8/2021 | 2/18/2021 | On 2/18/21, 10 days after receiving the vaccine, I donated blood as usual. About 30 minutes later I was light headed, had abdominal cramping pain, bowel emptying and possibly fainted. I was transported by EMTs to the ER and was later diagnosed with inflammatory bowel by a CT scan. I took antibiotics and was feeling fine. My gastroenterologist performed a colonoscopy on 3/24/21 and the findings were that I was healed and tissue samples were normal. 3/25/21 I had an annual physical and was told I was in good health. Later that afternoon I began feeling light headed upon standing. In the night I called my health insurance hotline because my blood oxygen meter was beeping continuously. The Dr. on call told me to go by ambulance to the ER. When sitting or lying down, I felt fine and all the tests at the ER for my heart and my vital signs were good. A few hours later, they did a chest Xray and then a CT scan of my lungs which showed a saddle embolism. I had also thought I had bruised my knee if and when I fainted on 2/18 and 10 hours later a blood clot was found by ultrasound of my left knee. I was given blood thinners in the ER and then in ICU where I spent the next night. I am now taking Eleris. I was also given pantoprazole for GERD coughing the next day. I continue to have periods of abdominal cramping/pain, light headedness in waves and pressure in my head. I have discontinued the stomach medication with some feeling better with the lightheadedness. |
| 1243653 | 4/22/2021 | | 17 | M | 4/22/2021 | 4/22/2021 | pt fainted, lost LOC x 20 sec according to mom, upon arrival pt was awake, alert, clammy and pale, HR=85, laid pt in supine position, monitored HR x 15 mins, pt awake and alert, oriented, described a syncopal episode, stated he hadn't eaten yet today, engaged in conversation, then sat pt in sitting upright position x 15 mins, HR=85, gave pt juice = 50gms carb, pt continued stated he felt much better, still appeared pale, then 15 mins pt able to ambulate without difficulty, HR=85, mom refused to go to emergency room as counseled. mom states he has a history of syncopal episodes with blood draws, or getting shots. |

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| 1243633 | 4/22/2021 | IL | 16 | F | 4/21/2021 | 4/21/2021 | Patient was on observation having a conversation with her father when suddenly she started passing out and exhibiting twitching like having Petit mal convulsions and not able to arouse, and later in 2 minutes she recovered eyes open appears pale in face and lips, not aware that she had passed out, and became responsive. Father claims that HR is always running on low side because she is an athlete. On around 4:40pm she was released under the care of her parent and recommended to get an appointment with her PCP for further evaluation Patient status was checked the following day 4/22 and Pediatrician said that it must be a vasovagal Syncope per Neurologist he consulted no further appointment will be needed at this time |
| 1243565 | 4/22/2021 | GA | 17 | F | 4/13/2021 | 4/13/2021 | Moments after receiving vaccine patient passed out. Mom and Dad were with her. Pharmacist had dad lay her on the floor, pharmacist lifted legs and patient immediately regained consciousness. Pharmacist asked patient to stay in the waiting area until she felt better. Patient was given frozen water bottle wrapped in paper towel (store was out of immediately cold ice packs). When patient indicated she was ready to leave, pharmacist instructed parents to walk near in case she felt faint again. Pharmacist called patient a few hours later to check but no answer. Left message but no return call. |
| 1243337 | 4/22/2021 | NY | 64 | F | 3/27/2021 | 3/29/2021 | 1st occurrence: After 1st vaccination on March 6th, 2021- intense pain in left leg, passed out, went to urgent care 2nd occurrence: After 2nd dose on March 27th, 2021 - on the 28th flu like symptoms- on the 29th intense leg pain, passed out, transported to hospital by ambulance, doppler revealed blood clot, blood work normal, placed on Eliquis I have since been to the hematologist and had a work up... blood tests are normal |
| 1242073 | 4/22/2021 | | 18 | F | 4/20/2021 | 4/20/2021 | near syncope, fatigue |
| 1242983 | 4/22/2021 | RI | 17 | M | 4/22/2021 | 4/22/2021 | Vasovagal syncope with fall and head contusion. Refused transport to ER. |

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| 1242650 | 4/22/2021 | MN | 18 | F | 4/22/2021 | 4/22/2021 | Patient had vasovagal syncope starting about 5 minutes after vaccination that resolved within 10 minutes. She stayed in pharmacy area for an additional 15 minutes for monitoring |
| 1242564 | 4/22/2021 | VA | 36 | M | 4/1/2021 | 4/1/2021 | Client received Jansen Covid Vaccine and was getting ready to walk to his vehicle when he felt "weak" and fainted. Client was supported by his wife along a worker and he was slided to the ground, client did not sustained any visible injuries. BP was 89/44 p 52. Ambulance was called, client was evaluated and transported by Medic. |
| 1242520 | 4/22/2021 | KS | 35 | F | 3/10/2021 | 4/17/2021 | 35 y/o with asthma (on alvesco and singulair), GERD, morbid obesity (BMI 45) and RA (on prednisone and MTX, SZA.) Vaccinated for COVID 2.12. and 3.10 Recent lab 3/17- normal, including negative CRP. Code continued for 50 minutes, no shock advised. PEA, gave Epi X 4. Normal BS. Considered narcan. Over the weekend- 4/17 Chest pain that started with eating. Labile blood pressure. EKG showed NSR rate 64. Treated with ASA 325, clear liquid diet and rest. Treated with toradol and Zofran. Improved. At f/u on Monday, discussed chronic knee pain was overall better. Normal for her exam. BP 136/79. Felt dizzy and then passed out, hitting her head, became pulseless an apneic and was coded for over an hour. |
| 1242346 | 4/22/2021 | IL | 86 | F | 1/23/2021 | 4/21/2021 | 4/21/21 ER hpi: 86 y.o. female who presents with unresponsive episode. Patient is a resident of a nursing home and was apparently talking to members of her family when she collapsed prior to arrival several minutes ago. Paramedics report patient hypotensive on arrival to scene. Blood pressure and level of consciousness have improved during transport. Patient is hypertensive and is on multiple medications. At this time she has no complaints and states she feels all right. She does have a history of multiple recurrent urinary tract infections. Admitted observation to hospital 4/21/21 dx syncope and collapse, positive d-dimer, acute uti |

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| 1241995 | 4/22/2021 | DE | 73 | F | 4/7/2021 | 4/20/2021 | April 20 2021: suffered a fainting/blackout episode where I collapsed onto my apartment building's outside entry stair. I hit the deck causing contusions to my knees and upper back. I regained consciousness after _about 10 seconds, was helped up another flight of stairs by a friend and neighbor where I - again - blacked out falling to the hallway floor. I regained consciousness in another 10 seconds. |
| 1242252 | 4/22/2021 | | 31 | F | 4/11/2021 | 4/11/2021 | Vasovagal. Lost bladder control Improved on her own. Called 911 but canceled Has fainted in the past |
| 1242148 | 4/22/2021 | VA | 26 | F | 4/8/2021 | 4/8/2021 | 4/8-4/9: arm pain, chills, chattering teeth, fever, sweating, dehydration, insomnia 4/9: fatigue, brain fog/confusion 4/8-4/22: random muscle pains mostly in legs, ankles, feet 4/17: insomnia, sweating, neck pain, nausea, dizziness, fainting, muscle pains, dehydration, anxiety/elevated heart rate -> went to ER at 4am on 4/18, tests found no abnormalities 4/17-4/22: neck pain and upper back, fatigue, muscle pains, anxiety/elevated heart rate (intermittent chest pain/sensitivity), insomnia, general discomfort overall and thus depression from not feeling normal for so long |
| 1242016 | 4/22/2021 | NC | 45 | F | 4/9/2021 | 4/10/2021 | Severe allergic reaction - Hives, Itching, Burning, loss of breath, fainting I was unable to sit or stand. So my husband called ambulance and they took me to emergency room |
| 1244982 | 4/22/2021 | | 16 | M | 4/21/2021 | 4/21/2021 | Syncope, flushing/dizziness, sweating, BP 92/50 (pulse 77). F/u pulse 116/56, O2 sat 99%. |
| 1241970 | 4/22/2021 | IL | 45 | M | 4/10/2021 | 4/10/2021 | Patient experienced syncope and hypotension post vaccination, recovered and released |

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| 1243319 | 4/22/2021 | MI | 44 | F | 4/8/2021 | 4/8/2021 | A few hours after the vaccine I felt really bad. I had severe diarrhea and abdominal pains which caused me to go to the ER d/t abdominal pain. I was so severely sick, in bed and couldnt hardly move. On Sat I was being transported to the hospital when I got super nauseaed so my husband pulled over and I passed out and went unconscious and fell out the car onto the ground. EMT was called and transported me to the hospital when a CT Scan and EKG was performed. I was given IV fluids, monitored and released after some time. Over the next few days I felt absolutely awful. On 4/15 I had a phone F/U visit with my PCP. I still havent felt to myself to date and had to go back to the ER last night because I was so nauseaed and dizzy I couldnt stand or do anything and I am still having the diarrhea also |

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| 1235773 | 4/21/2021 | MO | | M | 4/6/2021 | 4/6/2021 | fainted/passed out; fainting/passed out; This is a spontaneous report from a contactable pharmacist. A contactable physician reported similar events for 3 patients. This is one of 3 reports. A male patient of an unspecified age received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Formulation: Solution for injection, Lot/Batch number: ER8729; Expiration Date: 20Jul2021), via an unspecified route of administration on 06apr2021 as SINGLE DOSE for covid-19 immunization and saline [sodium chloride] via an unspecified route of administration from on unspecified date (Batch/Lot Number: 6023228) for an unspecified indication. The patient medical history and concomitant medications were not reported. The patient had just received the Covid 19 vaccine and was still being watched within the 15-minute post vaccination time. On 06Apr2021, the patient was fainting and passed out had some issues with vaccines in the past. HCP wants to know if there have been any reports of having these reactions associated with the specific lot number: ER8729. The events considered as medically significant with outcome unknown.; Sender's Comments: Based on the temporal association, a possible contributory role of vaccination with BNT162B2 to the reported events fainting and passed out cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified. |

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| 1235968 | 4/21/2021 | | | M | | | <p>PASSED OUT; This spontaneous report received from a consumer via a company representative concerned a male of unspecified age (young under 25) received via social media. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported, frequency once total for prophylactic vaccination. The batch number was not reported. The batch number was not reported. As per procedure, no follow-up will be requested for this case No concomitant medications were reported. On an unspecified date, the patient passed out in the waiting area and was quickly attended to by medical personnel. He was sitting up fine. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from passed out. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to 20210420123 and 20210421172.; Sender's Comments: V0: 20210420375 - COVID-19 VACCINE AD26.CO2.S - Passed Out. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.</p> |

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| 1235967 | 4/21/2021 | CO | | U | | | <p>FAINTING; INCREASED BREATHING; DIZZINESS/ LIGHT HEADEDNESS; NAUSEA; This spontaneous report received from a company representative concerned patients. The patient's weight, height, and medical history were not reported. The patient's received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration not reported, batch number: Unknown) frequency one total, dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. The caller reported that she saw on the news that patients in Colorado experienced dizziness/ light headedness, nausea, fainting and increased breathing after getting Janssen Covid-19 vaccine and two out of the eleven patients went to the hospital. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the dizziness/ light headedness, nausea, increased breathing and fainting was not reported. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to: 20210420809; Sender's Comments: V0: 20210420362-COVID-19 VACCINE AD26.COV2.S-Fainting. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.</p> |

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| 1235962 | 4/21/2021 | IL | | U | | | <p>FAINTED; UNSPECIFIED ADVERSE REACTIONS; This spontaneous report received from a consumer concerned multiple patients. The reporter saw this information on the media. The patients' weight, height, and medical history were not reported. The patients received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported) dose, start therapy date were not reported, 1 total administered for prophylactic vaccination. The batch number was not reported. Per procedure, no follow up will be requested for this case. No concomitant medications were reported. On an unspecified date, the patients had a couple of reactions and fainted. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the fainted and unspecified adverse reactions was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: 20210420119-covid-19 vaccine ad26.cov2.s-Fainted. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p> |

| <i>VAERS_ID</i> | <i>RECVDATE</i> | <i>STATE</i> | <i>AGE_YRS</i> | <i>SEX</i> | <i>VAX_DATE</i> | <i>ONSET_DATE</i> | <i>SYMPTOM_TEXT</i> |
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| 1235960 | 4/21/2021 | NY | | U | | | <p>FAINTING; LOW BLOOD PRESSURE; This spontaneous report received from a consumer concerned multiple patients. The reporter saw this information on the news. The patient's weight, height, and medical history were not reported. The multiple patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unk) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow up will be requested for this case. No concomitant medications were reported. On an unspecified date, the multiple patient experienced fainting and low blood pressure after getting the covid-19 vaccine. Laboratory data (dates unspecified) included: Blood pressure (NR: not provided) as Low. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the fainting and low blood pressure was not reported. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to 20210420138; Sender's Comments: 20210420027-covid-19 vaccine ad26.cov2.s-Fainting. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.</p> |

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1235958 | 4/21/2021 | GA | | M | | 4/7/2021 | <p>PASSED OUT; ERRATIC BODILY MOVEMENT FOR THREE SECONDS; CONFUSED; SLOUCHED OVER IN CHAIR LIKE HE PASSED OUT; STARTLED; PALE; DID NOT KNOW NAME; FELT TIRED; This spontaneous report received from a health care professional concerned a male of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 201A21A expiry: UNKNOWN) dose was not reported, administered on 07-APR-2021 for prophylactic vaccination. No concomitant medications were reported. It was reported that on 07-APR-2021, the patient while sitting in the observation area slouched over in chair like he had passed out. On 07-APR-2021, he began to have erratic bodily movement for three seconds. He lowered to the floor. He opened his eyes and was very startled and confused. He did not know name. He was evaluated by emergency medical services (EMS), and all the tests were normal. He refused transfer to the hospital. On 07-APR-2021, he complaint of feeling tired, and was pale. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the erratic bodily movement for three seconds, confused, slouched over in chair like he passed out, startled, pale, passed out and did not know name was not reported. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to 20210417256, 20210417209, 20210417456 and 20210417122.; Sender's Comments: V0-20210417550- Covid-19 vaccine ad26.cov2.s-Passed out. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.</p> |

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1235804 | 4/21/2021 | PA | 38 | U | 4/2/2021 | 4/1/2021 | I fainted, I hit my head when I fainted; I fainted, I hit my head when I fainted; Tiredness; Headache; Muscle pain; Chills; Joint pain; Nausea; the arm hurt; This is a spontaneous report from a contactable consumer (patient). A 38-year-old patient of an unspecified gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), first dose via an unspecified route of administration, administered in arm left on 02Apr2021 at age of 38-year-old (Batch/Lot Number: ER8733) at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were none. On an unspecified date in Apr2021, the patient got the tiredness, headache, muscle pain, the chills, the joint pain, the arm hurt, nausea, and then on 06Apr2021 patient fainted, I hit head when the patient fainted. Treatment in response to events was none. The outcome of the events was unknown. |
| 1236063 | 4/21/2021 | IL | | U | | | PASSED OUT; This spontaneous report received from a consumer concerned a patient of unspecified age and sex. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, administered 1 total, start therapy date were not reported for prophylactic vaccination. Batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the subject experienced passed out. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of passed out was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0-20210422259- Covid-19 vaccine ad26.cov2.s- passed out. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.. |

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1235803 | 4/21/2021 | AR | 51 | F | 4/1/2021 | 4/1/2021 | All my muscles and whole body is hurting; All my muscles and whole body is hurting; Chills; Joint pain; I had some wired nausea, I can even hardly eat; I had some wired nausea, I can even hardly eat; My heart rate is kind of low but it's been 125 for last 2 days; I have a rash; I feel dizzy and weak; cannot stand up and walk; I feel dizzy and weak; cannot stand up and walk; I feel dizzy and weak; cannot stand up and walk; My lymph nodes are very swollen; I have ray nods also that's circulation disorder; I feel like I have been freezing cold ever since I got the second shot; I got half fever; I have ray nods also that's circulation disorder; I feel like I have been freezing cold ever since I got the second shot; I got half fever; I have been passed out; I had mine my fever gone up to 104.9 and down to 103; my arm is swollen, hard and hurts terribly; my arm is swollen, hard and hurts terribly; whole arm get deep red; This is a spontaneous report from a contactable consumer (patient). A 51-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, in the left arm on 01Apr2021 (Batch/Lot Number: EN6199) (at the age of 51 years old) at a single dose for covid-19 immunisation. Medical history included lupus and high blood pressure both from an unknown date. Concomitant medications included sertraline hydrochloride (ZOLOFT), clonazepam (KLONOPIN) and topiramate (TOPAMAX) all taken for an unspecified indication, start and stop date were not reported. The patient previously took the first dose of BNT162B2 on 12Mar2021 (lot number: EN6198) (at the age of 51 years old) and reported that she was really not feeling well. On 01Apr2021, the patient got the second dose of covid vaccination and reported that she had a pretty serious side effect since the first one. The patient then reported her fever gone up to 104.9 and down to 103 and reported that she was worried about herself, not only the fever; her arm is swollen, hard and hurts terribly; patient reported that all her muscles and whole body is hurting and the chills, the joint pain of course the fever and further reported that had some wired nausea, she can even hardly eat. The patient then stated that within a few hours after her shot, she started having mild problems: swelling of her arm, her whole arm get deep red and throughout pain in her arm. The patient had a video call with her primary care doctor, the doctor said it's |

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just normal, don't worry about it, the doctor didn't let the patient give all her symptoms (as reported). The patient further stated she have that pain and something is not right in her body and that she have been taking Tylenol. The patient also reported that her heart rate is kind of low but it's been 125 for last 2 days (as reported), patient reported that she has a rash, feel dizzy and weak, cannot stand up and walk, the patient have attended to go for her family house for the Easter and she was there for 15 minutes. Keep in mind Covid normally they all were vaccinated and it's been a very special time, but within 15 minutes the patient have been passed out and had been taking home and further reported that her lymph nodes are very swollen and her head is killing her. The patient have an electric blanket in her arm because she have chills so bad, her joints are hurting and she have ray nods (as reported) also that's circulation disorder and she feel like she have been freezing cold ever since she got the second shot. The outcome of the events was unknown.

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| 1235786 | 4/21/2021 | RI | 31 | F | 4/3/2021 | 4/4/2021 | Fainted about 12 hours after receiving the vaccine after waking up to go to the bathroom/diagnosed with a concussion and syncope; unconscious for an undetermined amount of time; Fell to ground and was then diagnosed with a concussion and syncope at the ER; Fell to ground and was then diagnosed with a concussion and syncope at the ER; fever; body aches; This is a spontaneous report from a contactable consumer (patient). A 31-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: er8735) at the age of 31-year-old, via an unspecified route of administration, administered in left arm on 03Apr2021 16:45 as single dose for COVID-19 immunisation. Medical history included allergies to penicillin and seafood, and was diagnosed with COVID-19 prior vaccination. Concomitant medication included clonazepam. The patient was not pregnant at the time of vaccination. On 04Apr2021 05:30AM, the patient fainted (also reported as about 12 hours after receiving the vaccine) after waking up to go to the bathroom, was unconscious for an undetermined amount of time, fell to ground, and was then diagnosed with a concussion and syncope at the ER. CT scan and EKG 12 lead were clear on an unspecified date. In addition to this, the patient also has fever and body aches on 04Apr2021 05:30AM. No treatment was received for the events. The event resulted to emergency room/department or urgent care. The patient underwent lab tests and procedures which included Nasal Swab: pending results on 04Apr2021. The outcome of the events was not recovered. |

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| 1235818 | 4/21/2021 | | 30 | F | 4/1/2021 | 4/1/2021 | fainted; felt dizzy and lightheaded; heart palpitations; sweaty; glucose levels in my body dropped to 50; not felt like myself; felt sick after eating; This is a spontaneous report from a non-contactable consumer (patient). A 30-year-old female patient received the first dose of bnt162b2 via an unspecified route of administration, administered in Left arm on 01Apr2021 15:00 (Batch/Lot number was not reported) as single dose for covid-19 immunisation. The patient medical history was not reported. There were no concomitant medications. The patient was allergic with Bactrim and Iodine. The patient was not pregnant. 5 minutes after receiving her first dose of the COVID-19 vaccine, she fainted. In the days following (Apr2021), she had felt dizzy and lightheaded, had suffered from heart palpitations and had been very sweaty. Her glucose levels in her body dropped to 50. She had not felt like herself and also had felt sick after eating. The events resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Life threatening illness (immediate risk of death from the event). The patient received the treatment (Multiple doctor's visits) for the events. The outcome of the events was not recovered. No follow-up attempts are possible; information about lot/batch number cannot be obtained. |

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| 1235986 | 4/21/2021 | CA | 58 | M | | 4/7/2021 | PASSED OUT; LIGHT HEADED; VERY SLEEPY; ARM PAIN; This spontaneous report received from a patient concerned a 58 year old male. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported and batch number: 043A21A, expiry: UNKNOWN) dose was not reported, 1 total administered on 07-APR-2021 to left deltoid for prophylactic vaccination. No concomitant medications were reported. On 07-APR-2021, the patient was very sleepy and experienced arm pain. On 08-APR-2021, the patient passed out in shower and felt light headed, he awoke in shower with no known duration and with no injuries The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from passed out, and the outcome of light headed, arm pain and very sleepy was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0. 20210420738-covid-19 vaccine ad26.cov2.s -Passed out. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s). |

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1235992 | 4/21/2021 | PA | 46 | F | 4/5/2021 | | <p>SHORTNESS OF BREATH; HEART PALPITATIONS; SEVERE DIZZINESS; STOMACH UPSET; NAUSEA; HEADACHE; FAINTED; FEELING UNWELL; CLAMMY CHILLS; TEMPERATURE RAISED A LITTLE; GENERAL FATIGUE; NIGHT SWEATS AND WAKE UP FROM SLEEP; DRY HEAVING; This spontaneous report received from a patient concerned a 46 year old female. The patient's height, and weight were not reported. The patient's past medical history included possible COVID-19 infection in FEB-2020 (not confirmed). The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 042A21A, expiry: UNKNOWN) dose was not reported, 1 total, administered on left deltoid muscle on 05-APR-2021 13:00 for prophylactic vaccination. No concomitant medications were reported. On 05-APR-2021, the patient was fainted for about 5 minutes after vaccination and about 8 hours later, she experienced dry heaving, clammy chills, night sweats and wake up from sleep, feeling unwell, temperature raised a little, general fatigue and headache. It was reported that, the clammy chills subsided by 07-APR-2021 after patient took Tylenol (paracetamol), but then later reported that it was still ongoing. On 09-APR-2021, the patient experienced severe dizziness, more temperature raising, further nausea and stomach upset. On 10-APR-2021, the patient experienced shortness of breath, heart palpitations, increased nausea and stomach upset. It was reported that the patient had visited emergency room at hospital at around 2 PM on the same day for shortness of breath, heart palpitations, increased nausea and stomach upset, dry heaving and temperature increase. The symptoms that were ongoing included the night sweats which wake from sleep, nausea and stomach upset and other symptoms were resolved. On 10-APR-2021, the patient's normal laboratory data included complete blood count (CBC), differential white blood cell count, electrocardiogram, fragment D dimer, glomerular filtration rate, glucose, liver function test, magnesium, metabolic function test, NT-proBNP, and troponin T. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from fainted on 05-APR-2021, severe dizziness, shortness of breath, heart palpitations, dry heaving, feeling unwell, and temperature raised a little on APR-2021, and general fatigue, and</p> |

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headache on 07-APR-2021, and had not recovered from clammy chills, nausea, stomach upset, and night sweats and wake up from sleep. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210420859 - covid-19 vaccine ad26.cov2.s - fainted. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.

FAINTING; This spontaneous report received from a consumer via a company representative concerned multiple patients. The patient's weight, height and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration not reported, batch number: Unknown) frequency one total, dose was not reported, administered on 07-APR-2021 for prophylactic vaccination.. No concomitant medications were reported. The batch number was not reported. Per procedure, no follow-up will be requested for this case. The consumer reported about the article which said that multiple people on 07-APR-2021 experienced fainting after receiving the vaccine. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from fainting on unspecified date in APR-2021. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to 20210420898.; Sender's Comments: V0: 20210421103-covid-19 vaccine ad26.cov2.s-fainting. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.

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| 1236067 | 4/21/2021 | NJ | 38 | M | 4/1/2021 | | SWOLLEN FACE; BAD RASH ALL OVER BODY; PASSED OUT; This spontaneous report received from a patient concerned a 38 year old male. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 041A21A, expiry: UNKNOWN) dose was not reported, 1 total, administered on left arm on 01-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On 01-APR-2021, the patient passed out and had no symptoms until seven days. On 07-APR-2021, the patient experienced pretty bad rash. On 08-APR-2021, the patient experienced swollen face and rash all over body which made him to visit an urgency clinic where he was prescribed with prednisone for rash. The patient visited doctor or healthcare professional office for events passed out, swollen face, and bad rash all over body and emergency room or department or urgent care for events swollen face, and bad rash all over body. It was reported that, the medication had not eradicated the symptoms but only calmed them down. According to the patient, if he had stop taking the medications the symptoms would go back to the same intensity as before. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from passed out on 01-APR-2021, and had not recovered from swollen face, and bad rash all over body. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210422310-covid-19 vaccine ad26.cov2.s -Passed out. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event. |

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| 1236128 | 4/21/2021 | | | M | | 3/1/2021 | <p>FAINTED; This spontaneous report received from a consumer concerned a male of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported) dose was not reported, administered on 17-MAR-2021 for prophylactic vaccination. The batch number was not reported. We are unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date in MAR-2021, the patient fainted approximately after 35 hours of being vaccinated. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from fainted on MAR-2021. This report was serious (Other Medically Important Condition).; Sender's Comments: V0:covid-19 vaccine ad26.cov2.s-fainted. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.</p> |
| 1236317 | 4/21/2021 | VA | 40 | F | | 4/3/2021 | <p>4/3/2021 Fainted within 5 minutes of receiving vaccine. Taken by ambulance to hospital. Have been sick with chills, severe shaking, panic attacks, sweating, since then (almost 3 weeks).</p> |

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| 1235780 | 4/21/2021 | | 43 | M | 4/1/2021 | 4/1/2021 | passed out; body temperature rose fast; sweating; blood pressure and ECG went low; blood pressure and ECG went low; This is a spontaneous report received via COVAES from a non-contactable consumer (patient). A 43-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, first dose via an unspecified route of administration, administered in right arm on 01Apr2021 10:00 (Lot Number: EP7534) as single dose for covid-19 immunisation. Medical history included allergies to penicillin. Concomitant medication(s) included diphenhydramine hcl. Side effects started about 4 minutes after getting the shot. At first, the body temperature rose fast, and patient started sweating. Then, patient passed out, and both blood pressure and ECG went low. Patient was sent to the emergency room and released a few hours later. AE resulted in Emergency room/department or urgent care. Treatment included fluids. No Covid prior vaccination. No Covid tested post vaccination. The event outcome for events was recovered. No follow-up attempts are possible. No further information is expected. |

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| 1235669 | 4/21/2021 | CA | 50 | F | 4/9/2021 | 4/10/2021 | episode of passed out; severe allergic reaction at injection site; injection arm is irritating; itchiness; injection arm is hurting; redness; swelling at injection site; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (episode of passed out) in a 50-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Blind (patient is legally blind in the left eye). Concomitant products included QUETIAPINE FUMARATE (SEROQUEL) for Seizure, PARACETAMOL (TYLENOL), CYCLOPENTAMINE, ESZOPICLONE, CLONAZEPAM (KLONOPIN), VITAMIN B COMPLEX and CYANOCOBALAMIN (VITAMIN B12 FORTE) for an unknown indication. On 09-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 10-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (episode of passed out) (seriousness criterion medically significant), VACCINATION SITE PRURITUS (itchiness), PAIN IN EXTREMITY (injection arm is hurting), IRRITABILITY (injection arm is irritating), INJECTION SITE HYPERSENSITIVITY (severe allergic reaction at injection site), VACCINATION SITE ERYTHEMA (redness) and VACCINATION SITE SWELLING (swelling at injection site). At the time of the report, LOSS OF CONSCIOUSNESS (episode of passed out) outcome was unknown and VACCINATION SITE PRURITUS (itchiness), PAIN IN EXTREMITY (injection arm is hurting), IRRITABILITY (injection arm is irritating), INJECTION SITE HYPERSENSITIVITY (severe allergic reaction at injection site), VACCINATION SITE ERYTHEMA (redness) and VACCINATION SITE SWELLING (swelling at injection site) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 10-Jan-2021, SARS-CoV-2 test positive: Positive. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Concomitant medication not reported. Treatment medication not provided.; Sender's Comments: Based on the current available information and temporal association between |

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| | | | | | | | the use of the product and the start date of these events, a causal relationship cannot be excluded. |
| 1236338 | 4/21/2021 | MA | 33 | M | 4/20/2021 | 4/20/2021 | Systemic: Confusion-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Severe, Systemic: Nausea-Mild, Systemic: Shakiness-Medium, Additional Details: Patient passed out about 3 minutes after receiving injection. He experienced mild to moderate trembling and became unresponsive for about a minute. I contacted 911 and they sent emergency response. Patient came to but was still lethargic and confused. First responders gave patient oxygen for several minutes, took vitals. Patient felt better after oxygen and declined to be taken to hospital. I monitored him for an additional 15 minutes after first responders left. He felt safe to drive home. |
| 1236341 | 4/21/2021 | TX | 17 | F | 4/20/2021 | 4/20/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild |
| 1235997 | 4/21/2021 | | | U | | 4/11/2021 | FAINTING; This spontaneous report received from a pharmacist via a company representative concerned a patient of unspecified age and sex. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration not reported, batch number: Unknown) frequency 1 total, dose was not reported, administered on 11-APR-2021 for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On 11-APR-2021, the patient experienced fainting after the vaccine was administered. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of fainting was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210420923-COVID-19 VACCINE AD26.CO2.S-fainting. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event. |

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| 1235714 | 4/21/2021 | VA | 19 | F | 3/23/2021 | 3/23/2021 | Nausea; Passed out; Felt a little dizzy; Mumbling, slurred speech; Developed a "static" feeling in her head; Eye shutting; Weakness in her left arm and leg; This is a spontaneous report from a contactable physician. A 19-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number/expiration date not reported), intramuscular on 23Mar2021 as single dose for COVID-19 immunization. Medical history included seasonal allergies from an unknown date. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, it was unknown if the patient has been tested for COVID-19. Concomitant medication included fluoxetine 60 mg taken for an unspecified indication, and an unspecified oral contraceptive. It was reported that on 23Mar2021, the patient received Pfizer Covid vaccine and felt a little dizzy on 11:00. She also started noting mumbling, slurred speech, passed out for about 15 (unspecified) after using the bathroom, developed a "static" feeling in her head and then noted her left eye shutting and then weakness in her left arm and leg. She was taken to the Emergency Room (ER) for evaluation. Symptoms lasted about 5 hours. She fell asleep in the ER. Symptoms seemed to clear by about 8:30 PM. She had lab and head CT at the hospital which were essentially normal. She felt okay the next day, but had some nausea for a couple days starting on the 3rd day on 25Mar2021. She stated she feels fine at the time of report in the Student Health Clinic and asked whether she should receive her second Pfizer dose scheduled on 20Apr2021. The adverse events result in Doctor or other healthcare professional office/clinic visit and Emergency room/department or urgent care. No treatment was received for the adverse events. The outcome of the event nausea was recovered in Mar2021, and for other events was recovered on 23Mar2021 20:30. Information about lot/batch number was requested.; Sender's Comments: Based on the information currently available and temporal association, a possible causal relationship cannot be excluded between the suspect product BNT162B2 and the reported event Passed out. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, |

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| | | | | | | including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate. | |
| 1236345 | 4/21/2021 | CA | 39 | M | 4/20/2021 | 4/20/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Medium, Additional Details: Pt fainted following second dose of vaccine, from sitting position, 20 minutes following vaccination. pt was back to normal about 30 minutes after fainting. pt declined any additional treatment or monitoring |
| 1238604 | 4/21/2021 | CA | 16 | M | 4/21/2021 | 4/21/2021 | Patient appeared pale, light headacheness, near fainting, tunnel vision, skin cold and clammy within 10 minutes of 2nd Pfizer injection. Patient rested on gurney and felt better. 1st BP taken at 10:45 BP 85/47, HR 56. 2nd BP taken at 10:55 BP 95/57, HR 61. Patient left the facility 30 minutes after his vaccination with stable condition. |

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| 1235512 | 4/21/2021 | FL | 71 | F | 2/3/2021 | 2/3/2021 | break her ankle; nausea; shaking chills; she fell and passed out; severe dizziness; did not feel her self as well for a couple of days; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (she fell and passed out) in a 71-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 028L20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No reported medical history.). On 03-Feb-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 03-Feb-2021, the patient experienced LOSS OF CONSCIOUSNESS (she fell and passed out) (seriousness criterion medically significant), DIZZINESS (severe dizziness), MALAISE (did not feel her self as well for a couple of days), NAUSEA (nausea) and CHILLS (shaking chills). On an unknown date, the patient experienced ANKLE FRACTURE (break her ankle). On 04-Feb-2021, LOSS OF CONSCIOUSNESS (she fell and passed out) had resolved, DIZZINESS (severe dizziness) and NAUSEA (nausea) outcome was unknown. At the time of the report, MALAISE (did not feel her self as well for a couple of days), ANKLE FRACTURE (break her ankle) and CHILLS (shaking chills) outcome was unknown. Not Provided No treatment information was provided. No relevant concomitant medications was provided. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested. |

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| 1235515 | 4/21/2021 | MI | 91 | F | 2/23/2021 | 2/23/2021 | 48 days post first vaccine and has not received the second dose; Weak; Underweight; Nausea; Dry Heaving; Upper Respiratory Infection; Fainted; Chills; This spontaneous case was reported by a consumer and describes the occurrence of SYNCOPE (Fainted) in a 92-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 023M20A) for COVID-19 immunisation. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event. On 23-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 23-Feb-2021, the patient experienced SYNCOPE (Fainted) (seriousness criterion medically significant) and CHILLS (Chills). On 16-Mar-2021, the patient experienced UPPER RESPIRATORY TRACT INFECTION (Upper Respiratory Infection), DYSPNOEA (Dry Heaving) and NAUSEA (Nausea). On 12-Apr-2021, the patient experienced INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (48 days post first vaccine and has not received the second dose), ASTHENIA (Weak) and UNDERWEIGHT (Underweight). On 23-Feb-2021, SYNCOPE (Fainted) had resolved. On 28-Feb-2021, CHILLS (Chills) had resolved. On 06-Apr-2021, UPPER RESPIRATORY TRACT INFECTION (Upper Respiratory Infection) had resolved. On 12-Apr-2021, INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (48 days post first vaccine and has not received the second dose) had resolved. At the time of the report, DYSPNOEA (Dry Heaving), ASTHENIA (Weak), UNDERWEIGHT (Underweight) and NAUSEA (Nausea) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, SARS-CoV-2 test: negative (Negative) Negative. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. She reported that she Fainted, and had chills, after the first vaccine. About 2-3 weeks after Vaccination she had an Upper Respiratory Infection with Negative COVID Test. She had Nausea, and Dry heaving since then. She feels Weak and Underweight. Today 12APR2021 and 48 days post first vaccine, She has not recovered from her upper respiratory infection. MD and Cardiologist told her to get the second vaccine. She wants to receive the second |

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vaccine but she would like to delay it more, until she feels 100% well. Patient had a pneumonia shot and Flu shot SEP2020.; Sender's Comments: This case concerns a 92-year-old female with a serious unexpected event of syncope, and nonserious unexpected upper respiratory tract infection, dyspnea, asthenia, underweight, inappropriate schedule of product administration and expected chills, nausea. Event onset the same day as first dose mRNA-1273. Events resolved. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.

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| 1235525 | 4/21/2021 | GA | 55 | F | 3/22/2021 | 3/22/2021 | <p>Passed out; Strain on heart; Confusion; Lethargic; Not feeling well; This spontaneous case was reported by an other health care professional and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out) in a 55-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 023M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Drug hypersensitivity, Hypertension and Anxiety. Concomitant products included AMLODIPINE BESILATE (NORVASC), CLONIDINE HYDROCHLORIDE (CLONIDIN), BUPROPION HYDROCHLORIDE (WELLBUTRIN), LEVOTHYROXINE and CEFIXIME (FLEXERIL [CEFIXIME]). On 22-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 22-Mar-2021, the patient experienced LOSS OF CONSCIOUSNESS (Passed out) (seriousness criterion medically significant), CARDIAC DISCOMFORT (Strain on heart), CONFUSIONAL STATE (Confusion), LETHARGY (Lethargic) and MALAISE (Not feeling well). At the time of the report, LOSS OF CONSCIOUSNESS (Passed out), CARDIAC DISCOMFORT (Strain on heart), CONFUSIONAL STATE (Confusion), LETHARGY (Lethargic) and MALAISE (Not feeling well) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. The patient followed up with doctor on 03/26/2021. No treatment medication was provided by the reporter. Patient reports after she left the site and drove about thirty minutes away, she had to pull into parking lot because she felt bad and confused. States she has passed out x2 that same day. Reported feeling lethargic and a strain on her heart.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. The patient's medical history of drug hypersensitivity, and anxiety remain as confounders.</p> |

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| 1235650 | 4/21/2021 | CO | 62 | F | 3/3/2021 | | <p>took 3 steps and just blacked out and passed out; coughing; black eye; didn't remember losing her consciousness; When she sneezes or cough her chest hurts; can't turn over while sleeping at night; she has not gotten back to normal; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (took 3 steps and just blacked out and passed out) in a 62-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 019B21A and 011A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No reported medical history.). On 03-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 01-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient experienced LOSS OF CONSCIOUSNESS (took 3 steps and just blacked out and passed out) (seriousness criterion medically significant), COUGH (coughing), EYE CONTUSION (black eye), MEMORY IMPAIRMENT (didn't remember losing her consciousness), CHEST PAIN (When she sneezes or cough her chest hurts), MOVEMENT DISORDER (can't turn over while sleeping at night) and FEELING ABNORMAL (she has not gotten back to normal). At the time of the report, LOSS OF CONSCIOUSNESS (took 3 steps and just blacked out and passed out), COUGH (coughing), EYE CONTUSION (black eye), MEMORY IMPAIRMENT (didn't remember losing her consciousness), CHEST PAIN (When she sneezes or cough her chest hurts), MOVEMENT DISORDER (can't turn over while sleeping at night) and FEELING ABNORMAL (she has not gotten back to normal) had not resolved. Not Provided Treatment information was provided as tylenol. No concomitant information was provided. Patient mentioned she is a vegan no meat, dairy, does not take pills. Woke up next morning, she had a black eye, her reading glasses were broken, didn't remember losing her consciousness. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested. This</p> |

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1235659 4/21/2021

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4/13/2021

4/19/2021

case was linked to MOD-2021-076632 (Patient Link). Reporter did not allow further contact; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested.

HISTORY OF PRESENT ILLNESS: 21 yo F p/w midsternal chest burning since 2200 last night. Acute, sharp/burning, constant, mild. No similar prior pain. Reports associated subjective dyspnea. Denies fever, chills, nausea, vomiting, syncope, palpitations, back pain, abdominal pain, weakness/numbness. Patient states she received the J&J COVID vaccine 3 days ago, and had chills, fatigue and body aches that resolved the following day. She has since been asymptomatic.

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| 1235667 | 4/21/2021 | IL | 82 | M | 3/18/2021 | | <p>Covid-19 Pneumonia; Fainted twice and hit his head a few times/Oxygen level went below 53; Hit his head a few times from fainting; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of COVID-19 PNEUMONIA (Covid-19 Pneumonia) and SYNCOPE (Fainted twice and hit his head a few times/Oxygen level went below 53) in an 82-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (no medical history was reported). On 18-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced COVID-19 PNEUMONIA (Covid-19 Pneumonia) (seriousness criterion hospitalization) and SYNCOPE (Fainted twice and hit his head a few times/Oxygen level went below 53) (seriousness criterion hospitalization). an unknown date, the patient experienced HEAD INJURY (Hit his head a few times from fainting). The patient was hospitalized for 15 days due to COVID-19 PNEUMONIA and SYNCOPE. At the time of the report, COVID-19 PNEUMONIA (Covid-19 Pneumonia) outcome was unknown and SYNCOPE (Fainted twice and hit his head a few times/Oxygen level went below 53) and HEAD INJURY (Hit his head a few times from fainting) had resolved. Not Provided DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In March 2021, Oxygen saturation: below 53% (Low) below 53%. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Concomitant medications and medical history were not reported. The patient felt that he had COVID-19 before he took the vaccine because his family members had it as well. Company comment:Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p> |

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| 1235674 | 4/21/2021 | MA | 65 | F | 3/8/2021 | 4/5/2021 | <p>Passed out and broke foot; broke foot; lightheaded; Massive headache and couldn't lift her head up; Not feel good; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out and broke foot) in a 65-year-old female patient who received mRNA-1273 (batch nos. 025B21A and 036A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No medical history reported). On 08-Mar-2021, the patient received first dose of mRNA-1273 (Intramuscular) 1 dosage form. On 05-Apr-2021, received second dose of mRNA-1273 (Intramuscular) dosage was changed to 1 dosage form. On 05-Apr-2021, the patient experienced FEELING ABNORMAL (Not feel good). On 06-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (Passed out and broke foot) (seriousness criteria medically significant), FOOT FRACTURE (broke foot), DIZZINESS (lightheaded) and HEADACHE (Massive headache and couldn't lift her head up). At the time of the report, LOSS OF CONSCIOUSNESS (Passed out and broke foot), FOOT FRACTURE (broke foot), DIZZINESS (lightheaded) and HEADACHE (Massive headache and couldn't lift her head up) had not resolved and FEELING ABNORMAL (Not feel good) outcome was unknown. Not Provided For mRNA-1273 (Intramuscular), the reporter did not provide any causality assessments. Concomitant medication included medication for thyroid. Treatment information included for an events Advil and Aleve. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p> |

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| 1235685 | 4/21/2021 | OH | 62 | F | 3/9/2021 | 4/6/2021 | <p>Dizzy; Fever 101 degrees Fahrenheit; Nausea; Body aches; Seizure; Symptoms like the flu; Felt like she was going to faint; This spontaneous case was reported by a non-health professional (subsequently medically confirmed) and describes the occurrence of SEIZURE (Seizure) in a 62-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 016B21A and 029A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No medical history provided.). On 09-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 06-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 06-Apr-2021, the patient experienced SEIZURE (Seizure) (seriousness criterion medically significant), INFLUENZA LIKE ILLNESS (Symptoms like the flu), DIZZINESS (Dizzy), PYREXIA (Fever 101 degrees Fahrenheit), NAUSEA (Nausea) and MYALGIA (Body aches). On an unknown date, the patient experienced PRESYNCOPE (Felt like she was going to faint). At the time of the report, SEIZURE (Seizure), INFLUENZA LIKE ILLNESS (Symptoms like the flu), PRESYNCOPE (Felt like she was going to faint), DIZZINESS (Dizzy), PYREXIA (Fever 101 degrees Fahrenheit), NAUSEA (Nausea) and MYALGIA (Body aches) outcome was unknown. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. This case was linked to US-MODERNATX, INC.-MOD-2021-054366 (E2B Linked Report). This case was linked to MOD-2021-077998, MOD-2021-077998 (Patient Link).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. US-MODERNATX, INC.-MOD-2021-054366:</p> |

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| 1235774 | 4/21/2021 | MO | | M | 4/6/2021 | 4/6/2021 | fainted/passed out; patient passed out; This is a spontaneous report from a contactable pharmacist reporting same events for suspect products for 4 patients. This report is for the 4th patient. Follow-up (06Apr2021) was received from same reporter and processed together with initial information. A male patient of an unspecified age received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Lot Number: ER8729; Expiration Date: 20Jul2021), via an unspecified route of administration on 06Apr2021 as SINGLE DOSE for covid-19 immunization. The patient medical history was not reported. Concomitant medication(s) included saline [sodium chloride] (SALINE [SODIUM CHLORIDE]). The patient reported that after administering the Covid 19 vaccine on 06Apr2021, within about 20 minutes there were 4 patients with reactions. The patient experienced fainting/passed out on an unspecified date and patient passed out on 06Apr2021. Three people fainted and one had seizure after receiving the first dose of the Pfizer-BioNTech Covid-19 Vaccine. These patients had just received the Covid 19 vaccine and were still being watched within the 15-minute post vaccination time. All 4 patients received the Covid 19 vaccine from the same lot number but not from the same vial. Seriousness of events was medically significant. The outcome of events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Considering close temporal association, a possible contributory role of bnt162b2 to the events fainted and passed out cannot be completely excluded. Relevant medical history and details of clinical course are missing for further assessment. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate. |

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| 1235717 | 4/21/2021 | AZ | 32 | M | 3/31/2021 | 3/31/2021 | Fainting; Swelling of arms and hands; Feeling hot; Hives on the face and limbs; Shortness of breath; This is a spontaneous report from a contactable consumer (patient). A 32-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection) (at 32 years of age), dose 1 via an unspecified route of administration, administered in arm left on 31Mar2021 14:30 (Batch/Lot Number: EW0150) as a single dose for COVID-19 immunisation. Medical history was None. The patient's concomitant medications were not reported. The patient did not receive any other vaccine within 4 weeks prior to the covid vaccine. He was not diagnosed with Covid-19 prior to vaccination. He has not been tested for covid since the vaccination. He had no allergies to medications, food, or other products. The patient experienced swelling of arms and hands, feeling hot, hives on the face and limbs. He also had shortness of breath and fainting. The events started on 31Mar2021 18:45 with outcome of recovered with sequelae. Therapeutic measures were taken as a result of the events as the patient was administered with IV saline, steroids and antihistamine. The events resulted to Emergency room/department or urgent care. Information on the lot/batch number has been requested. |
| 1235730 | 4/21/2021 | FL | 50 | F | 4/8/2021 | 4/9/2021 | After approximately 8 hours, initially very lethargic and expected left arm pain at injection site. A few hours later developed Severe headache, light headedness nearly fainting, motion sickness, mild cough, general fogginess, tingling of head (possibly nerves & related to severe headache). Left arm pain & lethargy are not active. |

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| 1235739 | 4/21/2021 | NY | 47 | F | 2/3/2021 | 3/17/2021 | positive COVID test; positive COVID test; felt dizzy and fainted; Blacked out several weeks ago while going to bathroom; felt dizzy and fainted/light-headed; abnormal EKG; got head injury; Had a weird rash on elbows; headaches; concussion; sore throat; Started feeling more unwell several days ago; been fatigued for weeks; coughing with phlegm; mouth sores; laryngitis; muscle aches; This is a spontaneous report from a contactable consumer (patient). A 47-year-old female patient (non-pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK9231), via an unspecified route of administration, administered in right arm on 14Jan2021 at 08:30 at a single dose, second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL8982), via an unspecified route of administration, administered in right arm on 03Feb2021 at a single dose for COVID-19 immunisation at hospital. Medical history included known_allergies Penicillin, sulfur, NSAIDs. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, patient was not diagnosed with COVID-19. The patient received medications within 2 weeks of vaccination. Concomitant medications included gabapentin, trazodone, fluoxetine hydrochloride (PROZAC), oxymetazoline hydrochloride (CLARITIN ALLERGIC). Since the vaccination, patient has been tested for COVID-19. After second dose, but before patient left waiting area, on 17Mar2021, felt dizzy & fainted. Taken to ER. Had an abnormal EKG. Followed up with heart doctor. Blacked out several weeks ago while going to bathroom & got head injury. Husband and 2 sons tested positive for COVID mid March. Had a weird rash on elbows, been having headaches. Went to doctor about rash; not sure of cause. Told representative several times during contact updates for sons; representative said patient can't get COVID if she has been vaccinated. Went to doctor about head injury (diagnosed concussion on 17Mar2021. Supposed to see cardiologist and orthopedist for follow up but need to postpone due to positive COVID test on 17Mar2021. Started feeling more unwell several days ago; been fatigued for weeks. Symptoms included coughing with phlegm, headache, light-headed, mouth sores, sore throat, laryngitis, extreme fatigue, muscle aches. Positive rapid test 05Apr2021; PCR test on 05Apr2021; waiting |

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| 1235740 | 4/21/2021 | CA | 60 | F | 3/4/2021 | 3/4/2021 | <p>for results. Treatment received for the adverse events. The outcome of the event positive COVID test was unknown and patient was recovering from all other events.</p> <p>I fainted; blood clots; light headed; I lost all color and my skin was wet and clammy; I lost all color and my skin was wet and clammy; This is a spontaneous report from a contactable consumer. A 60-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) lot number: EN6199, via an unspecified route of administration, administered in right arm on 04Mar2021 15:00 as single dose for Covid-19 immunisation. Medical history included known allergies to Atovaquone/proguanil. Concomitant medications were not reported. On 04Mar2021, approximately 10 minutes post vaccine, the patient fainted in the waiting area. She was told by a witness that she fainted two times. EMTs administered an IV and did a simple EKG. The patient lost all color and her skin was wet and clammy. EMTs were concerned about her heart and transported her to the ER where she had a full EKG and lab work for D-Dimer to consider blood clots. The patient has remained lightheaded for weeks after the vaccine. The outcome of the events was recovered with sequelae.</p> |

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| 1235741 | 4/21/2021 | NC | 46 | F | 4/1/2021 | 4/1/2021 | <p>passed out and went completely unconscious; Nauseous; felt weak like someone sucked all her energy out; in between going unconscious and coming to, she threw up and peed on herself and had shaking and chills; in between going unconscious and coming to, she threw up and peed on herself and had shaking and chills; in between going unconscious and coming to, she threw up and peed on herself and had shaking and chills; in between going unconscious and coming to, she threw up and peed on herself and had shaking and chills; in between going unconscious and coming to, she threw up and peed on herself and had shaking and chills; This is a spontaneous report from a contactable consumer (patient). A 46-year-old female patient received bnt162b2 (BNT162B2), dose 1 via an unspecified route of administration at the age of 46-years-old, administered in Arm Left on 01Apr2021 13:30 (Lot Number: ER8734) as single dose for COVID-19 immunization. Medical history included ongoing High Blood Pressure, hyperthyroidism from 28Mar2021 and ongoing, allergy to Cheese and penicillin. Everyone in her family has done fine with the vaccine except her. Concomitant medications included thiamazole (METHIMAZOLE) taken for hyperthyroidism from 28Mar2021 and ongoing; atenolol, chlorthalidone (ATENOLOL AND CHLORTHALIDONE) taken for hypertension from an unspecified start date and ongoing; amlodipine (AMLODIPINE) taken for hypertension from an unspecified start date and ongoing. On Thursday 01Apr2021, the patient had her first shot and she stayed for 30 minutes. After she was allowed to leave, she passed out and went completely unconscious and she was rushed to the ER. She sat for the 30 minutes, then got to her car and it took 10 minutes to get to department store and with in 7 minutes of being at department store she started feeling nauseous then came the fatigue and she felt nauseous and felt like she was going to pass out so she sat down, she didn't know what was going on. It started with her feeling nauseous and then she started to feel weak like someone sucked all her energy out. She states in between going unconscious and coming to, she threw up and peed on herself and had shaking and chills. The EMS took her to the ER. The adverse events occurred on 01Apr2021 14:30 (as reported). The ER let her go home Thursday night. They gave her an IV and did lab work and the lab work came back fine. It was a combination of her meds and the vaccine or it was just the vaccine. Her primary doctor said it was the vaccine.</p> |

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She is scheduled 22Apr2021 for her second one and she is calling to see if there is any advice or anything she needed to do for the second shot. Her doctor told her that when she takes it, she needs to be close to the ER so a doctor can monitor her. Treatment for events included IV fluids to help from being dehydrated and throwing up, Emergency Room, possibly Benadryl. The events required a visit to Emergency Room on 01Apr2021 and to the Physician Office on 05Apr2021. The outcome of the events passed out and went completely unconscious and felt weak like someone sucked all her energy out was recovered on 02Apr2021 while for the rest of the events was recovered on 01Apr2021. The events were considered as serious (medically significant). No Prior Vaccinations (within 4 weeks), no adverse events following prior vaccinations. Information on Lot/Batch number was available. Additional information has been requested.

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| 1235758 | 4/21/2021 | FL | 40 | F | 3/16/2021 | 3/16/2021 | Numbness in right leg from the hip all the way down. A few days later, left leg went numb from the knee down. A week later, right arm went numb; This is a spontaneous report from a contactable consumer (patient herself). A 40-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; Lot number: EW6206), via an unspecified route of administration on 16Mar2021 10:00 AM at single dose in left arm for COVID-19 immunization at hospital. The patient medical history included asthma, syncope and had allergy to sulfa. Patient was not pregnant at time of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to the vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. Concomitant medications included loratadine (CLARITINE), and Multivitamin within 2 weeks of vaccination. On 16Mar2021 18:00, the patient experienced numbness in right leg from the hip all the way down, a few days later, left leg went numb from the knee down. a week later, right arm went numb, and patient was hospitalized for 1 day. The patient did not receive any treatment for the event. The event resulted in Emergency room/department or urgent care. The outcome of the event was not recovered. Information on Lot/Batch number was available. Additional information has been requested |

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| 1235768 | 4/21/2021 | CA | 48 | F | 3/30/2021 | 3/31/2021 | became faint and passed out onto the floor; hit my chin and jaw so hard it was bleeding; hit my chin and jaw so hard it was bleeding and obviously very sore and swollen; hit my chin and jaw so hard it was bleeding and obviously very sore and swollen; nauseous; light headed; chills; flu like symptoms; arm felt sore/arm at site of injection remains sore; at site of injection remains sore and itchy; This is a spontaneous report from a contactable consumer (patient). A 48-year-old female patient received BNT162B2 (lot number: ER8733) first dose on 30Mar2021 12:30 PM on left arm at single dose for COVID-19 immunisation. Medical history included IDDM (Type 1 diabetes mellitus) and MS (Multiple sclerosis). Patient is not pregnant. No other vaccine in four weeks. No known allergies. Concomitant medications in two weeks included Insulin for IDDM, dimethyl fumarate (TECFIDERA) for MS. Had vaccine at 12:30pm. At 3am (31Mar2021), arm felt sore and felt both nauseous and light headed as well as having chills and flu like symptoms. Went to bathroom and on way back to bed, became faint and passed out onto the floor. Patient hit chin and jaw so hard it was bleeding and obviously very sore and swollen. It's been nearly a week since that incident and arm at site of injection remains sore and itchy. She still feel nauseous at times and her face is still swollen from falling onto the floor and passing out. She was now fearful of having the second dose on 20Apr2021 as due since her reaction to 1st dose was so severe. The outcome of the events was recovering. No treatment for the events. No Covid tested post vaccination. |

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| 1235773 | 4/21/2021 | MO | | M | 4/6/2021 | 4/6/2021 | fainted/passed out; fainting/passed out; This is a spontaneous report from a contactable pharmacist. A contactable physician reported similar events for 3 patients. This is one of 3 reports. A male patient of an unspecified age received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Formulation: Solution for injection, Lot/Batch number: ER8729; Expiration Date: 20Jul2021), via an unspecified route of administration on 06apr2021 as SINGLE DOSE for covid-19 immunization and saline [sodium chloride] via an unspecified route of administration from on unspecified date (Batch/Lot Number: 6023228) for an unspecified indication. The patient medical history and concomitant medications were not reported. The patient had just received the Covid 19 vaccine and was still being watched within the 15-minute post vaccination time. On 06Apr2021, the patient was fainting and passed out had some issues with vaccines in the past. HCP wants to know if there have been any reports of having these reactions associated with the specific lot number: ER8729. The events considered as medically significant with outcome unknown.; Sender's Comments: Based on the temporal association, a possible contributory role of vaccination with BNT162B2 to the reported events fainting and passed out cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified. |

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| 1235495 | 4/21/2021 | MA | | F | 3/26/2021 | 3/27/2021 | extreme dizziness; fainted; unable to get a reading because the pressure was so low; diarrhea; felt like I was hallucinating; sweating; shivering; vomiting; nausea; This spontaneous case was reported by a consumer and describes the occurrence of SYNCOP (fainted) in a 40-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 011J20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No reported medical history). On 26-Mar-2021 at 1:45 PM, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 27-Mar-2021, the patient experienced HYPOTENSION (unable to get a reading because the pressure was so low), DIARRHOEA (diarrhea), FEELING ABNORMAL (felt like I was hallucinating), HYPERHIDROSIS (sweating), CHILLS (shivering), VOMITING (vomiting) and NAUSEA (nausea). On 27-Mar-2021 at 1:30 AM, the patient experienced SYNCOP (fainted) (seriousness criterion medically significant) and DIZZINESS (extreme dizziness). 27-Mar-2021 at 1:30 AM, the patient experienced LOSS OF CONSCIOUSNESS (lost consciousness) (seriousness criterion medically significant). At the time of the report, SYNCOP (fainted), DIZZINESS (extreme dizziness), DIARRHOEA (diarrhea) and VOMITING (vomiting) had resolved and HYPOTENSION (unable to get a reading because the pressure was so low), FEELING ABNORMAL (felt like I was hallucinating), HYPERHIDROSIS (sweating), CHILLS (shivering) and NAUSEA (nausea) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 27-Mar-2021, Blood phosphorus: 0.6 mg/dl and 4.7 mg/dl. On 27-Mar-2021, Electrocardiogram: abnormal (abnormal) elongated heart rhythm (Arrhythmias) and normal normal. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Treatment for the events included IV fluids and oral phosphorus.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |

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| 1238209 | 4/21/2021 | CO | 16 | M | 4/21/2021 | 4/21/2021 | patient saw black stars in his eyes and fainted. Fainted for about 5 seconds and came back very pale white. Has history of vasovagal reactions post injections. After laying down on flat surface for about 20 minutes with water and chocolate bar he started feeling better and his face got more color. |
| 1237460 | 4/21/2021 | IN | 28 | M | 4/21/2021 | 4/21/2021 | PATIENT RECEIVED VACCINE THEN BECAME DIZZY WHEN ENTERING THE OBSERVATION AREA. WAS LOWERED TO THE FLOOR WITH ASSISTANCE FROM ANOTHER PATIENT. FAINTED BUT RECOVERED WITHIN 10 SECONDS. NURSES MONITORED FOR EXTENDED PERIOD OF TIME. |
| 1237623 | 4/21/2021 | CA | 46 | M | 4/20/2021 | 4/20/2021 | Patient reported feeling feverish and reported passing out in the evening after receiving the 2nd dose of vaccine in the morning. He cut his face when he passed out and went to hospital for treatment. |
| 1237645 | 4/21/2021 | GA | 41 | M | 4/21/2021 | 4/21/2021 | patient reported he has previously fainted immediately following vaccine. His wife brought an ice pack and water. After vaccination i sat with pt a few minutes to make sure he was feeling well and ready to move to a chair in front of the pharmacy to sit for 30 minutes and make sure he is feeling well. I notified my manager that pt in front has fainted before and he kept a close eye on him. I was administering shot to the next pt and heard a sound. I left vaccination booth and saw pt on the ground. I placed his legs/feet in front of him and his wife held his head and ice pack. Our pt reported that he did not hit or hurt his head and did not need other assistance. we monitored the patient an additional 20 minutes and he was feeling well, vital signs good and accompanied by his wife. |

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| 1237672 | 4/21/2021 | CT | 84 | M | 2/10/2021 | 4/13/2021 | Presents with dyspnea for a few days. Pt was tested positive for COVID 19 one wk ago (outside health system). Pt also c/o L arm numbness. Pt denied f/c, CP, n/v/d, abd pain, HA, syncope. In ED, Pt was found to have hypoxic O2 sat at 89% and was put 2L NC. Pt got loading dose of ASA and dexamethasone (7 day course), completed 5 day course of remdesivir and received tocilizumab due to increased oxygen requirements. Pt also has mildly elevated troponin and cardiology was consulted in ED. St elevation noted 4/20 AM, heparin bolus given for acute coronary syndrome and ticagrelor LD. Left heart cath on 4/20/21 showed 3 vessel disease but due to difficulty revascularizing LAD in setting of worsening K+, Bicarb, S no further revasc attempts were made. Upon return to MICU, pt found to be hypotensive and bradycardic. PEA arrest. Family contacted during code and in agreement to transition to comfort measures. |
| 1237710 | 4/21/2021 | | 24 | F | 4/21/2021 | 4/21/2021 | Patient denied symptoms during 15-minute required observation period. When she got up from chair to pick up vaccination card, endorsed near-syncope and bilateral lower extremity weakness like "she felt she was walking in sand." Denies visual symptoms, oral swelling, dyspnea, pruritis, nausea. Patient sat back down and was attended to. She was noticeably nervous (hand/leg shaking). SpO2 99%, HR 62. Patient endorses history of anxiety that is treated with beta blocker. Patient felt back to her baseline after approximately 15 additional minutes of rest and sipping on water. Trial of ambulation at that time with complete resolution of symptoms. She was cleared to return to work with return precautions. |
| 1237779 | 4/21/2021 | IL | 30 | M | 4/14/2021 | 4/14/2021 | Patient experienced syncope and possible seizure post vaccination, transported to hospital via ambulance |
| 1237813 | 4/21/2021 | PA | 32 | U | 4/21/2021 | 4/21/2021 | Patient had a vasovagal reaction. Became diaphoretic, had syncope. Was alert and oriented within less than 30 seconds. Vitals remained stable throughout. Initially 120/80 pulse of 74 pulse ox 98%. |

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| 1238024 | 4/21/2021 | NY | 30 | F | 4/20/2021 | 4/20/2021 | Patient was given the Moderna Covid 19 vaccine, sometime between 9:30 and 9:45am with no incident. At around 10am the pharmacist was called to the front of the store to assist a patient who has fainted. The pharmacy assisted the patient into a chair, by this time the patient was alert and talking. It was reported by another customer that patient was unconscious on the floor when he found her. The decision was made to call an ambulance. The EMTs took patient blood pressure which was low, for the safety of patient and her unborn baby, it was decided the patient would be taken to the hospital for further evaluation. A phone call was placed to the patient the next day but there was no answer. |
| 1237308 | 4/21/2021 | TX | 27 | F | 4/21/2021 | 4/21/2021 | PATIENT FAINTED AFTER THE VACCINATION |
| 1238201 | 4/21/2021 | TX | 42 | F | 2/4/2021 | 4/7/2021 | On 4/7/21 patient was unable to go to work due to fatigue. She was sent home from a free-standing ER who reported she most likely had a viral illness. She passed out getting into the bathtub and presented to Hospital. At this hospital her chief complaints were excessive fatigue, myalgia, fever, chills. She was diagnosed with TTP with portal venous thrombosis. She was refractory to high dose steroids, plasmapheresis, and rituximab x2. She is now set to begin treatment with caplacizumab and is currently on day 12 of hospitalization. |
| 1238351 | 4/21/2021 | | 50 | M | 4/20/2021 | 4/20/2021 | Patient passed out after receiving first dose of Pfizer COVID19 vaccine. He did not hit the ground as someone else caught him. His BP was taken and read 70/59 originally and then came back up to 144/83 after laying on floor with feet on chair. Patient said that this has happened before when giving blood or dealing with needles. |

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| 1238249 | 4/21/2021 | CA | 17 | F | 4/6/2021 | 4/6/2021 | emale client received her first dose of Covid Vaccine (Pfizer, Lot # ER8729, Expiration date: 07/31/2021) at 1132. This minor client, accompanied by her mother proceeded to the observation room for her 15 minute wait period. Co-lead RN, was present in the observation room assessing another client. At 1137 this client's mother loudly voiced from the back of the room, "she's feeling dizzy" and co-lead observed client was hanging her head. Co-lead and EMT1 hurried to her side, and client stated she was feeling lightheaded and dizzy and was suddenly pale and diaphoretic. EMT1 immediately transferred her from chair to floor with full assistance to prevent a fall/injury. Client was placed in trendelenburg position by elevating feet and placing them on the chair. Client was unresponsive for about 15 seconds until she regained consciousness and returned to baseline mentation. Client verbalized she "blacked out" and did not remember being placed on the floor. Client denied pain and respiratory distress. EMT1 called 911 at 1138. Client and her mother deny she has any medical issues, allergies, medications, or previous incidence of syncope. At 1145, first set of vitals taken by EMT1 indicate hypotension and bradycardia as follows: BP 68/44, HR 58, and RR 16. At 1145 paramedics arrived and assumed care after receiving report from EMT2. At 1150 medics took VS with BP 70/50, HR 54, and blood glucose 95, and determined they would start an IV to administer a 500cc bolus for dehydration and to improve BP. Client was also placed on 2L O2 for comfort, no desat noted. At 1200, medics advised client's mother and co-lead they would transport client to the Hospital for further evaluation. Medics departed at 1205 to transport client to the hospital. |
| 1238859 | 4/21/2021 | KS | 18 | M | 4/21/2021 | 4/21/2021 | Patient had syncope episode approximately 5-10 minutes after IM vaccine given- no long term adverse effect anticipated |

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| 1239128 | 4/21/2021 | HI | 17 | F | 4/20/2021 | 4/20/2021 | Per recovery RN notes: "At approximately 0841, patient stated feeling dizzy. Mother noted with patient. Patient anxious. Pt loss of consciousness for approximately 10 seconds. Rapid response called. Patient regained consciousness. Patient with emesis x1. Vital signs stable BP 109/70 HR 64. SpO2 at 99 on room air. Rapid response team arrived at scene. MD assessed patient. Per mother, patient has a history of syncope after vaccinations. Per MD, ok to go home once stable. Patient noted to leave facility at 0904, in stable condition." |
| 1239172 | 4/21/2021 | HI | 18 | F | 4/12/2021 | 4/12/2021 | Patient: Female, Per RN notes: "1610 vaccinated L deltoid, Reaction time: 1611 Fainted, Chin lift and head support, Patient recovered BP 82/55, HR 73 at 1614. Slight nausea. After vaccine administered, patient stated she "didn't feel good". Encouraged patient to deep breathe and wiggle toes. Noted pale in color and she lost consciousness. Noted breathing, still rapid response called. Patient awake, alert, transferred patient to gurney. Patient agreed to go/be transferred to the ER with security and ER nurse. ~~ |
| 1239241 | 4/21/2021 | WI | 17 | F | 4/20/2021 | 4/20/2021 | Patient received her 2nd dose of COVID (Pfizer). She walked out of the immunization room to wait in the store, made it about 2 aisles over, and fainted. Patient's father and the Pharmacist immediately got to her side. She came to within less than 1 minute. In the meantime EMS was called and the Pharmacist waited with the patient until they arrived. EMS looked over the patient and patient was able to leave on her own after waiting out the nausea and dizziness that had occurred. Patient also reported a headache which was most likely from hitting her head on the way down. |
| 1239445 | 4/21/2021 | CA | 18 | M | 4/21/2021 | 4/21/2021 | After the patient is given 1 st dose of Moderna and sat in the chair for 10 to 15 min. When he came to pharmacy register to make 2nd appointment, he fainted and hit his head on the floor. No bleeding found. He looked pale and was sweating, no redness or SOB. Applied a cold compress to patients face, neck and wrist. BP is normal 107/58. Pt is alerted and oriented. Store management called 911 and EMT came to monitor patient. Patient feel better and doesn't want to ER. |

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| 1236549 | 4/21/2021 | IN | 21 | F | 4/19/2021 | 4/19/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: she became semi unresponsive, was dizzy and sat for atleast 45 minutes |
| 1238252 | 4/21/2021 | CT | 44 | F | 4/10/2021 | 4/11/2021 | Approximately 2 hours after the vaccination I felt very minor side effects (headache / soreness on injection site). The next morning I felt the more intense side effects (fever of 101.1, chills, fever, extreme sweat, loss of appetite, body aches and fatigue). While the majority of the side effects have passed I still have no appetite. I am a very healthy adult that does strength training 4x a week, I typically eat and snack every 3 hours. Since the vaccination day I have no desire to eat and I am down to 2 meals (breakfast and dinner). I am also experiencing headaches and dizziness but this could be from the lack of nutrients. Because I feel dizzy I am forcing myself to eat as I almost fainted during a morning workout and had shortness of breath. This particular morning I had coffee, a protein shake and a banana prior to my workout. I have not read or seen any additional information on the loss of appetite lasting this long and I am getting concerned |
| 1238154 | 4/21/2021 | TN | 54 | F | 3/24/2021 | 3/26/2021 | nausea, fever, myalgias, headache, syncope. Patient is treated with normal saline fluids. |
| 1236810 | 4/21/2021 | OK | 34 | M | 4/20/2021 | 4/20/2021 | Client was moved to observation for 15 minute wait time. Client was anxious about receiving vaccine. While sitting in chair in observation, client fainted and fell to the ground. Client was sweating and loss control of bladder and bowel. Client bent big toe nail back during fall and was bleeding. Client was moved to another area and vitals were checked once client came to, vital signs stable. Ambulance was called but client declined treatment. |

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| 1236573 | 4/21/2021 | CA | 27 | M | 4/20/2021 | 4/20/2021 | Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Mild, Systemic: Chills-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Additional Details: Patient was sitting for 15 minute observation when I heard a thump outside. Came out to patient face down on the floor. Immediately woke up when I called out, but was unaware he had fainted. Gave patient water and gatorade and continued to monitor for 40 minutes. Patient continued to feel clammy and lightheaded but eventually felt okay to go home. |
| 1236585 | 4/21/2021 | AL | 23 | F | 4/14/2021 | 4/14/2021 | Systemic: Fainting / Unresponsive-Severe, Additional Details: Her response was not to the vaccine. As soon as the nurse administered the shot, she said she passes out cold after ANY vaccination |
| 1238954 | 4/21/2021 | MO | 18 | F | 4/21/2021 | 4/21/2021 | Patient did not tell us she has a history of fainting because it happened so long ago, they felt it was unimportant, but patient was fine, received vaccine while mom was standing nearby, and fainted and fell off of the chair. she was conscious shortly after (about 5 seconds) and didn't realize she even fainted she said. they waited in our waiting area and refused to call EMS. |
| 1237261 | 4/21/2021 | IL | 17 | M | 4/20/2021 | 4/20/2021 | Patient experienced syncope post vaccination, recovered and released |
| 1236589 | 4/21/2021 | MI | 40 | F | 4/20/2021 | 4/20/2021 | Severe neck pain, arm pain, dizziness (fainted at 3 am), nausea, headache, stomach cramps, |
| 1236794 | 4/21/2021 | MI | 42 | F | 4/20/2021 | 4/21/2021 | I am reporting that I nearly fainted early in the morning. I woke up feeling uncomfortable and hot and went to the kitchen for an ibuprofen. I immediately felt wobbly and nauseous. I sat on the floor a minute in the kitchen. Took the ibuprofen and walked back upstairs to my bedroom. Again I felt nauseous and then felt my face get hot, lips tingle, vision get grey, realized I was about to faint and lied down on the floor. A minute later I went back to bed feeling the chills, slept two hours and felt fine when I got up. Checked my Blood Pressure and it was normal. I don't normally faint. It was unexpected. |
| 1236852 | 4/21/2021 | NY | 32 | M | 4/11/2021 | 4/11/2021 | syncope, sweating, increased heart rate |

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| 1236859 | 4/21/2021 | AR | 23 | F | 3/31/2021 | 3/31/2021 | Almost 12 hours after receiving the vaccine my legs felt very tingly and I passed out in the front yard |
| 1236872 | 4/21/2021 | MD | 23 | F | 4/20/2021 | 4/20/2021 | Pt. became light headed after vaccination and fainted-falling from a sitting position onto the floor. Regained consciousness quickly and was assessed by EMS on site- neuro check was within normal limits. Pt. given water and food and observed for 30 minutes post event and allowed to go home on her own. |
| 1237048 | 4/21/2021 | | 24 | M | 3/26/2021 | 3/26/2021 | Pt. reports left arm pain/heaviness after receiving 2nd dose of vaccine. Pt. was given 2nd dose in the right arm. Pt. described the feeling in his left arm as aches and mild heaviness. He reports pain in his left arm after the first dose that went away after a few hours. He denied chest pain and chest tightness, swelling, itching, and syncope. Pt. appeared stable after vaccine. He improved after further observation. Pt. given directions to go to ER if symptoms worsen. |
| 1237128 | 4/21/2021 | WI | 34 | M | 4/20/2021 | 4/20/2021 | At about 9:30 pm, 5 hours after getting the shot, I was in the shower with my wife and felt nauseous, then faint. She got my onto the floor right as I fainted. She called the ambulance, my BP was low and I had zero color in my face but felt ok enough to not go in the ambulance. I have never fainted before |
| 1236630 | 4/21/2021 | MI | 17 | F | 4/20/2021 | 4/20/2021 | Patient became dizzy and passed out after returning to her car. Guardian beeped horn and nurses evaluated patient. Patient aroused easily. Patient very pale. Patient vomited x 1. BP 88/50, P 53, R 14, Spo2 99%. 911 called, arrived within 15 minutes. Vitals and blood sugar stable. Patient denied any further dizziness and reported not eating prior to vaccination appointment. Patient also reported similar incident one other time after receiving a shot. Patient discharged home, no EMS transport. Follow up phone call revealed patient was feeling fine. |
| 1237207 | 4/21/2021 | CT | 28 | F | 4/21/2021 | 4/21/2021 | patient fainted |

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| 1236898 | 4/21/2021 | NC | 34 | M | 3/30/2021 | 3/30/2021 | Patient was diaphoretic and became unresponsive (fainted) about 5-7 minutes after his first dose of the Moderna COVID-19 vaccine. Blood pressure was 90/50 mm Hg, pulse 46, temperautre 97.8, respirations 16/minute, blood glucose 92 mg/dL. Patient reported chronic low blood pressure and feeling nervous about his vaccine. No food had been consumed prior to the vaccine. |
| 1237181 | 4/21/2021 | IL | 35 | M | 4/20/2021 | 4/20/2021 | Patient experienced syncope post vaccination, recovered and released |
| 1237248 | 4/21/2021 | MN | 18 | F | 4/20/2021 | 4/20/2021 | Within minutes of pt receiving covid vaccine, verbalized to 'not feel well' and fainted. A friend and staff members gently assisted pt to the floor. Immediate assessment of vital signs and pt taken to private area for monitoring. Pt may have had vasovagal response due to anxiety. |
| 1237010 | 4/21/2021 | NY | 20 | F | 4/12/2021 | 4/12/2021 | Patient fainted and hit her head on floor of gym. All vital signs are normal. She has anxiety and bee allergies. Patient fainted for 30 seconds |
| 1236996 | 4/21/2021 | AR | 18 | F | 4/20/2021 | 4/21/2021 | Fainting (witnessed) the morning after the vaccine. Vaccine was given at 1330 4/20/2021, fainting occurred the following morning at 0830. Difficulty sleeping |
| 1236983 | 4/21/2021 | FL | 33 | M | 4/20/2021 | 4/20/2021 | Pt. got a COVID-19 on 4/20/21 around 5:15 PM and fainted after a few minutes. He gained conscious after 4 minutes. He just complained that he feel felt light headiness and very nauseous but never thrown up. He laid down on floor and then moved to 3 chairs to lay down and rested for over an hour before his wife drove him home. |

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| 1237090 | 4/21/2021 | MI | 27 | F | 2/5/2021 | 2/7/2021 | Vertigo Presents to medical clinic. C/o dizziness x 2 wk Feeling persistently dizzy since the visit on 1/25/21 (12 days ago) for near-syncope. No syncopal episodes. Light-headed, mild imbalance/unsteady. Able to walk but feels like she is floating. Receives 2nd cov-2 vaccine Friday 2/5/21 at about 5pm. Tolerates well. However on Sunday 2/7/21 - awakens with profound dizziness - room is spinning. Persistent. Not positional. Unable to get out of bed. Slept all day. No vomiting. NO paresthesias/HA or other focal neurologic symptoms. Today there is significant improvement but continues to have persistent light-headedness/off-balance/floating - Ok with walking and position changes. No fevers/C/S/Headache. No cough/cold symptoms. 4/20/21 re-evaluation - continues to have mild intermittent light-headedness/dizziness, 1 recurrence of severe acute vertigo with duration 2 days. |
| 1232538 | 4/20/2021 | IN | 30 | F | 4/20/2021 | 4/20/2021 | Pt. received vaccination and less than a couple of minutes the patient was sitting in a chair and fell face first on the floor. She fainted and was not responsive when the pharmacist arrived to the scene. At that point the pt. had a pulse but lying face first on the floor, that is when the EpiPen 0.3mg dose was injected in the right thigh. The pt. was at that point able to communicate and able to identify her name and date. App. 5 min later the paramedics took over the scene and the pt. sat up and started to feel better. |
| 1232611 | 4/20/2021 | CO | 25 | M | 4/20/2021 | 4/20/2021 | Patient passed out shortly after receiving his second dose of moderna vaccine. |
| 1232626 | 4/20/2021 | OH | 27 | M | 4/20/2021 | 4/20/2021 | Patient experienced syncope shortly after receiving first dose of Pfizer COVID vaccine in the lobby during his 15 minute waiting period. Patient hit chin and did lacerate it; this was attended to by NP who was administering shots at the time. Patient mentioned that he "tasted like he threw up," was instructed to drink water. NP took vitals and patient showed no sign of concussion. In the mean time patient was trying to get ahold of a friend or family member to come pick him up. Still felt lightheaded 15 minutes after being attended to, at this time we called the squad. Before the squad could show up patients brother came to pick him up... was whisked away too quickly for us to stop him. Patient was adamant about us not calling squad because he does not have insurance. |

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| 1232601 | 4/20/2021 | NC | 29 | F | 4/20/2021 | 4/20/2021 | immediately after infection, pt reported dizziness, EMT and MD notified, pt then experienced syncope for approx 20 seconds, spontaneously resolved. normal vital signs. tolerated food/drink after, talkative and in good spirits shortly after regaining consciousness, no head trauma or fall. pt arranged for someone to drive her home. did not require hospital evaluation. |
| 1232637 | 4/20/2021 | NE | 19 | M | 4/20/2021 | 4/20/2021 | Syncope after receiving the immunization. Recovered immediately with no lasting effects |
| 1231543 | 4/20/2021 | AZ | 55 | M | | 4/6/2021 | SEIZURE; HIT HIS HEAD ON THE CONCRETE; This spontaneous report received from a consumer concerned a 55-year-old male. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported) dose was not reported, 1 total administered on 06-APR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 06-APR-2021, the patient was sitting with his wife after receiving the JANSSEN COVID-19 vaccine, when he had started to slump over. Patient experienced seizing (passed out and slipped out of his chair and started). It was reported that the patient hit his head on the concrete. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the seizure (pass out and slumped over) and hit his head on the concrete was not reported. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to 20210414732 and 20210414751.; Sender's Comments: V0 20210415021-Covid-19 vaccine ad26.cov2.s-Seizure. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event. |
| 1232565 | 4/20/2021 | WA | 20 | M | 4/20/2021 | 4/20/2021 | Near Syncope, Bradycardia and Hypotension |

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| 1232550 | 4/20/2021 | NC | 42 | F | 4/16/2021 | 4/16/2021 | Approximately five minutes after receiving the vaccine, pt's husband called out for assistance as the pt had complained of dizziness and then appeared to have a near-syncope as she leaned onto her husband while sitting in her chair. Monitoring MD and RN support team responded and lowered pt to the floor, checking vitals and LOC. Pt remained conscious but drowsy, pallor and weak pulse at first check with pulse normalizing once supine. Pt denied trouble breathing or chest pressure. Pt and spouse endorsed pt has history of panic attacks as well as syncopal episodes. Pt admitted she had not eaten since the night before. Pt was given time to rest followed by water and juice, and ongoing assessments. Pallor resolved and pt stated she felt much better. |

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| 1232481 | 4/20/2021 | GA | 35 | F | 4/11/2021 | 4/11/2021 | I recieved the vaccine on 04/11/2021 at Pharmcy in the left arm and started having numbness/tingling in my extremities 72 hours later. I had fever chills and aches within the first 24 hours after the vaccine. The body aches were there till Thursday. Once the body aches started subsiding, I felt the numbness and tingling in the legs on Thursday. Then it spread to my arms. Stays in the legs. Then I started feeling in back of arms and upper back. Certain things make it worse, laying and sitting is worse. Standing helps it. I have no swelling. I have never had a reaction before to a vaccine. No problems ambulating, no breathing problems, no wheezing. I would also like a refill of my headache medication and inhaler today. The patient is a 35 year old female who presents with a complaint of COVID vaccine reaction. COVID Janssen J&J vaccine recieved on 04/11/2021 at Pharmacy, IM in left deltoid. Several hours later I had fever/chills/body aches/ racing heart which lasted 24 hours. The body aches lasted for 72 hours. I began noticing numbness and tingling in my extremities as well as in my upper back. The numbness and tingling worsens when I sit and lay down. No bowel/ bladder problems. I also have Raynaud's and I do not know if that ties in to my symptoms at all. My nipples have also been abnormally hard and sensitive. Note: hx of raynauds denies cp/sob/rash/abdominal pain/n/v/bowel or bladder incontinence/seziures/syncope. symptoms are constant. no fam hx of neurological conditions. no injury and no fall. able to walk okay. no muscle weakness. no rashes. pt denies anaphylaxis |
| 1232643 | 4/20/2021 | CA | 20 | F | 4/16/2021 | 4/16/2021 | patient c/o shortness of breath and dizziness. Started at 2:05PM, Dr. was notified and evaluated patient Vitals: 100/72mm hg Pulse: 82 SPo2: 98% DX: Vasovagal syncope Monitored patient symptoms for 30 minutes patient was stable and was release home |
| 1233019 | 4/20/2021 | NH | 17 | F | 4/20/2021 | 4/20/2021 | Transient lightheadedness with brief syncope. Subsequent NV controlled with position of comfort. Patient had not eaten anything today and had only coffee so far. Pt was given fruit, muffin and water and was monitored for an additional 45 minutes with continued improvement and no other symptoms. |

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| 1232479 | 4/20/2021 | NY | 44 | F | 4/19/2021 | 4/19/2021 | Laid down approximately 4pm on Monday April 19th, 2021 with the intention of taking a brief nap. Woke up thinking that it was still Monday April 19th, 2021. Looked at my cell phone and discovered it was 1pm Tuesday April 20th, 2021. I unintentionally passed out for 21 hours straight and I am still in a daze with serious brain fog. |
| 1232469 | 4/20/2021 | OH | 20 | M | 4/15/2021 | 4/15/2021 | Student passed out sitting in chair a few minutes after receiving the vaccine. This was witnessed and medical care was at student side immediately. SPO2-94% HR-80. 2:41p Student opened eyes spoke then passed out again while in chair. Student was lowered to ground x3 assist and legs elevated on chair BP-120/78, SpO2-96%, HR-57 cold and diaphoretic. 2:48p BP-100/72, HR-80, SpO2-99% student alert and talking legs repositioned on floor without issues. 3p assisted to standing position x2 assist then to chair. 3:10p ambulated with standby assist without issues. Vitals checked every 5-10 mins and remained stable. Student admitted to having similar episode in Summer 2019 with blood draw. Student had little to drink and nothing to eat this day. 3:15p Student's roommate arrived to walk home with student. Encourage student to eat and drink plenty of fluids for remaining day and ensure that he eats and drinks fluids prior to 2nd vaccine dose. 3:30p Student was cleared by PA to leave at his convenience. |
| 1233967 | 4/20/2021 | | 28 | F | 4/17/2021 | 4/17/2021 | syncope, legs shaking |
| 1232652 | 4/20/2021 | OH | 27 | M | 4/20/2021 | 4/20/2021 | Patient experienced syncope resulting in a laceration to the chin in the 15 minutes following vaccination. Patient was tended to by the NP on duty, instructed to lie down and drink water while she tended to his cut. Patient mentioned it "tasted like he threw up" and still felt lightheaded after 15 minutes after the event. Patient was insistent that we should not call the squad as he does not have insurance. Patient in the meantime was trying to get ahold of a friend or family member to pick him up as we advised him that he could not leave in this state. We elected to call the squad as he had not recovered yet. Before the squad could come, the patients brother showed up and quickly whisked him away. Squad did show up but there was nothing to attend to so left without intervention. |

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| 1232668 | 4/20/2021 | CA | 17 | M | 4/20/2021 | 4/20/2021 | Patient was sitting in observation for approximately 5 minutes , started feeling light headed and passed out. Patient was out for approximately 15 seconds before recovering. There were no seizure like symptoms or post-ictal state. Patient was helped onto a cot and a set of vitals was taken, BP 118/84, O2 98%, HR 84. Patient was advised to wait at least 15 more minutes and told not to leave until after the 15 minutes had passed and he was no longer having any symptoms. Patient was brought home by a family member. |

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| 1232700 | 4/20/2021 | IA | 77 | F | 3/3/2021 | 3/20/2021 | <p>Pfizer COVID Vaccine EUA Patient received Pfizer vaccine 3/3/21. COVID Positive 3/20/21 3/20/21: Patient is a 77-year-old female with past medical history of bilateral breast cancer (post bilateral mastectomy), CHF, CAD, CKD stage II/III, HTN, obesity, obstructive sleep apnea (not on CPAP), and spinal stenosis presenting today. Patient presented via ambulance her daughter. Patient was unable to cooperate, HPI obtained from patient's daughter. Patient's daughter stated approximately 1 week ago patient started to be "unresponsive" and was not talking/responding often. Mostly answered "yes/no" questions. She seemed to be "acting different". When asked, pt denied any pain over the last week. Her daughter denies any infectious process such as fever/chills or cough cough. Her daughter notes approximately 2 years ago patient has similar event, was seen in the ED, but nothing remarkable was found. Reviewed today, patient's daughter stated the patient had a "shaking" episode in had "on responses ". It was described as "shivering" and a blank stare during this unresponsive state. Episode lasted approximately 1 minute. The daughter denied any history of strokes or seizures. Pt usually lives with another daughter and so the daughter present was unable to verify if pt takes her prescribed medications daily. Her daughter denies knowing any Advance Directives or POA set up. Smoking, alcohol, and illicit drug use were denied. Pt was seen 9/2019 for a similar event with concern of stroke vs syncope vs TIA that resolved on its own. 3/25/21: 77-year-old F presented on admission that began approximately 6 days prior. HPI obtained from patient's daughter on admission. Patient's daughter stated approximately 1 week ago patient started to become "unresponsive" and was not talking/responding often. Mostly answered "yes/no" questions. Patient's daughter stated the patient had a period of unresponsives and was shaking her left arm on the day of admission. It was described as "shivering" and a blank stare during this unresponsive state. Left sided weakness was noted. In the ED, vitals signs significant for 88% on room air. CXR showed bilateral infiltrates in lower lobes, CT of head was unremarkable, EKG normal sinus with sinus arrhythmia, CT of chest completed due to elevated D-Dimer showed no PE but showed ground-glass airspace disease and stable 14mm nodule at lower</p> |

VAERS_ID RECVDDATE STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

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| | | | | | | | pole of right thyroid. Pt was admitted for Acute Encephalopathy with unknown etiology. COVID testing came back positive. Patient started on Routine COVID management protocol which included IV dexamethasone, remdesivir, vitamin D, vitamin C, zinc, with daily labs (d-dimer, CPK, CRP, CMP, LDH until stable/not upward trending). Patient to continue vitamin D, vitamin C, and zinc upon discharge to rehab. Patient had MRI obtained which showed scattered foci of acute infarcts right posterior parietal lobe/multiple foci of acute microhemorrhages likely hypertensive. Neurology consulted, stated infarct could be due to COVID so continued on lovenox and stopped aspirin. Recommended to keep blood pressures 110-140/80-90. Last documented note from neurology was 03/22/2021 - contacted multiple times but unable to reach afterwards. Discharging patient on xarelto for 30 days and recommending to follow-up outpatient to transition to aspirin and plavix. With this management on board, patient's symptoms improved significantly since admission. Patient discharged in stable condition to rehab. |
| 1232738 | 4/20/2021 | NY | 52 | M | 4/13/2021 | 4/14/2021 | I received my second COVID vaccination in the afternoon and started to experience side effects from the shot around 1:00 in the morning. When I woke up to go to the bathroom at 4:30 in the morning I was not feeling well in my stomach and I felt a little dizzy. On my way back to bed from the bathroom I fainted and fell face first into the wall heater and then to to the floor. This action fractured my nose and gave me multiple bruises and cuts in my face and upper body. |
| 1232747 | 4/20/2021 | NJ | 28 | F | 4/11/2021 | 4/11/2021 | Janssen COVID-19 Vaccine EUA: Vaccine recipient experienced overheating and syncope. Vaccine recipient was monitored by EMS. |
| 1232756 | 4/20/2021 | | 27 | M | 4/15/2021 | 4/15/2021 | Patient had syncope, dizziness, flushing/sweating, seizure, urinary incontinence. BP 119/79 -- > 103/53 -- > 108/50, HR 47 -- > 38 -- > 37 -- > 64 -- > 62, RR 16, O2 100%, Temp 97.3F. EMS called at 17:06, arrived at 17:13. |

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| 1232791 | 4/20/2021 | | 31 | M | 4/20/2021 | 4/20/2021 | Patient with syncope after vaccination. No prior history. Given juice, crackers and rest. BP initially soft, but improved after 10 minutes. Patient able to leave asymptomatic prior to discharging home. |
| 1233000 | 4/20/2021 | IN | 19 | F | 4/19/2021 | 4/19/2021 | Patient was given Moderna shot #1 by pharmacist. She was waiting her 15 minutes afterwards and she fainted in her chair and then fell out of her chair. There was no loss of consciousness. She does not know if she hit her head or not. She was on the ground and we got her leaning up against the wall sitting down. She said she was not feeling well before she fainted (did not report to staff) and then she did not remember passing out. She felt nauseous and hot/clammy afterwards. |
| 1233060 | 4/20/2021 | MA | 33 | M | 4/18/2021 | 4/18/2021 | Participant was in observation area when they fainted. Recovered quickly and left on his own accord. |
| 1233150 | 4/20/2021 | MA | 34 | M | 4/20/2021 | 4/20/2021 | syncope after 15 post administration |
| 1233166 | 4/20/2021 | PA | 44 | M | 4/17/2021 | 4/18/2021 | Lost consciousness, Either a seizure or passed out. Cardiac events - Varied and Rapid Heart rate, Low Potassium and Low Magnesium |
| 1233174 | 4/20/2021 | OH | 42 | M | 4/16/2021 | 4/16/2021 | While in waiting area client experienced loss of consciousness and seizure-like activity lasting approximately 48 seconds per nurse that responded to incident. Loss of bladder control noted. Squad responded and transported patient to the hospital via ambulance. Patient was coherent prior to transport. He states he was admitted to the hospital and Observation x 24 hours. He had a CT scan and bloodwork, both normal. Neurologist at the hospital told him he experienced syncope and no seizure activity was suspected. He states a history of feeling faint when he sees blood. He states the Neurologist advised he get the second dose and lay down after the shot. |

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| 1232432 | 4/20/2021 | VA | 59 | F | 3/4/2021 | 3/9/2021 | Immediately following the vaccine, at 3 minutes into my 15 minute waiting period, I had saw black dots on the ceiling, had rapid heartrate and a dizzy spell. It quickly subsided. Five days later, I experienced another vertigo type dizzy spell and from that time, I have been generally very dizzy. At times, the dizzy spells have also included rapid heart rate and a feeling of near fainting. At the time the dizziness started, I also had spleen pain and gut fizzing. I am now over six weeks past the vaccine, and the rapid heart rate, gut fizzing and spleen pain have subsided but the dizziness is persisting. |
| 1232076 | 4/20/2021 | FL | 61 | F | 4/20/2021 | 4/20/2021 | Patient suffered a syncopal episode and confusion while under observation following her booster vaccination. Patient has a history of diabetic related emergencies but this syncope/confusion resolved itself while under the care of on site paramedics. Patient was transported to a hospital of her choosing. |
| 1232815 | 4/20/2021 | OH | | U | | | Abdominal pain, vomiting, headache, hypotension, syncope, coma, shock, death at 2:00 pm 03/08/2021 |
| 1232154 | 4/20/2021 | CA | 30 | M | 4/19/2021 | 4/19/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Headache-Mild, Systemic: Hypotension-Medium, Additional Details: pt hx of vagal response to needles. passed out and fell foward. 0.5 inch laceration to left forehad as a result of forward fall from glasses hitting head and floor. Bleeding controlled by direct pressure. 98% osat. pulse 64. Bp was 128/90. slight headache. gave 2 tabs 500mg acetamiophen from pharmacy supply |

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| 1233196 | 4/20/2021 | MA | 20 | M | 3/12/2021 | 3/20/2021 | Admission HPI: Right-sided chest pain began 2 days prior to admission (3/19) after getting out of car, without identifiable trigger. Pain was sharp, pleuritic, and worst with movement; didn't feel it when still. Pain not responsive to ibuprofen or heating packs. Reported 30-60 seconds of self-resolving heart racing during ocular migraine which has been his baseline for years. Not associated with SOB (at rest or with exercise), palpitations, presyncope, or syncope. No viral URI symptoms, N/V, or rash. He did receive his 2nd Moderna COVID vaccine about 1 week PTA, followed by 36hrs of fevers, chills, and body aches. Given persistence of pain, Patient asked his parents to present to urgent care. In UC, he was noted to tachycardic with CXR with bibasilar atelectasis and b/l effusions, per report. Given continued tachycardia, decision was made to transfer to ED to r/o PE. In ED, tachycardic to 104-116 and tachypneic 22-26. Had one episode of tachycardia to 182 iso ocular migraine. Endorsed chest pain but points to R middle abdomen when asked where worst. Exam was unremarkable. He received 1 dose of morphine which reduced pain from 10/10 to 0/10. Labs notable for leukocytosis (14.61), thrombocytopenia (422), elevated d-dimer (1.56), and elevated CRP (5.6). Otherwise normal chem and coags. COVID/RVP negative. CXR unremarkable. CTPA showed scattered PEs in b/l lower lobes with small pulmonary infarct in RML. No evidence of right heart strain. Heme was consulted who recommended starting him on lovenox and sending lupus anti-coagulant. Cardiology was consulted who recommended EKG, BNP, and troponin, all of which were normal and reassuring against right heart strain. ECHO was therefore deferred to the AM. The decision was made to admit. Upon arrival to the floor, Patient was tachycardic 114 and tachypneic to 22, otherwise stable vitals. He denied any pain since morphine. Denied any unexpected weight loss; reports that car ride was short. Mom reports that Patient has been less active d/t cold weather and baseball being on hold. Denies family or personal history of clots. Last seizure ~13 years ago. Hospital Course: (3/21 - 3/22) Patient was admitted to the hematology service. He was therapeutically anticoagulated with LMWH injections and his anti-Xa level prior to discharge was 0.92. (goal 0.5-1.0) Lower extremity ultrasound with Doppler showed patent veins |

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1231608 4/20/2021 NC

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and no evidence of DVT and upper extremity ultrasound showed no evidence of DVT, though there was potential evidence of collateralization seen in mid and distal third of right subclavian vein and left internal jugular vein. Since this was an unprovoked PE, a full thrombophilia workup was sent and will be followed up by the outpatient hematology clinic. Cardiology consulted regarding possibility of right heart strain and the tachycardia during migraine episodes. Echocardiogram performed on 3/22 was technically limited but showed no gross abnormalities. The cardiology team requested a repeat echo scheduled outpatient for 1-2 months after discharge.

FAINTING; INCREASED BREATHING; LIGHTHEADEDNESS/DIZZINESS; NAUSEA; This spontaneous report received from a consumer concerned multiple patients (18). The reporter saw this information on the news. The patients' weight, height, and medical history were not reported. The patients received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported) dose, start therapy date were not reported, 1 total administered for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, 18 patients experienced fainting, increased breathing, dizziness/lightheadedness, and nausea. 4 out of the 18 patients went to the hospital. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the nausea, lightheadedness/dizziness, fainting and increased breathing was not reported.. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to 20210420362.; Sender's Comments: V0-20210420809-covid-19 vaccine ad26.cov2.s -Fainting. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).

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| 1231636 | 4/20/2021 | | 35 | M | | | <p>FAINTED; This spontaneous report received from a parent. The reporter obtained the information from news/media. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported) dose, 1 total, start therapy date were not reported for prophylactic vaccination. Batch number was not reported. Per procedure, no follow up will be requested for this case. No concomitant medications were reported. On an unspecified date, the parent reported that the patient had fainted in doctor's office 10 minutes after vaccination. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of fainted was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210422263-JANSSEN COVID-19 VACCINE Ad26.COVID.S- Fainted. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.</p> |

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| 1231642 | 4/20/2021 | IL | | F | | 4/12/2021 | <p>FAINTED/PASSED OUT; NOT FEELING QUITE RIGHT; VERY TIRED; This spontaneous report received from a parent concerned a white and Not Hispanic or Latino female of unspecified age. The patient's height, and weight were not reported. The patient's past medical history included faint, and concurrent conditions included seizure, non-alcohol user, and non-smoker. The patient had no history of drug abuse or illicit drug usage. The patient experienced drug allergy when treated with erythromycin, and ketamine. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 207A201A, expiry: UNKNOWN) dose was not reported, 1 total, administered on right arm on 12-APR-2021 for prophylactic vaccination. No concomitant medications were reported. It was reported by the patient' parent that, on 12-APR-2021, within 5 minutes after vaccination the patient had fainted/passed out. On the same day, the patient was not feeling quite right and was very tired. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from fainted/passed out, very tired, and not feeling quite right. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210422792-JANSSEN COVID-19 VACCINE Ad26.COV2.S- Fainted/Passed out. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.</p> |
| 1231719 | 4/20/2021 | | 24 | F | 4/19/2021 | 4/19/2021 | <p>The patient had a syncope episode 2 minutes after administration of the vaccine. The patient recovered and was released on their own accord.</p> |

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| 1231981 | 4/20/2021 | WA | 45 | F | 4/8/2021 | 4/8/2021 | Immediately after receiving vaccine, pt had complete loss of consciousness for approximately 30-45 seconds. Pt was lowered to the floor and placed in trendelenburg. BP 132/71, HR 93, 98% on RA. BP 10 minutes later with pt lying down dropped to 83/49, HR 52 and 99% on RA. Each time we attempted to have pt sit up, Pt would begin to have tingling in extremities and ringing in ears. EMS called. BP eventually raised to 127/66 with pt sitting upright but EMS preferred to transport pt to Hospital. Pt evaluated in ED and notes indicate that EKG was done and revealed normal sinus rhythm. Determined to be vasovagal reaction leading to syncope. Pt discharged to home in stable condition. |
| 1232017 | 4/20/2021 | MN | 20 | M | 4/20/2021 | 4/20/2021 | Patient was given dose 1 of the vaccine and instructed to wait at least 15 minutes in the chairs in front of the RPH for observation. He waived at us and sat down. We asked if he was ok and he waived again stating he didn't feel well. He sat back down and we proceeded to check on him. As we were coming to check on him, he fainted and fell face forward on to the floor. We called 911 and rolled him gently to his back. He had a laceration above his eye from the fall. EMT came and assessed the patient. After observation, he was allowed to be picked up from his friend and taken to a clinic for stitches. |
| 1232023 | 4/20/2021 | MD | 26 | F | 3/19/2021 | 4/19/2021 | Dizziness, syncope. Blood pressure 121/77 Vital signs were monitored, hydration was encouraged. The patient was instructed to go to the nearest ER or call 911 for signs and symptoms of hives or shortness of breath. |
| 1232087 | 4/20/2021 | CA | 26 | F | 4/19/2021 | 4/19/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Tingling (specify: facial area, extremities)-Mild, Additional Details: Patient fainted about 5 minutes after received Covid vaccination. Hit head against soft chair and came to quickly with some initial confusion. Called 911 who responded within a few minutes and took away. No medications administered before EMS arrived as patient only started feeling tingling right before EMS arrived\r\n |
| 1232107 | 4/20/2021 | TX | 20 | F | 4/16/2021 | 4/16/2021 | Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Additional Details: Patient was fainted and was unresponsive. EMS was called. Father stated this was a known issue. It was more of a phobia. |

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| 1232116 | 4/20/2021 | MA | 26 | M | 4/19/2021 | 4/19/2021 | Systemic: Allergic: Difficulty Breathing-Severe, Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Medium, Systemic: Exhaustion / Lethargy-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Hypotension-Mild, Systemic: Seizure-Mild, Additional Details: Patient was found unresponsive on the floor by bystanders with ? siezure like activity, this RN and RN responded. EMS called to store and was sent to the ER. |
| 1232120 | 4/20/2021 | MD | 16 | F | 4/19/2021 | 4/19/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Exhaustion / Lethargy-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Headache-Mild, Systemic: Nausea-Mild, Systemic: Shakiness-Mild, Systemic: Tingling (specify: facial area, extemities)-Mild, Systemic: Tinnitus-Mild, Systemic: Visual Changes/Disturbances-Mild, Systemic: Weakness-Mild, Additional Details: Tingling in face and legs |
| 1232104 | 4/20/2021 | TX | 16 | M | 4/12/2021 | 4/12/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Additional Details: Patient fainted and hit his head and scratched his right arm |
| 1232149 | 4/20/2021 | CO | 46 | F | 4/5/2021 | 4/5/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium |
| 1232396 | 4/20/2021 | OH | 24 | F | 4/15/2021 | 4/15/2021 | Student became lightheaded and dizzy after the vaccine and passed out while sitting in the chair and fell off chair landing face first onto the floor. PA to the students side immediately and student was breathing but not alert. Student aroused easily but 9-1-1 was called as a precaution due to student hitting head. Student was observed but was not transported via EMS. No meds were given and he was able to ambulate out to the clinic without issues after the episode. |
| 1232161 | 4/20/2021 | MA | 34 | F | 4/19/2021 | 4/19/2021 | Systemic: Fainting / Unresponsive-Medium |
| 1232192 | 4/20/2021 | PA | 45 | F | 4/19/2021 | 4/19/2021 | Approximately 10 minutes after administering the Moderna vaccine patient began to feel warm and then fainted. |

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| 1232206 | 4/20/2021 | NY | 18 | M | 4/15/2021 | 4/15/2021 | BRIEF FAINTING AT THE TIME OF VACCINATION; PATIENT STARTED "FEELING FUNNY", "WAS UNABLE TO HEAR ANYTHING", OPENED HIS EYES WITH A BUNCH OF PEOPLE STANDING IN FRONT OF HIM; PATIENT REMAINED SITTING IN A CHAIR; PALE AND DIAPHORETIC; ASSISTED TO A STRETCHER AND BROUGHT TO ED; PATIENT DISCHARGED IN STABLE CONDITION |
| 1232220 | 4/20/2021 | VT | 48 | M | 4/20/2021 | 4/20/2021 | Patient reported a history of anxiety related to vaccine injections and a history of fainting post vaccination. Patient was brought to a private room for the vaccination and did faint about 5 minutes post vaccination. Patient was brought to the ground. Patient was able to respond to questions and only lost full consciousness for about 10 seconds. Patient recovered from the event after about 15 minutes and waited at our clinic 30-40 minutes post vaccination. By the time the patient left, he had fully recovered. |
| 1232225 | 4/20/2021 | RI | 17 | M | 4/20/2021 | 4/20/2021 | Near syncope, weakness 30 min after vaccine admin. Patient was C&A, self ambulatory & in no signs of immediate distress, strong regular bi lateral radial pulses w/ warm dry skin & regular respirations with good rate depth quality. Vital signs were obtained w/ no remarkable findings patients condition improved while in EMS care & was then released to patients father whom assumed responsibility of patients father. Patient was instructed to stay hydrated & eat food & Both patient & patients father where instructed to seek medical attention if symptom's worsened or reoccurred. |
| 1232231 | 4/20/2021 | | 45 | F | 4/20/2021 | 4/20/2021 | Syncope w/ poss seizures down for 2 min. Shallow reps placed on NRB 21. BP 167/110. Hr112. RR 15.oxygen sat 100%. BGL 339mg/dl. 911 and transferred to ER. |
| 1232268 | 4/20/2021 | KY | 52 | F | 4/20/2021 | 4/20/2021 | syncope, multiple episodes of LOC, lethargic, nauseated, Complaints of chest pain right after her COVID shot. wheezing and mild headache |

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| 1232280 | 4/20/2021 | FL | 49 | F | 4/20/2021 | 4/20/2021 | Patient received the vaccine around 12:30 pm. After administering the vaccine, patient was told to wait 15 min in the waiting/observation area. After 10 min waiting her husband waived at the pharmacist stating she was not feeling ok. When I approached to her ask how she was feeling, she stated she had shortness of breath and was feeling that she was fainting. I decided to lay patient on the floor and pull legs up and ask patient to start breathing. I then asked patient if she was feeling ok and she stated was out of breath and had numbness on the lips and the arms. I asked the other pharmacist to call 911 and decided to administer an EpiPen after checking on patient again and stated that she was out of breath and lips were still numb. After 5 mins patient continued with the shortness of breath and numbness but emergency services arrived at that moment and checked her vitals, administered IV fluids, and she was taken to hospital. She left awake and apparently ok and she never lost consciousness. |
| 1232306 | 4/20/2021 | WA | 40 | M | 4/20/2021 | 4/20/2021 | Patient had reaction to COVID-19 vaccine. Patient was monitored after COVID-19 vaccine as recommended per ACIP guidelines. The following reaction signs/symptoms were observed: syncope, vomiting Emergency response notified: EMS (911) EpiPen administered by RN as per JH standing order?: No Required VAERS reporting completed?: No Report given to EMS (911) Patient was given vaccine at 0918, immediately flagged for nurse at 0920. Nurse went to patient and obtained vitals. BP 150/80 HR 56 regular SP02 99% R 18 regular Called EMS, patient was given water and emesis bag. Vital taken again: BP 130/70 HR 60 regular EMS evaluated patient and stayed 10 mins, advised of nurse hotline on COVID packet & further medical evaluation. Patient was then release to go home. |

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| 1232310 | 4/20/2021 | PA | 25 | F | 4/20/2021 | 4/20/2021 | Pt c/o clogged ears, which happened last time she passed out during blood draw. Denies dizziness, denies LOC. Pt placed on back on floor with feet on chair in pod while awaiting stretcher arrival. Pt able to stand and ambulate to stretcher, transported to med obs #1. Pt reports resolution of symptoms upon arrival to med obs. VSS. No s/s of distress noted. Requesting to d/c to home. Pt escorted to exit with staff and significant other. VS are as follows: 1640: BP 138/90, HR 97, RR 17, O2 sat 99% on RA |
| 1232341 | 4/20/2021 | | 40 | M | 4/19/2021 | 4/19/2021 | ~~Administered - 4/19, time unknown Adverse event started - 10:06 Patient had syncope, flushing/sweating. BP 109/53 -- > 114/55, HR 68 -- >64, RR 16 -- >16 , O2 100% -- > 99%, Temp 97.3F. Given PO juice, Graham crackers. Patient stable, released from vaccination site.~~ |
| 1232345 | 4/20/2021 | | 26 | M | 4/19/2021 | | ~~Administered - 14:30, Adverse event started - 14:38. Patient had syncope, flushing/sweating, dizziness. History of ~~"blackouts during blood draws~~". BP 92/53 -- > 93/58y, HR 74 -- > 68, RR 18 -- > 18, O2 97% -- > 98%. Patient stable, released from vaccination site.~~ |
| 1232393 | 4/20/2021 | NY | 27 | M | 4/15/2021 | 4/15/2021 | PATIENT BROUGHT WITH RAPID RESPONSE TO ED FROM VACCINATION ROOM; SYNCOPE IMMEDIATELY AFTER VACCINE SHOT; PATIENT FELL FROM STANDING AND HIT HEAD ON TABLE; C-COLLAR IN PLACE; PATIENT REPORTS LOSS OF CONSCIENTIOUSNESS; PATIENT STATES HE HAD PAIN TO LEFT SIDE OF HIS ARM; NO SIGNS OF SOFT TISSUE INJURY |

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| 1232131 | 4/20/2021 | CA | 16 | F | 4/19/2021 | 4/19/2021 | Systemic: Chills-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Exhaustion / Lethargy-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Nausea-Medium, Systemic: Seizure-Medium, Systemic: Weakness-Medium, Additional Details: Patient fainted in chair shortly after receiving vaccine. She came to within a minute, but body became very rigid and she began to seize throughout her whole body. This lasted less than 30 seconds and she was very pale and lightheaded. Patient described feeling extremely nauseous with chills, slowed breathing and lightheadedness. Moved patient to a new area to elevate feet, stated feeling better but was extremely nauseous and unaware that she had fainted or seized. 911 called per parents request |
| 1234841 | 4/20/2021 | | 28 | F | 4/19/2021 | 4/19/2021 | Passed out about 5 minutes after getting the vaccine |
| 1234422 | 4/20/2021 | CA | 18 | M | 4/20/2021 | 4/20/2021 | syncope episode, hypotension |
| 1234444 | 4/20/2021 | NY | 16 | F | 4/16/2021 | 4/16/2021 | The patient passed out completely while sitting after having her 1st covid vaccine. She was alert shortly thereafter but had blurry vision and low blood pressure. She said she was very hot and was sweating somewhat. We gave her some water and gradually she started feeling better. In the meantime, we had call 911 and when they evaluated her, they felt it was somewhat of a panic attack since she did have anxiety before getting the vaccine. |
| 1234469 | 4/20/2021 | PA | 34 | F | 4/20/2021 | 4/20/2021 | sweaty, light-headed, near syncope |
| 1234484 | 4/20/2021 | CO | 17 | F | 3/27/2021 | 4/17/2021 | Felt dizzy at work the next day after the second shot. Passed out and then was sitting down and I felt nauseous. I threw up 5 times and my arms started to get numb. I had a fever when I got home and I couldn't move because my body hurt so badly. Migraine and dizziness has been persistent ever since and is interfering with my daily life. Been treating with tylenol which helps a little but not completely. As soon as I stand up and move I feel like I'm going to pass out. |
| 1234485 | 4/20/2021 | PA | 27 | M | 4/20/2021 | 4/20/2021 | Nausea/fainted |

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| 1234496 | 4/20/2021 | MI | 68 | F | 4/20/2021 | 4/20/2021 | Pt was feeling nervous and felt lightheaded and fainted and was still conscious but wanted to take the ambulance to be safe |
| 1234535 | 4/20/2021 | IN | 26 | F | 4/20/2021 | 4/20/2021 | Patient passed out about 15-30 seconds after receiving the vaccination and regained consciousness between 45 seconds to 1 minute. Patient was alert and oriented after regaining consciousness. |
| 1234556 | 4/20/2021 | NH | 27 | M | 4/20/2021 | 4/20/2021 | Patient fainted and hit head on floor upon fall. Paramedics were called. He was cleared of a concussion. |
| 1234562 | 4/20/2021 | FL | 18 | M | 4/20/2021 | 4/20/2021 | Patient received 1st dose of vaccine, about 5 minutes later patient fainted/passed out in the chair during the observation period. Hit head on floor and had a hematoma form. 911 was called and patient went to hospital for observation. Blood pressure was running low after fainting in the 90/60 range. When patient came too said this happens all the time, was asked about issues with previous vaccines before shot and said no issue and marked on cdc checklist and consent form no issues to vaccine. |
| 1234571 | 4/20/2021 | CO | 57 | M | 4/19/2021 | 4/19/2021 | chills, fever, nausea, light headed and fainting |
| 1234572 | 4/20/2021 | MI | 63 | F | 3/3/2021 | 3/30/2021 | Pt had fever, dizziness, syncope, hypomagnesemia, hypophosphatemia, elevated LFTs and eosinophilia 24 hours after second dose of pfizer vaccine. Admitted to hospital. Treated with abx for possible pneumonia (although clinically pt did not have pneumonia - no cough, no shortness of breath, no hypoxia). |
| 1234593 | 4/20/2021 | MO | 18 | M | 4/20/2021 | 4/20/2021 | Patient fainted a couple of minutes after receiving vaccine. Patient fainted while sitting up, was move to the floor and laid flat on back with feet elevated. He regained consciousness quickly, within several seconds. Gave cold compress and applied to neck. Paramedics called and arrived and took over. |

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| 1234269 | 4/20/2021 | MD | 32 | F | 4/20/2021 | 4/20/2021 | The patient fainted in the pharmacy 5 minutes after her second shot. She was conscious back in 30 seconds and had a racing heart. we gave her gatorade and she started to feel a little better. She was seated in the pharmacy for about an hour she started to feel much normal then left the pharmacy with her friend driving her home. |
| 1234811 | 4/20/2021 | CA | 19 | M | 4/20/2021 | 4/20/2021 | PATIENT RECEIVED FIRST FOSE COVID19 VACCINE AT 10:20AM TODAY, SECONDS TO A MINUTE AFTER THAT PATIENT FAINTED FOR A FEW SECONDS BUT RECOVERED IMMEDIATELY NOT KNOWING WHAT HAPPENED. 911 WAS CALLED STAT AND ARRIVED WITHIN APPROX 5 MIN. PATIENT WAS COMMUNICATIVE IMMEDIATELY AFTER INCIDENT, SAID HE FEELS GOOD NOW BUT DIZZY BECAUSE HE DID NOT EAT FOOD IN THE AM. FATHER WAS PRESENT. EMT NOTICED PATIENT'S BLOOD PRESSURE VERY LOW AND TOOK PATIENT TO THE HOSPITAL RIGHT AWAY. PATIENT DID NOT WANT TO GO TO HOSPITAL IMMEDIATELY BUT AGREED AFTER ADVISED TO DO SO. PATIENT DENIED TROUBLE BREATHING OR ANY OTHER SYMPTOMS WHILE PRESENT AT PHARMACY. PATIENT AND EMT LEFT SITE BY 10:39AM |
| 1234842 | 4/20/2021 | CA | 31 | F | 4/15/2021 | 4/17/2021 | 40 hours after vaccination severe light sensitivity causing paralysis and fainting in daylight. |
| 1235122 | 4/20/2021 | WA | 26 | M | 4/20/2021 | 4/20/2021 | About 5 minutes after administration, patient experience brief syncope (recovery within 10 seconds). When sitting, patient experienced confusion and pallor. Patient denied history of DM, but mentioned history of hypoglycemia. Provided 15 grams glucose tablets and water. Monitored patient until cleared by EMS. No additional ADRs. |
| 1235139 | 4/20/2021 | | 31 | F | 4/20/2021 | 4/20/2021 | Pt fainted after injection. Pt was pale and weak. Pt was brought to medical area and laid down with feet elevated. Pt vital signs were taken and hr was 49-40, bp was 104/72, resp 18, spo2 was 98% ra. Pt rested with feet elevated for 20mins. Pt felt better vs improved. Hr increased to 71. No was increased to 113/77. Resp 18. Spo2 98% ra. Pt felt better and was released to observation area. Pt checked herself out w/o incident. |

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| 1235151 | 4/20/2021 | IL | 57 | M | 4/20/2021 | 4/20/2021 | After 8 minutes I broke out in a cold sweat and immediately passed out for 30-45 seconds. I woke up laying on my back not knowing how I got there. |
| 1235162 | 4/20/2021 | NV | 22 | M | 4/20/2021 | 4/20/2021 | PATIENT WAS SEATING IN THE LOBBY AFTER THE IMMUNIZATION. TEN MINUTES LATER THE PATIENT PASSED OUT. PARAMEDICS WERE CALLED AND AFTER THEIR EXAMINATION ALL VITALS ARE NORMAL, THE PATIENT WAS RELEASED AND NO ADDITIONAL MEDICAL ATTENTION WAS PROVIDED. |
| 1235185 | 4/20/2021 | VA | 30 | M | 4/20/2021 | 4/20/2021 | Sudden dizziness after 10 mins. Had sweat a lot for 10-15 minutes. Had a feeling of about to get fainted. Symptoms subsided automatically within 15 minutes without any intervention. |
| 1235201 | 4/20/2021 | FL | 18 | F | 4/20/2021 | 4/20/2021 | patient fainted after about 5 to 10 minutes. when I found the patient, she was already standing and talking. she looked pale and shaky. her blood pressure at the time was 97/75 with pulse 75 and oxygen at 98. about 15 to 20 minutes later, her blood pressure was 96/65 and pulse 70 and oxygen 99. she was no longer pale and her color looked like before she was given the shot. she has no other symptoms. she said she feels normal again with no difficulty breathing or any heart symptoms. patient was advised to see a doctor and she had a friend take her home. |
| 1235390 | 4/20/2021 | CA | 56 | M | 4/20/2021 | 4/20/2021 | THE PATIENT WAS SEATED IN THE LOBBY AFTER HIS IMMUNIZATION. HE THEN SAW A PATIENT FAINTED AND IMMEDIATELY PASSED OUT ALSO. PARAMEDICAS WERE CALLED AND AFTER EXAMINATION THEY TOOK HIM TO THE HOSPITAL |

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| 1235462 | 4/20/2021 | WA | 62 | F | 3/26/2021 | 3/26/2021 | 2 hours after receiving the vaccine, I grew exhausted and had to sleep into late evening and was chilled, had a fever of 101 and developed severe pain and inflammation on the top of my collar bone that was feverish and migrated toward my shoulder region on the same side as my vaccine. Ibuprofen would not help with the pain but helped with the fever. My mind told me that I had things to tend to the next day, but still was forced to sleep off and on for 2 more days. After a week and a half, not only did I have thirst, but also food didn't taste right and was metallic. This lasted for 2 days and finally my taste was restored. The exhaustion lasted off and on for 2 weeks and I just listened to my body. The pain and inflammation on my collar bone has subsided 4 days ago but still have pain in my shoulder when I sleep. On April 5 around 8:30 a.m. a nasty virus hit me out of the blue. I grew weak and tired and had to go to bed. I slept all day until around 9:00 p.m. and woke to uncontrollable diarrhea and fainting spell while in the bathroom. I had abominable pain and nausea that last for a half hour and then I returned to bed. The next 2 days, I was weak and exhausted but continued with my regular routine. My equilibrium is still affected from time to time. |
| 1235557 | 4/20/2021 | AZ | | U | | | Vomiting, Diarrhea, Dizziness upon standing, Fainting when walking or standing, Muscle aches, Abdominal Cramping |
| 1235567 | 4/20/2021 | WA | 37 | M | 4/19/2021 | 4/19/2021 | Hypotension, Fainting, Stomach Upset |
| 1233913 | 4/20/2021 | OH | 23 | F | 4/20/2021 | 4/20/2021 | After patient received the vaccination, within moments she fainted and fell to the floor from a seated position, pharmacist immediately responded and patient regained consciousness almost immediately. Patient reports hitting her head and a sore neck. patient was monitored by pharmacist until patient was back to baseline. Upon leaving patient states feeling fine and refused additional medical treatment at the time of leaving. |

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| 1233320 | 4/20/2021 | NJ | 22 | M | 4/20/2021 | 4/20/2021 | Patient fainted 15 minutes after getting his first dose of covid-19 vaccine. He fainted for about 15-20 seconds and came back saying his vision decreased and thought he was dreaming. He was breathing normal upon waking and didn't complain of anything else. he was lying flat until EMS arrived on site after approximately 10 minutes. He was able to get up and leave the facility by himself and didn't get transported to any medical facility. |
| 1234781 | 4/20/2021 | | 45 | F | 4/5/2021 | 4/6/2021 | day after shot: syncope, fever, chills, running high BP and has a cold. Following up with PCP. |
| 1233611 | 4/20/2021 | NC | 20 | M | 4/19/2021 | 4/20/2021 | Patient had bowel movement after waking up and going to bathroom. He fainted, calling for help to his parents on his way down to the floor. Parents found him on floor cognitively responsive but not moving body (He does not remember anything after coming to kneel on floor). Parents found him clammy. Mother called 911 and was instructed to keep him lying on floor. He complained of being cold but was sweaty. Blanket placed over him on floor and kept there until EMS arrived. Patient c/o nausea. They got him into rolling chair and was going to leave when he had another episode of dizziness, clammy and nausea. EMS transported him to hospital. Blood work was done with no abnormalities noted. Upon discharge he complained of headache. Nausea dissipated upon eating and some ginger ale. Patient had previous had "covid arm" with first injection but no other complaints. |
| 1235138 | 4/20/2021 | CA | 27 | M | 4/19/2021 | 4/19/2021 | Fainting (laid head on table) within seconds after vaccine administration. Assessed and aroused patient. Took blood pressure, put cool wet towels on neck, kept patient alert and put in supine position with legs elevated on chair. Continued to monitor blood pressure and when able to sit up was given food and water. Patient was observed for approximately 1 hour |

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| 1234250 | 4/20/2021 | MA | 29 | U | 4/19/2021 | 4/19/2021 | Patient received Covid vaccine. During her 15 minutes of monitoring her boyfriend came to get us saying she fainted. When I touched her arm and said her name she was responsive to me. We got her an ice pack, she started drinking water and then told me she felt nauseous. I got her a trash can and she vomited. After she stated she felt better and she started to regain her color. We made her monitor for an additional 15 minutes after the incident. |
| 1233390 | 4/20/2021 | UT | 29 | F | 4/16/2021 | 4/16/2021 | After receiving first COVID vaccine, patient became lightheaded, nearly passed out, and nauseated. Patient was hypotensive and tachycardic, feeling chest tightness and lump in her throat. the sensation of tongue swelling occurred in the ED. Vitals were performed and the patient was given fluids. Initial vitals were 80/52, HR 89, O2 97% on RA while sitting up right. After 15 more minutes and after providing 400 ml to drink, her BP was 115/80 O2 sats 100%. When cardiac symptoms and throat sensation were expressed, the an RRT was called and the patient was taken to the ER for observation. In the ED she was given juice and observed. She was later discharged after monitoring. |
| 1233405 | 4/20/2021 | TX | 19 | F | 4/20/2021 | 4/20/2021 | SYNCOPE,PASSING OUT ,CAME BACK NORMAL AFTER FEW MINUTES |
| 1233422 | 4/20/2021 | MN | 30 | F | 1/27/2021 | 1/27/2021 | About 4-5 minutes after receiving my vaccine, my entire body got flush, and I almost passed out. I was able to stay conscious, but my sight became extremely blurry. I was not able to see well for the next 4 hours or so afterwards. I also developed a vertigo, and needed to take 2 days off of work, plus the entire weekend to begin to recover. The only thing that helped the headache, my eyes, and my head feel somewhat normal was to sleep. I slept on and off for most of the following 5 days after my vaccine. |
| 1233478 | 4/20/2021 | FL | 30 | M | 4/20/2021 | 4/20/2021 | Patient became lightheaded, fainted and lost consciousness for approx 5 seconds. Let patient lie down, gave juice and protein bar, patient left on own will approx 15-20 minutes later (patient has prior hx of fainting and had no morning breakfst) |

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| 1233489 | 4/20/2021 | NY | 20 | M | 4/4/2021 | 4/20/2021 | Felt dizziness and lightheaded about two minutes after receiving shot. I passed out and when I woke up I was struggling to regain consciousness control of my body as I was having a seizure. |
| 1233526 | 4/20/2021 | MO | 63 | F | 4/16/2021 | 4/16/2021 | After the patient waited her 15 minutes, she left the pharmacy by driving her vehicle. While in her vehicle, she was stopped at a stop light and thinks she fainted or blacked out. She woke up in the middle of the intersection and was able to hit the gas before she was hit by another car. She did not go anywhere for treatment and has not experienced the same side effect since that time. |
| 1233683 | 4/20/2021 | WA | 23 | F | 4/20/2021 | 4/20/2021 | Near syncope, Hypotension, Bradycardia |
| 1233690 | 4/20/2021 | | 89 | F | 3/31/2021 | 4/16/2021 | Acute syncope with two syncopal episodes, found to have bilateral subsegmental pulmonary emboli and oxygen requirement |
| 1233731 | 4/20/2021 | RI | 25 | M | 4/20/2021 | 4/20/2021 | Vasovagal syncope leading to fall, hit head, facial laceration |
| 1233734 | 4/20/2021 | RI | 26 | M | 4/20/2021 | 4/20/2021 | NEAR SYNCOPE, DIZZY, ABNORMAL FEELING IN THROAT Primary/secondary assessment / observation Vital signs stable, lung sounds clear through out, warm dry skin w/ regular bi lateral radial pulses Patient denied any CX pain, SOB, dyspnea, headaches, visual disturbances, N/V while in observation, patient informed provider he began to feel better & was able to leave. Patients vital signs presented with out any abnormal findings Patient was advised to seek emergency medical treatment if any adverse reactions presented |
| 1233770 | 4/20/2021 | ID | 22 | F | 4/20/2021 | 4/20/2021 | Patient received blood draw directly after the immunization for a blood work order. Shortly after that she fainted while making her follow-up appointment. She was only momentarily out and did not hit her head as she slumped forward (per the person who witnessed it, who was not me). She remained in the clinic for observation for almost 30 minutes and given Gatorade. She then left under her own power with no problems. |
| 1234182 | 4/20/2021 | CA | 23 | F | 4/20/2021 | 4/20/2021 | Patient fainted a few minutes after receiving the covid-19 shot. |

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| 1234194 | 4/20/2021 | NC | 65 | F | 3/27/2021 | 4/12/2021 | Lightheaded (Presyncope - per what I have read); more lethargic than typical and having to sleep longer; less stamina for typical aerobic exercise; shortness of breath at times. That this was not a direct result of the vaccination (which I experienced fever, aches and chills for 18 hours starting 12 hours post-shot) -rather the disequilibrium or presyncope symptoms began a couple of weeks later-is what was unexpected to me. |
| 1233520 | 4/20/2021 | | 39 | M | 4/20/2021 | 4/20/2021 | PATIENT FELT DIZZY AND ALMOST FAINTED WITHIN 5 MINUTES OF ADMINISTRATION. HE WAS VERY SWEATY AND AT FIRST HAD SOME ISSUE BREATHING WHICH RESOLVED AFTER A FEW SECONDS |
| 1234183 | 4/20/2021 | MI | 21 | M | 4/1/2021 | 4/20/2021 | Fainted immediately after the shot. This is not the first time he has fainted after a shot, though. |
| 1233779 | 4/20/2021 | | 58 | M | 4/13/2021 | 4/13/2021 | The patient is a 58-year-old male who presents as a transfer from Hospital for evaluation and of recurrent syncope and management of a left-sided mandibular fracture. The patient reports that his symptoms first started after his first dose of the moderna vaccine. He reports that he felt recurrent nausea and diaphoresis however had no syncopal episodes. Following his second dose of vaccine on 4/13 he reports 3 episodes of syncope. He describes the sensation of nausea and diaphoresis followed by loss of consciousness. After the first episode he passed out and he hit him his jaw and has pain in his left jaw since that time. He had 2 further episodes of syncope 2 of which were witnessed. No seizure activity was described by by witnesses and the episode lasted approximately 1-1/2 minutes. He denies any palpitations or chest pain or incontinence or tongue biting. He denies similar symptoms previously. |

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| 1234112 | 4/20/2021 | GA | 46 | F | 3/31/2021 | 3/31/2021 | The evening that I took the vaccination I was running a fever body aches and chills the day after taking the vaccination I had the same effects fever body aches chills 5 days after taking the vaccination very sick not feeling well not feeling myself passed out twice at home the sixth day after taking the vaccination I proceeded to work was sent home before I could even get in the building went to ER was treated for an allergic reaction after telling them I was 6 days from vaccination then on 4-9-2021 I was taken by my husband to the ER my entire left side was numb tingling sensation couldn't lift my leg couldn't hold my arm up had no peripheral vision severe headache at the ER I was seen by my neurologist and I was told that I had 20 minutes to make a decision whether to take the TPA shot which I chose to take I was released from the hospital on 4/11/2021 I am finally going back to work tomorrow (4-21-2021) I am now having more anxiety I've had extreme weight loss I've lost 20 lb since this occurred |
| 1234028 | 4/20/2021 | WI | 22 | M | 4/20/2021 | 4/20/2021 | Patient had full syncope episode approximately 15 minutes after receiving the vaccine. Patient was able to arouse quickly. Vital Signs: 1320: BP-124/73 P-74 R-16 Pox-95% 1328: BP-114/77 P-84 R-24 Pox-97% No trauma sustained in fall. Patient alert and orientedx3. Patient remains very pale and weak. Transported to Emergency Room via ambulance for further assessment. |
| 1234023 | 4/20/2021 | MO | 71 | F | 4/20/2021 | 4/20/2021 | patient fainted after injection while trying to stand up. blood pressure ok, pulse ok, breathing ok. All vitals monitored by emt on site. revived after about 10 minutes. Refused to be taken by ambulance. Emt indicated just a sign of anxiety and not from vaccine |

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| 1233992 | 4/20/2021 | NJ | 24 | M | 4/9/2021 | 4/9/2021 | Immediate Effects: 10 Minutes - Heat Flash, Feeling of Fainting, Gasp for Air (Lasted 20 seconds) Post-Immediate Effects: 45 Minutes - Extreme Difficulty Breathing while driving; Symptoms of Panic Attack Set in (Never Had a Panic Attack Prior - Arms, Legs and Lower Jaw was tingling and numb; Could not speak; Difficulty in Dialing 911 from rapid finger movement.) Received Medical Attention from EMT and chose to go home when severe symptoms subsided after 20 minutes. Long Term Effects: Day 2 to Present: Difficulty breathing, confusion, unable to do any physical task (walking up stairs) without being dizzy, disoriented and gasping for air, pain near arteries in neck, knee and heart - with each pulse. On 4/12/2021 - Urgent Care Visit - Long Term Symptoms Present. PulseOx read 96; Tested Negative for COVID-19. Nurse Practitioner recommended ER if condition worsened. On 4/17/2021 - ER Visit - Severe Long Term Symptoms Present. Blood Panel Done; Chest X-Ray, EKG, Brain MRI. ER Doctor recommended seeing neurologist, immunologist and cardiologist. |
| 1233831 | 4/20/2021 | MA | 30 | M | 4/18/2021 | 4/18/2021 | Systemic: Chills-Mild, Systemic: Confusion-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Hypotension-Mild, Systemic: Shakiness-Mild, Additional Details: patient was rushed to the hospital by the ambulance, i followed up with the patient and he left the hospital hours after on the same day. patient is now recovered and feeling well. |
| 1233912 | 4/20/2021 | WI | 73 | M | 3/27/2021 | 4/19/2021 | Intermediate Risk PE-diagnosed due to symptoms of pre-syncope, palpitations. Clinical history includes long car ride |
| 1233896 | 4/20/2021 | ME | 22 | F | 4/20/2021 | 4/20/2021 | PATIENT EXPERIENCED SYNCOPE IN POST VACCINATION WAITING AREA. ELEVATED FEET WITH ANOTHER CHAIR, GAVE A WATER, AND A WATER PAPER TOWEL TO COOL OFF WITH. AFTER THE RECOMMENDED 15 MINUTE WAIT TIME WAS UP, PATIENT WAS FEELING BETTER AND LEFT WITH NO ISSUES. |
| 1233850 | 4/20/2021 | | 21 | M | 4/20/2021 | 4/27/2021 | Dizziness,syncope |

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| 1233843 | 4/20/2021 | FL | 29 | F | 4/15/2021 | 4/15/2021 | Client experienced an episode of syncope immediately after receiving the vaccine. Patient was put in Trendelenberg and administered ammonia inhalant. Fire Rescue at scene to evaluate client. Blood pressure very low during assessment although patient became a+ox3. Client refused transport to ER as recommended by Fire Rescue. Client transitioned to passenger seat and mother drove client home and was given instructions to call 911 if any symptoms of hypotension occurred. |
| 1233922 | 4/20/2021 | IL | 48 | M | 4/11/2021 | 4/11/2021 | Patient experienced sweating, feeling hot and syncope post vaccination, recovered and released |
| 1229312 | 4/19/2021 | IL | 56 | M | 3/8/2021 | 4/17/2021 | 4/17/21 ER HPI: 56 y.o. male who presents with asymptomatic tachycardia. The patient purchased a home blood pressure monitoring device approximately 2 weeks ago and at that time he noted that the machine recorded his pulse at 150-160 beats per minute. The patient has repeatedly taking his blood pressure at home with this device and every time and has recorded his pulse in the same range. He denies fevers chills chest pain palpitations syncope lightheadedness peripheral edema or dyspnea. He presents today for evaluation of this as the machine again indicated that his pulse was 100 50-160 beats per minute |
| 1229307 | 4/19/2021 | MA | 26 | F | 3/24/2021 | 3/24/2021 | Approximately five minutes after receiving the vaccine, the patient began to lose consciousness (fainted) while sitting upright in a chair. The patient lost vision, then hearing, then eventually laid down on the floor until she regained consciousness. |
| 1229253 | 4/19/2021 | AL | 18 | F | 4/7/2021 | 4/7/2021 | 1328 - Father stated daughter didn't feel well - walked to stretcher and fainted. 1330 - Patient awake, VS taken, on stretcher, color improved, talking. BP = 98/53, HR = 74, RR = 22, O2 Sat = 100% 1335 - Patient sitting up. 1340 - Patient talking, drinking soda. BP = 117/76, HR = 80, RR = 22, O2 Sat = 100% 1350 - Patient's color pink, in no apparent distress. BP = 129/71, Hr = 83, RR = 16, O2 Sat = 98% 1351 - Patient ambulated out of clinic with father. |
| 1229240 | 4/19/2021 | | 21 | M | 4/19/2021 | 4/19/2021 | Syncope |
| 1229219 | 4/19/2021 | | 26 | M | 4/19/2021 | 4/19/2021 | Severe dizziness/ presyncope |

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| 1229158 | 4/19/2021 | NY | 21 | M | 4/11/2021 | 4/11/2021 | a number of minutes after receiving the vaccine, patient fainted while seated, fell backwards in his chair, and hit his head on the floor. as a result of the fall, the back of his head was cut. he remained on the floor and gauze was held against the cut to slow/stop the bleeding until the ambulance service arrived. Patient was taken to the hospital for treatment of the cut. Patient is currently in good health. |
| 1229126 | 4/19/2021 | MN | 59 | F | 4/13/2021 | 4/18/2021 | Presyncope. Was walking around lake and for about 45 minutes I felt like I was going to faint. I never did faint but I had to stop and rest. This has never happened before when I was walking or running or anything. I still feel the remnants of that feeling today 1 day later but otherwise ok. The episode had nothing to do with low blood sugar as that is a completely different feeling. This felt like a blood flow to brain issue. |
| 1229056 | 4/19/2021 | FL | | U | | | Intense shoulder pain at time of injection. Shoulder joint pain, not actually at injection site. 24 hrs after shot got a high fever, vomiting, fainting, and still more shoulder pain. Can not move my arm to brush teeth, brush hair, very limited mobility in the right arm. Not getting better and this is day 4. |
| 1229043 | 4/19/2021 | FL | 54 | F | 4/19/2021 | 4/19/2021 | 11:15. Patient had fainted after her first vaccination, so we had her receive the second dose in a quiet, secluded part of clinic. Shortly after the 2nd dose, she said she felt weak, and slumped in her chair. She was assisted to the floor. EMS and NP in attendance. Patient was quiet but anxious. VS 144/84; HR 99; r 22-25/ Pulse oximeter 100 on RA. Fingertick glucose 111 @ 11:20 am. Patient was more awake, talking about her family. Her cousin and sister in law were in attendance as well. Continued her observation period in the quiet environment. Recovered without incident and left at 11:40 am. |

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| 1228868 | 4/19/2021 | FL | 49 | M | 4/19/2021 | 4/19/2021 | Patient received vaccine at 10:29am. Upon walking toward post-vaccination area, patient fainted at 10:30am. He struck his head on the ground when he passed out. Patient regained groggy consciousness at 10:31am and was able to answer basic questions and seemed somewhat alert. Cold compress was applied to head and neck. EMS was called to assess patient for potential concussion. Patient was taken to local emergency room for follow up assessment/treatment |
| 1228956 | 4/19/2021 | OH | 55 | F | 3/31/2021 | 3/31/2021 | Approximately 5-10 minutes after receiving vaccine, patient felt nauseous, lightheaded, and she fainted and lost consciousness. EMS was called and due to patient's blood pressure being very low, she was transported to the clinic emergency department. Patient reports she received something by IV to help with blood pressure and given the patient's heart history they performed a chest x-ray and blood work, which came back normal. Patient also reports that she experienced a heaviness in her chest for a week following vaccination, but after one week it went away. Patient denies any difficulty breathing. |

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| 1228872 | 4/19/2021 | NY | 26 | M | 3/18/2021 | 3/18/2021 | I received the J&J vaccine at 10:00am on March 18, 2021 at the Community Center. By about 5:00pm, I started to feel minor flu-like symptoms, but as the night progressed it got significantly worse. Around 8-9pm, I was bedridden with the worst chills/shaking I've ever experienced in my life. Around 9:30-10:00pm, I was filling water at my sink and projectile vomitted multiple times into the sink and could not make it to the bathroom. Subsequently, I ate a bagel and drank lots of water, knowing my vomitting could make me dehydrated. Throughout the night, I was awake and shaking, and drank and filled my water bottle repeatedly. At 8:00am, I was filling my water, and without my knowledge of awareness, fainted on my kitchen floor, dropping the Brita filter and likely hitting my head. My roommate heard the commotion and saw me passed out in our kitchen. He tried to wake me up and I phased in, but then subsequently phased out again 20-30 seconds later as I was trying to stand and likely hit my head again. My roommate eventually got me over to our couch and called EMTs. Upon their arrival, EMTs checked my pulse, which was fine, and saw an open laceration on the back of my head, so they took me to Hospital to access the Trauma Center. On the way, I threw up repeatedly and was very lightheaded. Upon my arrival at Hospital, I was checked for any neck bone breaks, given an IV, a CT scan, an EKG, and staples were placed in the back of my head to heal the laceration. After my release, I was bedridden for 2-3 days and required a daily nap during work (1-2) hours for the next 1 1/2 to 2 weeks. For a while, everything was fine, but recently during the first two weeks of April, it has become apparent that my head is foggy and reacts to changes in the weather, which leads me to believe that I likely banged my head pretty good when I fainted those two times. |
| 1228812 | 4/19/2021 | | 61 | M | 4/8/2021 | 4/8/2021 | Feeling unwell. "Burning" head to toe, shakes, near syncope, sweats, tiredness, dizziness, lightheaded. Onset of symptoms less than 1 hour. Patient denied symptoms of chest pain, (L) arm pain, or SOB. Patient sent by EMS to local emergency department. |

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| 1228836 | 4/19/2021 | IL | 70 | F | 2/10/2021 | 4/17/2021 | female who presents with complaint of a dry cough and dyspnea. She denies fever chills chest pain orthopnea paroxysmal nocturnal dyspnea palpitations syncope or peripheral edema. Her dyspnea had onset 2-3 days ago and has progressively worsened. Patient does have a history of COPD 12/30/21 Pfizer EJ1646 1/20/21 Pfizer EL3249 x3 covid vaccines given to patient by nursing home: 2/10/21 Pfizer EN5318 |
| 1229689 | 4/19/2021 | FL | 27 | F | 4/19/2021 | 4/19/2021 | fainting following vaccination. full body assessment, contacted EMS. |
| 1229314 | 4/19/2021 | MD | 49 | F | 4/19/2021 | 4/19/2021 | PT waked up to the front of the observation room c/o feeling faint and fainted she was out for about 30 seconds upon waking her up we tried to sit her up and she became very pale PT was sent out 911 for observation |
| 1228968 | 4/19/2021 | TX | 28 | F | 3/6/2021 | 3/13/2021 | Started with chest pain, a couple of days after the shot. Fainted on 3/13/21, transported by EMS to emergency room. CT scan was done, Dr. said she has blood clots in her lungs. Was given a prescription for Eliquis 5 mg twice daily. |
| 1229527 | 4/19/2021 | VA | 17 | F | 4/15/2021 | 4/15/2021 | Syncope episode. EMS monitored, blood sugar taken resulted 97 after juice, declined transport after all s/s resolved (45 minutes) |
| 1227457 | 4/19/2021 | CA | 52 | F | 4/17/2021 | 4/18/2021 | Syncope, headache, chills, nausea, vomiting |
| 1228802 | 4/19/2021 | FL | 20 | M | 4/18/2021 | 4/18/2021 | Several minutes after receiving 1st dose of Moderna patient fainted and slid from chair onto floor. He was unresponsive for approximately 15-20 seconds and then regained consciousness. Pharmacist immediately took his blood pressure and it was 112/56. Patient stated that he was ok and had no trouble breathing. His grandmother accompanied him and they did not wish to call EMS. Patient was monitored for another 45 minutes and blood pressure was checked every 15 minutes where is was 122/64, 106/72, 107/78. After 45 minutes patient said he felt fine and wished to leave. Pharmacist accompanied patient to his car and grandmother drove him home. |

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| 1229780 | 4/19/2021 | ME | 20 | M | 4/19/2021 | 4/19/2021 | Vasovagal syncope induced from anxiety. While waiting in post vaccine observation while sitting, patient fainted briefly while still in chair. Mother braced him until I and my staff could assist. Elevated legs with another chair and provided and ice pack and bottle of water. After 5-10 minutes, the patient was fine and left without any issues. |
| 1229655 | 4/19/2021 | AZ | 36 | M | 4/10/2021 | 4/10/2021 | vaccination event. Patient was waiting his 15 minutes after receiving the vaccine; he "passed out". The local fire department responded and attended to him. He was not transferred to care |
| 1229604 | 4/19/2021 | ME | 20 | M | 4/19/2021 | 4/19/2021 | Patient had vasovagal syncope (due to anxiety) after being vaccinated roughly 5-10 minutes afterwards while sitting in post observation area. His mother was with him and propped him up from falling out of the chair until I and my other staff could assist. Propped his feet up with another chair, provided and ice pack and a bottle of water. Patient was fine after sitting for an additional 5-10 minutes. |
| 1229553 | 4/19/2021 | VA | 17 | F | 4/15/2021 | 4/15/2021 | Patient experienced severe syncope episode. Monitored by onsite EMS - 45 minutes until symptoms resolved. Patient waited additional 45 minutes. Patient declined transport to ED. |
| 1229649 | 4/19/2021 | NC | 55 | M | 4/4/2021 | 4/4/2021 | patient fainted |
| 1229531 | 4/19/2021 | | 21 | M | 4/13/2021 | 4/13/2021 | Patient received the vaccine and moments after passed out (head and eyes rolled back), starting slouching on his right side and started to show twitching/convulsions and turned pale. Regained conscience soon after his name was spoken to him. Called RRT, took vitals while waiting for RRT. Mother of patient explained that this happens every time the patient receives a shot or blood drawn. RRT showed up and assisted soon after. |
| 1229420 | 4/19/2021 | MD | 36 | M | 4/5/2021 | 4/5/2021 | Received first Covid 19 vaccine and was told to walk around by person who administered injection since they did not have enough chairs. Approximately five minutes after injection I was standing in an aisle when my vision became blurry and I felt a wave of heat come over my body. I began to crouch down and passed out hitting my head causing a concussion. |

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| 1229505 | 4/19/2021 | PA | 16 | F | 4/17/2021 | 4/17/2021 | Syncope |
| 1229501 | 4/19/2021 | VA | 19 | F | 3/26/2021 | 3/26/2021 | Syncope - two episodes after vaccine administration. Transported to local hospital for evaluation. |
| 1229466 | 4/19/2021 | IA | 22 | F | 4/18/2021 | 4/18/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: rec'v vaccine at 2:20pm, reaction of less than 2 seconds of faintness at 2:25pm, EMS was called and arrived @2:29pm, vitals were good, condition was confirmed ok and pt declined transport with EMS. Left on her own accord after a full 30 minutes post vaccine wait. |
| 1229460 | 4/19/2021 | FL | 20 | F | 4/19/2021 | 4/19/2021 | FAINTED, THROAT TIGHTNESS, DIZZINESS, HARD OF HEARING |
| 1229448 | 4/19/2021 | NY | 24 | F | 4/18/2021 | 4/18/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: pt fainted but woke up immediately after and was responsive and aware -Mild, Additional Details: pt fainted and hit her head, woke up 30 seconds after and was responsive and aware of what happened and surroundings. she hit her head on the wall corner when she fainted but claimed to be okay. we called 911 and she refused treatment when they arrived. her mom picked her up and she went home. |
| 1229442 | 4/19/2021 | | 16 | M | 4/15/2021 | 4/15/2021 | Patient passed out in observation area, another patient called out for assistance. Patient appeared diaphoretic, bp 85/50. I have patient water and observed him for an additional 15 mins afterward. Retook blood pressure, 110/78. patient awake, talking to father. States he "feels much better". |
| 1229430 | 4/19/2021 | | 21 | F | 4/15/2021 | 4/15/2021 | Around 10 min after injection patient flagged down a technician and said she thought she was going to faint. Fainting has happened to her in the past and she could feel it coming on. The pharmacist moved her closer to the area and gave her water. While pharmacist was standing with her she lost consciousness and control of her bladder. Pharmacist held patient upright as she was still in the chair as to not obstruct breathing. Patient was out for around a min and regained consciousness. Pharmacist in that time had called EMS who arrived later and checked all vitals. Patient drove alone nearly an hour so Pharmacist want to make sure she was ok before driving the long distance home. |

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| 1229550 | 4/19/2021 | NC | 46 | F | 3/20/2021 | 3/21/2021 | Passed out two different times. |

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| 1227821 | 4/19/2021 | IL | | F | 4/6/2021 | 4/6/2021 | bad GI gastric feeling; diarrhea/diarrhea movement/bowl moment; had cold; nausea/feel like throw-up; headache; feeling like shut down; hyperventilation; her face was gray/both hands and arms are white/ her face was gray; passed out; Reality perception off; small bowl moment; injected to wrong site; stomach got hungry; her vision was different,; was not able to sleep; Very painful contraction; This spontaneous case was reported by a physician (subsequently medically confirmed) and describes the occurrence of LOSS OF CONSCIOUSNESS (passed out) and ACUTE PSYCHOSIS (Reality perception off) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 025B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event. On 06-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 06-Apr-2021, the patient experienced PRODUCT ADMINISTERED AT INAPPROPRIATE SITE (injected to wrong site), INCREASED APPETITE (stomach got hungry), VISUAL IMPAIRMENT (her vision was different,), INSOMNIA (was not able to sleep) and PAIN (Very painful contraction). On 07-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (passed out) (seriousness criterion medically significant), ACUTE PSYCHOSIS (Reality perception off) (seriousness criterion medically significant), GASTROINTESTINAL DISORDER (bad GI gastric feeling), DIARRHOEA (diarrhea/diarrhea movement/bowl moment), FEELING COLD (had cold), NAUSEA (nausea/feel like throw-up), HEADACHE (headache), MALAISE (feeling like shut down), HYPERVENTILATION (hyperventilation), SKIN DISCOLOURATION (her face was gray/both hands and arms are white/ her face was gray) and ABDOMINAL DISCOMFORT (small bowl moment). On 06-Apr-2021, PRODUCT ADMINISTERED AT INAPPROPRIATE SITE (injected to wrong site) had resolved. At the time of the report, LOSS OF CONSCIOUSNESS (passed out), INCREASED APPETITE (stomach got hungry), VISUAL IMPAIRMENT (her vision was different,), INSOMNIA |

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(was not able to sleep), DIARRHOEA (diarrhea/diarrhea movement/bowl moment), FEELING COLD (had cold), NAUSEA (nausea/feel like throw-up), HEADACHE (headache), MALAISE (feeling like shut down), HYPERVENTILATION (hyperventilation), SKIN DISCOLOURATION (her face was gray/both hands and arms are white/ her face was gray) and PAIN (Very painful contraction) had not resolved, ACUTE PSYCHOSIS (Reality perception off) and ABDOMINAL DISCOMFORT (small bowl moment) outcome was unknown and GASTROINTESTINAL DISORDER (bad GI gastric feeling) had resolved. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Treatment information include Ibuprofen 200mg initially 1 tablet a day, then every 4 hours in order to get inflammation down. Based on the current available information and the temporal association between the product use and the start date of the events a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and the temporal association between the product use and the start date of the events a causal relationship cannot be excluded.

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| 1227816 | 4/19/2021 | IA | | F | | 4/7/2021 | <p>FAINTED; SEIZURE; STOPPED BREATHING; LIGHT HEADED; CYANOSIS; This spontaneous report received from a health care professional (public health nurse) concerned a female of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration not reported, batch number: 043A21A, and expiry: 31-DEC-2069) dose was not reported, 1 total, administered on left arm on 07-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On 07-APR-2021, about 5 minutes after vaccination, the patient experienced lightheadedness, then fainted, had a seizure, stopped breathing (for 10 seconds), and developed cyanosis (turned blue). The nurse did cardiopulmonary resuscitation (CPR) and the Emergency Medical Services (EMS) was called. By the time the EMS arrived, the patient felt better. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from stopped breathing on 07-APR-2021, and was recovering from light headed, fainted, seizure, and cyanosis. This report was serious (Other Medically Important Condition, and Life Threatening). This case, from the same reporter is linked to 20210417723.; Sender's Comments: v0 This report involves a female patient of unspecified age who experienced lightheadedness, then fainted, had a seizure, stopped breathing and developed cyanosis about 5 minutes after receiving Janssen COVID-19 Vaccine Ad26.CO2.S for prophylactic vaccination. Given the close temporal relationship the events are considered possibly related to the vaccination.</p> |

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| 1228194 | 4/19/2021 | CA | 22 | M | 4/18/2021 | 4/18/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Additional Details: Patient felt dizzy/light-headed within 1-2 minutes of receiving his 2nd dose of Moderna vaccine on 4/18/21 at ~12:30pm. Patient stood up from the waiting area, walked approximately 20 feet to the pharmacy window to request assistance where he fainted and hit his head on the counter ledge. He has a raised bump (approximately 2 inches wide) on his right temple above his eyebrow. Patient remained conscious, received water/juice/granola bar & was monitored by the RPh for an additional 30-40 minutes. |
| 1228190 | 4/19/2021 | NJ | 36 | M | 4/18/2021 | 4/18/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Medium |
| 1228187 | 4/19/2021 | NJ | 26 | F | 4/18/2021 | 4/18/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Exhaustion / Lethargy-Medium, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild |
| 1228182 | 4/19/2021 | CA | 47 | M | 3/17/2021 | 3/17/2021 | Systemic: After patient was directed to sit down for 15 min to be observed. A few min after patient sat down in chair he passed out and fell off his chair. Nurse gave epipen called 911. Had scrape on R front scalp and some blood on nostril.-Medium, Systemic: Flushed / Sweating-Mild, Additional Details: Patient reported that he had a phobia of needles prior to vaccination. Vaccine was given at approximately 2:50pm. After he fell, the nurse noted he was face down. The nurse asked him to roll on his back and he responded after a few moments. His skin was red, blotchy, and sweaty. Patient said that he was ok and didn't want to get sent to ER. Epipen was administered at 3:02pm on 3/17/21 and ambulance arrived 3:07pm. The nurse noted some improvement but pt was complaining of hand and arm pain. |

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| 1227977 | 4/19/2021 | IN | | M | 3/24/2021 | 3/26/2021 | <p>Pulmonary embolism/ blood clot/ passed out; This is a spontaneous report from a contactable consumer (patient's daughter). A male patient of an unspecified age received BNT162B2 (Pfizer COVID-19 vaccine), dose 1 via an unspecified route of administration, administered in arm, side unknown, on 24Mar2021 14:30 (Lot Number: EN6208) as single dose for COVID-19 immunisation. Vaccination facility type was clinic. Medical history included colon cancer in 2011. He had cancer in 2011 but resolved that year without chemotherapy or radiation. His lab work was good. There were no concomitant medications. No prior vaccinations (within 4 weeks). No family medical history relevant to AE. The patient experienced pulmonary embolism on 26Mar2021 with fatal outcome. The reporter was reporting on the Pfizer COVID vaccine that her father received. She stated he died from a blood clot after receiving the first dose. Stated she needs help because he had no health issues and he died. She just wanted this information to be out there and for people to be aware. This morning they had been reading on the news that the Johnson and Johnson vaccine is on hold. It seems to be put on the market without research. She felt like her father was a guinea pig. Her mother didn't want to get her second dose. Stated there seems to be an issue with Pfizer too. Her father had no issues whatsoever. His death certificate stated the cause of death was a pulmonary embolism, but he had no history of blood clots. Passed away Friday 26Mar2021 at 11:33 am. The reporter stated when he went to Emergency Room they thought he was having a heart attack. All physicians were wondering what happened because he had no health issues. The event required a visit to the emergency room that day because he passed out at his job. The patient underwent lab tests and procedures which included lab work: good in 2011. The patient died on 26Mar2021. An autopsy was performed that revealed pulmonary embolism.; Reported Cause(s) of Death: Pulmonary embolism; Autopsy-determined Cause(s) of Death: Pulmonary embolism</p> |

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| 1228203 | 4/19/2021 | CA | 24 | M | 4/18/2021 | 4/18/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Additional Details: After vaccination around 4:30 pm, patient fainted briefly and became alert again after attending to him. Patients says he sometimes feels dizzy after giving blood or other vaccinations. He said he felt okay after we gave him water and candy, and elevated his legs when he lied down. No epipen was given. Patient felt ok to go home without any assistance. |

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| 1227829 | 4/19/2021 | | 62 | F | 4/5/2021 | 4/12/2021 | I received the Janssen COVAX on Monday morning, 5 Apr 2021. A week later, on Monday evening, 12 Apr 2021, I experienced extremely painful leg cramps and broke out in a sweat. I felt extremely nauseous, and weak, this was followed by a sever pain in my head that was so extreme that I passed out. After coming to, the pain in my head finally began to subside, along with the leg cramps. My husband indicated that I was unconscious for just under a minute. For the next two days, I had bouts of nausea, headaches, sweats, and was extremely tired. On Wednesday, 14 Apr, after learning of the issues related to the Janssen vaccine, and the symptoms described being what I experienced, I contacted the advice (cont'd)..Additional information for Item 18: Line and was told to go to Emergency Room at the hospital, which I did. I do not feel that they addressed my concerns or the symptoms that I was experiencing, and at no time did they try to determine if it was due to the vaccine. The discharge papers did not even address the "event" and the "symptoms" that I described. They did not take any information down related to the vaccine, lot number, etc., that I had received. They seemed to go through a set routine: blood pressure, blood work, temperature, EKG, and CAT scan. 21. (continued)...Visited Emergency Room, however, was requested by ER to go to Primary Care as follow-up, however, as a Employee we cannot be seen by Primary Care on THIS site. Instead , we have to go on the local clinic to receive care. The issue is that this was a vaccine that I was scheduled by my leadership to receive, with no choice in choosing which vaccine I could receive, and without follow-up care for adverse reactions. The hospital did not indicate to me that I should report this incident, however, I am concerned as a result of the "event" that I experienced, that it should be reported. Furthermore,we should have a choice as to which vaccine we want to receive, just as everyone does. Your form does not allow for input addresses Also, your form does not allow for a phone number. I am out of the country. |

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| 1228210 | 4/19/2021 | NJ | 34 | M | 4/15/2021 | 4/16/2021 | Woke up at 4am went to pee and felt dizzy disoriented and almost as if hallucinating. Starting to lose balance and go in and out of consciousness for a few seconds, hitting walls in bathroom with face then exited bathroom and fainted and was unconscious for 30ish seconds. Wife called 911 emt came blood pressure was low around 90/48. Went to PCP at 230pm later that day and blood pressure back to normal and no other issues found |
| 1229782 | 4/19/2021 | CA | 43 | F | 4/19/2021 | 4/19/2021 | At approximately 11:47, patient presented with syncope, nausea and vomiting, headache, and ear pressure. EMS was notified at approximately 11:49 and arrived at 11:54. Pt agreed to transport to hospital. |
| 1227461 | 4/19/2021 | WA | 17 | M | 4/17/2021 | 4/17/2021 | Adverse Event Safety Officer reports guest who received Pfizer vaccine (Lot #EW0164) had a syncope episode within seconds of being vaccinated. Intervention/Treatment/Why it Happened Guest was assisted to the supine position and LE elevated. Aid (EMT?s) were called and responded and assessed for further interventions. (B/P: 110\49, P-84, SPO2 ? 98% r/a). Guest reported to EMT?s that he has a history of feeling faint with vaccinations. Outcomes Guest was assessed by EMT?s and no further interventions indicated and released to the Vaccination Post Op Area. Monitored for 30 minutes with partner and reported no further concerns or issues. |
| 1229869 | 4/19/2021 | CA | 16 | M | 4/18/2021 | 4/18/2021 | Patient fainted and fell on the floor. Patient was awake and oriented on the floor. Vitals taken, BP 100/52,pulse 72, respiration 12. EMS called. Patient transported to hospital for further evaluation. |
| 1227437 | 4/19/2021 | CA | 41 | F | 4/15/2021 | 4/16/2021 | In the middle of the night I passed out while walking from the bathroom. I broke my front tooth in half and smashed in 2 other front teeth. Also bruised cheek, lip, and knee. I had been feeling chills, aches, and flu-like symptoms throughout the night. It required a dental surgeon, dentist, and probably braces. The advice nurse advised going to the Emergency Room due to her concern about a head injury. |
| 1227429 | 4/19/2021 | CA | 41 | F | 3/12/2021 | 3/12/2021 | Vasovagal syncope, 1 week later extremely swollen lymph nodes and unusual fatigue for approx. 2 weeks. |

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| 1227418 | 4/19/2021 | AK | 23 | F | 4/18/2021 | 4/18/2021 | Patient was seated, given injection IM into right deltoid and immediately fainted and gave a jerk of the body. Immunizing pharmacist yelled out for Rapid Response from the ER. Emergency room staff was on scene within 1 minute. They measured patients pulse and BP and took her to the emergency room for monitoring. Patient was gone from immunizing area for 30 minutes. She came back to see us, looking much better and said that she faints all the time. She remarked she was glad she was seated because when she faints when she stands and hits her head she has a sore head for days. She proceeded to schedule her second vaccination utilizing the QR reader we had provided to all patients. Although she didn't tell us beforehand, afterward she told us she faints all the time, that it isn't unusual, and that she had deliberately eaten food and drank plenty of liquids before she came so that it wouldn't be a problem. Patient stated that she was fine and fit to drive and unconcerned about the reaction. |
| 1227406 | 4/19/2021 | | 25 | M | 4/14/2021 | 4/14/2021 | Patient complained of feeling anxious a few minutes after receiving the vaccine, while he was just about to walk up stairs to the observation area. . Stated, "I could not see, my eyes went black, and my fingers were tingling. I almost passed out". Clinician immediately sat patient on a chair and gave him water, which he drank. Medics were called to see patient. Vital signs were WNL. Once cleared by medics, patient was escorted to the ground level observation area. He soon reported that he was back to baseline. Medics cleared him as being medically stable. Patient reported that he no longer was light headed and had no visual disturbances. {Patient did say that he often gets anxious with needle injections. |

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| 1227948 | 4/19/2021 | FL | 67 | M | 4/4/2021 | 4/4/2021 | fainted; collapsed; This is a spontaneous report from a contactable other health care professional. A 67-year-old male patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, formulation: Solution for injection, Lot number: EP6955), via intramuscular route of administration in deltoid on 04Apr2021 at 02:00 PM at single dose for COVID-19 immunisation. Medical history included allergy to penicillin (PCN), congestive heart failure (CHF), diabetes mellitus (DM) and had chronic/long-standing health conditions (pacemaker). Concomitant medication was not reported. Patient previously received first single dose of bnt162b2 (Lot number: EP6955, Pfizer Covid Vaccine) via intramuscular on 14Mar2021 on deltoid for Covid-19 immunization. Patient fainted while shopping after receiving second dose of vaccine. Patient was fine for initial 15 mins but shortly after collapsed. Patient had BP Of 120/70 an unknown glucose level. Patient was conscious coherent the entire time. On 04Apr2021, patient underwent lab test included blood pressure (BP) with result 102/70. Adverse events were resulted in emergency room or emergency department visit. The outcome of events was unknown. Follow-up attempts are needed; Information related to batch/lot number could be requested. |
| 1228449 | 4/19/2021 | NY | 26 | M | 4/19/2021 | 4/19/2021 | Pt was vaccinated in med eval area with vaccine and recovered 10 minutes lying down and ambulated to observation area with no dizziness. Pt c/o dizziness after sitting in chair & diaphoretic. VS taken 118/72 68P 20R 100%sat. Pt brought to med eval area and lying down with icepack. Recovered lying down, fluids offered. Transition to sitting then standing and walking in med eval area. Denies any dizziness. Recovered for total of 25 minutes. Feeling better after drinking, discharge ambulatory home. HX: fainting, dizziness with vaccines , labwork and BP taken. |

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| 1228744 | 4/19/2021 | VA | 64 | F | 4/15/2021 | 4/16/2021 | Arm pain , swelling, hardness Felt cold all night Upon rising, sudden and severe diaphoresis, wave of nausea (without vomiting), passed out cold onto bathroom floor. Woke up disoriented sometime later (Time out?) Felt "off" all day with a headache in the back of my head Went to bed early Friday night due to feeling tired felt relatively normal by saturday afternoon. (Vaccine was Th. morning) |
| 1228720 | 4/19/2021 | FL | 39 | F | 3/12/2021 | 3/12/2021 | syncope episodoe, hand tremors, dizziness, |
| 1228603 | 4/19/2021 | NJ | 58 | F | 2/12/2021 | 2/20/2021 | Passed out and was taken via ambulance to the hospital. All test were ok. Followed up with the cardiologist and did a 2 week halter monitor that was also fine. No reason for this to have occurred except that it was after the second COVID vaccine. |
| 1228585 | 4/19/2021 | OK | 60 | M | 4/19/2021 | 4/19/2021 | Several minutes after injection patient began feeling hot and fainted - Patient never lost consciousness, breathing remained regular, but complained of neck pain |
| 1228577 | 4/19/2021 | MN | 23 | M | 4/8/2021 | 4/8/2021 | Patient received COVID-19 vaccination (Moderna) at 12:04pm. He sat at the table for observation period –stood up and turned, stated he was feeling nauseated, took a step forward and then fainted forward onto a different table. Staff responded and lowered him backward onto the floor. Vitals assessed –BP 100/62, P 72, O2 SAT 98% on room air. Ice pack applied to forehead; patient sweaty but responding, stated hands tingled but no other complaint. Breathing regular, not labored. Admits he had a similar reaction to a vaccination about 3 years ago –does not recall type of vaccine but agreed not life threatening reaction. Denied having any allergies that he is aware of. Admits did not eat recently. (to Continuation Page)Additional information for Item 18: Patient stated he did not hit his face when he fell onto the table, denied physical injury. Assisted to sit up while on floor for a while, then to stand and sit back onto a chair. Given bottle of water and granola bar. Orthostatic blood pressure checked at 12:25pm –sitting blood pressure was 110/72 and standing 108/62. Patient stated feeling well; had him wait out a 30-minute observation period rather than 15-minute period. Walked out of building with staff and his sister; encouraged sister to drive them home, and for him to eat. |

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| 1228533 | 4/19/2021 | TX | 43 | M | 4/8/2021 | 4/8/2021 | Prior to receiving dose of the Janssen Cov-19 vaccine, the patient expressed that he had a fear of needles. The vaccine was administered and the patient was asked to stay seated in the waiting area after the injection. After a few minutes the patient passed out while seated and was moved to being seated on the floor by staff. The patient was given water and his blood pressure was monitored periodically for the next hour before releasing the patient. |
| 1228201 | 4/19/2021 | CA | 18 | M | 4/18/2021 | 4/18/2021 | Systemic: Fainting / Unresponsive-Mild |
| 1228506 | 4/19/2021 | MN | 23 | M | 4/8/2021 | 4/8/2021 | Patient received COVID-19 vaccination (Moderna) at 12:04pm. He sat at the table for observation period ?stood up and turned, stated he was feeling nauseated, took a step forward and then fainted forward onto a different table. Staff responded and lowered him backward onto the floor. Vitals assessed ?BP 100/62, P 72, O2 SAT 98% on room air. Ice pack applied to forehead; patient sweaty but responding, stated hands tingled but no other complaint. Breathing regular, not labored. Admits he had a similar reaction to a vaccination about 3 years ago ?does not recall type of vaccine but agreed not life threatening reaction. Denied having any allergies that he is aware of. Admits he did not eat recently. Patient stated he did not hit his face when he fell onto the table, denied physical injury. Assisted to sit up while on floor for a while, then to stand and sit back onto a chair. Given bottle of water and granola bar. Orthostatic blood pressure checked at 12:25pm ?sitting blood pressure was 110/72 and standing 108/62. Patient stated feeling well; had him wait out a 30-minute observation period rather than 15-minute period. Walked out of building with staff and his sister; encouraged sister to drive them home, and for him to eat. |
| 1228799 | 4/19/2021 | NY | 21 | F | 4/19/2021 | 4/19/2021 | patient recvd vaccination with immediate onset presyncope with diaphoresis with eventual momentary LOC. recovered within 3 seconds. monitored in observation for 15 minutes. patient lucid with nl BP, 100/68. no dizziness with postural changes after recovery. patient was with mother who accompanied the patient out |

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| 1228423 | 4/19/2021 | MN | 16 | F | 4/17/2005 | 4/17/2021 | Patient was given a Pfizer covid vaccine and then immediately passed out. She was completely unresponsive and given 1 dose of epi and she responded to the epi. Her dad was with her and said that she has anxiety issues and this is probably the reason she passed out. EMS was called and it was decided between EMS and Dad that there was no reason to transport her to the hospital as she was doing fine after being checked out by EMS; Dad signed a waiver with EMS declining transport to the hospital. |
| 1228379 | 4/19/2021 | | 26 | F | 4/19/2021 | 4/19/2021 | Syncope/ dizziness |
| 1228313 | 4/19/2021 | TX | 62 | F | 4/17/2021 | 4/17/2021 | Patient in observation. Patient experienced syncope for approximately 10 seconds. Patient awakens. Patient vital signs BP-179/79 HR-76 T-98.6. When patient awoken, AOX3 and she began drinking a bottle of water. Patient monitored. Patient husband and daughter in car. Patient monitored. Vital signs retaken BP-138/78 HR-64 R-16. Patient verbalizes feeling better and anxiety has decreased. Patient and family educated on worsen symptoms and when to seek medical attention. |
| 1228286 | 4/19/2021 | FL | 25 | M | 4/14/2021 | 4/14/2021 | 10:48am Passed out, sweating and urinated. No reaction at site. |

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| 1228260 | 4/19/2021 | FL | 63 | F | 4/6/2021 | 4/7/2021 | The morning I received vaccine 4/6/21, I had no ill effects. I received the vaccine about 4 and 1/2 weeks after having Covid. The next morning 4/7/21 I had severe aches and pains and a fever of 99-100.5. I stayed in bed all day, the fever ended at 7 pm that evening. That evening I went to bed feeling weak tossed and turned the enter night had very severe aches and pains worse than normal my entire body from my neck to my legs, the aches and pains were unbearable. I took cipro at 5 am that morning 4/8/21 due to a UTI infection with a lot of water no food. I got up with the aches and pains I had and felt very nauseous. I decided to shower and felt faint. I passed out for 30-40 seconds on my bed according to my husband when I came to I had no recollection of fainting. This all happened at around 7am. I ate a few bites of a half of a ham sandwich and had juice which helped to get me to feeling a bit better. My husband took my pressure that was very low my doctor who I spoke to said this may have caused me to faint but that the vaccine may have led to this as well. I was weak from it all but started to feel better and I?m fine now. My next vaccine is April 27, I?m afraid to take it but the doctor advised to take it. |
| 1228236 | 4/19/2021 | MD | 41 | M | 4/9/2021 | 4/9/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium |
| 1228227 | 4/19/2021 | FL | 18 | F | 4/18/2021 | 4/18/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Exhaustion / Lethargy-Severe, Systemic: Fainting / Unresponsive-Severe |
| 1228518 | 4/19/2021 | OH | 30 | F | 4/17/2021 | 4/18/2021 | Fainted, chills, fever, aches, nauseated, restless, fatigue, headache |
| 1230599 | 4/19/2021 | TX | 71 | F | 1/1/2021 | 1/18/2021 | All over body itching requiring 5 days antihistamines, syncope lightheaded leading to faint |

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| 1230447 | 4/19/2021 | MN | 24 | M | 4/19/2021 | 4/19/2021 | About 5 minutes after the patient received their injection, they fainted. After about 10 minutes, they fainted again. EMS was called on the scene for evaluation, pt was escorted to the ambulance. Prior to leaving the patient mentioned he was fasting and had not had anything to eat or drink. Patient denied the use of any medications, any health conditions, and past adverse reactions to vaccines. SCRT report was filed with Walmart concerning the incident. Patient denied any injuries, only dizziness was reported post-event. BP was checked prior to him being take for evaluation in an ambulance. |
| 1230901 | 4/19/2021 | CA | 20 | F | 4/17/2021 | 4/17/2021 | Brief fainting episode. Flushing/sweating. Given water. BPs 97/59 (pulse 62), 108/61 (pulse 72). 100% O2 sat. |
| 1230885 | 4/19/2021 | CA | 26 | M | 4/19/2021 | 4/19/2021 | Vasovagal syncope. Patient passed out, fell out of chair and hit head hard. When he was turned over he was shaking and then came to. He felt nauseous and vomited. Paramedics arrived and took him to hospital . Stated his temp and BP were fine but his heart rate was low |
| 1230871 | 4/19/2021 | WA | 33 | M | 4/19/2021 | 4/19/2021 | Near syncope. Flushed skin. |
| 1230845 | 4/19/2021 | | 43 | F | 4/13/2021 | 4/15/2021 | Fainted on day 3 of second dose. Have been experiencing short bouts of dizziness. Had nose bleeds and dizziness after first dose on March 23rd. Nose bleed was on day 3 after first shot. Went to urgent care to get it checked. |
| 1230819 | 4/19/2021 | ID | 58 | M | 3/19/2021 | 3/19/2021 | That evening chills, fever, headache started, little nausea, more frequent urination. Continued into the next day. Dizziness started 03-20-21. Blacked out if stood up too fast, but didn't hit your head. Severe dizziness, fainting spells continued with fever. At that point went 2 PM. |
| 1230919 | 4/19/2021 | CA | 26 | F | 4/18/2021 | 4/18/2021 | Syncope/vasovagal, dizziness. Vitals wnl. |

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| 1230765 | 4/19/2021 | PA | 35 | F | 4/15/2021 | 4/15/2021 | Patient was fine immediately after vaccination. She left our vaccination room to sit down and wait 15 minutes and for some reason did not sit down, but kept walking, then proceeded to lay herself down in an aisle of the store. She says she passed out. I only witnessed her being awake. She urinated herself. She asked for a pillow and cold wash cloth. We got her those. We tried to get her a snack and a juice, but she didn't take those. I had a technician call an ambulance and pressed a button we have that calls the police as well. The police arrived first. The ambulance crew took her out into their truck to be evaluated and said she was fine, but had her mom come pick her up because they just didn't want her to drive. She did tell me before I gave her the shot that she passes out from vaccines. |
| 1230929 | 4/19/2021 | CA | 31 | F | 4/19/2021 | 4/19/2021 | Pt has anxiety to vaccines and fainted. She felled off the chair and regained consciousness within minutes. |
| 1230588 | 4/19/2021 | | 37 | M | 4/19/2021 | 4/19/2021 | Vasovagal Syncope Patient was monitored and provided support so that he does not fall down. Patient was layed down slowly on the floor so that he does not fall. His breathing was monitored constantly. He came back to conciousness within few seconds. He had a orientation within few minutes. He was provided glucose cracker and water. He mentioned that he did not have any reaction during the first dose. He was monitored for 45 minutes. He was constatnly being monitored. His alterness was being checked by talking to him. |
| 1230557 | 4/19/2021 | CA | 16 | F | 4/17/2021 | 4/17/2021 | Syncope, dizziness, flushing/sweating. BPs 92/52, 94/58 (pulse 77), O2 sat 98%. |
| 1230554 | 4/19/2021 | AZ | 56 | M | 4/19/2021 | 4/19/2021 | Patient was administered vaccine approximately around 2:40pm. Patient was sitting down in observation area when he fainted and fell out of his chair approximately around 2:50pm. Both pharmacists on duty went to assist patient and technician was instructed to call 911. Pharmacist started one round of compressions. Patient regained consciousness approximately one minute after passing out. It appeared pt hit head during fall. Patient was sweating. EMT arrived shortly after and treated patient. Patient was released by EMT to go home on his own. |

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| 1230544 | 4/19/2021 | NJ | 22 | M | 4/19/2021 | 4/19/2021 | Patient was quiet and anxious prior to shot. Stated he never had a reaction to vaccination before, but has fainted before from blood pressure being taken. Shortly after vaccination he asked to lie down and then he fainted. He quickly regained consciousness and was sweating but talknig and alert. RPH administering the vaccine lowerd him to the floor with no impact. 911 was called and patient was alert and monitored for 30 minutes. He declined further treatment. |
| 1230504 | 4/19/2021 | MI | 39 | F | 4/15/2021 | 4/15/2021 | Patient was feeling chest pressure and feeling of fainting while standing. Was complaining of head ache. Called 911 and was transferred to the hospital in an ambulance. |
| 1230486 | 4/19/2021 | DE | 44 | F | 4/10/2021 | 4/10/2021 | At approx 11:30pm my wife woke up and ran to the bathroom complaining of extreme nausea, fatigue, and back pain. While I was getting her tylenol she fainted, hitting her head on the floor. When she came to, she started experiencing the chills along with an irregular body temperature. I put blankets on her, gave her water, and tended to her eye. I was able to move her from the floor to the bed within 15 minutes. She fell asleep around 2am. She has been doing better but has been experiencing off & on headaches & nausea. We did not go to the doctor since we do not have insurance. |
| 1230485 | 4/19/2021 | NC | 32 | M | 4/6/2021 | 4/6/2021 | 0 mins: Discomfort in arm flowing from injection site to the rest of the body 2-4 mins: Light-headedness 5-10 mins: About 2 minutes after sitting down at the 30-min waiting area, I began to feel more light-headed while checking my phone, though I don't remember it, I fainted and hit my head on the gym floor ~15 mins: I am awake and feel extremely foggy and have low blood-pressure and heart rate ~25 mins: I am told to sit back up in the chair ~26 mins: I start feeling light-headed again and lose consciousness again and am told that I had a seizure for 20 seconds before coming back again |
| 1230786 | 4/19/2021 | PA | 60 | F | 4/14/2021 | 4/14/2021 | Severe stomach pain, passed out cutting chin, neck, bruised windpipe, vomiting and chills |

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| 1231165 | 4/19/2021 | | 50 | F | 4/17/2021 | 4/18/2021 | I fainted Approximately at 5:30 am while was in the restroom , 18 hours after I received the second dose. Symptoms started with nausea then vomiting , fatigue, fever and chills, I was unconscious for 5 minutes, my jaws were completely locked and my tongue was rolled back to my throat keeping from breathing my family was next to me who was able to open my jaws and keep my tongue out to open my air ways. I was taken to the emergency room by an ambulance there it was decided that it was my bodies reaction to the vaccine. |
| 1231306 | 4/19/2021 | MI | 36 | F | 4/9/2021 | 4/9/2021 | 20 minutes after shot while passenger in vehicle I passed out and went into convulsions for 2 minutes The next day after shot at 7am I passed out again and went into convulsions while blacked out The next few days I did not feel right |
| 1231296 | 4/19/2021 | CA | 29 | M | 4/18/2021 | 4/18/2021 | After administration of the vaccine, pt stood up and fainted. He regained conscious quickly. Emergency service was called but he refused service and was fine later to go home. He stated that he got anxious getting vaccinations in general anyway. |
| 1231294 | 4/19/2021 | AZ | 22 | F | 4/16/2021 | 4/16/2021 | Patient experienced syncope after 0.3ML(30 MCG) OF COVID vaccine was injected intramuscularly in Left arm. Patient recovered after brief syncope incident |
| 1231281 | 4/19/2021 | NY | 60 | F | 4/12/2021 | 4/12/2021 | Sore arm started at 4 hours, starting at 8 hours: chills, fever 99.8, muscles aches, pains in feet, mid back, neck, burning pains in skin in linear pattern, felt faint in the middle of the night almost passed out when I got up. Next day April 13th - slept on and off most of the day, after a 3 hour nap woke up drenched in sweat, fever broke and then felt better. April 14th still felt worn out and weak. Neck discomfort on the side of the shot (left) still feel pressure and discomfort (Perhaps swollen cervical lymph nodes). Today (One week post vaccine) - feel a buzzing sensation on and off in left axillary lymph nodes and left breast (After the first dose left axillary lymph node and breast discomfort lasted for one week). Still feel more tired than usual. |

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| 1231276 | 4/19/2021 | NV | 18 | M | 4/17/2021 | 4/17/2021 | 18 YOWM PRESENTED TO PHARMACY FOR ADMINISTRATION OF 1ST DOSE OF MODERNA COVID VACCINATION. HE MENTIONED BEING "SCARED OF NEEDLES" BUT AWKKNOWLEDGED THAT HE WAS ON BOARD AND WISHED TO RECEIVE THE VACCINATION. AFTER PT WAS IN OBSERVATION FOR HALF OF THE 15 MINUTES REQUIRED, HE STARTED LOOKING PALE AND CONFUSED. PT FAINTED, AMBULANCE WAS CALLED, PT AWOKE AFTER 5 SECONDS FROM WHEN HE FAINTED. NO SWELLING OF TONGUE, FACE OR THROAT WAS APPARENT. PT STARTED TO VOMIT. ADMINISTERED 25MG OF ORAL DIPHENDYRAMINE SYRUP. AMBULANCE ARRIVED, CHECKED VITALS WHERE ALL WITHIN NORMAL RANGE. PT WAS PICKED UP FROM FACILITY BY HIS MOTHER. CALLED PT TO CHECK ON A FEW HOURS LATER, HE STATED HE WAS DOING WELL. |
| 1231246 | 4/19/2021 | KS | 35 | M | 4/19/2021 | 4/19/2021 | PT WAS FINE DURING THE IMMUNIZATION, BUT DURING THE POST-VACCINE WAITING TIME PT FAINTED. HE FELT LIGHT HEADED AND DIZZY THEN FAINTED. PT CAME ABOUT IN A FEW MINUTES AND FELT FINE DURING THE REMAINING WAIT TIME. |
| 1230905 | 4/19/2021 | FL | 16 | F | 4/15/2021 | 4/16/2021 | No immediate response, approx 4 hours after dose started not feeling well passed out 3 times with 5 minute time frame, EMS called, became coherent while they were route, continue to improve and vitals were checked and advised to monitor. Currently experiencing dizziness when standing from a seated position consistently with no improvement, also fatigued as well. In touch with Primary Care Physician and am monitoring . |

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| 1231200 | 4/19/2021 | MI | 39 | F | 3/31/2021 | 4/1/2021 | Day 1: moderate arm pain. Day 2: fatigue, headache for half a day in the am and started developing heavy breathing and sudden changes in cardiac rhythm (mild). Days 3-6 heavy breathing and changes in cardiac rhythm continued increasing, particularly at night. Took ibuprofen, increased liquid intake, rested. Days 7-8: Symptoms were a bit milder. Day 9: Tachycardia at night, sensation of fainting. Day 10 to 19 (today): dizziness that varies from lightheadedness to vertigo to nausea every single day. I went to the pharmacy on Day 16 and got Sea Band Accupressure bands, ginger Dramamine and ginger gum which have helped a little. As a side note, I am a very healthy person who has never suffered a side effect like this one from any vaccine. I haven't even had a cold in the past year. I had to google the symptoms online and found a thread at VEDA (vestibular.org) with a very long list of people who are suffering from the same thing. |
| 1231042 | 4/19/2021 | TX | 19 | F | 4/19/2021 | 4/19/2021 | Patient is an employee at this store. She passed out immediately after receiving injection. She was unconscious for no more than 5 seconds then regained consciousness and remained in the vaccination room for 15 minutes. She stated numerous times that she was ok and eventually went back to work on her own volition. |
| 1231132 | 4/19/2021 | CA | 18 | M | 4/19/2021 | 4/19/2021 | Patient fainted for a few seconds after he was waiting in the waiting area after receiving the Moderna shot. He did regain consciousness a few seconds afterwards. |
| 1229858 | 4/19/2021 | OH | 16 | F | 4/19/2021 | 4/19/2021 | Patient with near syncope, provided juice, ice pack and rest, continued to feel dizzy, moved to the cot to lay down, then a syncope episode occurred, Medics on site, transfer to local Emergency Department via squad. Vital Signs: B/P 120/73 P: 103 R: 18 Pulse ox: 100% |
| 1231058 | 4/19/2021 | | 72 | F | 4/16/2021 | 4/17/2021 | near syncope and went to ER. |
| 1229831 | 4/19/2021 | OK | 37 | M | 4/19/2021 | 4/19/2021 | Patient fainted about 10 minutes after giving the shot |
| 1231038 | 4/19/2021 | MO | 43 | F | 3/31/2021 | 4/1/2021 | Passout/ fainted |

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| 1231021 | 4/19/2021 | WA | 18 | M | 4/19/2021 | 4/19/2021 | Patient felt dizzy about 10-15 minutes after the shot. He was alert and able to speak while sitting in the chair. Then he vomited a lot. Patient felt fine afterwards and sat for over 30 minutes. Had a history of fainting and vomiting after shots |
| 1230999 | 4/19/2021 | WA | 41 | M | 4/19/2021 | 4/19/2021 | 5-10min after 2nd dose, pt fainted while sitting in waiting room chair. pt fell forward tipping chair and fell into blood pressure machine. head was scraped between the eyes--slight bleed. pt leg was bruised and pant leg torn from falling into machine. i told technician to call 911 while i went to pt and attempted to sit him up. pt was unresponsive for 20-30 seconds. as he came to, he was able to speak. moved to chair and gave him water as paramedics arrived. they did full assessment x 20-30min. pt did not want to be transported to hospital so they asked him to stay for additional 30min. he then said he was ok to go home. |
| 1231212 | 4/19/2021 | MN | 64 | F | 2/20/2021 | 2/22/2021 | Passed out on Monday hit head and got a concussion.Went to ER had . Headaches caused by optical and vestibular systems does to hitting head. Bump on right side of head that continues to hurt.Balance is off due to vestibular. Some short term memory issues.OT and PT. |
| 1229925 | 4/19/2021 | NM | 41 | F | 4/19/2021 | 4/19/2021 | Patient Fainted 2-3 minutes after receiving vaccine while in observation waiting area. Blood pressure was really low at 84/50. We monitored patient for 20 minutes more, had her put feet up, cool pack on chest, gave a cool water to drink, and checked BP 3 times. Patient was fine after initial fainting. She was walked to her vehicle and did get home safely |

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| 1230154 | 4/19/2021 | NY | 20 | F | 4/8/2021 | 4/8/2021 | At 11:20am the nurse, was called into vaccination room for near syncope. Patient was lying down with the assistance of two vaccinators. She was alert and oriented x3. She reported feeling lightheaded and was moved to a chair, then a wheelchair. She was transferred to the observation room on the second floor of the clinic. VS were obtained and the care was handed over to another nurse. Patient was given gatorade, applesauce and resting comfortably for observation. At 11:30am denies injury or loss of consciousness. Stated she had nothing to eat or drink prior to vaccine appointment. She denies history of syncope. |
| 1230142 | 4/19/2021 | CA | 57 | F | 4/11/2021 | 4/11/2021 | 5 minutes after injection my forearm and hand began to tingle and have pressure, nerve type pain. No breathing issues so was sent home. Reported the continued arm pain the next day to the doctor and she ordered an ultrasound. Report negative on blood arm clot. Got a fever, body aches, headache, tired, triggered a migraine per doctor, localized reaction of 2 3/4" at injection site with redness, swelling, pain. Almost passed out at a store - Became dizzy, tingling hands and sweating and taken to ER by ambulance. ER ruled out blood clot but found I had a UTI without any symptoms-prescribed an antibiotic. Continue to have minor headache and minor discomfort at injection site. Awful experience and adverse reactions! |
| 1230119 | 4/19/2021 | | 21 | M | 4/17/2021 | 4/17/2021 | Pt told administrator before shot that shots made him anxious. When administering the shot, he started having a little bit of clamminess. Immediately after the shot, he vomited several times into a bag he had brought. No syncope. Pt left before proper discharge. He was called and reported he was feeling fine and denied further symptoms. Precautions given. |

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| 1230077 | 4/19/2021 | CT | 20 | M | 4/12/2021 | 4/12/2021 | Nurse observed patient raising his hand in the post injection waiting area. Patient appears to be pale. He was moved from the chair to the floor with lower extremities fully elevated. Patient lost consciousness for approximately 1-2 seconds. Regained consciousness following post vasovagal syncope. No injury occurred. Patient was coherent and aware of surroundings. BP 109/60. Pulse 68. Respirations 14. O2 sat 96%. Patient was moved via wheelchair to clinic for further observation. Hand over care to nurse. |
| 1230066 | 4/19/2021 | AR | 53 | F | 12/28/2020 | 1/3/2021 | My arm was extremely sore and you could feel the knot in it. I went to work out at the gym a few days after the shot and accidentally hit my arm exactly where the shot was given on a door coat hanger. I almost fainted. I was in severe pain for days and the muscle in my arm has still not recovered. Its still sore three months later. |
| 1230043 | 4/19/2021 | MD | 33 | M | 3/22/2021 | 3/22/2021 | The patient experienced a seizure after administration of first Moderna Covid-19 dose approximately 4-5 hours and was involved in a car crash resulting from the seizure. The patient was taken to the emergency room Medical Center and was discharged in the afternoon with a diagnosis of vasovagal syncope. The patient also experienced a second seizure in his sleep later that evening and was hospitalized and discharged Wednesday of that same week (03/24/21). Witnesses of the car crash noticed patient had convulsed and crashed into three parked cars in a parking lot. His wife also witnessed convulsions during the evening seizure. |
| 1230177 | 4/19/2021 | CA | 19 | M | 4/16/2021 | 4/16/2021 | Syncopal post vaccination. Patient fell to floor while in a seated position. |

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| 1229968 | 4/19/2021 | NH | 56 | F | 4/16/2021 | 4/16/2021 | 12 minutes after the injection, I felt very dizzy, nauseous, a few minutes later, I totally blacked out, they took me into the emergency room and took my blood pressure, which was very low and my heart was racing. I came to about 7-10 minutes later with very dizzy feeling, a itchy throat and was feeling very dizzy. The hospital staff gave me water and took a EKG - I was told to just rest. I got the chills and felt waves of dizzy/nauseous for a while. After about an hour, I felt strong enough to go home. I went home and was very tired and still dizzy. I was tired and was too tired to do anything other than stay in bed for three days. I lost my appetite, had weird metal taste in my mouth and had a few dizzy episodes the next day where I couldn't walk to the bathroom without help. I am usually a very healthy person, never have passed out before and now three days later, I can only work a few hours a day without getting tired and my brain feels foggy - hard to focus. |
| 1229936 | 4/19/2021 | IN | 22 | F | 4/17/2021 | 4/18/2021 | Fainted, nauseous, light headedness, fever, chills, weakness, exhaustion. |
| 1229865 | 4/19/2021 | CT | 24 | M | 4/17/2021 | 4/17/2021 | APPROXIMATELY 5 MINUTES FOLLOWING ADMINISTRATION, PATIENT FAINTED WHILE SITTING IN THE OBSERVATION AREA POST-VACCINATION. PATIENT WITHIN A FEW SECONDS OF FAINTING. WAS HELPED BACK UP TO CHAIR AND GIVEN WATER. MONITORED CLOSELY FOR AN ADDITIONAL 30 MINUTES. PATIENT WAS FULLY AWAKE AND ALERT WITHIN A FEW MINUTES WITH NO OTHER REPORTED EFFECTS. FOLLOWED UP WITH PATIENT VIA THE PHONE A COUPLE HOURS LATER AND PATIENT STATED THEY HAD EXPERIENCED NO OTHER EPISODES OR SIDE EFFECTS UP TO THAT POINT. |
| 1229855 | 4/19/2021 | NY | 18 | F | 4/19/2021 | 4/19/2021 | Pt became nauseous/sweaty/dizzy 10 minutes after 1st vaccine. Passed out w/ EMS for about 20 seconds then vomited. Pt fully recovered and hydrated. Released home. |

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| 1229840 | 4/19/2021 | FL | 26 | M | 4/19/2021 | 4/19/2021 | Administered a Covid-19 vaccine and after 2 minutes of administration the patient fainted falling off his chair. Once the father notified me and I arrived to check on the patient he was conscious, breathing normally and stood right back up to sit back down on his designated seat. His father explained that this does occur when he receives vaccinations. After 20 minutes the patient did leave the pharmacy with no complications. We called 911 but they did not arrive since the patient was able to get off the ground with no complications. Patient recieved the shot at 12:47pm and fainted on 12:49pm. No treatment was administered |
| 1230445 | 4/19/2021 | MA | 19 | F | 4/11/2021 | 4/11/2021 | Patient fell from chair and hit head on table in waiting area approx. 5 minutes after receiving vaccine. Resulting from syncope event. Patient stated she has anxiety and is nervous when receiving vaccines. She had her boyfriend in the car and he came in and waited with her for approx. 20 to 30 more minutes. Patient had a small egg on forehead from hitting table and was given an ice bag and water to aid with symptoms. Patient stated she was trying to "breath through it". May have over breathed and resulted in too much CO2. Patient had no other episodes or symptoms following fainting. Patient was contacted and checked on that evening and the next morning, she stated she is feeling okay. |
| 1229839 | 4/19/2021 | MA | 28 | M | 4/18/2021 | 4/18/2021 | The patient received the vaccine on 4/18/21 at 12:56pm. As he was waiting 15-minute post-administration, he walked to the front, (~1 minute post-administration) and fainted. He was caught by his girlfriend and brought down to the floor, where he remained sitting. No injuries reported, reported no nausea, was oriented, held a normal conversation, reported being hot, temp was 95.5F. Paper towel soaked in cold water was applied to forehead, and gave him water to drink. Declined juice. The patient mentioned he had a reaction to a flu vaccine in the past where he was very ill after. He expressed a fear of needles, and he has fainted after bloodwork previously. EMS evaluated, patient declined hospital visit. |

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| 1231099 | 4/19/2021 | CA | 26 | F | 4/19/2021 | 4/19/2021 | Pt stated she faints when she gets shots, but still wanted to get the coronavirus shot. She fainted in the chair a couple of minutes after receiving the shot and came to in less than a minute. She seemed okay until she started thinking about the shot. I had the patient sit in the chair until she felt okay and she declined to have an ambulance check her out. Recommended that the patient eat some food and have something to drink. |
| 1230001 | 4/19/2021 | SC | 26 | M | 4/19/2021 | 4/19/2021 | t 1510 client received Moderna Covid-19 vaccination. At 1512 client reports syncope. Client is clammy to touch, pale, and reports blurred/loss of vision. Adverse reaction protocol initiated. EMS called at 1513 and arrives on site at 1521. Vital taken prior to EMS arrival are as follows: 1. 1514 BP 120/70, R 16, P 68. 2. 1519 BP 110/68 R 16 P 72. Client reports not eating prior to vaccination. Client given drink and consumes entire beverage within about 5 minutes. Client also consumes a pack of cheese crackers and two bottles of water. Client refused epinephrine, benadryl, and EMS transport to hospital. Client reports feeling better and being very nervous about needles. Client reports feeling fine. |
| 1230407 | 4/19/2021 | NY | 26 | M | 4/19/2021 | 4/19/2021 | Nausea, syncope |
| 1230442 | 4/19/2021 | TX | 68 | M | 4/6/2021 | 4/9/2021 | 1 bout of Violent diarrhea that occurred on 4/9/21 or 4/10/21- passed out on the bed after the episode, exhausted. Nausea followed the diarrhea. Comes and goes. Still happening. Experienced heart palpitations at night on 4/12/2021, never experienced before. Got EKG the next day- normal. Back ache began on 4/15/21 to 4/16/21. Not experienced this before. The ache comes and goes. Fatigue and weakness in the whole body. Comes and goes. Better after food. |
| 1230440 | 4/19/2021 | FL | 45 | F | 4/9/2021 | 4/10/2021 | Immediate pain in arm that got worse first 12 hours. About 15 hours post vaccine and an unrestful night, woke up around 5-6am and almost fainted or passed out. I was very nauseous, had a fast all over body drenching sweat, dizzy and numbing in fingers/toes (can't remember which but had tingling and was dizzy). Rest of day was low fever, headache and tired. Right arm was sore where couldn't lift it but that subsided after 2-3 days. Just wanted to report the fainting that almost occurred the next early AM. |

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| 1230435 | 4/19/2021 | SC | 38 | F | 4/7/2021 | 4/7/2021 | vision blurry, fainted, leg numbness, headaches |
| 1230187 | 4/19/2021 | NJ | 42 | F | 4/8/2021 | 4/9/2021 | PATIENT COMPLAINING OF GENERALIZED JOINT/MUSCLE PAIN, NAUSEA BEGINNING ON 4/9/2021, PATIENT FAINTED ON 4/12/2021 AND HAS COMPLAINED OF LACK OF ENERGY AND INABILITY TO EVEN HAVE STRENGTH TO HOLD HER HEAD UP AS OF CURRENT DATE FROM DAY AFTER VACCINE ADMINISTERED |
| 1230433 | 4/19/2021 | WI | 21 | F | 4/15/2021 | 4/15/2021 | WEAKNESS, NAUSEA, VOMITING, SYNCOPE WITH URINARY INCONTINENCE. DESCRIBED FEELING WEAK AND NOT GOOD BEING UP EVERY HOUR WITH NAUSEA. WOKE UP AT 7AM, VOMITED AND PASSED OUT ON BATHROOM FLOOR WITH INCONTINENCE OF URINE. ROOMMATE DESCRIBED SEIZURE LIKE ACTIVITY WHILE PT WAS ON THE FLOOR. PALLOR. DIZZINESS. PT GIVEN 1L NS, CT SCAN AND LABS. |
| 1230415 | 4/19/2021 | CA | 32 | M | 4/15/2021 | 4/15/2021 | Vasovagal syncope within 1 minute of vaccine administration. Recovered within 1 minute. |
| 1230371 | 4/19/2021 | IL | 44 | M | 4/10/2021 | 4/13/2021 | Patient passed away on 4/13 after presenting to local hospital with near syncope and AKI. Records from local hospital are unavailable, unclear regarding cause of death and circumstances thereof. |
| 1230341 | 4/19/2021 | PA | 44 | F | 3/16/2021 | 4/18/2021 | According to patient, she woke up at 2:00 a.m. to use the restroom and noticed she had a very dry mouth and was thirsty. She passed out and when she came to she experienced decreased vision. She was taken to the emergency room via ambulance for tests. She was diagnosed with a blood clot to her lungs after CT scans. She also had additional scans and blood work and stayed at Hospital in town (I am having trouble adding this to the shaded area in question 21). |
| 1230255 | 4/19/2021 | | 34 | M | 4/19/2021 | 4/19/2021 | Patient's wife came to one of the nurses to tell her that her husband felt like he was about to pass out. RN came to check on the patient, asked his name and then he passed out. He was assisted to the floor and transferred to a cot. EMS came and assess him. Patient felt better after the assessment and drank Gatorade. Patient denied transportation to hospital. |

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| 1230275 | 4/19/2021 | CA | 23 | F | 4/19/2021 | 4/19/2021 | Patient fainted, dropped out of the chair, had a seizure |
| 1230229 | 4/19/2021 | CA | 21 | F | 4/16/2021 | 4/16/2021 | syncope; laid patient on the ground with feet elevated. provided water, food and ice packs |
| 1230238 | 4/19/2021 | CA | 17 | F | 4/19/2021 | 4/19/2021 | FAINTED AND FELT LIGHT ENDED POST VACCINE, ALSO FELT NAUSOUS |
| 1230263 | 4/19/2021 | NJ | 22 | M | 4/8/2021 | 4/8/2021 | Nurse was called to vaccination room for patient evaluation. Patient was alert and oriented x3, lying down, no signs of injury or loss of consciousness. Reports history of near syncope with vaccine administration. VS obtained. BP 100/70. Pulse 82 Respirations 16 Oxsat 97%. Radial pulse strong. Denies nasuea/vomiting, throat swelling or chest pain. Patient was moved to the post vaccination observation room. Walked himself without assistance and was observed for 30 minutes. |
| 1230250 | 4/19/2021 | CA | 20 | M | 4/16/2021 | 4/16/2021 | Syncope while seated; patient was placed on the floor with legs elevated. Provided food, water, and ice pack until felt better. |
| 1230260 | 4/19/2021 | NJ | 22 | M | 4/8/2021 | 4/8/2021 | Nurse was called to vaccination room for patient evaluation. Patient was alert and oriented x3, lying down, no signs of injury or loss of consciousness. Reports history of near syncope with vaccine administration. VS obtained. BP 100/70. Pulse 82 Respirations 16 Oxsat 97%. Radial pulse strong. Denies nasuea/vomiting, throat swelling or chest pain. Patient was moved to the post vaccination observation room. Walked himself without assistance and was observed for 30 minutes. |
| 1230287 | 4/19/2021 | CA | 45 | F | 3/13/2021 | 3/13/2021 | 20 min after injection, I almost lost consciousness and my heart started pounding irregularly, hard, and out of sync. I would say I was 90% passed out, barely hanging on to consciousness. Luckily I was close to a fire department so I ran in there. My heart eventually calmed down after maybe 20 min. Then, March 15 from about 3am-5am, I woke up & couldn't fall back asleep. My heart was pounding hard and out of sync again, and I almost passed out again. I had the paramedics come and check me out, but they found nothing odd. My pulse oximeter was spiking to 130 bpm and going down to 90. Standard resting bpm for me is 70. I have also had non-stop ringing in my ears ever since Dose #2. |

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| 1225470 | 4/18/2021 | NH | 19 | F | 4/13/2021 | 4/16/2021 | While talking to my parents I started to say things completely opposite of the conversation we were having. My speech began to slur and then I passed out/fainted and was unconscious for approx 1 minute. Once I came to I was disoriented and nauseated. |
| 1225454 | 4/18/2021 | TN | 38 | M | 4/16/2021 | 4/17/2021 | Hey guys, just a heads up if you know anyone with a CPAP machine who just received a second dose of the vaccine. I received the shot on Friday. No reaction all day. No reaction all day Saturday. Saturday/Sunday night I started vomiting into my CPAP mask/machine while still asleep. I wouldn't have woken up unless my wife was there to hear me choking. She cleaned out my mask and had me lay on my side all night while monitoring me. Scary stuff. Just thought you should make your friends with apnea aware. I still don't remember the incident at all. I have a mild fever right now, 99.8. I used to tell my wife she saved my life, but now I don't mean it figuratively. UPDATE: I forgot to mention that I passed out Saturday night. I was standing in the kitchen and the next thing I knew I was on the ground. |
| 1225428 | 4/18/2021 | CO | 61 | F | 4/1/2021 | 4/3/2021 | Fainted on day 2. Woke up with a bruise under eye. Extreme pain in entire chest, shoulders. No headaches, no fever. Did not injure myself during fainting spell. Pain in chest and arms, occasional chills continued for 2 weeks solid. I needed to take pain relief round the clock. Pain when sneezing or coughing, continuing for 2 weeks. Prior to the 2nd shot, I would describe myself as in very good condition. After, very weak physical condition. I feel like I need to recover from this shot. |
| 1225334 | 4/18/2021 | FL | 43 | F | 4/14/2021 | 4/14/2021 | EXTREME HEART PALPATATIONS X 4 DAYS, TWITCHING AT NIGHT X 4 DAYS, RACING/POUNDING HEAR X 4DAYS, FAINTING FEELING, RIGHT ARM PAIN FOR ONE NIGHT THIS IS VERY EXTREME AND FEELS LIKE IM GOING TO HAVE A HEART ATTACK. NONE OF THIS WAS HAPPENING UNTIL I WAS VACCINATED. |

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| 1225207 | 4/18/2021 | CA | 34 | M | 4/17/2021 | 4/17/2021 | Site: Pain at Injection Site-Mild, Systemic: Confusion-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Additional Details: Patient passed out the first time for about 15-20 seconds then was sat down. Patient passed out again the 2nd time with some convulsions. Paramedics came and took pt away. |
| 1225229 | 4/18/2021 | MD | 31 | F | 4/18/2021 | 4/18/2021 | near syncope, dizziness |
| 1225490 | 4/18/2021 | IN | 39 | F | 4/16/2021 | 4/17/2021 | Woke up with a sore arm at injection site. Went downstairs to get Tylenol for pain, standing at cabinet got extremely hot and dizzy. Fainted and fell on the floor. Couldn't get up without extreme dizziness for 15-20 minutes. Now my left armpit lymph node is swollen and tender to touch. |
| 1225717 | 4/18/2021 | | 30 | M | 4/15/2021 | 4/15/2021 | Syncope. Pt had syncope while ambulating to OBS area. Pt denies injuries, A&Ox4. Prior Hx of Syncope w/ vaccines. BP 97/60 HR 65 RR 20 -- > 101/67, 72, 18. Patient stabilized and released from vaccination site. |
| 1225206 | 4/18/2021 | CA | 16 | M | 4/17/2021 | 4/17/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Medium, Additional Details: After getting the vaccine, patient was feeling lightheaded while he was sitting down. He tripped over the chair and fell over when he tried to get up too quickly. Patient fainted briefly as we were trying to get him to a chair and was pale initially. 911 was called. After he was given water and the paramedics arrived patient got better. paramedics tested vitals and everything was in normal range. patient reported being nervous about getting the vaccine. paramedics left after collecting info |
| 1225203 | 4/18/2021 | WI | 27 | F | 4/17/2021 | 4/17/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Mild, Systemic: Nausea-Mild, Additional Details: Patient briefly fainted after getting the vaccine. She was sweating and had nausea. After monitoring, she was feeling better. |

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| 1225330 | 4/18/2021 | IL | 69 | M | 3/4/2021 | 3/14/2021 | Patient was admitted on 4/14/21for work up of complaints of dizziness, lightheadedness, one episode of syncope, balance and gait issues, blurred vision, tinnitus that has been present for a little over a month. Patient underwent a CTA 4/14/21: intraluminal filling defects within the superior sagittal sinus and draining dural veins to the right and left of midline near the vertex. There are findings consistent with chronic thrombosis of the left transverse and sigmoid sinus with partial recanalization of the sigmoid sinus and jugular bulb at the skull base. Still in hospital today |
| 1225634 | 4/18/2021 | IL | 31 | M | 4/16/2021 | 4/16/2021 | Patient was walking around the store after the shot. He wasn't feeling well within about 10 minutes so sat down and then fainted. He came to quickly, but then kept fainting maybe 3 times. He was extremely pale/gray and sweating profusely. He was very groggy whenever he came to. We called the paramedics with in a few minutes of him fainting initially. |
| 1225643 | 4/18/2021 | | 34 | F | 4/16/2021 | 4/16/2021 | Syncope, vasovagal episode post vaccination. BP 96/66 HR 67, 98% RA. Patient released when felt better and VSS. |
| 1225691 | 4/18/2021 | | 29 | M | 4/15/2021 | 4/15/2021 | Syncope BP 105/69 HR 97 RR 16 O2 100%. Provided hydration and rest. Patient stable and released from vaccination site. |

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| 1225710 | 4/18/2021 | MN | 26 | F | 4/18/2021 | 4/18/2021 | Shortly after vaccine was administered member began to feel weak and heavy. Reports losing feeling in her extremities and having a hard time breathing, felt like heart was racing. Pt was slumped over in her chair but conscious and coherent with staff supporting her upright in chair. A wheelchair was brought and pt assisted in transfer to the wheelchair. Pt was taken to a private observation area. Vital signs were checked and were stable. Pt reported feeling cold and weak. Pt was transferred by staff to a cot and her legs were elevated. She was covered with her jacket and 2 blankets as she began to shiver. Reported tingling and numbness in extremities but had adequate color, good radial and pedal pulses. Reported numbness but able to feel with touched and able to move on command. Spouse was present during evaluation. When pt reported feeling difficulty with breathing but O2 sats were stable at 98-99%. Member was given directions on how to slow her breathing and engaged in conversation. Spouse stated she has a history of syncope and that this happens regularly. Member was brought back at 1021 and by 1051 she was able to sit independently and drink water. She sat in Cot for another 5 minutes and requested to leave. Member was able to stand independently and stably. She walked around observation area and again requested to go home. ER precautions were given to spouse. Spouse stated he would drive her home and in the event of another episode would go to emergency room. Member walked out of facility independently with spouse near by. Member began to feel weak outside facility and dropped to her knees. She remained conscious. Pt refused to return for evaluation and asked to be wheeled to her car. She was breathing at a normal rate and rhythm. No signs of distress. Spouse reported this was not out of the ordinary for her condition and would also like to be released home. Pt was offered several times evaluation which she declined. She was assisted to personal vehicle and left the site. |

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| 1225786 | 4/18/2021 | NY | 28 | F | 4/18/2021 | 4/18/2021 | PATIENT RECEIVED VACCINE IN LEFT DELTOID, MOVED TO NEIGHBORING CHAIR, FELT HOT SAID SHE FELT LIKE SHE WAS GOING TO PASS OUT. LESS THAN 30 SECONDS LATER PATIENT TURNED BLUE PASSED OUT AND 10 SECONDS LATER WAS CONSCIOUS AND DISORIENTED. PATIENT WAS ASKED QUESTIONS AND WAS AND REPLIED CORRECTLY TO ALL. ICE PACKS WATER AND OIRANGE JUICE PROVIDED. AMBULANCE RESPONDED AND PATIENT WAS CONSCIOUS AND AWARE BUT VITALS REMAINED TOO LOW |
| 1225714 | 4/18/2021 | PA | 32 | M | 4/18/2021 | 4/18/2021 | near syncope |
| 1225729 | 4/18/2021 | | 35 | M | 4/16/2021 | 4/16/2021 | Syncope, Flushing/sweating. BP 116/77 HR 90 O2 Sat 95%. Patient stable and released from vaccination site |
| 1225760 | 4/18/2021 | MT | 36 | F | 3/24/2021 | 3/29/2021 | Nausea, cramping in uterus, back ache, fatigue- I thought I was pregnant. I got my period one week early. On 4/30, I fainted in the morning. |
| 1225772 | 4/18/2021 | | 48 | F | 4/18/2021 | 4/18/2021 | vasovagal syncope |
| 1225194 | 4/18/2021 | FL | 27 | F | 4/17/2021 | 4/17/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild |

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| 1224419 | 4/18/2021 | OH | 51 | F | 3/22/2021 | 3/24/2021 | <p>passed out; ischemic colitis; This is a spontaneous report received from a contactable consumer (patient). This 51-year old female patient (not pregnant) received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number ER8727) at single dose via an unknown route in left arm on 22Mar2021 09:45 for Covid-19 immunization. Prior to vaccination, the patient was diagnosed with COVID-19. Patient had no allergies to medications, food, or other products. Other medications the patient received within 2 weeks of vaccination included fluoxetine hydrochloride (PROZAC), levothyroxine, colecalciferol (VITAMIN D 3), cetirizine hydrochloride (ZYRTEC), and fish oil. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Patient passed out on Weds evening 24Mar2021 at 09:00 PM, followed by nausea, vomiting, passing of blood, and stomach cramping and was admitted to the hospital on 25Mar2021. Duration of hospitalization was 5 days. Patient was diagnosed with ischemic colitis. This was a condition she had never had before and considered herself completely fine before this incident. A battery of tests uncovered no reason for the passing out to have happened. Lab data included nasal swab on 26Mar2021: negative. The adverse event result in Emergency room/department or urgent care. It was unknown if treatment received for the adverse event. Outcome of the events was resolving.</p> |

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| 1224057 | 4/18/2021 | FL | | M | | 4/7/2021 | <p>FAINTED; NOT ABLE TO GET UP OUT OF CHAIR; NAUSEA; HEADACHE; FEELS UNDER THE WEATHER; MUSCLE ACHE; This spontaneous report received from a parent concerned a male of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 041A21A expiry: unknown) dose was not reported, 1 total, administered on 07-APR-2021 14:45 at right arm for prophylactic vaccination. No concomitant medications were reported. On 07-APR-2021, after getting vaccine, patient fainted (dizziness) and immediately woke up. On the same day, he experienced nausea, headache, feels under the weather, muscle ache and he was not able to get up out of chair. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from fainted on 07-APR-2021, and nausea, and muscle ache in APR-2021, was recovering from headache, and feels under the weather, and the outcome of not able to get up out of chair was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210416848-Covid-19 vaccine ad26.cov2.s-FAINTED. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.</p> |

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| 1224529 | 4/18/2021 | CA | 77 | F | 2/22/2021 | | <p>joints were sore; This is a spontaneous report from a contactable consumer (patient). A 77-year-old female patient received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; Batch/Lot Number: EN9581), via an unspecified route of administration, administered in Arm Left on 22Feb2021 09:15 (at 77-year-old) as single dose for COVID-19 immunization. Medical history included ongoing AFib (She has had this condition for a about 6 years), ongoing getting anemic real easy (She says she has had this for the last 20 years), Glaucoma from 1998 (She says that in 1998 she had both eyes operated on and in 2016 she was operated on again), Cataracts from 2018, Pacemaker insertion (cardiac) (She states she has a pacemaker that controls her heart so the pulse does not drop below 65. She says that pacemaker was implanted, she thinks, 2014 maybe), Concomitant medications included metoprolol tartrate (METOPROLOL TARTRAS) taken for atrial fibrillation, blood pressure measurement from an unspecified start date and ongoing; warfarin (WARFARIN) taken for prophylaxis from an unspecified start date and ongoing; duloxetine (DULOXETINE) taken for anxiety from an unspecified start date and ongoing; montelukast (MONTELUKAST) taken for asthma from an unspecified start date and ongoing; folic acid (FOLIC ACID) taken for prophylaxis from 2015 and ongoing; ferrous sulfate (FERROUS SULFATE) taken for anaemia from an unspecified start date and ongoing; furosemide (FUROSEMIDE) taken for diuretic therapy from an unspecified start date and ongoing; baclofen (BACLOFEN) taken for muscle spasms from an unspecified start date and ongoing; hydrocodone bitartrate, paracetamol (NORCO) taken for arthritis from an unspecified start date and ongoing; calcium (CALCIUM) taken for arthritis from an unspecified start date and ongoing; ergocalciferol (VITAMIN D) taken for anaemia from an unspecified start date and ongoing; ongoing adult vitamins since her body doesn't absorb what she eats. The patient previously took BNT162B2 (Batch/lot number EL3246, Dosage text left arm) first dose on 04Feb2021 for COVID-19 immunization and experienced heart attack; must have passed out; the muscle that goes around her heart, it was having like a charley horse; heart rate, 102, 103, it went up to 200 in the ambulance; chest pain; Nausea; hard to breath; she</p> |

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| | | | | | | | didn't remember all the tests; sharp pain underneath her left rib cage/pain was number 10/still had pain off and on, periodically; broke out in sweat, real bad, number 10, she broke out in a clammy sweat. The patient said she has to leave in 20 minutes to a doctor's appointment. She says her second shot was on 22Feb2021 and the only reaction was it felt like a truck hit her, all her joints were sore (unspecified date), it lasted 2 days then went away, she feels good. Patient was hospitalized. She says she got the second dose to make sure she gets all the doses so she doesn't get sick. The outcome of the event was unknown. |
| 1225980 | 4/18/2021 | CO | 21 | M | 4/18/2021 | 4/18/2021 | Syncope: Patient became pale and was unable to answer questions roughly 2-3 minutes after receiving the vaccination. Shortly thereafter, his head rolled back and he slumped in the chair for ~10 seconds before regaining consciousness. After awaking, he regained his senses rapidly and was able to state his name and the date. I requested he remain in the area for an additional 30 minutes for his safety. He agreed. |
| 1225829 | 4/18/2021 | CA | 61 | F | 3/17/2021 | 3/17/2021 | Extreme weakness & Fatigue Dizziness Fainting Death 04/09/2021 |
| 1224209 | 4/18/2021 | FL | 24 | M | 4/6/2021 | 4/6/2021 | I received the J&J COVID-19 vaccine, within minutes, I passed out. While unconscious, I hit my head on the pavement, resulting in a laceration across my right eye-brow requiring 10 stitches. |

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| 1224285 | 4/18/2021 | OH | 41 | M | 3/25/2021 | | <p>Sleep for a few minutes, I didn't pass out but it was similar; Was pulled over "for minor traffic violation." He was told "to get out of the car and had a field sobriety test, and I looked intoxicated."; Felt heavy and tired/Run down; Had a headache; Upset stomach; sleep for a few minutes, I didn't pass out but it was similar/crashed for 4-5 hours in the middle of the day which I never do; aching; Over all weakness; Started feeling sick again at dinner; Woke up feeling really bad; Bad diarrhea; This is a spontaneous report from a contactable consumer or other non hcp. A 41-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration on 25Mar2021 (Batch/Lot number was not reported) as single dose for covid-19 immunization. Medical history included drug hypersensitivity from an unknown date and unknown if ongoing Allergic to sulfa, PCN and amoxicillin. The patients concomitant medications were not reported. On an unspecified date the patient experienced sleep for a few minutes, I didnt pass out but it was similar, was pulled over for minor traffic violation. He was told to get out of the car and had a field sobriety test, and I looked intoxicated, felt heavy and tired/run down, had a headache, bad diarrhea, upset stomach, sleep for a few minutes, I didnt pass out but it was similar, crashed for 4 to 5 hours in the middle of the day which I never do, aching, overall weakness, started feeling sick again at dinner, he went to the bathroom a few times, woke up feeling really bad. The patient was worried because everything was coming to a head right now. The caller got the first shot, he waited for 15 minutes and felt fine. As the caller walked to his car he began feeling heavy, had severe diarrhea, headache, aching, it was almost like he passed out, it felt like he went to sleep. The patient got home and crashed 4 to 5 hours in the middle of the day and woke up feeling really bad. The patient went to a very important dinner meeting that night. While the patient was at the meeting he went to the bathroom a few times and then excused himself because he felt so bad. The patient did not even finish one cocktail with dinner. The caller got pulled over for a minor traffic stop, cutting the corner and crossing the line or something small. The officers believed the caller was driving under the influence and started making him do a sobriety test with 40 degree wind gusts, the patient was</p> |

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| 1224307 | 4/18/2021 | TN | 24 | M | 3/30/2021 | 3/30/2021 | <p>miserable. The caller told the officers that he needed to seek medical attention but they ignored him. The officers forced the caller to do the urine test. It has been 5 days since his vaccination and he is just now feeling better. The outcome of events was recovering. No follow-up attempts are needed. No further information is expected.</p> <p>Prior to vaccine or was asked if any severe reactions occurred to previous vaccines; post vaccination patient states of light headedness and proceeds to faint onto the floor while pharmacy tech assist; Prior to vaccine or was asked if any severe reactions occurred to previous vaccines; post vaccination patient states of light headedness and proceeds to faint onto the floor while pharmacy tech assist; This is a spontaneous report from a contactable physician. A 24-years-old male patient received bnt162b2 (BNT162B2, PFIZER-BIONTECH COVID-19 mRNA VACCINE; Formulation: Solution for injection, Lot number: Batch/Lot Number: ER2613; Expiration Date: unknown), dose 1 intramuscular, administered in Arm Left on 30Mar2021 14:30 as SINGLE DOSE for COVID-19 immunization. Medical history included syncope, High blood pressure, Prone to fainting during medical procedures, Bell's palsy on 25Mar2021 with the outcome of not recovered. The patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. Since the vaccination, the patient was tested for Covid-19 was unknown. The patient was not diagnosed with covid-19 prior to vaccination. The patient's concomitant medications were not reported. No allergies to medications, food, or other products. On 30Mar2021 14:45 the patient experienced light headedness and proceeds to faint onto the floor while pharmacy tech assists to prevent harm. The outcome of the event light headedness and proceeds to faint onto the floor was recovered. No follow-up attempts are needed. No further information is expected.</p> |

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| 1224352 | 4/18/2021 | | 45 | M | 3/27/2021 | 3/27/2021 | passed out; fingers were tingling on both hands; very hot and sweating; breathing was labored; very hot and sweating; This is a spontaneous report received from a contactable consumer (patient) . A 45-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE) dose 1 via an unspecified route of administration, administered in Arm Left on 27Mar2021 (Batch/Lot Number: EP7533) as single dose (at the age of 45 years old) for covid-19 immunisation. The patient medical history was not reported. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Concomitant medication(s) included magnesium citrate taken for an unspecified indication, start and stop date were not reported. It was reported that about five minutes after the shot, the patient passed out in the observation area. When he awoke, his fingers were tingling on both hands, a was very hot and sweating, and his breathing was labored. Events onset date was 27Mar2021. The patient received lactated ringers as treatment. The outcome of the reported events was recovered. Since the vaccination, the patient has not been tested for COVID-19. |

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| 1224390 | 4/18/2021 | GA | 48 | F | 3/31/2021 | 3/31/2021 | Fainted; Fever 101.6; Vomiting; Nausea; Dizzy; This is a spontaneous report from a contactable consumer reporting for herself. A 48-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE) (lot number EN 9581/expiration date: not provided), via an unspecified route of administration, on 31Mar2021 at 10:45 (at the age of 48 years old) as a single dose in the left arm for COVID-19 IMMUNIZATION. Relevant medical history included lupus, scleroderma, Mixed connective tissue disease (MCTD), and high blood pressure (HBP). The patient did not have any known allergies to medications, food, or other products. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medication included hydroxychloroquine 200 mg, and losartan 50mg. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 31Mar2021 at 19:00, the patient experienced fainted, fever 101.6, vomiting, nausea and dizzy. The patient did not receive any treatment for these events. The outcome of the events fainted, fever 101.6, vomiting, nausea and dizzy was unknown. Since the vaccination, the patient had not been tested for COVID-19. |

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| 1224415 | 4/18/2021 | TX | 43 | M | 3/31/2021 | 3/31/2021 | Vasovagal syncope; Blood pressure drop - fainting; This is a spontaneous report received from a contactable consumer, the patient. A 43-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; Lot number: EP6955), via an unspecified route of administration on arm left on 31Mar2021 08:00 AM at single dose for COVID-19 immunization. The patient medical history included methylenetetrahydrofolate reductase gene mutation from an unknown date and unknown if ongoing , wolff-parkinson-white syndrome from an unknown date and unknown if ongoing , blood cholesterol increased from an unknown date and unknown if ongoing , gastroesophageal reflux disease from an unknown date and unknown if ongoing. The patient concomitant medications included omeprazole (ZEGERID [OMEPRAZOLE]) taken for an unspecified indication, start and stop date were not reported; ubidecarenone (COQ10 [UBIDECARENONE]) taken for an unspecified indication, start and stop date were not reported; vitamin d [vitamin d nos] (VITAMIN D [VITAMIN D NOS]) taken for an unspecified indication, start and stop date were not reported, fish oil, quatrefloic within 2 weeks of vaccination. The patient previously took ampicillin and experienced drug hypersensitivity. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 31Mar2021 08:30 AM, the patient experienced Blood pressure drop, fainting, vasovagal syncope. The seriousness criteria of the events has not resulted in death, Life threatening, Caused/prolonged hospitalization, Disabling/Incapacitating, Congenital anomaly/birth defect. The event was assessed as serious based on seriousness criteria. The patient did not receive any treatment for the events. The outcome of the events was unknown. |

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| 1224422 | 4/18/2021 | NJ | 53 | F | 3/30/2021 | 3/30/2021 | passed out; chills; fever; headache; tiredness; Shakes; This is a spontaneous report from a contactable consumer reporting for self. A 53-years-old female patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in Arm Left on 30Mar2021 08:00 (Batch/Lot Number: ER8733) as single dose for covid-19 immunisation. Patient received the first dose, administered in Arm Left on 08Mar2021 09:45 (Batch/Lot Number: EN6205). The patient medical history was not reported. Concomitant medications included sertraline hydrochloride (ZOLOFT) taken for an unspecified indication, start and stop date were not reported; vitamin d3 taken for an unspecified indication, start and stop date were not reported; progesterone taken for an unspecified indication, start and stop date were not reported; iron taken for an unspecified indication, start and stop date were not reported. The patient experienced passed out, chills, shakes, fever, headache, tiredness 30Mar2021 08:30. Outcome of events was recovering. Follow-up attempts are needed. Information on lot/Batch number was obtained. |

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| 1224486 | 4/18/2021 | IN | 20 | F | 3/31/2021 | 4/1/2021 | fainted/blacked out; fainted/blacked out; Fell on floor; Tired; achey all day; Face hurt and swelling from fall; Face hurt and swelling from fall; This is a spontaneous report from a contactable consumer (patient). A 20-year-old female patient (age at vaccination: 20 years) received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) (brand: Pfizer, lot: EP7533) in left arm on 31Mar2021 12:15 at a single dose for COVID-19 immunization. Facility where the most recent COVID-19 vaccine was administered was a Clinic. Medical history was none. Known allergies was no. Patient was not pregnant at the time of vaccination. Concomitant medications were not reported. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. There are no other medications the patient received within 2 weeks of vaccination. Patient experienced fainted/blacked out, fell on floor, tired and achey all day (Face hurt and swelling from fall), all on 01Apr2021 06:30 AM with outcome of recovering. No treatment was received for the adverse events. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. Information on Lot/Batch number was available. Additional information has been requested. |

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| 1224478 | 4/18/2021 | TX | 62 | F | 3/30/2021 | 3/30/2021 | passed out twice; Intense, rapid and irregular heartbeat (prolonged); intense pain in various organs and muscles (some short and some long duration); rash; cold; night sweat; no energy; intense dreams first night; This is a spontaneous report received from a contactable consumer (patient). A 62-year-old female patient (not pregnant) received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot Number: EP6955) via an unspecified route of administration, administered in arm left on 30Mar2021 13:30 at single dose for COVID-19 immunisation. The patient medical history was not reported. Concomitant medications included zolpidem tartrate (AMBIEN). The patient was healthy. No known allergies. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination. The patient had not been tested for COVID-19 since the vaccination. The patient received the first dose of BNT162B2 (Lot number: EN6199) in the left arm on 11Mar2021 11:00 AM at the age of 62-year-old for COVID-19 immunisation. The patient experienced passed out twice, intense, rapid and irregular heartbeat (prolonged), intense pain in various organs and muscles (some short and some long duration), rash, cold, night sweat, no energy, intense dreams first night; all on 30Mar2021 with outcome of not recovered. Doctor appointment was scheduled. The events resulted in doctor or other healthcare professional office/clinic visit. It was unknown whether treatment received for the events. |

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| 1224525 | 4/18/2021 | CA | 77 | F | 2/4/2021 | 2/6/2021 | she and they thought she was having a heart attack; she must have passed out because she didn't remember all the tests; she got a sharp pain underneath her left rib cage/pain was number10/still had pain off and on, periodically; broke out in sweat, real bad, number 10, she broke out in a clammy sweat; hard to breath, she got a sharp pain underneath her left rib cage; the muscle that goes around her heart, it was having like a charley horse; heart rate, She says 102, 103, it went up to 200 in the ambulance.; chest pain; Nausea; hard to breath, she got a sharp pain underneath her left rib cage; This is a spontaneous report from a contactable consumer (patient). A 77-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number EL3246), via an unspecified route of administration, administered in left arm on 04Feb2021 09:00 as single dose for COVID-19 immunization. Medical history included ongoing atrial fibrillation for a about 6 years , ongoing anemic for the last 20 years, glaucoma from 1998, had both eyes operated on and in 2016 she was operated on again, cataract had this 4 years ago in she says, in 1918, 1919, she clarifies 2018, Cardiac pacemaker insertion which pacemaker that controls her heart so the pulse does not drop below 65. She says that pacemaker was implanted, she thinks, 2014 maybe, blood pressure, arthritis throughout her body and had 30 operations, body doesn't absorb what she eats, anxiety, asthma, muscle spasms; she reported she has had a lot of surgeries, both of her ankles have had triple fusions, these were in 2005, 2010, 2014, 2018, both her ankles were fused, she had 5 surgeries on her feet; she has had both of her knees replaced because of arthritis, 2012 and 2015 she believes, had numerous other surgeries and she doesn't want to go through all of them, a right shoulder reverse rotator cuff repair, she had a rotator cuff put in, she doesn't have a rotator cuff, this happened in 2019, her left shoulder, because of an automobile accident, rotator cuff was so damaged that they couldn't repair it, she has minimum use of her left arm and has had operations on her left shoulder in 2005; had a pacemaker put in about 6 years ago, the next morning they kept her overnight, they came in, they took an Xray, she had to go back 2 days later because the lead had come of the heart, they had to go back in an reattach the lead to the heart; 2 years ago her |

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pacemaker was going all over her chest, the doctor did not believe her and it landed under her armpit, it was the size of an orange, the doctor thought it was a lump, she went to the hospital, her pacemaker started falling apart, they took it out and put a new one in, it was about 4 years ago; a lump in her breast, she has been put under 30 times, they were all necessary, nothing for glamorizing; had surgeries in her left arm and some fingers than were numb. There was no prior vaccinations within 4 weeks, no events prior vaccinations and no family history. Ongoing concomitant medication included baclofen taken for muscle spasms for about 2 years, calcium for arthritis and her bones degenerate for 30 years, ergocalciferol (CALCIFEROL VIT D) taken for gets anemic real easy for 20 years, duloxetine taken for anxiety, taking this about 3 years ago; ferrous sulfate taken for anemic real easy for about 20 years; folic acid taken to rebuild cells taking this she thinks in 2015, furosemide taken for a diuretic to get rid of fluid for 2 years, metoprolol tartrate taken for atrial fibrillation, and blood pressure, taking this since she had her pacemaker put in; montelukast for asthma for 20 years; hydrocodone bitartrate, paracetamol (NORCO) taken for arthritis for 20 years, and warfarin taken for blood thinner/thin the blood out so she doesn't get blood clots; and adults vitamins for bone supplement and metabolism for 20 years as her body doesn't absorb what she eats. She says she takes a lot of medications and when she does blood bloodwork she was low so they make her take them. The patient previously took rivaroxaban (XARELTO). On 06Feb2021, the patient experienced she thought she was having a heart attack. The patient reported that she had to call an ambulance at 11:30 at night, she thought she had a massive heart attack. She had chest pain, nausea, it was hard to breath, she got a sharp pain underneath her left rib cage. She stated that when the ambulance got here they thought she was having a heart attack, they did nitroglycerin, when they got to the house, when in the ambulance on the way to the hospital they did another pill of nitroglycerin when they got to the hospital. The pain was a number 10. She stated she broke out in sweat, once they got her all hooked up they got to the hospital 6 miles away to the hospital. She was there for 2 full days, they did Xrays, dye in her, checked her hears, and did bloodwork. When she had chest pain, she reported they

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gave the morphine, it lasted about 6 hours; she still had problems breathing, they took her, she must have passed out because she didn't remember all the tests, she was in and out of it, the severe pain stopped after 6 hours, still had pain off and on, periodically. When she got pain in the ambulance then the nausea went away. After the hospital nitro and another shot for the pain, the nausea stopped. After the hospital after this they gave morphine and the pain subsided a little but didn't totally go away until 6 o'clock in the evening, she still had problems breathing because every time she breathed she got pain under her left rib cage. She says the sweat was at home, real bad, number 10, she broke out in a clammy sweat, on the 6th when she was having pain. She says that after the hospital, a couple days after that, she saw her cardiologists, he told her what happened, it was related to vaccine, it was the muscle that goes around her heart, it was having like a charley horse, he says it felt like you're having a heart attack, her tests said her heart was good. She talks about her blood pressure and heart rate, and says 102, 103, it went up to 200 in the ambulance. She says they thought it was a heart attack, her blood pressure was usually low blood pressure and all the symptoms she was having was because of her muscle having a charley horse that felt like it was coming from the heart, if they had contacted him, he said she would have just needed a massive amount of anti-inflammatory and it would have stopped the pain. The events required an emergency room visit. She wanted to know if anybody else has been hospitalized for massive heart attacks and says that's what she was having. The patient had her second shot on 22Feb2021. Outcome of event nausea was recovered on an unspecified date; and outcome of the rest of events was unknown.

Systemic: Dizziness / Lightheadedness-Severe, Systemic: Fainting / Unresponsive-Severe, Additional Details: She complained to employee of lightheadedness. By the time I went to see her she had fainted. She opened her eyes again, but felt fainty . We called 911. Administered EpiPen. Rescue came and stayed with her for about an hour when her relative came to pick her up.

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| 1224591 | 4/18/2021 | CA | 31 | F | 3/31/2021 | 4/1/2021 | fainted; generally feeling fatigued; little dizzy; headache; cuts on her face and a bump on her head; This is a spontaneous report from a contactable consumer (reporting for herself). A 31-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in Arm Left on 31Mar2021 (Batch/Lot Number: Unknown) as single dose for COVID-19 immunization. The patient's medical history was not reported. Concomitant medication included marijuana taken for an unspecified indication, start and stop date were not reported. On 01Apr2021, the patient fainted. The patient also been generally feeling fatigued and a little dizzy. The patient fainted after going to the restroom, stood up after finishing her business and blacked out and woke up on the floor with cuts on her face and a bump on her head. The patient is fine now just a little tired, dizzy and headache. The patient did not received treatment for the events. The outcome of the events was recovering. The patient was not diagnosed with COVID-19 prior to vaccination and has not been tested for COVID-19 since the vaccination. Information on the lot/batch number has been requested. |

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| 1224604 | 4/18/2021 | CA | 28 | F | 4/1/2021 | 4/2/2021 | This is a spontaneous report from a contactable consumer (patient). A 28-year-old female patient (not pregnant) received bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), dose 2 via an unspecified route of administration, administered in Arm Left on 01Apr2021 11:15 AM (Lot Number: ER8737) as SINGLE DOSE for covid-19 immunisation. Historical bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), dose 1 via an unspecified route of administration, administered in Arm Left on 04Mar2021 12:15 PM (Lot Number: EN6199) as SINGLE DOSE for covid-19 immunisation. Medical history included migraine, irritable bowel syndrome (IBS), attention deficit hyperactivity disorder (ADHD). No covid prior vaccination, no known allergies and no covid tested post vaccination. The patient's concomitant medications included unspecified drug and not enough space. There is no other vaccine in four weeks. Patient experienced adverse events on 02Apr2021 included Arm Pain right after 02:00 AM, Headache around 2am, Nausea around 2:15am, Fainted around 2:20am, Weak Legs around 2:30am, Tingling in hand & feet around 2:30am, ringing in ear around 2:30am, Light fever around 7am, Headache persisting until just now after getting some sleep finally from 12pm-2pm now.AE resulted in Doctor or other healthcare professional office/clinic visit. There was unknown treatment were received for adverse events. The outcome of headache was not recovered. The outcome of other events was recovering. |

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| 1224611 | 4/18/2021 | NJ | 61 | F | 3/23/2021 | 3/24/2021 | dizziness; headache; fever; stomach cramps; migraine; no appetite; dry cough; fainting; stomachache; This is a spontaneous report received from a contactable consumer (patient). A non-pregnant 61-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at the age of 61 years old, administered in arm left on 23Mar2021 19:15 (Lot Number: EN6207) at single dose for covid-19 immunisation. Medical history included ongoing rheumatoid arthritis, arthrosis, osteoporosis, due to arthritis the patient couldn't eat pork because her joints get swollen. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Concomitant medications included etanercept (ENBREL); methotrexate sodium (METHOTREXAAT). The patient experienced fainting, stomachache, stomach cramps, migraine, no appetite, dry cough on 24Mar2021 15:30, dizziness, headache, fever on 25Mar2021. The patient stopped using Enbrel and taking Methotrexate a few days prior Pfizer's vaccine. Next day on 24Mar2021, the patient had stomachache, 3rd day (25Mar2021) started with dizziness, headache and fever. Symptoms kept going after 10 days. 5 days later the patient went to the hospital and was prescribed something for stomach cramps and migraine. But the fever continued. 3 days later doctor prescribed an antibiotic since she didn't know the reason of the fever. During the course of the fever the patient had been taking Tylenol on daily basis. Fever came and went and the patient had no appetite and keep with fainting. Doctor ordered lung rx but the patient couldn't do it. 10 days later the patient had dry cough (event onset date was also reported as 24Mar2021, 15:30). The same symptoms remained. The patient did not receive treatment for all events (except fever). Events resulted in Emergency room/department or urgent care and Doctor or other healthcare professional office/clinic visit. The outcome of the all events was reported as not recovered. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. |

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| 1224710 | 4/18/2021 | | | F | | | fainted after the first shot and fell down face forward and busted her lip; fainted after the first shot and fell down face forward and busted her lip; fainted after the first shot and fell down face forward and busted her lip; rash on arms, back and chest; Blurred vision; Joint and muscle pain.; Joint and muscle pain; Weak and having to walk with a cane.; This is a spontaneous report from a contactable consumer(patient). A 68 years old female patient received first dose BNT162B2 (Pfizer BioNTech Covid 19 vaccine), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The medical history and concomitant medications were not reported. The patient was having some symptoms and she need to talk to someone about what to do about them. She had nausea and diarrhea, severe pain in her abdomen feeling like a knife stabbing her mostly left side. It was excruciating. She got the second vaccine yesterday and all the above events started last night. She had chills, headache, mental clarity and can't think straight and weak after the second dose. She fainted after the first shot and fell down face forward and busted her lip. She had quite a few side effects. Blurred vision, rash on arms, back and chest. Joint and muscle pain. Weak and having to walk with a cane. The outcome of the events was unknown. No follow-up attempts are possible; information about batch number cannot be obtained. |

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| 1224818 | 4/18/2021 | NJ | 48 | M | 1/27/2021 | 1/28/2021 | Heart stopped 6 times; unresponsive; soreness; felt like unwell; vomiting; Body aches; achiness; passed out 7 times; fever; chills; Left arm soreness at injection site and up back of shoulders; Left arm soreness at injection site and up back of shoulders; This is a spontaneous report from a contactable consumer.A 48-years-old male patient received second dose of bnt162b2 (Pfizer-Biontech Covid-19 Vaccine, Formulation: Solution for injection, Lot Number: EN5318), intramuscular, administered in left arm on 27Jan2021 11:00 at single dose for covid-19 immunisation. Medical history included asthma, myocarditis and allergies to Fruit or nut that grows on trees. Concomitant medication included esomeprazole magnesium (NEXIUM). The patient's heart stopped 6 times on 29Jan2021, he had a low grade fever, achiness and chills at 01:30, but they were gone the next day. Basically, at first, he took the shot and got the reactions that everyone else does, right arm soreness 01:30. On 07Jan2021 17:00, patient took the first dose of bnt162b2 (Pfizer-Biontech Covid-19 Vaccine, Formulation: Solution for injection, Lot Number: EL1042), intramuscular, administered in left arm. No prior vaccination was given within 4 weeks. He fell in the shower and passed out and hit his head at 18:00. He was not hooked up to a machine. About 18:30, his wife got him to the couch. He drank carrot juice and ate a granola bar. At 18:30 his eyes were wide open, but he was unresponsive. About every 30 minutes, he was going down. The third one came about 18:45-19:00. The pass outs lasted 15-20 seconds. and all he remembers was waking up to her screaming at him. The next one came at 19:15 and was in the ambulance on the way to the hospital and that is when he vomited in the ambulance and on the couch. Pass out number 3 was at home and 4 was in the ambulance. There was vomiting with both of them. Pass out number 5 was in the hospital when she was getting in the bed and was not hooked up in the room yet. Finally, they got him hooked up to a machine at 20:30 and into a room. They said if you feel dizzy, press the button. He found out his heart rate went from 80's down to 30's. That was the 6th pass out. This was the first time he was on a machine. His heart did not actually stop, it just went down to 30's and would come back. Then, it happened one more time on the machine and at that point, they were hooking him up to an IV and giving him medication to |

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keep him from vomiting. He does not have the name of that medication or the dose or lot or expiration. He got stabilized but they had him hooked up shockpads in case anything happened. They recorded his heart stopping 6 times during the night and of those 6 times, he does not have the times. 2 seconds was the longest time of all of the stops. He does not know how many each were. This was when he woke up on 30Jan2021. He later stated he was hospitalized 28Jan2021 at 7pm and those 6 stops occurred 29Jan2021 through the night previously. The patient was hospitalized for heart stopped 6 times from 29Jan2021 and discharged on 01Feb2021. The patient underwent lab tests and procedures which included body temperature was low grade fever, echocardiogram, brain scan and electrocardiogram shows normal, heart rate: 80 beats, heart rate was down to 30 on his heart beat. They gave shot in the leg for blood clots, nausea medication and a bunch of pills given as treatment. The outcome of heart stopped 6 times was recovered with Sequel, patient passed out 7 times, body aches, fever and chills, left arm soreness at injection site and up back of shoulders was recovering, unresponsive and soreness next day felt like unwell and vomiting was unknown, achiness was recovered. No follow-up attempts are possible. No further information is expected

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| 1224830 | 4/18/2021 | WA | 29 | F | 4/2/2021 | 4/2/2021 | <p>passed out from exhaustion; Fever; was unable to stand unassisted.; writhing in pain/so much pain; in and out of consciousness/passed out; tongue swelled up, making it hard to breathe and impossible to speak; tongue swelled up, making it hard to breathe and impossible to speak; tongue swelled up, making it hard to breathe and impossible to speak; sweating profusely; couldn't support her own body without tipping over.; seizure; lymph nodes in her left armpit swelled up so much that she couldn't put her arm down without extreme pain; lymph nodes in her left armpit swelled up so much that she couldn't put her arm down without extreme pain; chills; extreme muscle pain; spasms; This is a spontaneous report from a non-contactable consumer (patient herself). A 29-year-old female patient received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine), dose 2 via an unspecified route of administration, administered in left arm on 02Apr2021 13:15 (Batch/Lot Number: ER8737) as single dose, for COVID-19 immunisation. Medical history was reported as no. Patient did not have COVID-19 prior to vaccination. Patient did not receive other vaccines within 4 weeks prior to COVID-19 vaccine. Patient's concomitant medication includes omeprazole, ethinylestradiol, levonorgestrel (MARLISSA), venlafaxine and gabapentin from unspecified dates, received within 2 weeks of vaccination, for unspecified indication. Patient historically took first dose of Pfizer BNT162B2 (Lot number: EN6204) on 13Mar2021 at 11:00 AM on the left arm for COVID-19 immunisation. Patient previously took hydrocodone bitartrate, paracetamol (VICODIN) on an unspecified date and indication and had allergy. On 02Apr2021, around 10pm, patient began having chills and extreme muscle pain and spasms, and the lymph nodes in her left armpit swelled up so much that she couldn't put her arm down without extreme pain. By midnight (03Apr2021 00:00), patient had a fever and was unable to stand unassisted. She was writhing in pain and arching uncontrollably off the bed. She believed in hindsight that this was a seizure as she went in and out of consciousness and her tongue swelled up, making it hard to breathe and impossible to speak. She was sweating profusely, and had to drink water constantly. Her husband had to help her get to the bathroom because she couldn't support her own body without tipping over. The chills and fever alternated all night, and</p> |

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she finally passed out from exhaustion at 03Apr2021 at 7am. The next 2 days, she was in a cycle of fever and chills again, and the fever got so bad that she seized twice more on Saturday (03Apr2021). She had to take the day off work on Monday (05Apr2021) as she was still in so much pain that she could barely leave bed except to use the bathroom. Events were reported as life-threatening, immediate risk of death from the events. Patient was not hospitalized. Treatment for the adverse events were cool baths, naproxen (ALEVE) for fever and pain, and PEDIALYTE. COVID-19 was not tested post vaccination. Vaccination facility type was at a hospital. The outcome of the events was recovering. No follow-up attempts are possible. No further information is expected.

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| 1224863 | 4/18/2021 | FL | 83 | M | 2/14/2021 | 2/14/2021 | Lightheadedness/almost fainted; Nauseous; Headache; fluish sick; This is a spontaneous report from a contactable consumer (patient). An 83-year-old male patient received second dose bnt162b2 (BNT162B2), via an unspecified route of administration, administered in Arm Left on 14Feb2021 11:30 (Lot Number: EL9267) as single dose for COVID-19 immunization. Medical history included artificial heart valve from Jun2018 and ongoing, transient ischemic attack (TIA), high cholesterol, blood pressure (abnormal), all from an unknown date and unknown if ongoing. Concomitant medications included apixaban (ELIQUIS) tablet taken for transient ischemic attack from Oct2019 and ongoing; rosuvastatin tablet taken for high cholesterol from an unspecified start date and ongoing; metoprolol caplet taken for blood pressure from Nov2020 and ongoing. The patient previously received first dose bnt162b2 (BNT162B2), administered in Arm Left on 22Jan2021 13:00 (Lot Number: EL9263) for COVID-19 immunization. Patient was reporting reaction to Pfizer COVID vaccine. Patient stated he read some articles to call and reported if you have a type of reaction or something after having the COVID vaccine. Patient had second COVID vaccine on 14Feb2021. Three or four days later (as reported), he began feeling lightheaded, nauseous and headaches beginning around 18Mar2021 or 19Mar2021. Patient reported he almost fainted a few times and it had gotten progressively worse. The patient reported having headaches not every day, but pretty much close to every day, 4 out of 5 days a week. Patient reported sometimes the headaches were bad and sometimes constant. Patient was hospitalized and had every test known to mankind. The patient reports actually being kind of fluish sick for 2 days after having vaccine, the normal feeling that every one says they have. He completely recovered; started night of the 14Feb2021, lasted next two days and then totally gone on 16Feb2021. Blood thinner stopped a couple of days before the shot per his doctor. Patient stated that every test he had was negative, nothing that would cause the symptoms. He had a Computerized axial tomogram (CAT) scan with dye; CAT scan without dye; carotid artery tested; echocardiogram; left the hospital said they didn't find anything to cause it. After talking to people and reading, he decided to call Pfizer. All results came back negative. Vaccination Facility Type was community |

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center - other. Vaccine was not administered at Military Facility. No additional vaccine was administered on same date of Pfizer COVID vaccine. No additional vaccine was administered. Adverse events lightheadedness, nauseous, headache required a visit to Emergency Room. The patient was hospitalized for 2 days from 29March2021 to 31March2021 due to lightheadedness, nauseous, headache. The outcome of event fluish sick was recovered on 16Feb2021, of other events was not recovered. Follow-up attempts were completed. No further information was expected.

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| 1224918 | 4/18/2021 | PA | 67 | F | 3/15/2021 | 3/15/2021 | bradycardia; fainting; Head and neck ache; Head and neck ache; first dose received on 09Mar2021; second dose received on 15Mar2021; first dose received on 09Mar2021; second dose received on 15Mar2021; This is a spontaneous report received from a contactable consumer (patient). A 67-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date unknown), via an unspecified route of administration in the right arm, on 15Mar2021 15:00, as single dose, for COVID-19 immunisation. Medical history included psoriasis, high blood pressure, scoliosis and low thyroid. The patient has no known allergies. The patient did not have COVID-19 prior to vaccination and was not tested for COVID-19 post vaccination. The patient was not pregnant at the time of vaccination. Concomitant medications included levothyroxine sodium (SYNTHROID); sertraline; sertraline hydrochloride (ZOLOFT); and levothyroxine sodium (LEVOTHYROXINE), all taken for unspecified indications, start and stop dates were not reported. Historical vaccine included the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date not reported) received at age 67 years, via an unspecified route of administration in the right arm, on 09Mar2021 14:45, for COVID-19 immunisation. On 15Mar2021, the patient experienced bradycardia, was fainting, and had head and neck ache. One week after the second vaccine, in Mar2021, the patient was taken to the hospital due to the events. Treatment for the events included "had to have a pacemaker put in". The patient reported that she never had heart problems before, and she was curious if these could have been side effects from the vaccine. The events resulted to physician office and emergency room visits, and hospitalization. The duration of the hospitalization was reported as 4 days. The events were reported as life-threatening illnesses. The patient was recovering from the events. Information about Batch/Lot number has been requested. |
| 1224984 | 4/18/2021 | SC | 29 | F | 4/17/2021 | 4/17/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Medium |

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| 1225169 | 4/18/2021 | MA | 31 | M | 4/17/2021 | 4/17/2021 | Systemic: Chills-Mild, Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Head pain from hit his head to the shelf-Medium, Systemic: Nausea-Mild, Systemic: Shakiness-Mild, Systemic: Tingling (specify: facial area, extremities)-Mild, Systemic: Weakness-Mild, Additional Details: Patient was resting in the observation area after getting his 1st shot. He fainted and hit his head on the shelf. Patient's main concern is the head pain from his head trauma. His wife will take him to the hospital for head scan. Wife will follow up with the store with his condition. |

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| 1224494 | 4/18/2021 | NV | 62 | F | 3/26/2021 | 3/26/2021 | eyes rolled back/passed out; my throat area under my jaw line started to hurt; my left leg was achy and tingly; my left leg was achy and tingly; headache; nauseated; weak; fever; just didn't feel good; sick; became rigid; This is a spontaneous report received from a contactable consumer (patient). A 62-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (brand=Pfizer-BioNTech, lot unknown=true, lot unknown reason=unable to locate or read the details) via an unspecified route of administration in right arm on 26Mar2021 11:45 (62-year-old at vaccination date) at a single dose for COVID-19 immunization. Medical history included hypertrophic cardiomyopathy (HCM), a bruit, ventricularomegaly, gastrointestinal (GI) issues, many female issues (before she got a hysterectomy), cancer activity, hepatitis C (Hep C), COVID-19 since 18Mar2021 (diagnosed as extremely positive, remained sick until 25Mar2021), and allergies to medications, food, or other products included Motion sickness meds. The patient was not pregnant at the time of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Other medications the patient received within 2 weeks of vaccination was reported as yes but unspecified. About 25 minutes after the vaccine, her throat area under her jaw line started to hurt, her left leg was achy and tingly, and she was started to get a bad headache. She became nauseated and weak. She made it home, took paracetamol (TYLENOL), and got in bed. Saturday her headache was on steroids, she had fever, and just didn't feel good. Later that day, she was so sick she went to the bathroom and she guessed she passed out. Basically, her husband said he found her on the floor after he heard a thump. He asked me what was his name. He said she responded correctly, but then her eyes rolled back, she became rigid, and he called 911. she knew 2 sets of paramedics arrived w/ambulances. They monitored her vitals and stayed until she was normal. They were willing to take her to the hospital, but offered other options for her husband and she to consider. They suggested she see her Primary care doctor (she did on 29Mar2021). Her doctor believed she should not take the 2nd dose of the vaccine. Adverse event start date was 26Mar2021 at 12:30 pm. AE resulted in doctor or other healthcare professional office/clinic visit. It was reported no |

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| | | | | | | | treatment received for the adverse event. The outcome of event was resolving. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. Information on the lot/batch number has been requested. |
| 1226994 | 4/18/2021 | IL | 37 | F | 4/16/2021 | 4/16/2021 | Loss of consciousness 10 minutes after administration while leaving pharmacy.. No syncope before episode or awareness of feeling unwell. Woke up on the floor and couldn't stand without syncope and nausea for 2 hours. Required emergency department visit and sent home once medically cleared. |
| 1226459 | 4/18/2021 | NJ | 33 | F | 4/7/2021 | 4/14/2021 | Initial symptoms in first 48 hours post vaccine: feeling of passing out (presyncope) followed by episodes of dizziness and chills. Exactly one week post vaccine: presyncope followed by severe vertigo, nausea, disequilibrium , shaking, extreme chills, tinnitus, panic, and intense migraine. MD prescribed steroid ear drops and Xanax. Also took ibuprofen Benadryl and Claritin with minimal relief. Symptoms of panic and vertigo have subsided after 4 days with medicine however still experiencing dizziness nausea anxiety tinnitus and migraine. Follow up with MD on 4/19/21. Wish I never got vaccine. No medical history. Young healthy 33 year old female |
| 1226474 | 4/18/2021 | CA | 24 | M | 4/17/2021 | 4/18/2021 | Shortly after vaccine was administered, patient appeared to have vasovagal response and fainted from chair in waiting area. Patient's legs were lifted as to bring blood flow back to the heart, patient started recovering within minutes. Patient did not sustain any injuries from fall. |

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| 1226481 | 4/18/2021 | VA | 35 | M | 4/18/2021 | 4/18/2021 | Patient received his first dose of the Covid-19 vaccine. After 5 minutes of sitting, he decided to walk around the store to shop. The patient experienced syncope and fell face first to the floor, cutting his lip. The patient was bleeding from his lips. Customers and pharmacy technicians tended to the patient. He was alert and responsive the entire time. The pharmacist called 911 and an EMS team was dispatched. The patient rose and sat in a chair. He was given water. He stated that he just felt overheated and that the store was very warm. EMS arrived, evaluated the patient, and stated that the patient just experienced a bout of syncope. They asked if the patient would like to go to the hospital and the patient declined. EMS left and the patient remained seated, resting for an additional 20 minutes. The patient left the pharmacy. The pharmacist spoke with the patient several hours later and the patient reported he was doing fine at home resting. The pharmacist counseled the patient to contact his primary care provider regarding the incident. |
| 1226496 | 4/18/2021 | MI | 48 | M | 4/17/2021 | 4/17/2021 | Extreme dizziness and nausea resulting in fainting twice and hitting chin on furniture. Diarrhea all night at least once per hour. Chills and shaking. Sweats, very fatigued, no appetite, no sleep. Rested all Sunday, no more chills but still nauseous, diarrhea all day. No energy or appetite. |
| 1226675 | 4/18/2021 | CA | 26 | M | 4/18/2021 | 4/18/2021 | syncope, fainting. patient mentioned he felt nervous when getting vaccine and felt better after taking xanax prescription |
| 1226700 | 4/18/2021 | TX | 25 | F | 4/18/2021 | 4/18/2021 | PT stated she is afraid of needles and ALWAYS faints when blood is drawn from her or given a vaccine or shot. PT fainted within a couple of minutes of the pharmacist administering the vaccine. she was sitting in a chair with arms. her friend and myself lowered her unto the pharmacy floor. he was at her head and I was at her feet. I lifted her legs. pt regained consciousness within 3 minutes. she sat up for another 15 minutes and then left with her friend. |
| 1226702 | 4/18/2021 | IL | 25 | M | 4/18/2021 | 4/18/2021 | syncope, lightheaded, fainting, dizziness |

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| 1226718 | 4/18/2021 | GU | 31 | F | 4/2/2021 | 4/2/2021 | Approximately 10 minutes after injection, I passed out. Witness said that I was unconscious for approximately 1 minute. My body shook, and it appeared that I had a seizure. Immediately upon waking I started vomiting and having uncontrollable bowel movements for about an hour. I felt confused for about 30 minutes and was unable to speak for a few moments upon waking. When I arrived at the hospital I was still vomiting and having uncontrollable bowel movements. I was given fluids and zofran and sent home without further testing. |
| 1226733 | 4/18/2021 | MS | 47 | M | 4/18/2021 | 4/18/2021 | Patient fainted within 5 min of receiving vaccine |
| 1226444 | 4/18/2021 | FL | 34 | M | 4/16/2021 | 4/16/2021 | 20mins after the shot. I rapidly developed a fever and had trouble seeing. Felt like fainting. Really nauseous stomach and diarrhea. Chills but with a high fever. Threw up 25mins after shot. Immediately after that felt really nauseous and couldn't see straight. Vision was black and I was seeing stars. Felt like hallucinating really bad. Couldn't focus my vision. Got home and showered with a really hot shower and immediately started feeling better. 45mins to 1 hour after shot started feeling way better! Just sluggish the rest of the night. For some reason was fighting going to sleep and fell asleep sitting up. Next day much better! |
| 1226921 | 4/18/2021 | MN | 28 | F | 4/18/2021 | 4/18/2021 | After receiving my second dose, about ten minutes after, I began to feel dizzy and very warm. I fainted and it lasted 5-7 seconds. During this time my arms seized up and my leg was twitching. I bit my tongue and my eyes were super dilated when I woke up (according to the attending nurse). I was very sweaty and had to wait and sit there for about a half hour. Then when I returned home I felt so sick and ended up vomiting. It was horrible. Now I have a slight headache, a sore arm, and am super tired. |

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| 1227300 | 4/18/2021 | WA | 52 | F | 4/18/2021 | 4/18/2021 | Patient received Pfizer vaccine at approximately 1815 and after about 15 minutes the observer on shift noticed that she was clearing her throat. This patient also reported feeling heated and flushed and itchy. Stated history of allergic relation to Baclofen, which caused lightheadedness and syncope. Her chart lists several more allergies. This patient was transported to the ER by one of the vaccinators on shift. This vaccinator reported that by the time they got down to the ER her voice sounded constricted and her breathing difficulty had increased. |

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| 1227132 | 4/18/2021 | OH | 17 | F | 3/1/2021 | 3/1/2021 | <p>Vasovagal Syncope; unauthorized age patient, 17 years of age; This spontaneous case was reported by a nurse and describes the occurrence of SYNCOPE (Vasovagal Syncope) in a 17-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 012A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Congenital heart disease NOS since 22-May-2003. On 01-Mar-2021 at 2:30 PM, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 01-Mar-2021 at 2:30 PM, the patient experienced SYNCOPE (Vasovagal Syncope) (seriousness criterion medically significant) and PRODUCT ADMINISTERED TO PATIENT OF INAPPROPRIATE AGE (unauthorized age patient, 17 years of age). On 01-Mar-2021, SYNCOPE (Vasovagal Syncope) had resolved. On 01-Mar-2021 at 2:30 PM, PRODUCT ADMINISTERED TO PATIENT OF INAPPROPRIATE AGE (unauthorized age patient, 17 years of age) had resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter considered SYNCOPE (Vasovagal Syncope) to be unlikely related. No further causality assessment was provided for PRODUCT ADMINISTERED TO PATIENT OF INAPPROPRIATE AGE (unauthorized age patient, 17 years of age). No relevant concomitant medications were reported. The patient did not receive any treatment. The event, SYNCOPE (vasovagal syncope) was an acute episode and recovered quickly within minutes. Follow-up received on 06-APR-2021 included additional reporter information, date of vaccine administration, patient's race, ethnicity and other relevant medical history, start and dates of product administered and the events, anatomical location, and reporter causality. This report refers to a case of inappropriate schedule of vaccine administered for mRNA-1273 (lot #unknown) with no associated syncope reported. The reporter considered SYNCOPE to be unlikely related. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information</p> |

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1227165 4/18/2021 NJ

33 F

4/2/2021

4/3/2021

incorporated above includes: On 06-Apr-2021: additional reporter information, date of vaccine administration, patient's race, ethnicity and concurrent condition, additional event - Syncope, onset and stop dates of the event, - Product administered to patient of inappropriate age, injection site, and reporter causality.; Sender's Comments: This report refers to a case of inappropriate schedule of vaccine administered for mRNA-1273 (lot #unknown) with no associated syncope reported. The reporter considered SYNCOPE to be unlikely related. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

Severe syncope; This is a spontaneous report from a non-contactable consumer (patient). A 33-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot Number: ER8737), dose 1 via an unspecified route of administration, administered in Arm Left on 02Apr2021 14:00 (at the age of 33years) as single dose for Covid-19 immunization. Medical history included oral allergy syndrome, polycystic ovarian syndrome, and Gluten, Apples, Almonds, Cherries allergy; all from an unknown date and unknown if ongoing. Concomitant medications included fexofenadine hcl and ethinylestradiol, norgestimate (TRI LO MARZIA), both taken for an unspecified indication, start and stop date were not reported. The patient is not pregnant at the time of vaccination. The patient was not diagnosed with COVID-19 prior to vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced severe syncope on 03Apr2021 (12:45PM). The event resulted in Emergency room/department or urgent care. It was unknown if treatment was received for the adverse event. The patient has not been tested for COVID-19 since the vaccination. The outcome of event was recovered on an unspecified date. No follow-up attempts are possible. No further information is expected. Information on lot number already obtained.

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| 1227196 | 4/18/2021 | CA | 50 | F | 4/2/2021 | 4/11/2021 | Drop attack. Fainted without prior physical warning signs. No memory of falling. Woke on ground. Left shin was cut after falling on to dropped food bowl that I had been carrying. I must have dropped bowl, fell onto it and it broke, and that gave me a cut on my shin. |

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| 1227205 | 4/18/2021 | AR | 68 | F | 3/22/2021 | 3/22/2021 | 19 second pause of no heartbeat and in third degree heart block; 19 second pause of no heartbeat and in third degree heart block; Awoke to throw up; Thinks she fainted; Oxygen level of 93 on oximeter; she wasn't feeling well; This is a spontaneous report from a contactable consumer (patient). A 68-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), via an unspecified route of administration, administered in left arm on 22Mar2021 at 15:00 (Lot Number: EN6198) as single dose for covid-19 immunization. Medical history included mild stroke from 18Jan2020 and not ongoing, suspected she had atrial fibrillation and she had a heart monitor placed 21Feb2020. Her heart monitor never showed Atrial Fibrillation after one year of being monitored. Ongoing low thyroid/hypothyroidism and blood cholesterol increased from an unknown date. Concomitant medications included levothyroxine taken for low thyroid/hypothyroidism from an unspecified start date (started probably been 10 years) and ongoing; atorvastatin taken for reduce cholesterol from 2020 (started right after she had stroke, either Jan2020 or Feb2020) and ongoing. No additional vaccines administered on same date of the Pfizer suspect. No prior Vaccinations (within 4 weeks). The patient previously took the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), via an unspecified route of administration, administered in left arm on 01Mar2021 (at age of 68 years old, Lot Number: EN6200) as single dose for covid-19 immunization. She was fine right after the first dose. She only had a sore arm for 3 days. Just last week, she had a severe adverse reaction right after her vaccine. With the second dose, she had everything possible. Twelve hours after, on 23Mar2021 at 03:00, she awoke to throw up. She thinks she fainted. She had to throw up 2 more times that night. She had been wearing a heart monitor. On 24Mar2021 her cardiologist called her and told her she had a 19 second pause of no heartbeat and was in a 3rd degree heart block. The very next morning, they put in a pacemaker. She was overall healthy and athletic. She was a runner and golfs all the time. She had an outpatient procedure for the pacemaker placement at the hospital on 25Mar2021. She was still recovering but improving. Caller added it was scary when your heart |

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stops. Caller added she did not see this as a possible related side effect, but that evening when she was not feeling well, 22Mar2021, she checked her oxygen level with her oximeter. It was 93 and usually runs around 99. It is back to normal now. She checked it the night she was vomiting. Stated this was before the third degree heart block by a few hours. She did not think it was related. All her symptoms are gone other than the placement of her pacemaker. The outcome of the events " 19 second pause of no heartbeat and in third degree heart block" was recovering. The outcome of the event " Oxygen saturation decreased" was recovered. The outcome of other events was unknown.

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| 1227220 | 4/18/2021 | GA | 67 | F | 3/11/2021 | 3/11/2021 | <p>Blurred vision; Headaches; Chills; Itching rash on arms, back, neck and chest; Fainted at home, fell, and busted her lip/ she dropped to the floor and everything was turning black; Fainted at home, fell, and busted her lip/ she dropped to the floor and everything was turning black; busted her lip and it was bleeding real bad; Weakness/ feeling weak; Feel weak in her arms and legs; Sweating profusely; Aching of joints and muscles kind of like flu symptoms in shoulders and arms; Aching of joints and muscles kind of like flu symptoms in shoulders and arms; Aching of joints and muscles kind of like flu symptoms in shoulders and arms; Foggy Brain; This is a spontaneous report received from a contactable consumer (patient). A 67-year-old female patient received (PFIZER-BIONTECH COVID-19 VACCINE; Dose 1) intramuscularly, administered in the left arm on 11Mar2021 (batch/lot number: EN6205) at 67 years old as a SINGLE DOSE for COVID-19 immunization. The vaccine was administered at a Pharmacy/ drugstore. The patient's medical history included compromised immune status; respiratory illness, genetic /chromosomal abnormalities; endocrine abnormalities (including diabetes) and obesity; asthma diagnosed since childhood; diagnosed allergies, allergies (seasonal and food); food allergies included gluten, dairy, artificial sweeteners including Sorbitol and Xylitol, broccoli, cauliflower, cabbage, brussel sprouts, asparagus, all "percifirous"/ cruciferous vegetables; she also has allergies to cats, pollen, trees, grass, ragweed, mold, mildew, and dust; and allergies to Codeine, Penicillin, Sulfa, Iodine, Epinephrine, Morphine, and Clindamycin (patient does not have a manufacturer, lot or expiration to any of these medications). The patient had no family medical history. Concomitant medications included unspecified prescription medications for years which she did not feel they were relevant. On 11Mar2021, the patient experienced "weakness/ feeling weak" (weakness), "feel weak in her arms and legs" (weakness of limbs), "fainted at home, fell, and busted her lip/ she dropped to the floor and everything was turning black" (faint), "fainted at home, fell, and busted her lip/ she dropped to the floor and everything was turning black" (fall), "busted her lip and it was bleeding real bad" (bleeding lips), sweating profusely (excess sweating), "aching of joints and muscles kind of like flu symptoms in</p> |

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shoulders and arms" (Flu-like symptoms), "aching of joints and muscles kind of like flu symptoms in shoulders and arms" (Joint pain), "aching of joints and muscles kind of like flu symptoms in shoulders and arms" (muscle pain), and foggy brain (foggy feeling in head). On 12Mar2021, the patient experienced headaches, chills, itching rash on arms, back, neck and chest (itchy rash). On 13Mar2021, the patient experienced blurred vision. It was reported that after the first shot, on 11Mar2021, patient experienced weakness, then she got home and she fainted, fell, and busted her lip and it was bleeding real bad. Then she began sweating profusely. She started feeling weak 30 minutes after getting the shot. Someone took her there because she would not have been able to drive. They brought her home and she was in the kitchen. While over the sink, she started to feel weak in her arms and legs. Before she could tell her husband that she was feeling weak, she dropped to the floor and everything was turning black. She fell face first and busted her lip and it was bleeding real bad. The weakness gradually started getting a little better on 30Mar2021. She is having to walk with a cane now because of the weakness. She was not using a cane before. Two days later on 13Mar2021, she was in the kitchen again and she felt that feeling coming and her husband was able to grab her and sit her down and she did not faint but she could tell it was coming. Patient also reported that from 12Mar2021, she is getting headaches every day off and on and in different spots of the head. Sometimes it is in the forehead, top, side and back. For about a good week, she had chills and it tapered off after the first dose. Also, on 12Mar2021, she experienced itching rash on arms, back, neck and chest. They were fine bumps and they just itch. The patient was recovering from the events faint, fall, bleeding lips, excess sweating, and itchy rash; and has not recovered from the events weakness, weakness of limbs, flu-like symptoms, joint pain, muscle pain, foggy feeling in head, headache, chills, and blurred vision. Follow-up attempts are completed. No further information is expected.

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| 1227271 | 4/18/2021 | FL | 55 | M | 3/27/2021 | 3/27/2021 | actually passed out slightly; Really dizzy; can't move and stand by; This is a spontaneous report from a contactable consumer (patient). A 55-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Dose 1) via an unspecified route of administration on 27Mar2021 (batch/lot number: ER8730) at 55 years old at a SINGLE DOSE for COVID-19 immunization. The patient's medical history included Type II diabetes, Thyroid inactive, and blood pressure management, all from an unknown date. Concomitant therapy included unspecified blood pressure medication. On 27Mar2021, the patient actually passed out slightly (loss of consciousness), got really dizzy (dizziness), and can't move and stand by (movement disorder). It was reported that about 5 minutes after vaccination, patient got really dizzy and actually passed out slightly and was dizzy for about that day; he was dizzy all day, he can't move and stand by. Patient stated that he actually got better but took five days. Patient further stated, "I just determine, because of the reaction, people say, second is worse and I don't know if its allergic reaction or is that normal. If they consider." Outcome of the events was recovering. |
| 1227339 | 4/18/2021 | NC | 21 | F | 4/8/2021 | 4/8/2021 | RPH ADMINISTERED JANSSEN'S COVID-19 VACCINE AT 10 AM AND WITHIN A FEW MINUTES, PATIENT FAINTED AND SLIPPED OFF HER CHAIR TO THE FLOOR. PATIENT CAME TO WITHIN A MINUTE AND RPH HELPED HER TO THE CHAIR, OFFERED HER WATER AND A BANANA, AND THE PATIENT DID NOT SEEM HURT. RPH MONITORED THE PATIENT'S BLOOD PRESSURE AND COLORING/ SWEATING FOR 30 MINUTES BEFORE SHE LEFT THE PHARMACY AND HER FATHER DROVE HER HOME. |

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| 1227387 | 4/18/2021 | NM | 44 | M | 4/16/2021 | 4/16/2021 | Approx 15mins after having the shot administered I sat in my car and felt the medication coming on by it clouding my vision then causing me to faint (and by description from my fiancé) I had what appeared to be a mild seizure. I was out for a minute or two and when I was conscious again my vision was blurry and I felt very drunk for the next 45mins - hour. I also felt like I could taste the chemicals from the vaccine when I became conscious again. The drunk/vertigo feeling subsided slowly over time but I was given a Benadryl from the pharmacist so I?m not sure when the dizziness stopped but I definitely could not drive home. My fainting was not due to any anxiety due to having a shot or anything, I was perfectly fine for approx 10-15 mins after the vaccine then I felt a cold feeling coming on from my right shoulder then up my neck then I got foggy and dizzy and passed out |
| 1225895 | 4/18/2021 | NJ | 61 | M | 4/18/2021 | 4/18/2021 | Patient received vaccine was sitting for 15 minutes and got up in the middle of his 15 minutes to approach the pharmacist and the pharmacist sat him down again and he passed out onto the floor hitting his head with a cut on his eyebrow and nosebleed. Ems arrived and got patient back into chair and he again passed out and began seizing. He again regained consciousness and was taken away in a stretcher. |
| 1225838 | 4/18/2021 | | 28 | M | 4/18/2021 | 4/18/2021 | syncope, cleared, pt. left site. |
| 1226760 | 4/18/2021 | CO | 38 | M | 4/18/2021 | 4/18/2021 | Patient passed out after receiving vaccination. He was unconscious for about 5 seconds before regaining consciousness. |
| 1225956 | 4/18/2021 | | 26 | F | 4/15/2021 | 4/15/2021 | Syncope. Patient passed out 5 min after injection - has phobia of needles. No Resp distress VSS, A&Ox4. Pt given juice and crackers. Pt left w/ mother in stable condition under her own power. Refused wheelchair. |

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| 1227354 | 4/18/2021 | NC | 29 | M | 4/8/2021 | 4/8/2021 | MINUTES AFTER SHE ADMINISTERED JANSSEN'S COVID-19 VACCINE TO PATIENT. HE FAINTED AND FELL OFF HIS CHAIR. SHE SAID HE CAME TO ALMOST IMMEDIATELY AND SHE HELPED HIM BACK IN THE CHAIR, OFFERING HIM WATER AND A BANANA. HE STAYED SEATED WHILE SHE MONITORED HIS BLOOD PRESSURE, CHECKED FOR PALENESS, AND SWEATING FOR 30 MINUTES. THEN HIS GIRLFRIEND/FRIEND DROVE HIM HOME. |
| 1225849 | 4/18/2021 | FL | 59 | F | 2/13/2021 | 2/13/2021 | about 45 min after shot....bronc spasms, could not speak or move, unable to move..... , passed out. In intense pain for 24 hours approx even wet my pants due to inability to move. My body is a hyper-adrenaline stimulator (per cardio med DX)...It is like a built in epi shot. I honestly think I would not be here without it. It seems with the odd reactions this year....there is the similar ingredients.....all PEG or their renamed cousins. It started with MIRALAX and 2 019 flu shot. |
| 1225840 | 4/18/2021 | FL | 30 | M | 4/18/2021 | 4/18/2021 | Received his vaccine at 10:46am. He fainted at 11:05am. The pharmacist ran out to assist him immediately and he was already conscious and sitting up on the floor. He was coherent and able to answer questions. |
| 1225861 | 4/18/2021 | MA | 54 | F | 4/15/2021 | 4/15/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Nausea-Mild |
| 1225863 | 4/18/2021 | NY | 19 | F | 3/28/2021 | 4/8/2021 | Patient presented to our primary care office 10 days after her Pfizer COVID booster shot was administered. She started with hives over her torso, arms and legs the day prior which was 9 days after her booster vaccine. Patient was placed on benadryl and pepcid for urticaira. Her symptoms progressed over that day with difficulty breathing, vomiting and syncope. She was taken to the emergency department. She was observed and placed on 5 days of oral prednisone. SHE DID NOT REQUIRE ANY EPINEPHRINE and was observed in the emergency department for hours prior to discharge. Symptoms resolved fully. |

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| 1226413 | 4/18/2021 | NC | 22 | F | 4/12/2021 | 4/12/2021 | At the time of vaccination, patient experienced a vasovagal reaction of nausea, headache, near-fainting. After eating a snack and drinking water symptoms improved over about 1 hour and patient returned home. Pharmacist call to check on patient the next day, she said she was feeling better, not 100%, but Ok. Since then, she had a headache for 4 days and started having mental distress (out of body feeling, memory loss, and covid-like symptoms). She also states she has had excessive sweating since a week ago and feels very unstable on her feet. She went to a doctor who tested her for covid. It came back negative. The doctor advised if the symptoms continue to get worse, she should go to the hospital. She was at work today, we discussed all these things here. She said she couldn't even remember her name or walk straight. I told her she needed to go to the hospital ASAP and not to work the rest of her shift. |
| 1225868 | 4/18/2021 | DE | 51 | F | 3/31/2021 | 4/5/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: Tachycardia-Medium, Additional Details: 6 days after vaccine |
| 1225859 | 4/18/2021 | TX | 18 | F | 4/18/2021 | 4/18/2021 | Patient fainted (syncope) within 2 minutes. Fell off her chair and hit her front tooth which broke off. 911 was called, her vitals were taken. Cleared by medical staff. Patient and mother refused to be taken to the Hospital. Both signed waivers of fact. Patient walked off without assistance. |
| 1226018 | 4/18/2021 | NY | 30 | F | 4/15/2021 | 4/17/2021 | At 2:15 am on 4/17/21, I woke up with nausea and stomach pain. Experienced fainting (twice), vomiting and diarrhea (twice). |
| 1226075 | 4/18/2021 | | 17 | F | 4/18/2021 | 4/18/2021 | Patient passed out, no injuries |
| 1226109 | 4/18/2021 | TX | 62 | F | 4/9/2021 | 4/9/2021 | started fever the evening after receiving the shot. By 3:00 am had body aches. 5:30 am fever over 101, nearly fainted. Fever lasted about 24 hours, low grade fever continued about 5 more days. Fatigue, body aches also. Controlled symptoms with ibuprofen. |

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| 1226147 | 4/18/2021 | CT | 30 | M | 4/9/2021 | 4/10/2021 | Extreme chills and high fever starting approximately 12 hours following vaccination. 14 hours after vaccination had high fever, profuse sweating, leading to heart palpitations and two syncope episodes resulting in hospitalization. CT scan and xrays, ekg and blood tests, all normal, sent home on fluids. 76 hours after vaccination presented axatia, slurred speech, confusion, dizziness, resulting in rehospitalization. MRI, EEG, EKG, blood, and urine tests all completed and normal. Sent home on steroid. |
| 1226193 | 4/18/2021 | | 29 | F | 4/11/2021 | 4/14/2021 | Vaccine administered Sunday at 2PM, severe chills/fever within 72 hours status post vaccine administration. 72 hours after: venous distention on vaccinated arm from the inner upper arm to wrist. Blood pressure <130/80. no fever, no chills. Thursday okay. Friday night at around 9PM, sudden feeling of loss of consciousness but without actually losing. Huge gush of warmth and blood to brain. After episode, cold and sweaty hands. Both arms had distended veins visible. Saturday morning, back to normal. no venous distention, no feeling of fainting. Saturday night at 10:30PM, BP 155/99, HR 88, distention of veins on both arms. 11:40PM, bilateral leg swollen, no pain, no signs or symptoms of VTE, no SOB. Sunday AM: blood pressure normal, swollen legs disappeared, achy and sore knee and hip joints bilaterally. Still monitoring signs and symptoms. PCP advised to take Aspirin 81mg daily. |
| 1226194 | 4/18/2021 | NY | 18 | M | 4/18/2021 | 4/18/2021 | pt fainted after receiving 1st dose of Moderna Covid vaccine. Pt fainted approximately 10 minutes after vaccine was administered. Pt came to after 10-15 seconds, and fainted 2nd time after about 90-120 seconds. pt came to after about 10-15 seconds. Pt felt weak, was sweating, had chills. Pt was able to talk, breath and swallow water which pt requested to drink. Pt and mom decided that they would like EMT's to check him out. EMTs brought pt to ER and was released after a couple of hours.. |

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| 1226241 | 4/18/2021 | CT | 26 | M | 4/18/2021 | 4/18/2021 | Patient received dose 1 of Moderna COVID-19 vaccine. Approximately 5-10 minutes after administration, the patient's mother alerted me that the patient was feeling faint and sweaty. I came to check on the patient. He appeared pale and diaphoretic. Patient said his vision was narrowing and he subsequently lost consciousness for approximately 10-20 seconds. I checked the patient's blood pressure and initial result was 88/64. Upon regaining consciousness, patient reported immediately feeling better. His blood pressure was still low at 94/70. He remained seated and drank some cold water and a cool compress was applied to his forehead. I questioned the patient to determine if he was experiencing any other symptoms that may indicate anaphylaxis (skin itchiness, tight throat, stomach upset) and he denied any other symptoms. I continued to monitor the patient for approximately 30 minutes. During monitoring, the patient told me he is nervous of needles, and has fainted trying to give blood in the past. After 30 minutes of monitoring, diaphoresis had resolved, color returned to patient's face, blood pressure recheck was 116/84, and patient self-reported feeling fine. He was escorted home by his mother. |
| 1226345 | 4/18/2021 | PA | 26 | M | 4/18/2021 | 4/18/2021 | DIZZINESS/LIGHTHEADNESS FOR ABOUT 5 MINUTES, FAINTED FOR 5 SECONDS |
| 1226363 | 4/18/2021 | VA | 25 | F | 4/14/2021 | 4/14/2021 | Pt noted rash in trunk and upper back starting 6 hours post-vaccination, described as redness, skin peeling, and hives - has gotten worse over next few days and decided to report the situation April 18, 2021. Pt denied dizziness, syncope, respiratory distress. Pt sees dermatologist on a routine basis and is due for her skin injection (dupilumab) for eczema. |
| 1226370 | 4/18/2021 | FL | 73 | F | 4/14/2021 | 4/14/2021 | Lethargic, passed out twice, loss of appetite, headache, sweating, feverish but feet and hands like ice, unstable - loss of balance Kept taking Tylenol after called Dr. on April 16. Was told could do nothing else because was not supposed to suppress symptoms. |

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| 1226140 | 4/18/2021 | CA | 34 | M | 4/18/2021 | 4/18/2021 | At 1140, RRT was activated for a 34 y/o M that passed out for a few seconds. He stated, "I felt like I was in a dream." His eyes rolled back before passing out. When he was alert after his fainting episode, he stated that his right arm was numb and had c/o nausea, weakness, a brief moment of blurry vision, and "feeling hot?". Head-to-toe assessment completed. Client was diaphoretic and pale. Client also reported that he was feeling hot and then feeling cold all of a sudden and this was ongoing. Client vaccinated on the R arm at 1130. NKA, no past medical hx. Does not take any medications but smoked marijuana just prior to his appointment. Vitals ? BP: 138/98, RR: 20, HR: 65, 0/0 pain. EMS called. Client's condition improved during monitoring period but as EMS arrived, client began to feel same symptoms again but did not pass out. EMS arrived at 1149. Vitals when they arrived were: BP: 142/77, HR: 48. Client's condition did not improve significantly but did not get worse. Client opted to have ambulance transport to Community ER to be further evaluated and treated. Client left vaccination clinic via Representative, accompanied by Fire Engine and unit @ 1200. Girlfriend, who came with client, followed client to hospital. Client left in stable condition, AA0x4, breathing even and unlabored, in no acute distress. |
| 1226410 | 4/18/2021 | NM | 60 | M | 3/26/2021 | 3/26/2021 | Approximately 1 hour after the vaccination, Patient reported feeling a sudden "pop" in his head. That was followed by loss of balance, weakness, and inability to walk. He collapsed and either passed out or slept for 2-3 hours. Upon awakening he still felt weak and unbalanced. He also had bitten his tongue and lip while unconscious. He slowly recovered over a period of 3-4 days after the vaccination. He has never before had a stroke or a seizure. No one was with him to observe any of his symptoms. |
| 1225867 | 4/18/2021 | TX | 40 | M | 4/3/2021 | 4/3/2021 | Patient fainted while sitting in observation area. Patient regained consciousness within a few seconds. Patient was assessed and left vaccination clinic in stable condition. |

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| 1226373 | 4/18/2021 | | 46 | F | 4/15/2021 | 4/15/2021 | Known allergy to Ants. Syncope, Flushing/sweating, dizziness. Pt had an episode of syncope for a few seconds. Complained of dizziness and itchiness. Gave 50mg PO Benadryl. VSS and released from vaccination site. |
| 1226398 | 4/18/2021 | AZ | 27 | F | 4/18/2021 | 4/18/2021 | A few minutes after rec. vaccine, pt started to feel lightheaded, passed out for <30 seconds, came to , reclined in car. EMS evaluated 121/76, 79, 95%. Had not eaten enough this am, takes metformin not for diabetes, he of lightheaded ness with blood draws. Observed for 30 min, husband drove home, symptoms had cleared |
| 1222534 | 4/17/2021 | KY | 61 | F | 3/10/2021 | 3/18/2021 | Presented as a TIA (mini stroke) Had vision issues, difficulty speaking, vertigo, could not walk, passed out and taken to hospital by ambulance . Began at around 10am. Felt like I was dying. Placed on Stroke Unit. Scans and tests all negative for stroke and Drs. thought could be panic attack or TIA. Since then my lingering effects point to TIA, Seemed to clear up around 2pm with gradual improvement through the day. Still experiencing some side effects including tinnitus, memory and word retrieval issues, fatigue, anxiety. DO NOT HAVE PANIC ATTACKS. The only time I have had a panic attack was at 26 after the death of my mother. |
| 1222642 | 4/17/2021 | | 23 | M | 4/16/2021 | 4/16/2021 | Syncope, Dizziness, patient sitting in chair and passed out (unwitnessed). Does not recall fall, small abrasion on forehead A&Ox4. MD present. Med Medics Present. Inital BP 72/35; HR 78. NO medical Hx, no current meds. Denies EtOH/drug use. Given water, juice, and crackers. Last BP 141/70, HR 78 and did not require ACLS transport to ED. Patient stable and released from vaccination site. |

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| 1222617 | 4/17/2021 | GA | 37 | M | 4/3/2021 | 4/7/2021 | Worst sickness/flu like symptoms I have ever experienced. Bad dehydration, diarrhea, throwing up, fatigue, light headed, chills, fainting/passing out. Had to diarrhea over 30 times in one day, throw up several times. Went to emergency room for treatment. IV treatment plus anti naseau and anti cramping Medication. Cramping was severe in upper intestine. Symptoms have decreased, but still linger after 2 weeks of 2nd shot. Concern if side effects are permeant. I still very tired/fatigued, have cramping, dirahaha, throwing up, aches muscles and joints- not feeling like myself and regret taking the vaccine if it results in lifelong side effects. |
| 1222591 | 4/17/2021 | | 31 | M | 4/17/2021 | 4/17/2021 | Patient got dizzy after 5 minutes of getting shot, had syncope episode and fell to ground. Patient was very pale and sweaty afterwards. |
| 1222573 | 4/17/2021 | FL | 30 | F | 4/16/2021 | 4/16/2021 | Patient was nervous about the vaccination and stated she had needle phobia. She got her vaccine and felt great immediately after. 5-10 minutes after her vaccine she felt well and walked to the front of the pharmacy near our registers. As we were talking she fainted and her mother tried to catch her. She hit her head on the ground and a bump formed. She stayed on the ground and her mother told us not to worry because this happens to her after any encounters with needles. After 10-15 minutes after the fall, she sat up and felt better. She declined further assessment and treatment and went home. |
| 1222551 | 4/17/2021 | MT | 54 | F | 4/16/2021 | 4/16/2021 | Time Course/Signs/Symptoms: 8-10minutes after vaccine -> bilateral arm "paralysis", Then, syncope. Was laid down. Awake and spoke her name. Then, Hyperventilation x 3-5 minutes @ about 100 rpm. Lost consciousness. O2 applied. BP=135/90; HR = 90/min. No wheezing, good B breath sounds. Ambulance arrived @ about 11:40am. Reportedly prolonged seizures and severe hypertension. Helicopter ambulance met road ambulance in route. Personnel immediately intubated the patient. Reportedly, this led to "a fountain of blood". |

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| 1222503 | 4/17/2021 | TX | 25 | M | 4/12/2021 | 4/12/2021 | After receiving injection patient walked out of pharmacy and sat in chair in front of pharmacy. About 8 minutes or so later, patient fell back in the chair and passed out. I ran over and called the patient's name who came to, and he felt warm and sweaty. Patient was able to recall his name, the day of the week, and where he was. About 2 or 3 minutes later after coming out to the patient, he vomit into a trash can and then stated he felt much better. |
| 1222569 | 4/17/2021 | FL | 19 | F | 4/17/2021 | 4/17/2021 | patient turned white and fainted, hyperventilation and low BP 79/69 |
| 1222649 | 4/17/2021 | NH | 19 | M | 4/17/2021 | 4/17/2021 | Several minutes after receiving the vaccination, while waiting in the post vaccine area, patient had either a seizure or fainted. I did not witness the occurrence. 911 was called and patient was transported to the hospital. |
| 1222679 | 4/17/2021 | | 27 | M | 4/17/2021 | 4/17/2021 | Vasovagal syncope. Patient stood up and walked around immediately after getting vaccine and then fainted shortly after. |
| 1222698 | 4/17/2021 | MD | 50 | F | 4/17/2021 | 4/17/2021 | The patient felt dizzy/ was shaking a couple minutes after receiving the Pfizer Covid-19 vaccine and then passed out/ was unconcious for about 30 seconds, while still shaking and breathing. She regained consciousness, but still felt dizzy/ sweaty. Emergency services were called and evaluated the patient, who left under her own will. |
| 1222715 | 4/17/2021 | MD | 30 | M | 4/17/2021 | 4/17/2021 | Patient fainted approximately 5 minutes after receiving vaccine. Patient fainted about 3 times after initial incident. He was evaluated and cleared by paramedics |
| 1222729 | 4/17/2021 | CA | 38 | M | 4/17/2021 | 4/17/2021 | 5 minutes post 2nd vaccination, patient sitting in chair felt funny, thought it was anxiety, remembers waking up on the ground. patient was transferred from ground to stretcher and brought to pod b first aid. MD assessed patient in triage, pt had history of syncope in high school. 1 cm laceration identified to patient left eye, below eyebrow and small abrasion below left nare. MD determined patient needed sutures for laceration in ED. |
| 1222732 | 4/17/2021 | OH | 32 | M | 4/17/2021 | 4/17/2021 | syncope, near fainting, dizziness, diaphoresis, nausea |

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| 1222734 | 4/17/2021 | MN | 27 | M | 4/17/2021 | 4/17/2021 | Patient fainted shortly after vaccination while walking to waiting room. Patient was treated by pharmacist until paramedics arrived. Patient was released by paramedics after assessing patient for low blood sugar. |
| 1222493 | 4/17/2021 | IN | 39 | M | 4/15/2021 | 4/16/2021 | I received the vaccine around 11am and did not experience any adverse reactions aside from a sore arm throughout the day. I went to sleep at 10pm and was awakened at 3am with moderate soreness in my arm and I began to feel feverish and woozy. About 2 minutes later I could tell that I was going to faint. The thing I remember was waking up on the floor next to my bed with my wife holding me up. She said that I started making sudden, loud guttural noises and she was afraid that I had been choking. She reached over to touch my arm and my body jerked out of bed and I hit the ground. When I woke up, I realized that I had fainted (I have passed out after a flu shot a couple years ago, but that incident happened about 15 minutes after injection) and my entire body was trembling and sweating profusely. My wife left the bedroom to get me some water and a cold towel. I got myself back into bed and passed out again. The trembling and sweating continued but gradually decreased for about 15 minutes until I felt back to normal. After I had calmed down, I felt no adverse symptoms and fell back asleep and have felt fine since the incident. |
| 1222786 | 4/17/2021 | TN | 30 | F | 4/16/2021 | 4/17/2021 | Near-syncope Symptoms started as an intense wave of nausea. I sat down. Within 30 seconds to one minute, I become very hot and diaphoretic. Then, black spots appeared in my vision, and I heard ringing in my right ear. I felt like I might lose consciousness, so I laid down on the ground. Within another minute, the symptoms started to pass. I never lost consciousness. This event only occurred one time. |

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| 1222154 | 4/17/2021 | GA | 18 | M | 4/16/2021 | 4/16/2021 | Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Nausea-Medium, Additional Details: Pt mother stated pt was nauseous and then that he was passing out. RN ran over to check on pt as pt eye rolled back and pt limbs fell limp. Pt moved to the floor by RN, rolled to the side by RN. Pt regained consciousness almost immediately and was laid on his back with feet elevated. Pt stated he felt fine, did not recall exactly what happened. Pt helped up into chair, given water and crackers. Pt stated he felt fine, observed by medical personnel for 30 min and pt was able to ambulate off site. |
| 1222795 | 4/17/2021 | | 16 | M | 4/16/2021 | 4/16/2021 | Patient fainted in chair and regained consciousness and transferred to med bay. Patient states vision and hearing went fuzzy, nausea, lightheadedness. Pt given juice, decreased ____, A&Ox4. Mild HypoTN and Brady at baseline. BP 103/58, HR 50, RR 16 -- > 114/66,52, 16 Pt able to stand and walk. Released from vaccination site. |
| 1222773 | 4/17/2021 | | 17 | F | 4/16/2021 | 4/16/2021 | Dizziness, Syncope; Cough abd pain, sweating. BP 101/53, HR 60; RR 24 -- > 119/59, 67,20 -- > 94/67, 57. Given OJ and water, pt felt fine after drinking water and OJ. Patient stable and released from vaccination site. |
| 1222111 | 4/17/2021 | FL | 28 | F | 4/13/2021 | 4/13/2021 | I felt perfectly fine after the shot at 8:30AM. Began to feel a bit tired & sluggish around 5PM. Was standing in the kitchen, moving my arm around as instructed, and became light headed & seeing stars. I took one step to sit down and the next thing I knew I woke up on the ground. I had fainted unexpectedly. I had to lay on the ground for about 10 minutes until I gained the strength to get myself off the ground. The day afterwards I was extremely weak & could not focus. Still a few days later I am not feeling 100%. |
| 1222355 | 4/17/2021 | PA | 64 | F | 4/12/2021 | 4/12/2021 | The patient received vaccine at the pharmacy and stayed for an observational period of 15 minutes. The patient left the pharmacy seeming fine but then reported on 4/17 that she had fainted at her residence and she was taken in an ambulance to a hospital. Patient said that the hospital ruled out a blood clot. |

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| 1222800 | 4/17/2021 | CT | 55 | F | 4/13/2021 | 4/14/2021 | Fainting. After the COVID vaccine she was feeling completely normal, however about 23 hours after she woke up lightheaded, nauseous, became dizzy and fainted. (hit her head, elbow, knee, face when she fell) She then was helped up, was confused. When she was being walked to her bed with help she again collapsed in the person's arms. It looked like here eyes were staring, unable to respond, mouth was open, possible facial drooping. |
| 1221545 | 4/17/2021 | WI | 20 | F | 4/15/2021 | 4/15/2021 | Around 11:00 in the morning I was starting to feel weak and hard of breathing with a sore arm where the injection site was. As the day went on it progressed to muscle aches and a low fever, I went to bed with chills, muscle pain, heavy breathing, and a 100.8 fever. I work up in the middle of the night to go to the bathroom and felt nauseous, I don?t remember much but I remember waking up on the floor in a cold sweat, so I assume I passed out from the nausea. I went back to bed and I woke up with a 101.8 fever and weakness and muscle pains. My mother told me to take Tylenol every 4 hours and be on top of things, my symptoms have been decreasing since this morning but as I am filling this out at 11:00 at night I?m slowly getting my fever back. I will add this is exactly how I felt when I got covid back in November of 2020. |
| 1221578 | 4/17/2021 | CA | 62 | F | 4/9/2021 | 4/12/2021 | Received the vaccine friday then monday has numbness to the tongue , near syncope, dizziness, ems called taken to ER and admitted to hospital for TIA. CT of neck, head, abd done, chest xray, full blood work, echo, results sent to primary care said all test ok |

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| 1221581 | 4/17/2021 | PA | 27 | F | 4/7/2021 | 4/7/2021 | After shot felt increasingly nauseous and dizzy and tired. I went to the bathroom and threw up. Upon return to the observation area, I lost consciousness, fainted, and woke up on the floor. My blood pressure was low but within normal range and my blood sugar was normal. I was not nervous about receiving the shot or possible symptoms and do not have a history of fainting not relating to medication side effects (meds I am no longer on) and over exertion (ie. likely not psychosomatic). Fainting on a hard surface led to a serious concussion with effects (brain fog, fatuige, headache, and dizziness primarily) continue to persist. I saw doctors at an urgent care and then the ER where they performed a pregnancy test (negative), blood sugar test (normal). EKG (normal), and a concussion screening that led to a CT scan (normal). I left with no explanation as to why I felt sick and fainted after the vaccine and was only told later by my psychiatrist to report. The only clear side effect was pain in the arm of the injection site. Other possible vaccine symptoms overlap with concussion symptoms. |
| 1221594 | 4/17/2021 | CA | 46 | F | 4/8/2021 | 4/13/2021 | I got Jonson and Jonson vaccine on 4/8/2021 . I was fine after that and suddenly on 4/13 /2021 I had cramping in my both leg and foot whole day. At night I woke up from deep sleep and started crying that my leg was hurting badly and felt like something was stuck in my knee couldn?t move for couple min. 5 min later I got up to take pain medicine and try to walk and I was able to walk after that so went to use bathroom (to urinate) while I got up. After that since I had pain in my leg earlier I went to grab pain medicine than again I started crying and saying I don?t feel good than I passed out completely and was unconscious. My husband picked me up and brought me to bed and said I had black out and fell on my face on floor . |

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| 1221600 | 4/17/2021 | FL | 38 | F | 4/10/2021 | 4/10/2021 | I received the vaccine in my left arm. I immediately felt a shooting pain and my left arm became heavy. My left hand experienced the same shooting pain followed by tingling in my fingers. My right arm then experienced the same pain and tingling. I then began to sweat, get dizzy and felt like fainting. I have had pain and tingling in my hands and feet ever since, along with sensitivity. I also have pain in my joints and legs similar to what I imagine arthritis would feel like. I also have throbbing chest pain and pain in my legs since vaccination. |
| 1222232 | 4/17/2021 | NH | 24 | M | 4/16/2021 | 4/16/2021 | Patient was light headed, dizzy and stomach hurt. Patient then fainted. We offered to call the ambulance but patient and girlfriend refused. After questioning the patient we found out the patient hadn't eaten or drink water in the past 12 hours. we gave the patient water and snacks and some ice to cool him down. we also found out the patient has a fear of needles. once the patent started to eat and drink more he started to look and feel better. |
| 1222105 | 4/17/2021 | AZ | 77 | F | 3/2/2021 | 3/3/2021 | Morning after injection, I sat down at the breakfast table and said to my husband" I can see you, but everything else out the windows (there is a bank of windows surrounding table) is completely grey....I can't see trees or house next door." The next I knew he was peeling me off the floor after I completely fainted and fell off my chair. No injury other than small bruises and head bump. He got me back to bed and doctor was not needed. |
| 1222486 | 4/17/2021 | CO | 37 | M | 4/12/2021 | 4/13/2021 | Fever: 2 days Severe chills and body aches, very painful skin to the touch: 3 days Fatigue: 4 days Severe knee and ankle pain that limited ability to walk: 8 hours Fainting: 1?event Brain fog: started on day 4 |
| 1222194 | 4/17/2021 | WI | 21 | M | 4/16/2021 | 4/16/2021 | Systemic: Fainting / Unresponsive-Severe, Additional Details: Patient fainted, body stiffened, eyes rolled back. Epi-pen was administered and patient regained consciousness. 911 was called after epi-pen was administered. Paramedics arrived and assesed patient. He decided to go home with parents and not be trasported to the hospital. |

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| 1222267 | 4/17/2021 | KS | 49 | F | 4/13/2021 | 4/13/2021 | <p>Patient received a Covid-19 vaccination manufacturer Pfizer. The patient experienced symptoms of nausea and patient felt throat swelling. These symptoms were Mild and were treated with diphenhydramine, supportive care and glass of water. The patient was discharged to Rapid Response Team to the Emergency room after close observation for 20 minutes in stable condition. In ED patient further treated - Review of Systems Constitutional: Negative. HENT: Negative. Negative for drooling, facial swelling, trouble swallowing and voice change. Eyes: Negative. Respiratory: Negative. Negative for cough, chest tightness, shortness of breath, wheezing and stridor. Cardiovascular: Negative. Negative for chest pain. Gastrointestinal: Positive for nausea. Negative for abdominal pain and vomiting. Genitourinary: Negative. Musculoskeletal: Negative. Negative for myalgias. Skin: Positive for itching. Negative for rash and wound. Neurological: Positive for dizziness. Negative for seizures, syncope, light-headedness and headaches. Psychiatric/Behavioral: Negative for confusion. All other systems reviewed and are negative. Medications given in ED: diphenhydrAMINE (BENADRYL) injection 25 mg (25 mg Intravenous Not Given 4/13/21 1508) ondansetron (ZOFRAN) 4 mg/2 mL injection (has no administration in time range) sodium chloride 0.9% (NS) IV Bolus (0 mL Intravenous Stopped 4/13/21 1540) methylPREDNISolone sod suc(PF) (Solu-MEDROL) injection 125 mg (125 mg Intravenous Given 4/13/21 1507) famotidine (PEPCID) injection 20 mg (20 mg Intravenous Given 4/13/21 1508) sodium chloride 0.9% (NS) IV Bolus (0 mL Intravenous Stopped 4/13/21 1700) Symptoms resolved discharged to home</p> |

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| 1222291 | 4/17/2021 | IL | 50 | F | 4/1/2021 | 4/2/2021 | sudden side effects around one hour after taking my thyroid medication. Nausea, dizziness and weakness - very winded. Pain at injection spot. Difficult to walk and just get back to bed or call someone. Blacked out in bed, waking up soon after to extreme shaking, cold, extreme pain at inject shot. Again difficult to get out of bed to find extra blankets/covering. I am not sure I feel back to sleep or just passed out but woke around 7am, extreme pain full arm, with fever 102.7, was able to get to kitchen get ice cubes. fever dropped to 101. took Tylenol once I could hold some food in stomach. Nausea, but felt like I needed to eat something. back to bed. bed rest most of the day, when I trying to get up to eat something or pick up mail, very dizzy, light headed. Temp lingered around 101 for the next day or so. Through weekend was very winded, but was able to contact via email doctor what was going on. Sunday temp was under 99. other pain at injection and fategue lasted for week. Metal taste in month started Sunday 3 days after shot. Doctor not sure if I should get 2nd shot. Help. what do I do? |
| 1222309 | 4/17/2021 | NV | 38 | F | 4/17/2021 | 4/17/2021 | Patient states she has a vasovagal reaction to needels/injections. After vaccine was administered patient was askied how she was feeling. She stated she felt the vaccination but felt fine. She proceeded to sit in the seat in the lobby , but then fainted a few minutes later |
| 1222377 | 4/17/2021 | GA | 32 | M | 4/16/2021 | 4/16/2021 | Pt fainted. Staff alerted by customers that someone was laying in floor. We immediately ran out. Pt was laying face door on floor. Pt was tapped, and verbally asked if he could hear us. Initially there was no response. Checked for breathing, then begin checking for pulse, but he came to. He started speaking with us, saying he was feeling light headed, and got up to notify us, but then he couldn't remember the rest. Asked if he had a history of seizures or diabetes and he said no to either. At some point he went out again, briefly. Meanwhile, the tech called 911. He came to again, begin talking with us. At some point he requested water, which we got. After seeping, he wanted to sit up. We asked him to place his back against the wall, if he wanted to. He did so, and after a few seconds said he wanted to lay down again. EMS came. They asked if he wanted to go to the ER which he consented to. They rolled him out on a stretcher. |

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| 1222401 | 4/17/2021 | MD | 24 | F | 4/16/2021 | 4/16/2021 | The patient received the Pfizer vaccine, given by HCP. After the vaccine, the patient felt a little anxious with increased heart rate so she asked HCP for a bottle of water. HCP went to get the water and informed the pharmacist on duty. Both pharmacist and HCP came back to the patient. She got the bottle and was about to open the bottle, but closed her eyes and started shaking like having a seizure and passed out. She came back right after passing out but didn't know what happened. She then started shaking again for a few seconds but didn't pass out. Everything happened so quickly when she remained sitting on the chair. We called 911 and paramedics came. She mentioned that the seizure happened to her before, maybe once or twice a year. When paramedics came, they checked her blood pressure and it was ok. We asked her and she wanted to come to the hospital to check out to make sure that she is ok. |
| 1222414 | 4/17/2021 | SC | 20 | M | 4/17/2021 | 4/17/2021 | patient was nervous after the injection-stepped out of the immunization room and sat in chair- felt light headed and passed out for about 5 seconds |
| 1222446 | 4/17/2021 | IN | 50 | F | 2/12/2021 | 2/12/2021 | Syncope, collapse, seizure, amnesia, brain fog, migraine, nausea, vomiting, double vision; all ongoing since time of second dose administration |
| 1222101 | 4/17/2021 | | 20 | M | 4/17/2021 | 4/17/2021 | The patient was hot, pale, near syncope, weak and nauseated. HR was 54, RA 94%, 94/80. Patient felt better when lying down. The patient didn't want a drink or a snack. |

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| 1223886 | 4/17/2021 | CO | 22 | M | 4/17/2021 | 4/17/2021 | Patient fainted shortly after receiving second dose of Moderna Covid vaccine. When I approached the patient he was laying on the ground and very pale but still breathing. I rolled him onto his back and elevated his feet and asked him to keep breathing and try to stay calm. I asked someone to grab him some water and someone else to run to the pharmacy and grab the pharmacy manager while I monitored the patient. I asked if I could help him sit up to drink some water and he accepted. After sitting up I asked if he had eaten and if I could get him something to eat. He stated he hadn't eaten all day and that he had a panic disorder and felt like he was having a panic attack. I asked if he had medicine he needed to take to help him feel better, he stated no, he needed to just wait it out. Then he told me he felt like he was going to throw up and I got him a waste basket that he threw up in right away. I asked the patient if he hit his head or if he wanted us to call an ambulance; he stated no to both questions. The pharmacy manager arrived and sat with the patient for the next half hour or more until he felt better. He stated that his dad was going to take him home now that he felt better. Some store staff had us fill out an incident report and the pharmacy manager walked the customer out to his car where he said he would call and find his dad. |
| 1223647 | 4/17/2021 | | 35 | F | 4/16/2021 | 4/16/2021 | pt had vasovagal response, one she woke up she told me she had a history if, She was in a chair when she passed out, we attempted to get her on the ground with feet up but in the process her head bumped the floor (it was not too bad it seemed), paramedics came as i called them when she was unresponsive, they did take her to the hospital i assume for low blood pressure but I am not sure what for (she was awake, i had to walk away for a few minutes and let the paramedics takeover), |

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| 1223670 | 4/17/2021 | OH | 16 | M | 4/17/2021 | 4/17/2021 | pt was getting his first covid vaccine with his mom. pt was vaccinated first then mom was vaccinated. After mom was vaccinated I had my bad to the patient and his mom throwing away supplies, Pt passed out and was not responsive to mom or to myself the pharmacist. I thought the patient needed an EpiPen and went to get the EpiPen out of the pharmacy and while my back was turned mom stated that the patient convulsed a few times. By the time I returned with the EpiPen pt was not convulsing and had passed out and started to recover and become responsive. Pt was pale but was aware of his name, birthday, date, and current president. A tech called EMS. Pt was talking when EMS arrived and color had started to return to normal. pt was able to walk out to the ambulance to be checked out. Mom stated she wanted to take pt to ER for more evaluation. |
| 1223689 | 4/17/2021 | PA | 62 | F | 1/27/2021 | 1/29/2021 | 2 days after the injection i started getting real dizzy, i had to call someone cause i nearly passed out. they took me back to the office and let me sit there till someone came to relieve me. then i went home. that was on Friday Jan 29, 2021. I stayed out of work for 3days, went back to work on Mon Feb 1, 2021, still being dizzy i continued working till my days off on Wed Feb 3 and Thurs Feb 4,2021. went back to work Friday Feb 5,2021. had to leave work again because of severe dizzines. Called immediately to see if i could get an appointment and got one Saturday Feb 6,2021. then tried again to return to work again on a MondayFeb 8, 2021, worked through with vertigo again till days off Wed Thurs Feb 10 & 11,2021. Tried to work again same thing on Fri Feb 12, 2021. Left work again and been out ever since. |
| 1223696 | 4/17/2021 | | 16 | M | 4/16/2021 | 4/16/2021 | Syncope, Flushing/sweating Pt felt light headed, assisted to ground by RN. Placed in wheelchair and moved to med bay. VSS on arrival. Pt eating and drinking w/ no issues. Feeling normal. Observed patient to stand. Stron/steady gait. BP 130/85, HR 93, RR 22 -- > 130/80, 81, 18. Patient stable and released from vaccination site. Grass allergy |

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| 1223726 | 4/17/2021 | CA | 55 | M | 4/17/2021 | 4/17/2021 | About five minutes after administering vaccine, patient's spouse reported that patient is not feeling good and about to faint. Pharmacist on duty immediately attended the patient. Patient was sitting on a chair, started fainting, didn't completely faint though. Patient responded to pharmacist and reported he felt like he was going to sleep and all sudden woke up. Called for emergency help, EMT team checked patient, all the vitals were ok, patient decided not to go to hospital. Patient waited in the store for additional 15 minutes and left the store around 12:45pm |
| 1223738 | 4/17/2021 | WA | 16 | F | 4/9/2021 | 4/9/2021 | Vasovagal syncope. She began to get very warm, then fainted and became very pale. She was better within 5 minutes. |
| 1223742 | 4/17/2021 | OR | 74 | F | 4/15/2021 | 4/16/2021 | Approx 12-18 hrs after 2nd dose of Moderna vaccine, had episodes of dizziness, syncope and sinus pause. Observed overnight in hospital with no recurrence and condition resolved by d/c. Pt is very healthy, cyclist capable of 30 mi qod rides with no issues. |
| 1223750 | 4/17/2021 | CA | 16 | M | 4/17/2021 | 4/17/2021 | Patient received Pfizer vaccine and was standing with parents during his suggested 15 minute wait time. During this time, parents noted that he "passed out" but they caught him. He then gained consciousness immediately and sat down to be monitored by pharmacists on duty. His vitals were checked immediately. O2 saturation was 97-99. Blood pressure 138/83mmHg with HR of 81. Patient had trouble breathing for 2 minutes. O2 saturation did not change. After 2 minutes, he breathing improved and patient was calm. |
| 1223558 | 4/17/2021 | | 28 | M | 4/17/2021 | 4/17/2021 | After client received 1st dose of Pfizer in left deltoid, client stood up to receive vaccine card and ID. Client then passed out, fell on the floor and hit head. C/O right side jaw hurts. MD & EMT evaluated. 130/75, 75, 97%, zero bumps felt on head/scalp. Girlfriend at side, instructed to go to ER to be evaluated today. |
| 1223869 | 4/17/2021 | IL | 32 | M | 4/1/2021 | 4/16/2021 | headache, chills, blurred vision, muffled hearing, faintedness |
| 1223871 | 4/17/2021 | MN | 16 | F | 4/17/2021 | 4/17/2021 | Patient passed out shortly after getting shot--recovered fully after 10 minutes |

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| 1223939 | 4/17/2021 | CA | 16 | M | 4/17/2021 | 4/17/2021 | Recipient experienced brief loss of consciousness (few seconds per report) / vasovagal syncope from a standing position. He fell and hit his right frontal bone of skull upon fainting. Patient awoke after a few moments per report and was AAOx4 within moments of this reporting clinician's arrival to scene. Vital signs stable. Patient's frontal bone with minor red abrasion / erythema and scant swelling. He did not complain of changes in vision/ nausea / emesis. Neurological and Musculoskeletal exam intact without issues. |
| 1223953 | 4/17/2021 | CA | 56 | F | 4/16/2021 | 4/16/2021 | Dizzy and briefly fainted about a hour later. Next day vomiting, aches, fever (100.4), chills, dizzy, muscle and joint pain, patchy red skin all over body, feeling exhausted and dehydrated. |
| 1223957 | 4/17/2021 | MS | 60 | F | 4/17/2021 | 4/17/2021 | Moderna COVID-19 Vaccine: The PQCF was reviewed with the patient who stated that she was feeling ok today: no cough, diarrhea, vomiting and didn't require a tetanus shot for an injury. The patient did state that she was allergic to Penicillin and that she had just completed a course of antibiotics Cipro 500mg for an UTI. After she was administered the Moderna vaccine 1st dose, the patient was advised to sit for a couple of minutes near the pharmacy area where she had just taken her shot while her husband was administered his vaccine and then they would be walked up together to the Post-Vaccination Sitting Area. The patient sat near the pharmacy for roughly 5-10 minutes and then walked over to one of the pharmacy Counseling windows to let us know that she was feeling funny and weird. No sooner than she uttered those words, she collapsed and fainted. 911 was called. Once conscious the patient stated that she truly wasn't feeling the best before getting the vaccine but wanted to go ahead and get her vaccine today. EMTs checked vitals. Her blood pressure and blood sugar were normal; however, her heart rate was low and skin turgor was poor. Her preliminary diagnosis before being transported to a nearby hospital was dehydration. I truly do not think that the vaccine caused her syncope spell but reporting since event occurred shortly after Moderna was administered. |

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| 1223987 | 4/17/2021 | TX | 17 | F | 4/15/2021 | 4/15/2021 | Nausea, dizziness and fainted for some few minutes. Paramedics were called, patient did not need any treatment and was able to go home.. Mom was counseled on signs and symptoms to watch out and if needed to seek medical care |
| 1224008 | 4/17/2021 | IL | 69 | F | 4/1/2021 | 4/8/2021 | Passed out |
| 1224026 | 4/17/2021 | | | U | | | Since Jan 2020 I have been experiencing positional/vasovagal fainting spells once every 4-6 weeks. They tapered off and were manageable. Since 3/6/2021, I have had 7 episodes, 5 of those since 4/2/2021, two weeks after my second vaccine. My family suggested I look thru my journal to see what could have triggered this explosion in events. My physician contact was thru messaging. I don?t go out much and had only two social interactions during that time period. I had my second Pfizer vaccine at same location on 3/18/2021 at 4 pm; lot number EP7534 |
| 1222303 | 4/17/2021 | AK | 24 | F | 3/20/2021 | 3/20/2021 | Patient came in for 2nd dose of Moderna COVID-19 vaccine on 04/17/2021. They reported fainting spells after receiving the 1st dose on 03/20/2021. Patient stated they fainted 3 times later in the evening after receiving their 1st dose. Patient said that she never hit her head. Patient was denied their 2nd dose at the pharmacy on 04/17/2021. Patient did not seek medical treatment and was fine thereafter. |
| 1222813 | 4/17/2021 | OH | 56 | M | 4/17/2021 | 4/17/2021 | Patient had a vasovagal reaction. 30 seconds after his vaccine he fainted. He was sitting and told his wife he was going to faint. According to him and his wife he has a history of that with injuries or pain. He did not have it on his first vaccine but it has happened to him several times in his life. He regained consciousness quickly and we had him sitting and gave him water. He was fine within 3 minutes. Rested for his 15 minutes and he and his wife left. |

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| 1223862 | 4/17/2021 | CA | 53 | F | 4/17/2021 | 4/17/2021 | PATIENT STARTED OUT BEING NERVOUS ABOUT THE VACCINE. I CALMED HER DOWN AND ADMINISTERED VACCINE. I INFORMED PATIENT TO WAIT FOR 15 MIN. I CHECKED ON HER IN A FEW MINUTES AND SHE SAID SHE HAD NAUSEA. I GAVE HER A PLASTIC BAG TO BARF IN IF NEEDED AND I RAN TO THE FRONT OF STORE TO GET A BOTTLE OF WATER. MANAGER SENT ME TO BREAK ROOM TO GRAB A BOTTLE OF WATER. AS I WAS RUNNING BACK, I OBSERVED PATIENT PASSED OUT ON THE FLOOR WITH BLOOD AROUND, NOT RESPONDING. I CHECKED PULSE (LOW) AND ASSUMED SHE HAD AN ANAPHYLAXIS REACTION TO THE VACCINE, SO I ADMINISTERED EPIPEN 0.3 MG AND PATIENT WOK UP. SHE HAD BLOOD NEAR HER MOUTH AND BLOOD ON THE FLOOR. WE CALLED 911 AND THEY ARRIVED WITHIN MINUTES AND TOOK HER IN THE AMBULANCE. I HAVE NO FURTHER INFORMATION ON THE PATIENT. |
| 1223001 | 4/17/2021 | | 85 | F | 2/13/2021 | 3/3/2021 | admitted 3/3/2021 with syncope |
| 1222867 | 4/17/2021 | CA | | F | 4/17/2021 | 4/17/2021 | Fainting, vomiting |
| 1223898 | 4/17/2021 | CA | 18 | F | 4/16/2021 | 4/16/2021 | Patient fainted upon receiving the vaccine. Her body also shuddered. I used two ammonia inhalers and she responded. Patient mentioned both her hands were numb, then tingling. Her mother massaged her hands. She stayed for observation for 40 minutes. She left with both her mom and dad. She said she felt ok. I called her the same evening to check in. She had a nap and said she felt fine. |
| 1222859 | 4/17/2021 | KS | | U | | | Pt reported dizziness, and fainted, woke up quickly and vomited. Ambulance was called for. Blood pressure was extremely low and pulse rate was high as reported by ems. pt became more alert and did decline ambulance ride to the hospital. spoke later to spouse and they did go to emergency room. |

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| 1223555 | 4/17/2021 | IL | 19 | M | 4/17/2021 | 4/17/2021 | PT FELT DIZZY ABOUT 10-15 MINUTES AFTER RECEIVING VACCINE. UPON STANDING HE FELL TO THE FLOOR AND BRIEFLY PASSED OUT. PT STATES HE DOES NOT REMEMEBER FALLING. HE DID NOT EAT PRIOR TO VACCINATION. GAVE PT ORANGE JUICE. PATIENTS MOM CAME IN AND STATED HE HAS HAD THE SAME ISSUE IN THE PAST. PARAMEDICS CAME TO MAKE SURE PT DID NOT HIT HIS HEAD AND HAVE A CONCUSSION. HE WAS FOUND TO BE OK AND WENT HOME WITH HIS MOM. |
| 1222936 | 4/17/2021 | NY | 20 | F | 4/17/2021 | 4/17/2021 | Patient got first COVID vaccine at 9:49 AM. Pt. started having syncope reaction two to three minutes after getting the injection. Pt was found in a chair on the floor, at 9:52. Pt, was found COAx3 and had a patent and self-maintained airway. Pt. was transferred to the back via a wheelchair where she laid down. Vitals were obtained with a HR of 83 BP of 115/74, RR of 14. Pt stated that she felt fine after laying down. Pt, waited in the back for fifteen minutes where her vitals remained stable. After fifteen minutes Pt, walked without any obvious difficulties to observation one where she waited for another 15 minutes. Pt went home after fifteen minutes in observation one and walked out without any further incident and without any obvious difficulties. |
| 1222950 | 4/17/2021 | CO | 27 | F | 4/16/2021 | 4/16/2021 | Passed out 3 minutes after shot, after 30 mins or more laying down I was okay. About 3 hours after the shot I got a severe headache and a runny nose. Then 24 hours after I felt 100% normal again. |
| 1222999 | 4/17/2021 | CO | 47 | F | 4/9/2021 | 4/10/2021 | I basically passed out, felt drugged around 10pm with no other side effects except arm was a bit sore. Then In middle of night my body felt like I had been hit by a truck. Whole body aches rest of the night, all day Saturday and into Sunday. Arm sore. Just felt very sick and whole body hurt. |
| 1223063 | 4/17/2021 | FL | 34 | M | 4/17/2021 | 4/17/2021 | PT FAINTED AFTER THE VACCINATION, WAS UNRESPONSIVE FOR LESS THAN A MINUTE |
| 1223148 | 4/17/2021 | VA | 38 | F | 4/2/2021 | 4/2/2021 | Headache, muscle joint pain, vertigo, dizziness, near syncope, blurred vision, |

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| 1223449 | 4/17/2021 | CO | 61 | F | 4/15/2021 | 4/17/2021 | Fainted around 3:00 am on 4/17/2021. Fortunately, I was able to catch my fall by holding on to things, so no major injury. |
| 1223530 | 4/17/2021 | KY | 26 | F | 4/1/2021 | 4/1/2021 | Vasovagal syncope, I was taken out of the waiting room and laid down in a back room, they checked my blood pressure and let me go once my blood pressure increased again (I think this took 20-30 minutes; I'm not entirely sure) |
| 1223504 | 4/17/2021 | IL | 37 | M | 4/17/2021 | 4/17/2021 | Possible vasovagal near syncope post vaccination. Transferred to ED for evaluation. |
| 1222980 | 4/17/2021 | CT | 55 | M | 4/17/2021 | 4/17/2021 | Fainted in 3 mts after the vaccine administration. Tech helped the patient to sit. Then he was fine talking. He did mention that he did not eat anything before coming for the vaccine. Called 911. All vital signs were tested and were good. |
| 1223498 | 4/17/2021 | IN | 63 | F | 4/15/2021 | 4/15/2021 | Pain at injection site, generalized fatigue, ache ~10 hours post-injection- Chills, leg muscle cramps ~16 hours post-injection Nausea, headache (passed out for several seconds) ~19 hours post-injection Completely fine ~42 hours post-injection |
| 1223270 | 4/17/2021 | AK | 32 | M | 4/15/2021 | 4/15/2021 | Client received vaccine, where Health Center was holding a vaccine clinic for staff needing the vaccine. Client came in for his first dose of the Pfizer vaccine. He was nervous prior to receiving the vaccine. Stated that he didn't like getting vaccines. He stated that he had seasonal allergies and was on zyrtec or claritin. He did not have any other allergies or history of a serious allergic reaction to food, medications or vaccine components/vaccines. I vaccinated patient, and he went into the observation room with two APRN's for his 15 minute observation. He stayed in the room for 20 minutes per APRN. When he got up to leave, he walked 20 feet and fainted per APRN note. She stated, "he was cold, clammy pale, bradycardic and was difficult to rouse but spoke less than 2 words or none at a time. Blood pressure at 6:10 pm was 90/50, pulse 40, shallow respirations at 10/min. At 6:15 pm blood pressure was 120/60, pulse 70, and respirations at 10/min. At this time EMS arrived and put patient onto the gurney and transported him to Hospital. |

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| 1223427 | 4/17/2021 | IL | 44 | F | 4/10/2021 | 4/10/2021 | Feels hot, dizzy, passed out . transported by medics to observation area. BP low, Pulse stable. In observation for 30 minutes recuperate and went home on her own. |
| 1223406 | 4/17/2021 | NY | 19 | F | 4/16/2021 | 4/17/2021 | 11 hr after vaccine I fainted |
| 1223392 | 4/17/2021 | MA | 65 | F | 4/8/2021 | 4/8/2021 | By the first evening (Thursday), I had developed a low fever. Overnight, it rose to over 102, with shakes and body aches. When I got up during the night to use the bathroom, I passed out twice (I have only fainted twice before in my life). The following day (Friday), I took Tylenol about 7:30 am, and my fever remained over 101 (101.4, 101.2, 101.1) all day. That evening it dropped to 100.4, and remained there overnight. Over the course of the next day (Saturday), it remained over 100 (100.4, 100.2, 100.1) until about 5:00 pm, when it dropped to 99, and then went away overnight. On Sunday, I was exhausted, but felt okay by evening. I am still thrilled I got the vaccine. |
| 1223345 | 4/17/2021 | NJ | 41 | M | 4/14/2021 | 4/15/2021 | Syncope, fainting leading to fall and head injury. |
| 1223323 | 4/17/2021 | NJ | 49 | F | 4/10/2021 | 4/15/2021 | ON 4/15 had an anaphylactic reaction and went to the ER at medical center (throat closing and body swelling) saw MD, no admittance sent home, provided bendadryl, steroids and Pepcid . No blood work or scans. On 4/16 had collapsed/fainted at home. Went to ER at different medical center. Saw MD Just gave fluids, CT scan and chest X-ray and blood work. sent home. |
| 1219067 | 4/16/2021 | FL | 64 | M | 3/20/2021 | | 03/24/21, patient hotel , patient fainted , tried to revive by family , ems was called , patient underwent surgery , patient did not survive surgery , death certificate was for acute infarction and dyslipidemia , patient passed |
| 1218772 | 4/16/2021 | CA | 37 | F | 4/16/2021 | 4/16/2021 | Patient received first dose of Moderna Covid Vaccine. Asked to wait 15 minutes before leaving store, patient left right away and fainted in store by front register. Patient was conscious, breathing normally, with a pulse. No EpiPen was administered since there was no allergic reaction. |
| 1219207 | 4/16/2021 | | 26 | M | 4/13/2021 | 4/13/2021 | Assessed by provider. Given OJ and crackers due to patient report that he has not eaten since lunch. Syncope/dizziness; BP 131/95; HR 82; RR 18; SpO2 99% |

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| 1219161 | 4/16/2021 | NJ | 32 | M | 4/14/2021 | 4/15/2021 | Approximately 24 hours post dose experienced dizziness, low-blood pressure, chest tightness, almost fainting lasting ~30 minutes. Taken to ER via ambulance. Diagnosis of Near Syncope, Vasovagal. |
| 1219208 | 4/16/2021 | MA | 18 | F | 4/6/2021 | 4/6/2021 | 10 pm 3/6 fever chills body aches nausea headache 7 am 3/7 nausea headache and syncope x 2 mins low blood pressure 90/60 x 48 hours thereafter |
| 1219124 | 4/16/2021 | NJ | 25 | F | 4/14/2021 | 4/14/2021 | Patient received vaccine and was at second dose information table talking with agent at table. when she suddenly passed out and fell backward to the floor. EMS in house and immediately responded to the patient.. Patient was responsive , alert and oriented x 3. exam by EMS did not reveal any acute injury. EMS advised patient should go to hospital for evaluation since she appeared to hit her head on the floor. Patient declined EMS transport, requested a family member transport her to the hospital. Patient signed Refusal of transport form for EMS. Patient was monitored by EMS until family member arrives to transport to hospital. Spoke with patient today April 16th. Patient stated she was fine , all test at present are negative. Advised patien to contact Health Department if any changes. |
| 1219115 | 4/16/2021 | TX | 47 | F | 4/12/2021 | 4/12/2021 | near syncope |
| 1219105 | 4/16/2021 | OR | 24 | F | 4/13/2021 | 4/13/2021 | She was sitting in the 15 minute observation area when she reported pain in the arm of the vaccine and felt diaphoretic and fainted falling off chair & onto floor. She lost consciousness and both arms and legs trembling appeared like seizure like in nature; Medix ambulance called and assessment BP 94/58 P 74 O2 sat 98% blood sugar 89 L shoulder with approx 4cm red area bruising noted from fall onto floor ; when sitting up pt c/o dizziness and lite headed layed back down and was Alert and Oriented X 3; Medix to transfer to local hospital when transferring pt to gurney she has having tremors in her arms and legs eyes closed and able to answer questions appropriately |
| 1219086 | 4/16/2021 | TX | 29 | M | 4/12/2021 | 4/12/2021 | near syncope |

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| 1219076 | 4/16/2021 | IL | 35 | F | 4/8/2021 | 4/8/2021 | Within 15 minute observation period, patient reported not feeling well, feeling dizzy and hot. Patient stated she had been anxious prior to injection, after injection felt a pain in her neck and then did not feel well. Patient was brought by another staff member as patient appeared pale ,hands were clammy, and patient seem to have near syncope where she fell and patient was held by two staff members. This RN went to get vitals machine. Patient seemed to be hyperventilating, vital signs were checked while a provider was called for help. Oxygen was 100%, BP 94/63, HR 45. The doctor came in auscultated heart, patient was drinking water while speaking to provider, HR seemed to be improving to 70s and BP went to 101/67. Patient reported feeling better. The Doctor requested that fingerstick glucose and hemoglobin be checked which were also normal. Patient reported feeling much better after about 5-7 minutes. Patient was stable and sent home with call back parameters. Patient had follow up appointment with provider next day with improvement. |
| 1219162 | 4/16/2021 | ME | 24 | F | 4/16/2021 | 4/16/2021 | After vaccination and a brief conversation, patient was going to sit in our waiting area and upon arriving at her chair, she passed out. She was nervous leading up to the vaccination, but seemed ok right after. She regained consciousness quickly and was a bit disoriented. She proceeded to drink some water and sit for a while. After 15-20 minutes she looked much better and alert. She was unable to get someone to pick her up, but waited for 30-40 min after the event before she felt confident to drive. She stated that she had eaten breakfast and it was the first time she had every passed out before. She said a cold feeling came over her and she just went dark. |

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| 1219056 | 4/16/2021 | KY | 28 | M | 4/14/2021 | 4/14/2021 | Approximately 10 minutes after receiving the COVID vaccine (second dose) pt. Experienced a fainting episode, with the possibility of loosing his pulse for approximately 30 seconds according to RN. Pt. Was in his vehicle in the monitoring area. When RN arrived after approximately 1 minute, the patient had a strong carotid pulse of around 80. Airway was maintained until patient woke up. Pt stated that he had not eaten before coming. BP's follow: 1230:99/64, P-48-Sat 94% 1243:109/74,P-67,Sat-97% 1248: 102/63,P-73,Sat-95% 1253-106/72,P-68, Sat-93& 1258-105/64,P-66, Sat-94% 1305-106/73,P-63,Sat 95%. 1311-112/74,P-59,Sat 94% 1316-99/68,P-59, Sat 92% 1322-112/73,P59, Sat 94% Pt remained weak and nauseous for approximately 45 minutes. It was decided at that time he would need to go to the ER and EMS was called. At approximately 1330 Pt. Was assisted to the stretcher and transported to ER for further evaluation. ED physician determined that patient had a vasovagal reaction to the vaccine and was discharged home. |
| 1219031 | 4/16/2021 | NM | 64 | F | 3/29/2021 | 4/9/2021 | Diarrhea nausea belly pain- I fainted briefly- am fine now. Husband was with me. No medical attention needed. 3 am Could have been good poisoning as well but could have been related to vaccination |
| 1219007 | 4/16/2021 | | 43 | M | 4/14/2021 | 4/15/2021 | Fainting. It was sudden onset, I felt fine for 24h after the injection (and had no side effects to the first dose), then felt very suddenly dizzy and lightheaded, then passed out for a few seconds. After I came to, I was able to quickly catch my breath and recover with no additional episodes. Beyond this, I had a mild fever but no other serious adverse effects. |
| 1219005 | 4/16/2021 | FL | 24 | F | 4/15/2021 | 4/15/2021 | Stated that she "Passed Out." It was reported by observer individual exhibited rolling eyes activity. |
| 1218897 | 4/16/2021 | | 51 | F | 4/13/2021 | 4/13/2021 | Clammy, tingling in bilat hands, anxiety. Pt stated she fainted before - feels cold, clammy beforehand. She felt this way w/ bilat tingling & called for nurse. A&O x4. Vitals stable. Gave water - hasn't drank since 10 AM. After drinking water, pt stated she is feeling better. Offered w/c for exit, declined. Vitals still stable. Pt left Yahoo in stable condition. BP 123/63; HR 72; RR 18, SpO2 97% |

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| 1218879 | 4/16/2021 | MI | 21 | M | 4/16/2021 | 4/16/2021 | Syncope/Anxiety |
| 1218875 | 4/16/2021 | TN | 37 | F | 4/8/2021 | 4/8/2021 | Patient woke up intensely nauseous around 11:30 PM, walked to the bathroom, felt sudden full-body stiffness and then passed out. Patient woke up on the floor about 5 minutes later, where she remained for 10 more minutes until the muscle stiffness subsided enough for her to return to bed. Nausea subsided enough after an hour for her to return to sleep. |
| 1218796 | 4/16/2021 | FL | 27 | F | 4/16/2021 | 4/16/2021 | Pt. got the first shot of Covid 19 Moderna Vaccine. Pt was seated in the post vaccination area. After 5 min pt. fainted. Pt suffers of vasovagal syncope. Pt. had pulse and was breathing all the time. Pt. came back in less than 1 min. Pt was laid on the floor with her legs up. Pt. asked for alcohol swabs, I provided it. Pt. was feeling dizzy and throwed up after 15 min of being laid on the floor. Pt. asked for water, I provided. Pt. 's mom was next to her all time. Pt. stayed in the area of the event for one hour until she was ready to leave. Pt.'s mom drove her back home. |
| 1218777 | 4/16/2021 | LA | 53 | F | 4/8/2021 | 4/8/2021 | received her 2nd dose of Pfizer on 4/8@8:32am, was given discharge information, education and directed to our monitoring area. About 8:40am the clinic RN, went to assess the patient as she began to feel nauseated, began dry heaving without vomiting, had generalized redness, then complained of feeling light headed. She passed out so the RN eased her to the floor. A Rapid Response(RR) was called and the patient was moved to the stretcher. VS were taken and at about 8:50am the RR team arrived and assumed care. Once they arrived the patient began to seize. She was taken to the ER where she had another seizure. She remained in a post-ictal state for most of her stay at our facility. |

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| 1218765 | 4/16/2021 | OH | 18 | M | 4/16/2021 | 4/16/2021 | Patient recieved vaccine without any issues on 4/16/21. Patient walked to waiting area with pharmacist, was not having any issues or concerns, and was observed for several minutes by the RPH. Approximately 5 minutes after receiving the COVID-19 shot, the patient passed out, fell out of his chair, and hit his head. The patient immediately regained concousness and sat back in his chair. The RPH immediately had a pharmacy associate call 911 and observed the patient. Patient stated he felt a liquid tingle go down his arm from where he received his vaccine then passed out. Patient stated he had a headache and appeared clammy. RPH provided an instant ice pack and observed patient until EMS arrived. EMS provided care to patient and determined he did not need to go to the hospital. Patient was advised to go to hospital if he becomes nauseus. Patient claimed he was okay and just has a headache. Patient's mother took him home. |
| 1219214 | 4/16/2021 | MI | 31 | F | 4/10/2021 | 4/10/2021 | ABOUT 5 MINUTES AFTER THE INJECTION THE PATIENT BECAME DIZZY AND LIGHTHEADED , ALMOST FAINTED. SHE WAS HELPED TO A IMMUNICATION AREA WHERE SHE STATED THAT HER HEARING AND VISION WERE FADING. AFTER 5-10 MINUTES SHE STARTED TO FEEL BETTER , AND THEN THE SYMPTOMS RETURNED AGAIN FOR ANOTHER 15 MINUTES. THE PATIENT'S TEMP, BLOOD PRESSURE, AND PULSE WERE CHECKED FLUIDS WERE GIVEN AFTER ANOTHER 15-20 MINUTES THE BEGAN TO FEEL BETTER AND CALLED HER HUSBAND TO PICK HER UP |
| 1219537 | 4/16/2021 | RI | 41 | F | 4/16/2021 | 4/16/2021 | Vasovagal syncope with seizure-like tonic-clonic motion observed during syncopal event |

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| 1218785 | 4/16/2021 | IL | 61 | M | 4/15/2021 | 4/15/2021 | Patient told the vaccinating pharmacist he had a history of fainting after receiving vaccinations. Patient was feeling okay after vaccination and went into waiting area. Pharmacist was called over because patient fainted. By the time we got to the patient he was awake, alert and sitting upright. He knew who he was, where he was, and that he just received a covid vaccine. The patient said he felt light headed. We offered water and an ice pack as the patient was sweating but he did not say he was hot. The patient was able to get up after a few minutes of sitting and sat in a chair. After another few minutes, the patients head went backwards and he was making a snoring sound. I tried to talk to the patient but he didn't respond. We called 911. We placed the patient on the floor and turned him on his side. After about 1 minute he was with it again. He knew where he was and thought he fainted again. Upon speaking with the patient we received details about his history of seizures due to alcohol withdrawal. He also confirmed the last time he drank was that morning and he had "a few shots and was cutting back." Patient told us he was not on any medications but did take 50 mg of benadryl around 12:00pm that day. The paramedics arrived and took him to the hospital. |
| 1219339 | 4/16/2021 | WV | 70 | F | 3/25/2021 | 3/26/2021 | Patient passed out the day after vaccine from standing height |

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| 1219640 | 4/16/2021 | MN | 23 | M | 4/12/2021 | 4/12/2021 | Client fainted in the post-vaccine monitoring area at 12:57. The left forehead made contact with the floor. LOC for 5-10 seconds. PHN responded right away and advised client to remain laying on the floor while EMS was called. Vitals were WNL and client was coherent upon waking. Oriented x3. Fire EMS and hospital EMTs both responded and determined that client was OK. Offered client transport to ER for further evaluation but client declined. Discussed s/sx of concussion and when to seek treatment over the coming days. Continued to monitor client in first aid room -provided ice and water. Advised to call emergency contact for a ride home - client declined. Discussed importance of monitoring for concussion. Also discussed s/sx of allergic reaction. Client reports that he faints frequently, especially when receiving injections and other medical treatments. Advised client to request to receive 2nd dose laying down . Client remained on site for an hour and remained coherent and oriented. He called his mom and reports his mom and girlfriend would meet him at home but that he had no concerns and felt "normal". |
| 1219630 | 4/16/2021 | OR | 50 | F | 4/14/2021 | 4/14/2021 | 12 hours after I received the vaccination I got fever and chill, and extreme joint pain. 24 hours after the vaccination I began vomiting, had a splitting headache, and then my vision blurring, I called my husband to be near me and completely passed out for about 15 seconds. I woke up with no recall of what happened. I thought I had had a heart attack or stroke. My left side ached where I had the injection. I have NEVER fainted before. We were unsure if I had fainted or had a seizure. Apparently my head was shaking and my hand was also when I unconscious. I stayed in bed with a 101 fever the rest of the day. Today, 2 days from vaccination, I am feeling better. It was terrifying and we were considering going to the ER. I am pro vaccine but was inadequately prepared for what could have been a dangerous reaction. I was sitting when I passed out. I was home. I had someone with me....otherwise it could have been really terrible. |

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| 1219622 | 4/16/2021 | NC | 26 | M | 4/12/2021 | 4/13/2021 | Dose 1, no reaction. Dose 2, woke up at 2am to use bathroom and Passed out. Took a whole minute to come to. Called ambulance. Taken to hospital and kept for 12 hours. Head, both legs and back hurt so bad. Fever stayed at 100.3-100.6. Sent home slept for a couple hours and fever finally broke 36 hours later. |
| 1219580 | 4/16/2021 | KY | 64 | F | 4/7/2021 | 4/12/2021 | 5 DAYS AFTER RECEIVING 2ND VACCINE, DEVELOPED SYMPTOMS INCLUDING VOMITING, CRAMPING AND FAINTING |
| 1217856 | 4/16/2021 | OH | 85 | M | 4/15/2021 | 4/15/2021 | Systemic: Fainting / Unresponsive-Severe, Additional Details: according to daughter patient crashed about 1 hour after receiving vaccine, taken to hospital in diabetic coma with glucoesse level of 20..hospital trying to rule out TIA |
| 1219481 | 4/16/2021 | CA | 23 | F | 4/13/2021 | 4/13/2021 | dizzines, near syncope |
| 1218709 | 4/16/2021 | OH | 49 | F | 4/14/2021 | 4/15/2021 | The expected fever, aches, and joint pain started around 11pm on 4/14 and led to a very restless overnight. I got up around 5am on 4/15 feeling very thirsty and went to the bathroom to get a drink of water. I remember feeling extremely dizzy, nauseous, and lightheaded standing at the bathroom sink with a cup to fill with water. The next thing I remember is sitting on the bathroom floor with the bathroom cup next to me but I didn't know right away where I was (I hadn't turned on the bathroom light so it was dark) and I still don't know how I got there. I must've passed out. It was so difficult getting back to the bed that I had to ask my husband to help me. The fever, aches, and chills continued all day on 4/15 but the lightheadedness improved. |
| 1219448 | 4/16/2021 | TX | 52 | F | 4/13/2021 | 4/13/2021 | light headed, dizziness, near syncope |
| 1219430 | 4/16/2021 | SD | 19 | F | 3/18/2021 | 3/19/2021 | Pt was seen in the Emergency Room for syncope and a fall. Pt had to receive 2 liters of IV fluids, an EKG and multiple labs over the course of 4 hours. |

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| 1219412 | 4/16/2021 | AZ | 71 | M | 3/22/2021 | 3/30/2021 | taken to hospital, stayed 7 days, diagnosed with heart removed significant water, released and feeling well at home. i nearly passed out at doctor's office when it was decided to have an ambulance take me to nearby Medical Center where i was admitted and treated for 7 days. the diagnosis was a heart condition with water in my lungs. i never lost consciousness. was treated at night with a CPAC device and was told by the heart,lung and kidney doctor that i made significant progress each day. However, no one could explain after 70 years of no serious (flu) sickness that something suddenly caused my system to fail. At first i thought it might be a function of the COVID shot #2, and it may be. |
| 1219477 | 4/16/2021 | | 26 | M | 4/13/2021 | 4/13/2021 | Syncope, Flushing/sweating, Dizziness; provided hydration + rest |
| 1219355 | 4/16/2021 | WI | 63 | F | 4/9/2021 | 4/9/2021 | Felt dizzy 15 minutes after the shot and dizzy throughout the day on Friday, April 9, 2021 On Saturday, April 10, 2021 felt extremely dizzy in morning and passed out in a back room. Fell backwards on the floor and couldn't get up. Was yelling and screaming from the pain. Husband called 911 for an ambulance. I was taken to the Hospital and was admitted to hospital. Was very dizzy. Was not allowed to even get up for 2 days in the hospital because I was considered a serious fall risk. Stayed in hospital until Wed., April 14, 2021 when I was released to go home. |
| 1219229 | 4/16/2021 | NE | 83 | F | 2/10/2021 | 3/2/2021 | Pt. c/o symptoms of fatigue and dizziness on 3/2. On 3/3 pt. presents to ER, afebrile, c/o fatigue, feeling of being lightheaded, reports syncope and falling x's 2. Pt. according to MD documentation was in good health. Denies any recent illness. Pt. was found to be bradycardic, sick sinus syndrome, r/o MI. Pt. was transferred to higher level of care hospital on 3/3. Pt. had emergency pacemaker insertion. She became hypotensive and hypoxic post-op and was found to in lactic acidosis. Pt. expired on 3/3/21. |

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| 1219337 | 4/16/2021 | VA | 31 | F | 4/16/2021 | 4/16/2021 | Client c/o "feel like I can't breathe". V/S stable, no c/o nausea, no fainting. Client laid down on cot. VS monitored q5m for 15 min 0844: 164/89, 88/min, 100%RA 0850: 143/91, 84/min, 100% RA 0853: 137/97, 85/min, 99%RA Client sat up, stated feeling better. Given water, client exited clinic stable and without incident. |
| 1219305 | 4/16/2021 | | 32 | F | 4/16/2021 | 4/16/2021 | presyncope. Evaluated by EMS-Cleared |
| 1219301 | 4/16/2021 | | 21 | F | 4/13/2021 | 4/13/2021 | Syncope - hydration + rest; BP 123/57; HR 70; RR 18 |
| 1219298 | 4/16/2021 | CA | 26 | M | 4/16/2021 | 4/16/2021 | Client in Observation area post vaccine, client reported feeling dizzy and lightheaded fainted and landed face down on cement. Client responsive within seconds. EMT and MD on site, assessed client. Vitals taken BP 132/73, HR 80, O2Sat 99% Blood Sugar 87. Client reports did not eat or drink anything this am. Client assisted to chair, was provided gatorade and pretzels. EMT assisting with providing care to scrape to forehead. |

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| 1219296 | 4/16/2021 | NY | 22 | F | 4/16/2021 | 4/16/2021 | Patient appeared anxious prior to vaccine administration. When asked if she felt like she was going to pass out, patient advised she did not pass out from needles/shots before, but has fainted because of extreme anxiety; but did not feel like she would pass out at this time. After shot was administered, pt. was more relaxed, and advised she was feeling ok. Patient was ambulatory, with no complaints of light-headedness or adverse feelings, and walked to the observation area. Approximately five minutes following vaccination, patient told companion that she did not feel good, and laid down on the floor. She then experienced a syncopal episode. Patient did not hit head, or have any injury as a result of the syncopal episode. Patient was breathing normally, but was unresponsive for approximately 15-20 seconds. Following episode, patient regained consciousness (COAx3), and was upset from incident, but confirmed no injury or other illness, following episode. Patient was evaluated by EMTs on site, and was able to sit up and transfer from the ground, to a chair, and the chair to a wheel chair without issue. Further evaluation was conducted by EMT on site. Blood pressure was 110/80, SPO2 was 98% room air, and pulse was 66 at approximately 13:22 hours. Patient laid on gurney/cot on-site for approximately 20 minutes, to rest, and to be monitored for additional side-effects. During monitoring, patient advised the only thing she had eaten today was "one peanut butter cup." Patient was provided water and a juice box during monitoring time. Patient was released from monitoring area at 13:45 hours, after she advised she was feeling ok. She was wheeled into the parking area as a precaution, and left with her companion. Patient was the passenger of the vehicle. |
| 1219293 | 4/16/2021 | CO | 73 | M | 1/14/2021 | 2/22/2021 | On 2/22/21 I was walking on our treadmill. Became dizzy, passed out. Taken to Hospital . Had a HEART ATTACK. |
| 1219290 | 4/16/2021 | MI | 45 | M | 4/16/2021 | 4/16/2021 | HE PASSED OUT ABOUT 7 MINUTES AFTER RECEIVING THE VACCINE. ON SITE EMS RESPONDED. VITALS LISTED BELOW. HE SAYS HE HAS A HISTORY OF PASSING OUT. HE RECOVERED AND DID NOT WANT TO GO TO ER, SO HE WAS RELEASED TO HOME. |

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| 1219280 | 4/16/2021 | | 36 | F | 4/16/2021 | 4/16/2021 | Pre-Syncope. Evaluated by EMS-Cleared |
| 1219278 | 4/16/2021 | NC | 56 | M | 4/13/2021 | 4/15/2021 | Patient is 56-year-old male who presents to the ED for complaint of febrile reaction and swollen axillary lymph nodes after covid-19 vaccine. Patient reports febrile episode overnight. Patient reports fever up to 104, chills, and diaphoresis. Patient reports nausea without vomiting. Patient reports axillary lymphadenopathy, however no chest pain, shortness of breath, sore throat, syncope, palpitations, or diarrhea. Patient has history of CLL, which is currently just being monitored without treatment. Patient otherwise feels well, is a nonsmoker, has no significant confounding illnesses. Patient was hospitalized for viral pneumonitis subsequent to covid-19. |
| 1219262 | 4/16/2021 | | 47 | F | 4/14/2021 | 4/14/2021 | Patient was given her first dose of the pfizer vaccine at around 915 am she had mentioned that she had an allergy to penicillin but it wasn't an anaphylactic reaction. After the shot she went and sat in the chairs out front and shortly after someone called out that she needed help nurse ran to her side and she was unresponsive with shallow breathing and sweating and we called 911. As nurse was checking on her nurse 2 grabbed the epipen and administered right away. She came to after the epipen and we were able to talk to her a bit she mentioned that she has fainted a few times. We noticed that she had urinated at some point not sure if it was before or after epipen. The 911 operator suggested that we get her on the floor and have her lay down so we got her on the ground and laid her down as we were doing this she was going in and out of responsiveness. We attempted to take her blood pressure but the machine errored out a couple times. As we were trying to get the blood pressure the ambulance showed up and they took over care. She was transported to Clinic ER. She called later in the afternoon to let us know that she was doing okay and that she appreciated what we had done for her. |
| 1219232 | 4/16/2021 | MO | 59 | F | 3/27/2021 | 4/6/2021 | started having lots of leg and arm pains on april 6th, burning pains etc. very tired, felt like she would pass out and this continued till april 11th when she fainted and she went to hospital |

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| 1219356 | 4/16/2021 | CO | 32 | F | 4/15/2021 | 4/15/2021 | Slept poorly, fainted the following morning, sustained a concussion, facial laceration, bruised eye. Admitted to ER, received intravenous fluids, ekg, diagnosed with low blood pressure, mild concussion and received 3 stitches to close laceration above right eye. |
| 1216633 | 4/16/2021 | IL | 27 | F | 4/15/2021 | 4/15/2021 | PATIENT COMPLAINED OF DIZZINESS AND BLURRED VISION AFTER 5 MINUTES OF RECEIVING THE VACCINE. AFTER PHARMACIST CONSULTATION, IT WAS DETERMINED THAT THE PATIENT HAS A PREVIOUS HISTORY OF FAINTING WITH NEEDLES UPON BLOODWORK BUT NOT COMMONLY WITH VACCINES. THE PATIENT ALSO RELAYED TO THE PHARMACIST THAT SHE DID NOT EAT ANYTHING SINCE THE MORNING AND ALL SHE HAD TO EAT IN THE MORNING WAS A BANANA. WE GAVE HER WATER AND MOVED HER TO A ROOM IN WHICH SHE WAS ABLE TO REMOVE HER MASK AND BREATHE EASIER. SHE THEN REPORTED OF TINGLING IN HER UPPER LIP. SHE WAS GIVEN A SNACK TO ASSIST WITH SYMPTOMS OF POSSIBLY HYPOGLYCEMIA. WE MONITORED HER FOR ANOTHER 15 MINUTES CONTINUOUSLY CHECKING ON HER AND HER SYMPTOMS ALL STARTED IMPROVING AND RESIDING. AFTER 30 MINUTES OF CLOSE MONITORING THE PATIENT FELT WELL ENOUGH TO GO HOME. |
| 1218077 | 4/16/2021 | IN | 32 | F | 4/13/2021 | 4/13/2021 | Constant headache, fever of 100.5, full body aches, dizzy, nauseau, fainting, loss of appetite - all between 930pm and 3pm of next day. |
| 1217638 | 4/16/2021 | CA | 23 | F | 4/15/2021 | 4/15/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Hyperventilation-Mild, Additional Details: patient remained conscious. paramedics arrived and followed up with patient. |
| 1217625 | 4/16/2021 | CA | 27 | M | 4/15/2021 | 4/15/2021 | Systemic: Fainting / Unresponsive-Severe, Systemic: Shakiness-Mild, Additional Details: As soon as the vaccine was given, pt immediately passed out. Patient then began mildly shaking, this is when I administered the epipen. |

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| 1217599 | 4/16/2021 | CT | 18 | M | 4/15/2021 | 4/15/2021 | Site: Pain at Injection Site-Mild, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium |
| 1217592 | 4/16/2021 | OH | 30 | F | 4/14/2021 | 4/14/2021 | Patient given Pfizer vaccine and fainted after receiving it. This was a witnessed event. Patient did not fall or have any injuries. Patient re-gained consciousness and sat on the floor until she felt better. Water was provided to patient. |

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| 1217484 | 4/16/2021 | MN | 22 | F | 4/7/2021 | | <p>PAINFUL HEADACHE; FAINTING/LOSS OF CONSCIOUSNESS; HEART RACING; APPEARED WHITE; FELT WARMTH IN EARS; LOW GRADE FEVER; This spontaneous report received from a consumer concerned a 22 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included seasonal allergy. The patient was not pregnant at the time of reporting. The patient had no history of drug abuse/illicit drug use. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 203A21A, and expiry: unknown) dose was not reported, 1 total administered on 07-APR-2021 14:00 to right arm for prophylactic vaccination. No concomitant medications were reported. On 07-APR-2021, around eight hours later after vaccination, the patient felt a warm in her ears and her heart was racing. She appeared as white as a ghost and the patient fainted with complete loss of consciousness for approximately less than a minute. She had regained consciousness and still had accelerated heart rate until she ate and drank water and then calmed down. On 08-APR-2021, the patient had a very painful headache when she wake up and a low grade fever. She wanted to know if she can take Motrin or Tylenol for her events. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from feeling of warmth in ears, fainting, complete loss of consciousness, and heart racing on 07-APR-2021, had not recovered from very painful headache, and low grade fever, and the outcome of appeared white was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210416890-JANSSEN COVID-19 VACCINE-Fainting. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.</p> |

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| 1217373 | 4/16/2021 | FL | 42 | M | 4/15/2021 | 4/15/2021 | Site: Pain at Injection Site-Mild, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Additional Details: AFTER 5 MINUTES OF BEING VACCINATED, PATIENT WAS SEATED WAITING FOR THE 15 MINUTES AND FAINT LOSSING CONSCIOUSNESS FOR 5 MINUTES, THEN AFTER RECOVERED HE WAS PALE, SWEATING, COLDNESS OF THE HANDS AND DIZZY. WHEN 911 ARRIVED, HE SAID THAT HAD NOT EATEN ANYTHING SINCE 5:00 AM, 10 HOURS BEFORE THE EVENT HAD PLACE, SO MAYBE HE EXPERIENCED A HYPOGLYCEMIC EVENT. |
| 1217369 | 4/16/2021 | MA | 22 | M | 4/14/2021 | 4/14/2021 | Fainted briefly, EMS contacted and vitals were ok. He drove himself back to college |
| 1217367 | 4/16/2021 | NJ | 28 | F | 4/15/2021 | 4/15/2021 | Systemic: Fainting / Unresponsive-Severe, Systemic: Patient fainted a few minutes after receiving the vaccination-Medium, Additional Details: Patient was given Pfizer COVID-19 vaccination by RPH. A few minutes into the observation period, I heard a loud noise that sounded like a fall. I run outside to find Patient on the floor. She woke up within a few seconds, 911 was called. I kept her awake and took her vitals BP prior to EMS arrival= 118/72 mmHg. Upon Fire dept arrival BP= 148/65 mmHG. Transitioned to EMS/Fire Dept. |

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| 1216861 | 4/16/2021 | TX | 26 | F | | 3/12/2021 | BODY ACHES; JOINT PAIN; HEADACHE; INJECTION SITE PAIN /SEVERE ARM PAIN; PASSED OUT AT INJECTION; This spontaneous report received from a patient concerned a 26 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included vonn willebrand's disease, non-alcoholic, non-smoker, and needle phobia, and other pre-existing medical conditions included the patient had no known allergies and no drug abuse or illicit drug. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805031, expiry: UNKNOWN) dose was not reported, administered on 12-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 12-MAR-2021, the subject experienced passed out at injection. On 12-MAR-2021, the subject experienced injection site pain /severe arm pain. On 13-MAR-2021, the subject experienced body aches. On 13-MAR-2021, the subject experienced joint pain. On 13-MAR-2021, the subject experienced headache. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from body aches, joint pain, and headache on 15-MAR-2021, had not recovered from injection site pain /severe arm pain, and the outcome of passed out at injection was not reported. This report was non-serious. |
| 1217651 | 4/16/2021 | CA | 21 | M | 4/15/2021 | 4/15/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient received his moderna shot on april 15 at around 3:50pm, and was seated for observation for 15 minutes. Patient felt dizzy and fainted and fell to the ground and hit his head. I ran to him and he gained concious within few seconds and stood up. I helped him to lay back on the floor and raised his leg on a chair. At 4:02 Temprature was 97.2 & blood pressure 120/71. Patient was responding & mention he fainted also few days ago when he had blood drawn for some blood work. Ambulance took over |

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| 1216643 | 4/16/2021 | CA | 34 | F | 4/15/2021 | 4/15/2021 | Patient fainted about 5 minutes after receiving vaccine. Pharmacist checked patient and she had a pulse. Patient quickly gained conscious and laid down on the floor. Patient said she usually faints when she receives a vaccine or has her blood drawn. Pharmacist checked patient's blood pressure and pulse, within normal range. |
| 1217654 | 4/16/2021 | CA | 21 | M | 4/15/2021 | 4/15/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Additional Details: Redo: Pt was waiting for 15 mins observation, he felt dizzy and fainted and fell to the ground and hit his head. Called ambulance, temp. was 97.2 bp 120/71. pt gained concious right away and stood up. I assisted pt to lay back to the ground and raised his leg to a chair. ambulance came, checked blood sugar was 80. took him to hospital. |
| 1216616 | 4/16/2021 | CA | 23 | M | 4/15/2021 | 4/15/2021 | About 5 minutes after receiving the shot, patient complained of being light headed, hot, patchy vision, loss of hearing, pale color and almost passed out at the pharmacy contour. He had been helped to have a seat and drink some water, about 5 minutes later he felt much better but only experienced tingling in his fingertips. He stayed for another 20 minutes in pharmacy and mentioned he felt totally alright before leaving the pharmacy area. |
| 1216613 | 4/16/2021 | WA | 25 | F | 4/6/2021 | 4/6/2021 | I had the Pfizer-BioNTech vaccine on 4/6 and felt dizzy 30 minutes later. The dizziness continued for the next 84 hours. On 4/9 (three days after vaccination), I fainted on my driveway as I was heading home around noon time. I felt dizzy the whole afternoon but were trying to help out the groceries from the car. I fell down on the concrete driveway with two bags of groceries on my hand. I did not blackout, but were not able to get up for 10 seconds due to the dizziness. I eventually recovered from the dizziness 84 hours after the first dose of vaccine. I injured my knee as I fell, but the wound were treated at home immediately. As for the sore arm, I could not hold any items heavier than 1 lb. The arm soreness went away after 48 hours with ice pack applied on upper arm(injection area). |

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| 1216600 | 4/16/2021 | FL | 54 | F | 4/14/2021 | 4/14/2021 | Near syncope 10 minutes after vaccine administered. Severe drop in heart rate. Transported by ambulance to the ER medical center. Overnight stay in hospital. Weakness, dizziness, headache, shaky. |
| 1215787 | 4/16/2021 | NY | 38 | U | | 4/6/2021 | PASSED OUT; LOW BLOOD PRESSURE; DIFFICULTY BREATHING; DIARRHEA; BACK PAIN; CHILLS; HEADACHE; This spontaneous report received from a patient concerned a 38 year old of unspecified sex. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 042A21A) dose was not reported, frequency once total, administered on 06-APR-2021 on left deltoid for prophylactic vaccination. No concomitant medications were reported. On 06-APR-2021, Laboratory data included: Blood pressure (NR: not provided) low. The patient experienced side effects of chills, back pain, felt passed out, low blood pressure, headaches and diarrhea. The patient had difficulty breathing and went to emergency room stable at the time of reporting. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from passed out, low blood pressure, difficulty breathing, diarrhea, and chills on 06-APR-2021, and had not recovered from back pain, and headache. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210414531-JANSSEN COVID-19 VACCINE Ad26.COV2.S- Passed out. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event. |

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| 1215778 | 4/16/2021 | MD | 21 | F | | 4/1/2021 | ALMOST PASSED OUT BUT SHE DID NOT; LOSS OF TASTE; LOSS OF SMELL; FATIGUE; MUSCLE ACHE; This spontaneous report received from a health care professional concerned an adult female. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 041A21A expiry: UNKNOWN) dose was not reported, administered on 05-APR-2021 to left deltoid for prophylactic vaccination. No concomitant medications were reported. On APR-2021, the subject experienced loss of taste. On APR-2021, the subject experienced loss of smell. On APR-2021, the subject experienced fatigue. On APR-2021, the subject experienced muscle ache. On 05-APR-2021, the subject experienced almost passed out but she did not. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the fatigue, muscle ache, loss of taste, almost passed out but she did not and loss of smell was not reported. This report was non-serious. |

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| 1215770 | 4/16/2021 | DE | 26 | F | 4/3/2021 | | <p>SYNCOPE; MIGRAINE; WHOLE BODY TREMORS; VOMITING; NUMBNESS IN HAND AND FEET; WHOLE BODY ACHES; 105.0 F TEMPERATURE; This spontaneous report received from a patient concerned a 26 year old female. The patient's weight was 120 pounds, and height was 60 inches. Obstetrics history included gravida 1 para 1 (gave birth to a daughter 8 weeks ago). Concurrent conditions included penicillin allergy, non-alcohol user and non-smoker. The patient was not pregnant at the time of vaccination and had no history of drug abuse/illicit drug use. The patient experienced drug allergy when treated with amoxicillin. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 043A21A, and expiry: 21-JUN-2021) dose was not reported, administered on left arm on 03-APR-2021 for prophylactic vaccination. The product was stored properly from receipt to administration. No concomitant medications were reported. On 03-APR-2021, the patient experienced migraine, whole body tremors, vomiting, had a temperature of 105.0 F (required emergency room visit/urgent care), numbness in hand and feet, and whole body aches. On the same day, she recovered from whole body tremors. On 04-APR-2021, the patient experienced syncope. On the same day, she recovered from syncope, vomiting, and numbness in hand and feet. On 05-APR-2021, she recovered from whole body aches and 'temperature 105.0 F'. The patient was breastfeeding her child at the time of report. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from syncope, vomiting, numbness in hand and feet, 105.0 F temperature, whole body aches and whole body tremors, and was recovering from migraine. This report was serious (Other Medically Important Condition). This parent/child case is linked to 20210412341.; Sender's Comments: V0:20210411086-covid-19 vaccine ad26.cov2.s-Syncope. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p> |

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| 1215767 | 4/16/2021 | PA | 37 | M | 4/5/2021 | SEIZURE; DIARRHEA; | This spontaneous report received from a patient concerned a 37 years old male. The patient's height, and weight were not reported. The patient's concurrent condition included fear of needle. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, administered 1 total on 05-APR-2021 for prophylactic vaccination. Batch number was not reported and has been requested. No concomitant medications were reported. On 05-APR-2021, after receiving vaccination, the patient experienced seizure (fainting, tremor, tachycardia and bladder incontinence) and diarrhea. Upon examination of his vitals, heart rate was 112, showing tachycardia, blood pressure (BP) was 135/83, oxygen saturation was at 98 and glucose was 90. The patient was taken to the emergency room where he was released after evaluation. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from diarrhea on 05-APR-2021, recovered with sequelae from seizure on 05-APR-2021. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to 20210411486, 20210411395 and 20210410874.; Sender's Comments: V0: 20210410630 -COVID-19 VACCINE AD26.COV2.S-seizure. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the events. |

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| 1215765 | 4/16/2021 | CA | | F | | 4/1/2021 | <p>SYNCOPE (PASSED OUT) TWICE; MUSCLE SPASMS; VOMIT ONCE; SHAKING; SHIVERING; This spontaneous report received from a consumer concerned a female of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 043821A, and expiry: UNKNOWN) dose was not reported, administered on 05-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On an unspecified date, in APR-2021, the patient experienced shaking, shivering, muscle spasms, syncope (passed out) twice and threw up (vomit) one time about 8 hours ago. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from shaking, shivering, muscle spasms, passed out twice, and vomit once. This report was serious (Other Medically Important Condition).; Sender's Comments: V0 : 20210410013--COVID-19 VACCINE AD26.COV2.S-Syncope (passed out)twice. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p> |

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| 1215762 | 4/16/2021 | NC | | F | | 3/19/2021 | <p>CHILLS; SHOULDER PAIN; HEADACHE; NAUSEATED; PASSED OUT; HEARING LOSS GETTING WORSE; CHEST PAINS; SWELLED UP; RINGING IN LEFT EAR; TREMBLING; BRAIN FOG; This spontaneous report received from a patient concerned a 74 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included type 2 diabetes and arthritis in the lower back. The patient was not pregnant. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration not reported, batch number: 1805018, and expiry: unknown) dose was not reported, administered on left arm on 19-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 19-MAR-2021, 30 minutes post-vaccination, the patient passed out and was rushed to the hospital and later she recovered. On the same day, the patient also experienced chest pains, chills, brain fog, trembling, nausea, shoulder pain that was shooting up and down between shoulder and elbow, ringing in left ear, developed swelling; headache and hearing loss in left ear that got worse. Electrocardiogram (EKG) was performed for chest pains (result unknown). At the hospital, she was given treatment that included Benadryl (diphenhydramine hydrochloride), many different shots (unspecified) and 'intravenous' (IV). The patient was at the hospital for about 8 hours. The patient was sent to a hearing specialist for her hearing loss. On 21-MAR-2021, the patient recovered from the events chest pains, chills, 'swelled up', nausea and trembling. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from chest pains, chills, swelled up, nauseated, trembling and passed out, and had not recovered from brain fog, shoulder pain, headache, left ear hearing loss, and ringing in left ear. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210409641- covid-19 vaccine ad26.cov2.s - passed out. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.</p> |

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| 1217899 | 4/16/2021 | PA | 41 | F | 4/9/2021 | 4/14/2021 | Extreme fatigue - days 2-7 after vaccine Prolonged dizziness - comes and goes - not only from standing up too quickly - starting 4/14 - can be anything from momentary to 30 minutes. Occasionally fainting. Fainting - starting 4/14 - following dizziness - has happened 4 times Tinnitus - starting 4/14 - comes and goes - severity/loudness increases before dizziness |
| 1216662 | 4/16/2021 | CA | 50 | F | 4/8/2021 | 4/8/2021 | APPROXIMATELY 3 HOURS AFTER VACCINATION THE PATIENT EXPERIENCED A SLIGHT FEVER, CHILLS, SWEATS, AND AN EXTREME MIGRAINE HEADACHE. SHE TOOK TYLENOL FOR HER SYMPTOMS. OVER THE NEXT 2 DAYS THESE SYMPTOMS IMPROVED BUT SHE DEVELOPED A RASH WITH BUMPS ON HER TONGUE, DIZZINESS, AND SLOW COGNITION WHICH LASTED ABOUT 2 DAYS. SHE WAS FINE FOR 24-48 HOURS WHEN ALL THE PREVIOUSLY MENTIONED SYMPTOMS RETURNED BUT EVEN MORE PRONOUNCED AND SHE HAD EXPLOSIVE DIARRHEA WITH INCREASED PAIN AT THE INJECTION SITE. AT SOME POINT DURING ALL THIS SHE VISITED HER MAIN PHARMACY AND AS SHE WAS TELLING THE PHARMACIST ABOUT HER SYMPTOMS SHE FAINTED AND WOKE TO EMS AND WAS TRANSPORTED TO THE HOSPITAL. THE ER DID NOT FIND ANY REASON FOR HER FAINTING. SHE WAS HYDRATED AND THINKS IT WAS ANXIETY BROUGHT ON BY HER EXPERIENCE. SHE CALLED ME TODAY 4/15/21 TO TELL ME ABOUT HER SYMPTOMS AND EXPERIENCE. SHE STATED THAT SHE HAD A NEW SYMPTOM OF A SHARP PAIN IN HER BACK SO I STRONGLY SUGGESTED SHE GO BACK TO ER TO CONTINUE TESTING IN CASE THE PAIN WAS SOMEHOW RELATED TO THE VACCINE INCIDENT. SHE SAID SHE WOULD GO TO URGENT CARE IF SHE FELT THE PAIN WAS BAD ENOUGH. |

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| 1218264 | 4/16/2021 | FL | 32 | M | 4/15/2021 | 4/15/2021 | We had a customer pass out after a shot and came too quickly. He began to fall forward several minutes after the shot and another customer pointed out that he needed assistance. As I hung up quickly and went to the patient he was coming to and recovered. I wasn't sure if he bumped his head but did not see any lacerations or signs of obvious severe injury. Store manager was contacted to help assess reporting through Incident reporting process. His BP was 118/82 after spending a few minutes with him and giving him water. He had a sweaty forehead and sat with us for a bit. I did offer to call an ambulance and administer Benadryl. Patient declined. He mentioned fainting with blood donations in the past, never with vaccines. We discussed for second shot we will stand nearby ready for fainting again, or receiving the shot at an MD office in prone (lying down) position. There was no answer to a follow-up phone call the next morning. |
| 1218698 | 4/16/2021 | MN | 57 | F | 4/14/2021 | 4/15/2021 | Syncope event Vertigo |
| 1218648 | 4/16/2021 | OH | 57 | F | 4/15/2021 | 4/16/2021 | I received the second moderna vaccine at 11:00 a.m. I had some chills and was tired that evening and went to bed at approximately 10:15 p.m. At approximately 2:50 a.m., I got up to use the bathroom. After using the bathroom on the way out of the bathroom I fainted. After coming to, I felt light headed, tired, and slightly nauseous for approximately 35 minutes. |

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| 1218639 | 4/16/2021 | UT | 44 | F | 1/16/2021 | 1/16/2021 | body contracted again, started in calves and feet and hands, went into neck and face; full body tetany; Left side of face cured up/ left side of my face was drooping, could not smile/ happened again in the ER around 1:15 AM so i was admitted; Terrible headache/ massive headache/ headache around back of head persisted; Ringing in ears; Shortness of breath; Sometimes dizzy; Fatigue; lumbar puncture relieved excess CSF and reduced pressure; Couldn't move left side; elevated BP persisted; Could be a Tetany or dystonic reaction to the vaccine due to timing of everything/ Muscles tightened all over body/ within minutes after vaccination hands/ feet/ legs contracted/ curled up; Could be a Tetany or dystonic reaction to the vaccine due to timing of everything; passed out immediately following vaccine; Blood pressure was still high pulse was high 120/ BP went sky high (196/148)/ BP remained high; Fainted when she got the shot; Hyperventilation syndrome; Whole body hurt/ very sore body; This spontaneous case was reported by a patient (subsequently medically confirmed) and describes the occurrence of FACIAL PARALYSIS (Left side of face cured up/ left side of my face was drooping, could not smile/ happened again in the ER around 1:15 AM so i was admitted), HEMIPLEGIA (Couldn't move left side), HEADACHE (Terrible headache/ massive headache/ headache around back of head persisted), DYSTONIA (body contracted again, started in calves and feet and hands, went into neck and face), TETANY (full body tetany), HYPERTENSION (elevated BP persisted), DYSTONIA (Could be a Tetany or dystonic reaction to the vaccine due to timing of everything/ Muscles tightened all over body/ within minutes after vaccination hands/ feet/ legs contracted/ curled up), SYNCOPE (Fainted when she got the shot) and LOSS OF CONSCIOUSNESS (passed out immediately following vaccine) in a 44-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 041L20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Pneumonia on 08-Oct-2020. Concurrent medical conditions included COVID-19 (Positive for COVID; Sick for 5 weeks followed with pneumonia, long COVID-19) since 19-Sep-2020, Fainting (History of Fainting; reported as normal for the patient), Drug allergy, Blood pressure high since 19-Sep- |

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2020, Oxygen saturation decreased (2 L via nasal cannula on night) since 19-Sep-2020, Dizziness since 19-Sep-2020 and Headache since 19-Sep-2020. Concomitant products included SERTRALINE HYDROCHLORIDE (ZOLOFT) for Anxiety, AMFETAMINE ASPARTATE, AMFETAMINE SULFATE, DEXAMFETAMINE SACCHARATE, DEXAMFETAMINE SULFATE (ADDERALL) from 16-Jan-2021 to an unknown date for Attention deficit hyperactivity disorder, CLONAZEPAM for Sleep disorder NOS. On 16-Jan-2021 at 12:15 PM, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 16-Jan-2021, the patient experienced HEADACHE (Terrible headache/ massive headache/ headache around back of head persisted) (seriousness criterion hospitalization) and PAIN (Whole body hurt/ very sore body). 16-Jan-2021, the patient experienced SYNCOPE (Fainted when she got the shot) (seriousness criterion medically significant) and HYPERVENTILATION (Hyperventilation syndrome). On 16-Jan-2021 at 12:15 PM, the patient experienced LOSS OF CONSCIOUSNESS (passed out immediately following vaccine) (seriousness criterion medically significant) and HYPERTENSION (Blood pressure was still high pulse was high 120/ BP went sky high (196/148) BP remained high). On 16-Jan-2021 at 12:30 PM, the patient experienced DYSTONIA (Could be a Tetany or dystonic reaction to the vaccine due to timing of everything/ Muscles tightened all over body/ within minutes after vaccination hands/ feet/ legs contracted/ curled up) (seriousness criterion medically significant). 16-Jan-2021 at 12:30 PM, the patient experienced TETANY (Could be a Tetany or dystonic reaction to the vaccine due to timing of everything). On 17-Jan-2021, the patient experienced FACIAL PARALYSIS (Left side of face cured up/ left side of my face was drooping, could not smile/ happened again in the ER around 1:15 AM so I was admitted) (seriousness criterion hospitalization), HEMIPLEGIA (Couldn't move left side) (seriousness criterion hospitalization) and HYPERTENSION (elevated BP persisted) (seriousness criterion hospitalization). On 17-Jan-2021 at 7:00 PM, the patient experienced DYSTONIA (body contracted again, started in calves and feet and hands, went into neck and face) (seriousness criterion hospitalization) and TETANY (full body tetany)

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(seriousness criterion hospitalization). On 05-Feb-2021, the patient experienced LUMBAR PUNCTURE (lumbar puncture relieved excess CSF and reduced pressure). On an unknown date, the patient experienced TINNITUS (Ringing in ears), DYSPNOEA (Shortness of breath), DIZZINESS (Sometimes dizzy) and FATIGUE (Fatigue). The patient was hospitalized from 17-Jan-2021 to 18-Jan-2021 due to DYSTONIA, FACIAL PARALYSIS, HEADACHE, HYPERTENSION and TETANY, and then on 17-Jan-2021 due to HEMIPLEGIA. On 16-Jan-2021, DYSTONIA (Could be a Tetany or dystonic reaction to the vaccine due to timing of everything/ Muscles tightened all over body/ within minutes after vaccination hands/ feet/ legs contracted/ curled up), LOSS OF CONSCIOUSNESS (passed out immediately following vaccine) and TETANY (Could be a Tetany or dystonic reaction to the vaccine due to timing of everything) had resolved. On 18-Jan-2021, FACIAL PARALYSIS (Left side of face cured up/ left side of my face was drooping, could not smile/ happened again in the ER around 1:15 AM so i was admitted), DYSTONIA (body contracted again, started in calves and feet and hands, went into neck and face), TETANY (full body tetany) and HYPERTENSION (elevated BP persisted) had resolved. On 05-Feb-2021, HEADACHE (Terrible headache/ massive headache/ headache around back of head persisted) and LUMBAR PUNCTURE (lumbar puncture relieved excess CSF and reduced pressure) had resolved. At the time of the report, HEMIPLEGIA (Couldn't move left side), SYNCOPE (Fainted when she got the shot), TINNITUS (Ringing in ears), HYPERVENTILATION (Hyperventilation syndrome) and PAIN (Whole body hurt/ very sore body) outcome was unknown, HYPERTENSION (Blood pressure was still high pulse was high 120/ BP went sky high (196/148)/ BP remained high) had resolved and DYSPNOEA (Shortness of breath), DIZZINESS (Sometimes dizzy) and FATIGUE (Fatigue) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 16-Jan-2021, Blood pressure measurement: 196/148 High. On 16-Jan-2021, Blood test: normal normal. On 16-Jan-2021, Heart rate: 120 High. On 16-Jan-2021, Magnetic resonance imaging: normal normal. On 17-Jan-2021, Blood pressure measurement: 190/140 High. On 17-Jan-2021,

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Computerised tomogram: ruled out stroke normal. On an unknown date, Blood pressure measurement: 192/144 High. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter considered FACIAL PARALYSIS (Left side of face cured up/ left side of my face was drooping, could not smile/ happened again in the ER around 1:15 AM so i was admitted), HEADACHE (Terrible headache/ massive headache/ headache around back of head persisted), DYSTONIA (body contracted again, started in calves and feet and hands, went into neck and face), TETANY (full body tetany), HYPERTENSION (elevated BP persisted), DYSTONIA (Could be a Tetany or dystonic reaction to the vaccine due to timing of everything/ Muscles tightened all over body/ within minutes after vaccination hands/ feet/ legs contracted/ curled up), LOSS OF CONSCIOUSNESS (passed out immediately following vaccine), HYPERTENSION (Blood pressure was still high pulse was high 120/ BP went sky high (196/148)/ BP remained high), TETANY (Could be a Tetany or dystonic reaction to the vaccine due to timing of everything), PAIN (Whole body hurt/ very sore body) and LUMBAR PUNCTURE (lumbar puncture relieved excess CSF and reduced pressure) to be possibly related. No further causality assessments were provided for HEMIPLEGIA (Couldn't move left side), SYNCOPE (Fainted when she got the shot), TINNITUS (Ringing in ears), HYPERVENTILATION (Hyperventilation syndrome), DYSPNOEA (Shortness of breath), DIZZINESS (Sometimes dizzy) and FATIGUE (Fatigue). Treatment medication included: Injections of Benadryl and IV Benadryl en route to hospital, Ibuprofen daily as needed and a shot of Toradol. Case Comment/Sender's Comment - This case concerns a 44 year old, female patient, with history of fainting, COVID-19 (September 2020), who experienced a serious unexpected event of syncope, hemiplegia, facial paralysis and dystonia among others, 2 day after receiving 1st dose of mRNA-1273 (Lot# Unknown). Very limited information regarding this event has been provided at this time. Further information has been requested. Most recent FOLLOW-UP information incorporated above includes: On 12-Apr-2021: Updated patient medical history, concomitant

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| 1218634 | 4/16/2021 | | 37 | M | 4/15/2021 | 4/15/2021 | medications, treatment medication, new events, outcome and causality.; Reporter's Comments: This case concerns a 44 year old, female patient, with history of fainting, COVID-19 (September 2020), who experienced a serious unexpected event of syncope, hemiplegia, facial paralysis and dystonia among others, 2 day after receiving 1st dose of mRNA- 1273 (Lot# Unknown). Very limited information regarding this event has been provided at this time. Further information has been requested. |
| 1218628 | 4/16/2021 | | 23 | M | 4/8/2021 | 4/15/2021 | <p>~~Started to feel faint in the observation area. Told his wife that he feels lightheaded and pre-syncope. He had no recollection of what happened, but came to after a sternal rub. He denies hx of syncope, epilepsy or other medical problems. He does not take any medications. Endorses he ate and drank before getting the shot. Pt with a witnessed momentary LOC, was lowered gently to the floor by providers. States he felt better after laying down and having something to drink. Admit to some nausea, but denies vomiting, Next dose recommended: Yes ~~</p> <p>Seen Emergency Services on 4/15/21 Dr: Diagnosis with Vaccine reaction, initial encounter, near syncope, frontal headache, evaluated for possible vaccine reaction, received J&J vaccine 6 days ago, now headaches and episodes vision blacks out, pt does not have any thrombocytopenia, D- dimer negative, at this time does not feel needs CT of head, if s/s worsening or changes, return for imaging, supportive care at home, discharged home, tylenol or ibuprofen for headaches as needed, return if changes or worsening.</p> |

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| 1218620 | 4/16/2021 | | 37 | F | 1/12/2021 | 1/12/2021 | Within one hour of the shot administration I became tachycardia, hypertensive, and with chills. Over the next 48 hours my symptoms worsened to include headaches, dizziness, fatigue, and near syncope requiring an emergent visit to the ER. My symptoms persisted and two weeks later I required another visit to the ER and was admitted to the hospital overnight due to tachycardia, hypertension, diarrhea, chest pressure, headaches, fatigue, weakness, chills, and near syncope. Since the onset of events post the Pfizer vaccine, I have required multiple visits with MDs/specialist for management of symptoms and course of treatment. My local physician suspected postural orthostatic tachycardia syndrome (POTS) of which I sought medical opinion and met with a world expert and after meeting with him, he concluded my symptoms were in fact in line with POTS. Since then I have continued to experience flare-ups and episodes of tachycardia, most recently 4/14/2021. It has now been over 3 months since the onset of symptoms post vaccine and I continue to require treatment and management of above symptoms. I have not returned back to previous level of function nor have I been able to return to work. I do not have any prior medical history of this condition or set of symptoms. |
| 1218607 | 4/16/2021 | MI | 28 | F | 4/15/2021 | 4/15/2021 | Patient received vaccine and proceeded to observation area. While patient was sitting she had a brief episode of syncope but quickly regained consciousness. Patient was placed on the floor to lay down and given juice. She stated that she felt much better almost right away. We observed her for 20-30 minutes until the patient felt well enough to leave on her own. |
| 1218583 | 4/16/2021 | MI | 50 | M | 4/8/2021 | 4/8/2021 | Immediate onset with pre-syncope. Persistent profound fatigue, diaphoresis, nausea, foggy, weak legs, muscle aches. Improving after 8 days. |

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| 1218428 | 4/16/2021 | ME | 47 | F | 4/10/2021 | 4/10/2021 | The evening after the vaccine was administered I experienced severe pain in my right leg (4/10 at 7:30pm). The pain occurred in the groin and knee area and mostly through the thigh. I took 1000mg of Tylenol and it helped resolve the pain. The following day (4/11) I experienced the same leg pain and continued with Tylenol which helped. Monday I had dizziness and almost fainted so I went to the ED to get examined (4/11). I have a family history of clotting and carry the prothrombin gene mutation so I'm aware of issues with leg pain and get evaluated. The pain has continued over the week and is now in my left leg with mild pain. Visited walk in clinic to have a follow up on 4/15 and they administered a Covid test. |
| 1218427 | 4/16/2021 | | 29 | F | 4/11/2021 | 4/12/2021 | April 12, 2021 4:00am Intense Chill until passed out. 7:00am Woke up with body boiling. High fever. Until passed out. 7am-2pm cycles of intense chill and high fever 2:00pm Small amount of water intake. Realize Extreme arm pain. Took 2x advil. 7:00pm Woke up in soaking sweat. Drunk can soup. Took a shower. Chill came back after shower. 7pm-4am(April13, 2021) Cycles of moderate chill and moderate fever with fever. April13, 2021 Muscle soreness, tiredness, brain fog, lack of appetite, bouts of cold sweat throughout the day. |
| 1217644 | 4/16/2021 | CA | 23 | F | 4/15/2021 | 4/15/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Hyperventilation-Mild, Additional Details: patient remained conscious. paramedics arrived and followed up with patient. |
| 1218265 | 4/16/2021 | VA | 31 | U | 4/15/2021 | 4/15/2021 | PT RECIEVED VACCINE, WALKED TO RECOVERY AND SAT DOWN. ABOUT 3 MINUTES AFTER PT'S VACCINE SHE BEGAN TO COMPLAIN OF DIZZINESS. HER HUSBAND WAS WITH HER AND CAUGHT HER AS SHE PASSED OUT. A VOLUNTEER WENT OVER TO ASSIST. PT'S HEAD PUT IN BETWEEN HER KNEES. EMS OVER TO EVALUATE. PT PUT ON SCRETCHEER AND WHEELED TO A PRIVATE AREA FOR EVALUATION. VITALS STABLE. PT GIVEN GATORATE AND CRACKERS. PT AMBULATED AND LEFT WITH HUSBAND. |

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| 1218702 | 4/16/2021 | MO | 64 | M | 3/1/2021 | 3/29/2021 | 14 days after 2nd dose severe shortness of breath, fatigue, lightheaded, near syncope. Diagnosed with bilateral DVT and bilateral PE |
| 1218257 | 4/16/2021 | MA | 27 | F | 4/16/2021 | 4/16/2021 | Fainting |
| 1218213 | 4/16/2021 | GA | 38 | F | 4/14/2021 | 4/15/2021 | I fainted 3 times in the span of 10 minutes |
| 1218185 | 4/16/2021 | FL | 41 | F | 4/15/2021 | 4/15/2021 | patient fainted and had a seizure |
| 1218092 | 4/16/2021 | FL | 26 | F | 4/15/2021 | 4/15/2021 | Patient has history of anemia and vasovagal syncope. She had a witnessed syncopal episode 10 min after vaccine admin. Patient fell from chair to ground. Staff responded immediately. She was positioned supine on the ground. She was pale and diaphoretic. v/s were assessed. She spontaneously regained consciousness and was maintained on the ground. She denies neck pain, back pain, headache, numbness, weakness, tingling, changes in vision and was A&Ox3. No stair stepping palpated on neck no ecchymosis noted eyes PEARL. She was repositioned to trendelenburg and was given a gatorade. When BP was stable she was return to her chair. She was kept for an additional 20 minutes and provided crackers. She stated she felt much better and felt safe to go home with a plan of calling a friend to speak to during the drive. She was advised to call 911 if she has another episode or develops severe headache or changes in vision. |
| 1218084 | 4/16/2021 | FL | 23 | F | 4/13/2021 | 4/13/2021 | Feel like fainting X30 sec. and shaking. V/S BP 102/56, HR 70, O2Sat 99% 10:06am Pt. left accompanied by dad saying that she normally experiences these feelings after getting vaccines and is feeling better now. |
| 1219643 | 4/16/2021 | MI | 38 | F | 4/12/2021 | 4/12/2021 | Fever to 102, dizziness with syncope, arm pain bilateral. |
| 1217810 | 4/16/2021 | GA | 16 | M | 4/14/2021 | 4/14/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient has not eating anything for 20 hours and that was the possible cause of syncope |

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| 1217804 | 4/16/2021 | FL | 19 | F | 4/15/2021 | 4/15/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Additional Details: Patient got really cold and passed out in chair. Immunizers laid her down on the ground. Patient told paramedics that this is a hereditary issue and that this happens every time she gets a vaccine/blood work done . She came back around immediately after passing out. Ambulance service was refused but mother drove her to hospital just in case. |
| 1217792 | 4/16/2021 | PA | 31 | M | 4/15/2021 | 4/15/2021 | Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Pt urinated while unconscious-Medium, Systemic: Flushed / Sweating-Severe, Systemic: Nausea-Medium, Systemic: Shakiness-Medium, Additional Details: Pt reported no feeling well. Denied trouble breathing/swallowing. Pt lost consciousness. We were able to prevent him from falling or any\r\ninjury. 911 was called. He was out about 15 seconds. Regained consciousness. Was startled and confused but was quickly became reoriented to where he was, that he had just recieved vaccine and passed out. Patient's BP and condition was monitored until paramedics arrived. After coming around patient started to feel nauseous and felt like he would vomit. |
| 1217671 | 4/16/2021 | PA | 31 | M | 4/15/2021 | 4/15/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient fainted while waiting 15 mintues after vaccination. Responded immediately upon shoulder touch and vocal prompting. Indicated history of fainting post vaccination. 911 was called, paramedics deemed no further follow-up was needed. patient left 15 minutes later showing no symptoms |
| 1218309 | 4/16/2021 | TX | 79 | M | 3/26/2021 | 3/26/2021 | weakness, near syncope , hypotension |
| 1220844 | 4/16/2021 | WA | 41 | M | 4/15/2021 | 4/15/2021 | Fainting - never lost consciousness Shot given 10:10am. Was in waiting room and reported feeling light headed at 10:25am. 10:25am. Faint/dizzy/supine BP 124/77 Pulse 74. Respiration. 16 10:30am Supine BP 135/73. Pulse 63 10:35am. Supine BP. 134/80. Pulse 66 10:40am. Sitting BP 135/72. Pulse 62 ***follow-up call made 12:27pm had to leave message |

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| 1220579 | 4/16/2021 | CO | 16 | M | 4/13/2021 | 4/14/2021 | Patient had two events that our pediatrician encouraged us to notify about. First, on 4/15/2021 around 13:30, Patient stretched in class and fainted. He was unconscious about 30 seconds. Second, beginning 4/15/2021 around 2100 he noticed a rash across his chest and down both arms. The rash is spreading to his abdomen and back today (4/16/2021). We saw a physician at his pediatric clinic this afternoon for evaluation. |

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| 1220959 | 4/16/2021 | NJ | 39 | M | 3/10/2021 | 3/10/2021 | Passed out; Seizure; Fever; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out) and SEIZURE (Seizure) in a 39-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 040A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No reported medical history). No concomitant medication were reported. On 10-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form Lot # 040A21A.. On 10-Mar-2021, the patient experienced had a fever, passed out and had a seizure On 07 Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form Lot # 045A21A. After 12 hours he passed out and had a seizure. The patient experienced LOSS OF CONSCIOUSNESS (Passed out) (seriousness criterion medically significant), SEIZURE (Seizure) (seriousness criterion medically significant) and PYREXIA (Fever). The outcome of passed out, seizure and fever is resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) is not applicable as both vaccines had been administered. Description: On 10 Mar 2021, the patient had a fever, passed out (medically significant) and had a seizure (medically significant). No treatment information was provided. This case was linked to (E2B Linked Report).; Sender's Comments: Based on the current available information which includes a strong temporal association between the use of the product and onset of the reported events, and excluding other etiologies, a causal relationship cannot be excluded. Fever is consistent with the known safety profile of mRNA-1273. MOD-2021-072699:2nd dose case |
| 1217845 | 4/16/2021 | IN | 21 | F | 4/14/2021 | 4/14/2021 | Passed out and threw up within 15 minute waiting period. Since then have had a fever, body aches, headache, nausea, chills and joint pain. |

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| 1220942 | 4/16/2021 | TN | | F | 3/25/2021 | 3/25/2021 | <p>Almost passed out, almost blackout; woke up and broke out in sweats all over her body; restless was tossing and turning; symptoms hit her like a ton of bricks; threw up could not keep any food or water down; headache (throbbled with every heartbeat); Nausea; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (Almost passed out, almost blackout) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 032M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event. On 25-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 25-Mar-2021, the patient experienced LOSS OF CONSCIOUSNESS (Almost passed out, almost blackout) (seriousness criterion medically significant), HYPERHIDROSIS (woke up and broke out in sweats all over her body), RESTLESSNESS (restless was tossing and turning), FEELING ABNORMAL (symptoms hit her like a ton of bricks), VOMITING (threw up could not keep any food or water down), HEADACHE (headache (throbbled with every heartbeat)) and NAUSEA (Nausea). On 26-Mar-2021, LOSS OF CONSCIOUSNESS (Almost passed out, almost blackout), HYPERHIDROSIS (woke up and broke out in sweats all over her body), RESTLESSNESS (restless was tossing and turning), FEELING ABNORMAL (symptoms hit her like a ton of bricks), VOMITING (threw up could not keep any food or water down), HEADACHE (headache (throbbled with every heartbeat)) and NAUSEA (Nausea) had resolved. No concomitant medications were provided No treatment medications were provided This case was linked to US-MODERNATX, INC.-MOD-2021-071431 (E2B Linked Report).; Sender's Comments: This case concerns a female adult with a serious unexpected event of loss of consciousness, and nonserious unexpected feeling abnormal, hyperhidrosis, restlessness, and expected nausea, vomiting, headache. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. MODERNATX, INC.-MOD-2021-071431:Crosslinked case</p> |

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| 1220937 | 4/16/2021 | | | F | 4/3/2021 | 4/3/2021 | <p>near fainting spell/like intermittent fainting spells; feels like vertigo; This spontaneous case was reported by a non-health professional and describes the occurrence of SYNCOPE (near fainting spell/like intermittent fainting spells) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 021B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No reported medical history). On 03-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 03-Apr-2021, the patient experienced SYNCOPE (near fainting spell/like intermittent fainting spells) (seriousness criterion medically significant) and VERTIGO (feels like vertigo). At the time of the report, SYNCOPE (near fainting spell/like intermittent fainting spells) and VERTIGO (feels like vertigo) outcome was unknown. Onset date of events was 4 hours after second shot, which is again 03-apr-2021 and outcome as unknown. Action taken with mRNA-1273 in response to the event was not applicable. Concomitant product use was not provided by the reporter. No treatment information was provided.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. No further information is expected at this time.</p> |

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| 1220936 | 4/16/2021 | NY | 45 | F | 3/21/2021 | 3/21/2021 | <p>Numbness; numbness; anxiety; Heart rate; she was out of it; feeling drunk; Fainted; Tightness in her Face; Weakness in the legs; This spontaneous case was reported by a consumer and describes the occurrence of SYNCOPE (Fainted), MUSCLE TIGHTNESS (Tightness in her Face), MUSCULAR WEAKNESS (Weakness in the legs), HYPOAESTHESIA ORAL (Numbness) and HYPOAESTHESIA ORAL (numbness) in a 45-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 038A21A and 008B21-2A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No reported medical history). On 21-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 08-Apr-2021 at 9:00 AM, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 21-Mar-2021, the patient experienced SYNCOPE (Fainted) (seriousness criterion medically significant), MUSCLE TIGHTNESS (Tightness in her Face) (seriousness criterion medically significant) and MUSCULAR WEAKNESS (Weakness in the legs) (seriousness criterion medically significant). On 08-Apr-2021, the patient experienced HYPOAESTHESIA ORAL (Numbness) (seriousness criterion medically significant), HYPOAESTHESIA ORAL (numbness) (seriousness criterion medically significant), ANXIETY (anxiety), HEART RATE INCREASED (Heart rate), MALAISE (she was out of it) and FEELING DRUNK (feeling drunk). On 23-Mar-2021, SYNCOPE (Fainted), MUSCLE TIGHTNESS (Tightness in her Face) and MUSCULAR WEAKNESS (Weakness in the legs) had resolved. At the time of the report, HYPOAESTHESIA ORAL (Numbness), HYPOAESTHESIA ORAL (numbness), ANXIETY (anxiety), HEART RATE INCREASED (Heart rate), MALAISE (she was out of it) and FEELING DRUNK (feeling drunk) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 08-Apr-2021, Body temperature: 99.5 (Inconclusive) Degrees Fahrenheit. mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosing remained unchanged. No medication as administrated (No Epi Pen). Hospital doctor stated that</p> |

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| 1220931 | 4/16/2021 | FL | | M | 3/23/2021 | 3/23/2021 | <p>the patient had anxiety attack. Patient stated she does not have history of anxiety. Patient was released from ER in the same day. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested</p> <p>Passed out; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out) in a 58-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 045A21A) for COVID-19 vaccination. The patient's past medical history included No adverse event (No medical history provided). On 23-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 23-Mar-2021, the patient experienced LOSS OF CONSCIOUSNESS (Passed out) (seriousness criterion medically significant). On 23-Mar-2021, LOSS OF CONSCIOUSNESS (Passed out) had resolved. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No concomitant medication were reported. No treatment information was provided.; Sender's Comments: This case concerns a 58-year-old male with a serious unexpected event of loss of consciousness. Event onset the same day as first dose mRNA-1273. Event resolved. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.</p> |

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| 1220925 | 4/16/2021 | CA | | F | 2/25/2021 | 2/25/2021 | <p>started feeling really sick; lightheaded; didn't feel well; felt hot; felt like she was going to pass out; vomiting; nauseated; right shoulder became very sore; right shoulder became tender; sore right arm; This spontaneous case was reported by a consumer and describes the occurrence of PRESYNCOPE (felt like she was going to pass out) in a 62-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 010M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Stevens-Johnson syndrome. Concurrent medical conditions included Allergy to antibiotic (Name unknown. Antibiotic caused Stevens-Johnson Syndrome.). On 25-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 25-Feb-2021, the patient experienced PAIN IN EXTREMITY (sore right arm). On 03-Mar-2021, the patient experienced TENDERNESS (right shoulder became tender) and ARTHRALGIA (right shoulder became very sore). On 17-Mar-2021, the patient experienced PRESYNCOPE (felt like she was going to pass out) (seriousness criterion medically significant), MALAISE (started feeling really sick), DIZZINESS (lightheaded), MALAISE (didn't feel well), FEELING HOT (felt hot), VOMITING (vomiting) and NAUSEA (nauseated). On 03-Mar-2021, TENDERNESS (right shoulder became tender) and ARTHRALGIA (right shoulder became very sore) had resolved. On 17-Mar-2021, PRESYNCOPE (felt like she was going to pass out), MALAISE (started feeling really sick), DIZZINESS (lightheaded), MALAISE (didn't feel well), FEELING HOT (felt hot), VOMITING (vomiting) and NAUSEA (nauseated) had resolved. At the time of the report, PAIN IN EXTREMITY (sore right arm) had resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p> |

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| 1220907 | 4/16/2021 | FL | | F | 3/29/2021 | 3/29/2021 | almost passed out; Ear infection; Pneumonia; Arm hurt like crazy and couldnt lift up; This spontaneous case was reported by a health care professional and describes the occurrence of PNEUMONIA (Pneumonia) and PRESYNCOPE (almost passed out) in a 36-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 017B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Pulmonary embolism (Blood clot disorder) and Clotting disorder (Blood clot in leg). On 29-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 29-Mar-2021, the patient experienced PAIN IN EXTREMITY (Arm hurt like crazy and couldnt lift up). On 03-Apr-2021, the patient experienced PNEUMONIA (Pneumonia) (seriousness criterion medically significant) and EAR INFECTION (Ear infection). On an unknown date, the patient experienced PRESYNCOPE (almost passed out) (seriousness criterion medically significant). At the time of the report, PNEUMONIA (Pneumonia), PRESYNCOPE (almost passed out), EAR INFECTION (Ear infection) and PAIN IN EXTREMITY (Arm hurt like crazy and couldnt lift up) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. The patient reports receiving a steroid shot on Saturday and almost passing out Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded. |

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| 1220902 | 4/16/2021 | NJ | 87 | F | 2/16/2021 | 3/16/2021 | <p>urinary tract infection; passed out; foggy; missed her second dose; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of LOSS OF CONSCIOUSNESS (passed out) in an 87-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Urinary tract infection (She was given some medication and has significantly improved with her urinary tract infection.) on 05-Apr-2021. Concurrent medical conditions included Stomach cancer. On 16-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 16-Mar-2021, the patient experienced LOSS OF CONSCIOUSNESS (passed out) (seriousness criterion medically significant), FEELING ABNORMAL (foggy) and PRODUCT DOSE OMISSION ISSUE (missed her second dose). On 05-Apr-2021, the patient experienced URINARY TRACT INFECTION (urinary tract infection). On 16-Mar-2021, PRODUCT DOSE OMISSION ISSUE (missed her second dose) had resolved. At the time of the report, LOSS OF CONSCIOUSNESS (passed out) was resolving and FEELING ABNORMAL (foggy) and URINARY TRACT INFECTION (urinary tract infection) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. Her doctor and oncologist have told her to get the vaccine 1 week from today. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p> |

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| 1220977 | 4/16/2021 | GA | 25 | F | 4/2/2021 | 4/3/2021 | Fainted; Arm soreness; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of SYNCOP (Fainted) in a 25-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 030M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No medical history reported.). On 02-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 03-Apr-2021, the patient experienced PAIN IN EXTREMITY (Arm soreness). On 08-Apr-2021, the patient experienced SYNCOP (Fainted) (seriousness criterion medically significant). On 05-Apr-2021, PAIN IN EXTREMITY (Arm soreness) had resolved. At the time of the report, SYNCOP (Fainted) outcome was unknown. Not Provided DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood test: normal. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Concomitant product use was not provided by the reporter. Treatment medication included Ibuprofen. On 08-APR-2021, patient fainted at the work place. Patient was seen by the HCP on the same day and they did some blood work and all the blood work reports came within normal limits. So the HCP mentioned that possibly it could be a delayed reaction to vaccine and suggested to call the manufacturer and report it.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |

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| 1220848 | 4/16/2021 | IA | 20 | F | 4/16/2021 | 4/16/2021 | When checking out after the 15 minute wait time, patient said she didn't feel very well and fell down hitting her head on the pharmacy counter. When she came to, she said she felt "weird", lightheaded and clammy. We offered her a drink of water and before she could take a drink, she passed out cold. She was out for about 20 seconds and then came to again and we took her down to 1 layer on top and gave her a bag of ice while waiting for the ambulance to arrive. She was treated/observed by the ambulance crew and after another 15 minutes, agreed she was good to go home with her 2 friends that she had ridden with to get her vaccine. |

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| 1220978 | 4/16/2021 | TX | 53 | F | 3/9/2021 | 4/7/2021 | Still very weak; Tired; Sweating; Hurting; Chest oppression; Fainted; Difficulty breathing; Fast Heartbeat; Arm Pain; Couldn't sleep; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of SYNCOPÉ (Fainted) in a 53-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 036A21A and 012A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Allergy (Unspecified). Concomitant products included CETIRIZINE HYDROCHLORIDE (ZYRTEC ALLERGY) for Allergy. On 09-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 07-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 07-Apr-2021, the patient experienced HEART RATE INCREASED (Fast Heartbeat), PAIN IN EXTREMITY (Arm Pain) and INSOMNIA (Couldn't sleep). On 08-Apr-2021, the patient experienced SYNCOPÉ (Fainted) (seriousness criterion medically significant), DYSPNOEA (Difficulty breathing), HYPERHIDROSIS (Sweating), PAIN (Hurting), CHEST DISCOMFORT (Chest oppression) and FATIGUE (Tired). On an unknown date, the patient experienced ASTHENIA (Still very weak). On 08-Apr-2021, SYNCOPÉ (Fainted) had resolved. At the time of the report, DYSPNOEA (Difficulty breathing), HEART RATE INCREASED (Fast Heartbeat), PAIN IN EXTREMITY (Arm Pain), HYPERHIDROSIS (Sweating), PAIN (Hurting), CHEST DISCOMFORT (Chest oppression) and FATIGUE (Tired) had resolved and INSOMNIA (Couldn't sleep) and ASTHENIA (Still very weak) had not resolved. Not Provided The patient went to UC, where the doctors made an electrocardiogram (EKG), bloodwork (within normal limits), and said she should consult the vaccine providers. She is still very weak, and cannot sleep correctly. Treatment medications included Tylenol (acetaminophen) and Advil (ibuprofen). This case concerns a 53-year-old female with a serious unexpected event of syncope and nonserious unexpected chest discomfort, heart rate increased, dyspnea, asthenia, hyperhidrosis, pain, pain in extremity, insomnia, and expected fatigue. Event onset 2 days after second dose |

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| 1220821 | 4/16/2021 | NJ | 48 | M | 4/16/2021 | 4/16/2021 | mRNA-1273. Syncopal event resolved. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. This case was linked to MOD-2021-073382 (Patient Link).; Sender's Comments: This case concerns a 53-year-old female with a serious unexpected event of syncope and nonserious unexpected chest discomfort, heart rate increased, dyspnea, asthenia, hyperhidrosis, pain, pain in extremity, insomnia, and expected fatigue. Event onset 2 days after second dose mRNA-1273. Syncopal event resolved. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. |
| 1220812 | 4/16/2021 | GA | 18 | F | 4/16/2021 | 4/16/2021 | patient fainted about 7 minutes after his shot at the clinic. he was sitting and fainted in his seat. The nurse and pharmacists rushed over right away and he was barely responding. his tongue and lips were seen to be swelling. The nurse administered the auvi-q right away and less than a minute, the patient came back and was confused about what happened. he started sweating and his tongue and lips came back to normal. he was monitored for about an hour - he called his doctor because he refused to go to the hospital. his doctor assured he would be okay after being monitored an hour, said to take benadryl around the clock and call 911 if anything happens. patient agreed |
| 1220782 | 4/16/2021 | TX | 20 | M | 4/16/2021 | 4/16/2021 | Light-headed, dizzy, nausea, vomiting, fainting |
| 1220758 | 4/16/2021 | | 42 | F | 4/15/2021 | 4/15/2021 | syncope, lightheadedness, dizziness, clammy skin followed by unresponsive, shallow breathing and shallow pulse. Appeared to be in shock |
| 1220717 | 4/16/2021 | IL | 36 | M | 4/2/2021 | 4/2/2021 | Patient had syncope and nausea, BP 124/84, HR93, RR16, given apple juice and graham crackers, discharged in stable condition after 1 hour. |
| | | | | | | | Patient fainted post vaccination sitting in chair, fell on floor, scraped facial area, brief LOC, EMS placed on stretcher, recovered and released. |

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| 1220657 | 4/16/2021 | | 29 | M | 4/14/2021 | 4/14/2021 | <10 minutes after vaccination, patient had syncope episode, fall broken by another person, slight bump to head. Patient became conscious, was seated on a chair, and then had second syncope episode followed with convulsions. Stabilized patient. Vitals monitored, assessed by MD and released with referral to PCP. |
| 1220640 | 4/16/2021 | OH | 50 | M | 4/16/2021 | 4/16/2021 | Patient came in for first Covid shot. After the vaccination, he was instructed to stay for 15 minutes in the "post vaccination" area. He went and sat there and I walked back into the pharmacy to finish the paperwork. I then was alerted by a customer that the patient fell off the chair and hit his head. I ran over to him and by then, he was back in his chair and just realized that he had passed out. While I was with him and talking with him, we paged out for code white. I had instructed one of my techs to call 911 as he was pale and palms were sweaty. I had him walk over to the IMZ area and had him lay on some towels and had his feet propped up on a chair. He was given water and I kept talking with him until EMS arrived. They checked his vitals and were asking standard questions and after about 15-20 mins, he was feeling better and didn't want to go to ER. By then, his coloring was much better and he stated he was feeling a lot better. I asked him if he had a headache and he says that he didn't have a headache and was more embarrassed than anything. He thanked me for my professionalism and care and assured me that he felt back to normal. I called him 2 hours later and he was doing well. |
| 1220621 | 4/16/2021 | IN | 38 | M | 4/16/2021 | 4/16/2021 | Patient received vaccine about 5 minutes later he was pale, cold to touch, slouching and sweating. reported not feeling well. reported not being able to hear anything being said to him. Pressure was normal but he responsive but was almost to the point of passing out was sweating profusely. After laying on ground for a few minutes he was responding better said he has poor response to needles. He has passed out previously with needle stick. Emergency services was called patient was evaluated and released in good condition. |
| 1220592 | 4/16/2021 | WA | 26 | F | 4/16/2021 | 4/16/2021 | Near syncope |

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| 1220591 | 4/16/2021 | IL | 37 | F | 3/26/2021 | 3/27/2021 | Approximately 18 hours after the shot, I had a near syncope event. My arms and legs became weak and heavy. My limbs still have not recovered their strength. I cannot be left alone because of near syncope events and I cannot stand long enough to make food or shower by myself. I have had 6 more near syncope events, two of which landed me in the ER. About a week after the shot, I developed moderate vertigo with nausea and a worsening of tinnitus in my right ear. The tinnitus has returned to normal as of today, so far. The vertigo is decreasing slowly. I am still nauseous, especially first thing in the morning. I still have limb weakness and shaking. The intensity waxes and wains. I check my blood pressure multiple times a day, especially when feeling light headed or faint. Most of the time it is in 100-115/ 60- 90. The worst near syncope episodes were 102/56 and 108/60, respectively. Blood sugars within normal range. Oxygen between 97-99% and pulse between 80-95 bpm. Currently, I am on a 30-day event monitor for my heart. My doctor has prescribed a low blood pressure medication, 2.5 mg of midodrone, but haven?t taken it out of fear. |

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| 1220861 | 4/16/2021 | FL | 71 | F | 3/8/2021 | 3/9/2021 | <p>passed out; woke up the next day, caller said she did not remember anything of what happened; hallo feeling in the top of my head/funny feeling; Ended up in the floor/ fall down on the floor and her roommate found her and put her into bed; like a short neckless, red round in the top right of my head, that symptom lasted the whole; Chills; sore left arm for 2 or 3 days; This case was received via an unknown source on 30-Mar-2021 and was forwarded to Moderna on 30-Mar-2021. This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (passed out) in a 71-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 048A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No medical history reported). Concomitant products included TIZANIDINE, SERTRALINE, FUROSEMIDE, ATENOLOL, CLONIDINE, GABAPENTIN, COLESTIPOL and VALSARTAN for an unknown indication. On 08-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 09-Mar-2021, the patient experienced LOSS OF CONSCIOUSNESS (passed out) (seriousness criterion medically significant), MEMORY IMPAIRMENT (woke up the next day, caller said she did not remember anything of what happened), FEELING ABNORMAL (hallo feeling in the top of my head/funny feeling), FALL (Ended up in the floor/ fall down on the floor and her roommate found her and put her into bed), ERYTHEMA (like a short neckless, red round in the top right of my head, that symptom lasted the whole), CHILLS (Chills) and VACCINATION SITE PAIN (sore left arm for 2 or 3 days). At the time of the report, LOSS OF CONSCIOUSNESS (passed out), MEMORY IMPAIRMENT (woke up the next day, caller said she did not remember anything of what happened), FALL (Ended up in the floor/ fall down on the floor and her roommate found her and put her into bed), ERYTHEMA (like a short neckless, red round in the top right of my head, that symptom lasted the whole), CHILLS (Chills) and VACCINATION SITE PAIN (sore left arm for 2 or 3 days) outcome was unknown and FEELING ABNORMAL (hallo feeling in the top of my head/funny feeling) had resolved. Not Provided The</p> |

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| | | | | | | | action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. No treatment information was provided. 2nd dose scheduled on 05Apr2021. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Patient's advanced age along with concomitant medications may have been contributory for the occurrence of the events. Most recent FOLLOW-UP information incorporated above includes: On 01-Apr-2021: No specific follow-up information recorded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Patient's advanced age along with concomitant medications may have been contributory for the occurrence of the events. |
| 1221144 | 4/16/2021 | OK | 34 | M | 4/16/2021 | 4/16/2021 | Patient was shopping in the store after receiving the vaccine and passed out. Patient's spouse lowered him to the ground. Upon arrival to the scene, patient was talking "saying i'm fine). I helped patient to sit up and eventually helped him to sit in a chair. Patient said he could taste the vaccine while receiving the shot and he told the immunizing technician about it. Patient left after 20 minutes without any treatment. |
| 1219681 | 4/16/2021 | | 52 | M | 3/31/2021 | 3/31/2021 | Admitted with acute saddle PE with RV strain on 4/13/21, syncope, required TPA. LLE with acute DVT |
| 1221538 | 4/16/2021 | | 26 | M | 4/13/2021 | 4/13/2021 | Syncope, Flushing/sweating, dizziness; BP 132/76; HR 90, SpO2 99% |
| 1221536 | 4/16/2021 | | 26 | M | 4/13/2021 | 4/13/2021 | Fainted 5 seconds, sweating, loss vision - BP 102/58; HR 68, RR 16 -- > 104/60; HR 89 |
| 1221519 | 4/16/2021 | CA | 34 | F | 4/8/2021 | 4/8/2021 | VASOVAGAL SYNCOPE: SWEATING, DIZZINESS, NAUSEA, FLUSHING, OVERHEATING |
| 1221498 | 4/16/2021 | WA | 18 | M | 4/16/2021 | 4/16/2021 | Patient fainted about 5-10 minutes after receiving vaccine |

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| 1221449 | 4/16/2021 | TX | 66 | F | 4/5/2021 | 4/6/2021 | 04/06/2021 between 3:00 a.m. 9:45 a.m. Early morning hours at home experienced soreness in right arm where injected, chills, body aches, nausea, lightheaded, dizziness, fainted and hit head on hall tree before hitting the floor. When conscious saw tooth on floor beside me , bruises to chin and inside mouth, two front teeth pushed back in mouth. Called dentist emergency, then periodontist who called 911 when I became lightheaded with fluctuating blood pressure and heart rate. Was taken by EMS to Medical Center. Seen by Dr. who diagnosed me with Vasovagal Near Syncope Collapse. Periodontist treatment plan includes 3 implants to replace/repair lost and displaced teeth..ongoing. |
| 1221422 | 4/16/2021 | NC | 39 | F | 4/14/2021 | 4/14/2021 | Presyncope occurred the morning after receiving the vaccine. I did not actually faint, but when I got out of bed in the morning and walked across the house I suddenly had ringing in ears, started sweating profusely, felt lightheaded and felt like I was going to faint. This lasted for at least a couple minutes. I'd received the vaccine at 9:10am on 4/14. The first side effects started around 8:15pm and were along the lines of what I expected: body aches, low fever, fatigue, chills. Overnight, despite the fatigue, I had trouble sleeping due to heart palpitations and intermittently feeling too hot or too cold, and eventually I had a headache. All night, I was falling asleep and waking up a little while later. At around 6:30am on 4/15, after sleeping poorly, my headache had gotten bad enough that I decided to take acetaminophen. I had not previously taken any medicine leading up to the vaccine or after getting the shot. I got out of bed and walked across the house, and that's when the presyncope came. Feeling very faint, I sat down, took the acetaminophen, and waited for the feeling to pass. Once the feeling did pass, I started to feel better pretty quickly, which may have been the medicine working, and then I was able to sleep for a few hours. A slight fever came back over the course of the day, I took a couple more small doses of acetaminophen as needed, and then on 4/16 I woke up feeling fine. |

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| 1221330 | 4/16/2021 | | 39 | M | 4/11/2021 | 4/11/2021 | Patient is a 39 y.o. male with no significant past medical history who came to the ED with a sudden onset of chest pain that radiated initially to his right shoulder then to his left shoulder, left arm and back with intensity of 7/10 starting Tuesday 4/13/21 associated with SOB that is worse when laying flat or taking a deep breath. States he received his second Pfizer vaccine on Sunday, 4/11/2021 at 11 AM and started experiencing fever, chills, headaches, body aches and uncomfortable around 11 PM. He finally decided to take Tylenol x2 on Monday between 2 PM and 11 PM with some relief. He felt a little better on Tuesday morning and did some work from home but later around 7 PM, he notes a temp of 100.2, experienced body aches which he attributes to Vaccine side effects because his wife was also not feeling well post Vaccine. He went to bed and woke up later with cold sweats, felt pain in his chest and back. He described his chest pain as constant pain/heaviness that "felt like someone is sitting on his chest", he later felt pain in his left arm and back prompting ED evaluation. He denies similar episodes in the past, denies abdominal complaints, denies lightheadedness or dizziness, palpitations, shortness of breath at rest, orthopnea, PND, syncope, denies urinary complaints, denies smoking, drinks alcohol socially. States his father has CAD and MI x2 with stent in his 50s, his mother is doing okay with no cardiac history. In the emergency room, his EKG is consistent with pericarditis, initial troponin noted as 4.24 with repeat noted at 8.91, his LFTs are elevated at 107/123. He received full dose aspirin, Lopressor 25 mg with improvement in pain. IMG cardiology is on board with plan for cardiac cath today by doctor. Echocardiogram showed EF of 35-40% with wall motion abnormalities with initial reading. |
| 1221283 | 4/16/2021 | CA | 18 | F | 4/16/2021 | 4/16/2021 | about 10 minutes after getting vaccine. patient fainted |
| 1221271 | 4/16/2021 | OR | 45 | M | 4/5/2021 | 4/6/2021 | Suddenly got violently ill. Illness caused an episode of syncope while driving |

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| 1220974 | 4/16/2021 | NJ | 31 | F | 3/21/2021 | 3/21/2021 | fainted in the bathroom; Dizziness; Headache; This spontaneous case was reported by a non-health professional and describes the occurrence of SYNCOPE (fainted in the bathroom) in a 31-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 047A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (no medical history reported.). On 21-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 21-Mar-2021, the patient experienced SYNCOPE (fainted in the bathroom) (seriousness criterion medically significant), DIZZINESS (Dizziness) and HEADACHE (Headache). At the time of the report, SYNCOPE (fainted in the bathroom), DIZZINESS (Dizziness) and HEADACHE (Headache) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No relevant concomitant medications were reported. No treatment information was reported. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested |
| 1221207 | 4/16/2021 | FL | 35 | F | 4/16/2021 | 4/16/2021 | Patient fainted (syncope) and dizziness for 15 minutes. She was fine later on |
| 1221122 | 4/16/2021 | | 38 | M | 4/14/2021 | 4/14/2021 | Patient had syncope and sweating, BP 141/84, HR87, RR18. Given OJ and monitored, patient was stable and discharged in stable condition |

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| 1221112 | 4/16/2021 | OH | 54 | F | 3/8/2021 | 4/6/2021 | neck is all sore; Fainted; aching all over; Fall; temperature was 100; This spontaneous case was reported by a consumer and describes the occurrence of SYNCOPE (Fainted) in a 54-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 019B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No medical history reported). On 08-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 05-Apr-2021 at 9:10 AM, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 06-Apr-2021, the patient experienced FALL (Fall) and PYREXIA (temperature was 100). On 06-Apr-2021 at 6:00 AM, the patient experienced PAIN (aching all over). On 06-Apr-2021 at 3:30 PM, the patient experienced SYNCOPE (Fainted) (seriousness criterion medically significant). On 07-Apr-2021, the patient experienced NECK PAIN (neck is all sore). At the time of the report, SYNCOPE (Fainted), NECK PAIN (neck is all sore), PAIN (aching all over), FALL (Fall) and PYREXIA (temperature was 100) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 06-Apr-2021, Body temperature: 100 (High) 100. No concomitant medications were reported. On 06 Apr2021 at 6, the patient got up because she was aching all over. The patient fainted (medically significant) on the kitchen floor at about 3:30. Her temperature was 100. Her neck was all sore today 07 Apr 2021, so she was not sure if that was from the fall. Patient stated that she took some pain reliever on 06 Apr 2021. The patient received both scheduled doses of mRNA-1273 prior to the event, therefore action taken with the drug in response to the event is not applicable. Very limited information regarding these events has been provided at this time. Further information has been requested. This case was linked to MOD-2021-069995 (Patient Link).; Sender's Comments: Very limited information regarding these events has been provided at this time. Further information has been requested. |

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| 1221085 | 4/16/2021 | | 23 | F | 4/14/2021 | 4/14/2021 | Pt experienced syncope with flushing and sweating, BP 98/59, HR52, RR18. Outcome not reported. |

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| 1221079 | 4/16/2021 | LA | 49 | F | 3/12/2021 | 4/9/2021 | diarrhea; abdominal pain; Passed out; headache; chills; low grade fever; body aches; Exhaustion; blood pressure was really low; could not sleep that night/it was like if somebody gave me speed; nauseous; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out) in a 49-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. -26B21A and 012A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No medical history was reported.). On 12-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 09-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 2 dosage form. On 09-Apr-2021, the patient experienced INSOMNIA (could not sleep that night/it was like if somebody gave me speed) and NAUSEA (nauseous). On 10-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (Passed out) (seriousness criterion medically significant), HYPOTENSION (blood pressure was really low), HEADACHE (headache), CHILLS (chills), PYREXIA (low grade fever), MYALGIA (body aches) and FATIGUE (Exhaustion). On 12-Apr-2021, the patient experienced ABDOMINAL PAIN (abdominal pain). On 13-Apr-2021, the patient experienced DIARRHOEA (diarrhea). On 10-Apr-2021, LOSS OF CONSCIOUSNESS (Passed out) had resolved. On 11-Apr-2021, HYPOTENSION (blood pressure was really low), CHILLS (chills), PYREXIA (low grade fever), MYALGIA (body aches) and FATIGUE (Exhaustion) had resolved. At the time of the report, INSOMNIA (could not sleep that night/it was like if somebody gave me speed) and DIARRHOEA (diarrhea) outcome was unknown and ABDOMINAL PAIN (abdominal pain), NAUSEA (nauseous) and HEADACHE (headache) had not resolved. Not Provided Concomitant medications were not reported. Treatment medication included acetaminophen. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of |

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| | | | | | | | the product and the start date of the events, a causal relationship cannot be excluded. |
| 1221077 | 4/16/2021 | CA | | F | 4/16/2021 | 4/16/2021 | Patient in observation area began to feel "fuzzy" after vaccination. Patients mother stated she has a history of fainting. Patient was pale, diaphoretic, and limited responsiveness. PHN place patient on cot and administered oxygen at 6 liters. Vital signs of 109/73, HR 72, and 98% oxygen. Patient on oxygen for 10 minutes. Patient recovered well without concern. Patient sent home in stable condition with her mother and told to call her MD if she has further concerns. |
| 1221067 | 4/16/2021 | MD | 53 | F | 4/13/2021 | 4/14/2021 | Fainted twice |
| 1221059 | 4/16/2021 | WA | 50 | M | 4/16/2021 | 4/16/2021 | Patient made an appointment for the COVID-19 vaccine (Pfizer). Patient let us know that he has medical induced anxiety. He has passed out from random medical appointments in the past. Patient was sitting within eye view of the pharmacy. A passing by gentleman said "Dude, are you ok?". I looked over and the gentleman was no longer in his chair. Customer helped gentleman into the chair. The nurse who administered the shot and myself (pharmacist) ran out with the emergency kit. Patient was conscious, but had no color in his face. We gave him water, orange juice, and moist towel for his forehead. Nurse took pulse, it was within normal range. Called 911, EMTs arrived. Patient declined any more help. He walked out of the pharmacy area. Total time of event: 15 minutes. |
| 1221041 | 4/16/2021 | MN | 31 | M | 4/15/2021 | 4/16/2021 | Sore arm at injection site, continuing through next day. Low grade fever/chills about 12 hours after injection. Significant dizziness, lightheadedness, headache and short fainting episode about 16 hours after injection, then mild headache and body ache throughout the rest of the day. |
| 1221029 | 4/16/2021 | CO | 26 | M | 4/16/2021 | 4/16/2021 | Patient felt lightheaded, then passed out. |

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| 1221017 | 4/16/2021 | TX | 52 | F | 1/29/2021 | 2/1/2021 | Vertigo; Blood pressure 195/130; Extreme weakness; Passed out; Pain in the base of neck/Pain in brainstem area of neck; Ear fullness; Pain entire right side of brain/head; Disoriented; dizziness; Off balance; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out), VERTIGO (Vertigo), HYPERTENSION (Blood pressure 195/130) and ASTHENIA (Extreme weakness) in a 52-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 041L20A) for COVID-19 immunization. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (Patient reported no acute or chronic illnesses and no allergies.). Concomitant products included VITAMIN D3 from 10-Jan-2021 to 07-Feb-2021 for an unknown indication. On 29-Jan-2021 at 12:00 PM, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 01-Feb-2021, the patient experienced BALANCE DISORDER (Off balance). On 01-Feb-2021 at 10:00 AM, the patient experienced DIZZINESS (dizziness). On 08-Feb-2021, the patient experienced LOSS OF CONSCIOUSNESS (Passed out) (seriousness criteria hospitalization and medically significant), ASTHENIA (Extreme weakness) (seriousness criterion hospitalization) and DISORIENTATION (Disoriented). On 08-Feb-2021 at 4:00 AM, the patient experienced VERTIGO (Vertigo) (seriousness criterion hospitalization) and HYPERTENSION (Blood pressure 195/130) (seriousness criterion hospitalization). On an unknown date, the patient experienced NECK PAIN (Pain in the base of neck/Pain in brainstem area of neck), EAR DISCOMFORT (Ear fullness) and HEADACHE (Pain entire right side of brain/head). The patient was hospitalized from 08-Feb-2021 to 11-Feb-2021 due to ASTHENIA and VERTIGO, then on 08-Feb-2021 due to HYPERTENSION and LOSS OF CONSCIOUSNESS. On 08-Feb-2021, LOSS OF CONSCIOUSNESS (Passed out) had resolved. At the time of the report, VERTIGO (Vertigo), HYPERTENSION (Blood pressure 195/130), ASTHENIA (Extreme weakness), DIZZINESS (dizziness), NECK PAIN (Pain in the base of neck/Pain in brainstem area of neck), EAR DISCOMFORT (Ear fullness), BALANCE DISORDER (Off balance), |

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DISORIENTATION (Disoriented) and HEADACHE (Pain entire right side of brain/head) had not resolved.
DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 08-Feb-2021, Anion gap (10-20): 7.7 (Low) 7.7 mmol/L. On 08-Feb-2021, Basophil count (0.2-1.4): 1.5 (High) 1.5%. On 08-Feb-2021, Blood calcium (8.5-10.1): 9.3 (normal) 9.3 mg/dl. On 08-Feb-2021, Blood chloride (96-108): 108 (normal) 108 mmol/L. On 08-Feb-2021, Blood creatinine (0.6-1.3): 0.7 (normal) 0.7 mg/dl. On 08-Feb-2021, Blood glucose (70-100): 94 (normal) 94 mg/dL. On 08-Feb-2021, Blood magnesium (1.6-2.6): 2.2 (normal) 2.2 mg/dl. On 08-Feb-2021, Blood phosphorus (2.5-4.9): 3.2 (normal) Normal. On 08-Feb-2021, Blood potassium (3.6-5.2): 3.7 (normal) 3.7 mmol/L. On 08-Feb-2021, Blood pressure measurement: 195/130 (High) BP at 1630: 193/104 BP at 1755: 132/82. On 08-Feb-2021, Blood sodium (133-143): 140 (normal) 140 mmol/L. On 08-Feb-2021, Blood thyroid stimulating hormone (0.36-3.74): 1.74 (normal) 1.74 mIU/L. On 08-Feb-2021, Blood urea (7-18): 9 (normal) 9 mg/dL. On 08-Feb-2021, Body temperature: 98.8 (normal) Time: 1630. On 08-Feb-2021, Carbon dioxide (21-32): 30 (normal) 30 mmol/L. On 08-Feb-2021, Chest X-ray: normal (normal) Impression: No radiographic evidence of acute cardiopulmonary disease.. On 08-Feb-2021, Computerised tomogram head: inconclusive (Inconclusive) Impression: No acute intracranial abnormality Intracranial atherosclerosis. On 08-Feb-2021, Electrocardiogram: normal (normal) normal sinus rhythm. On 08-Feb-2021, Haematocrit (31.2-41.9): 42.9 (High) 42.9%. On 08-Feb-2021, Haemoglobin (10.9-14.3): 14.4 (High) 14.4 gm/dl. On 08-Feb-2021, Heart rate: 88 (normal) Time: 1630 Pulse 59 @1755. On 08-Feb-2021, Mean platelet volume (7.5-11.2): 7.2 (Low) 7.2 fl. On 08-Feb-2021, N-terminal prohormone brain natriuretic peptide (<125-Unknown): 35 (normal) 35 pg/mL. On 08-Feb-2021, Oxygen saturation: 98 (normal) 98 - Room air Time: 1630 98 - Room air Time: 1755. On 08-Feb-2021, Respiratory rate: 18 (normal) Time: 1630 Resp rate 16 @1755. On 08-Feb-2021, Thyroxine (0.7-1.46): 0.98 (normal) 0.98 ng/dL. On 09-Feb-2021, Alanine aminotransferase (12-78): 19 (normal) 19 units/L. On 09-Feb-2021, Anion gap (10-20): 8.5 (Low) 8.5 mmol/L. On 09-Feb-2021, Aspartate aminotransferase (15-37): 24 (normal) 24 units/L. On 09-Feb-2021,

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Bilirubin conjugated (0.0-0.3): 0.2 (normal) 0.2 mg/dL. On 09-Feb-2021, Blood albumin (3.4-5.0): 4.0 (normal) 4.0 gm/dL. On 09-Feb-2021, Blood alkaline phosphatase (45-117): 73 (normal) 73 units/L. On 09-Feb-2021, Blood bilirubin (0.0-1.0): 0.6 (normal) 0.6 mg/dL. On 09-Feb-2021, Blood calcium (8.5-10.1): 8.3 (Low) 8.3 mg/dl. On 09-Feb-2021, Blood chloride (96-108): 112 (High) 112 mmol/L. On 09-Feb-2021, Blood creatinine (0.6-1.3): 0.6 (normal) 0.6 mg/dl. On 09-Feb-2021, Blood glucose (70-100): 86 (normal) 86 mg/dL. On 09-Feb-2021, Blood potassium (3.6-5.2): 3.5 (Low) 3.5 mmol/L. On 09-Feb-2021, Blood sodium (133-143): 142 (normal) 142 mmol/L. On 09-Feb-2021, Blood urea (7-18): 8 (normal) 8 mg/dL. On 09-Feb-2021, Carbon dioxide (21-32): 25 (normal) 25 mmol/L. On 09-Feb-2021, Eosinophil count: 8.1 (High) 8.1%. On 09-Feb-2021, Haematocrit (31.2-41.9): 36.7 (normal) 36.7%. On 09-Feb-2021, Haemoglobin (10.9-14.3): 12.5 (normal) 12.5 gm/dl. On 09-Feb-2021, Lipase (65-230): 176 (normal) 176 units/L. On 09-Feb-2021, Mean platelet volume (7.5-11.2): 7.2 (Low) 7.2 fl. On 09-Feb-2021, Protein total normal (6.4-8.2): 7.0 (normal) 7.0 gm/dl. On 09-Feb-2021, Serum ferritin (3-244): 51.1 (normal) 51.1 ng/mL. On 09-Feb-2021, Ultrasound Doppler: normal (normal) Impression: No significant atherosclerotic plaque is identified. Based on velocities and waveforms, there are no hemodynamically significant stenoses.. On 09-Feb-2021, Vitamin D (30-100): 25.59 (Low) Adult range: Deficiency <20 ng/mL Insufficiency 20-20 ng/mL Sufficiency 30-100 ng/mL. On 10-Feb-2021, Alanine aminotransferase (12-78): 19 (normal) 19 units/L. On 10-Feb-2021, Anion gap (10-20): 8.2 (Low) 8.2 mmol/L. On 10-Feb-2021, Aspartate aminotransferase (15-37): 18 (normal) 18 units/L. On 10-Feb-2021, Blood albumin (3.4-5.0): 3.6 (normal) 3.6 gm/dL. On 10-Feb-2021, Blood alkaline phosphatase (45-117): 70 (normal) 70 units/L. On 10-Feb-2021, Blood bilirubin (0.0-1.0): 0.7 (normal) 0.7 mg/dL. On 10-Feb-2021, Blood calcium (8.5-10.1): 8.5 (normal) 8.5 mg/dl. On 10-Feb-2021, Blood chloride (96-108): 109 (High) 109 mmol/L. On 10-Feb-2021, Blood cholesterol (0-200): 199 (normal) 199 mg/dl. On 10-Feb-2021, Blood creatinine (0.6-1.3): 0.8 (normal) 0.8 mg/dl. On 10-Feb-2021, Blood glucose (70-100): 83 (normal) 83 mg/dL. On 10-Feb-2021, Blood potassium (3.6-5.2): 4.2 (normal) 4.2 mmol/L. On 10-Feb-2021, Blood sodium

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(133-143): 141 (normal) 141 mmol/L. On 10-Feb-2021, Blood triglycerides (0-150): 93 (normal) 93 mg/dl. On 10-Feb-2021, Blood urea (7-18): 8 (normal) 8 mg/dL. On 10-Feb-2021, Carbon dioxide (21-32): 28 (normal) 28 mmol/L. On 10-Feb-2021, Hepatobiliary scan: normal (normal) Impression: Patent cystic duct. Normal gallbladder injection fraction. On 10-Feb-2021, High density lipoprotein (36-86): 54 (normal) 54 mg/dL. On 10-Feb-2021, Low density lipoprotein (<100-Unknown): 133 (High) 133 mg/dL. On 10-Feb-2021, Magnetic resonance imaging: normal (normal) Impression: No acute intracranial abnormality. On 10-Feb-2021, Non-high-density lipoprotein cholesterol: 145 (Inconclusive) Goal ranges depend on risk factors.. On 10-Feb-2021, Protein total normal (6.4-8.2): 6.4 (normal) 6.4 gm/dl. On 10-Feb-2021, Total cholesterol/HDL ratio (0.0-4.3): 3.7 (normal) 3.7. On 10-Feb-2021, Ultrasound abdomen: normal (normal) Impression: Normal complete abdominal ultrasound. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Treatment included escitalopram. Based on the current available information and the temporal association between the product use and the start date of the events a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and the temporal association between the product use and the start date of the events a causal relationship cannot be excluded.

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| 1221004 | 4/16/2021 | OH | 62 | F | 3/10/2021 | 3/10/2021 | sweating; dizziness; weakness; passed out; arm soreness; headaches; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (passed out) in a 62-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No medical history). Concomitant products included LISINOPRIL for an unknown indication. On 10-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 10-Mar-2021, the patient experienced PAIN IN EXTREMITY (arm soreness) and HEADACHE (headaches). On 12-Mar-2021, the patient experienced LOSS OF CONSCIOUSNESS (passed out) (seriousness criterion medically significant), HYPERHIDROSIS (sweating), DIZZINESS (dizziness) and ASTHENIA (weakness). On 12-Mar-2021, LOSS OF CONSCIOUSNESS (passed out), HYPERHIDROSIS (sweating) and DIZZINESS (dizziness) had resolved. At the time of the report, PAIN IN EXTREMITY (arm soreness), ASTHENIA (weakness) and HEADACHE (headaches) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No treatment information was provided. Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded. |
| 1221249 | 4/16/2021 | FL | 22 | F | 4/16/2021 | 4/16/2021 | SYNCOPE AFTER VACCINE ADMINISTRATION, VITALS GOOD, NO TREATMENT NEEDED |

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| 1219820 | 4/16/2021 | NY | 87 | M | 3/16/2021 | 3/17/2021 | Patient passed out the day following the vaccine and was transported to the hospital by ambulance. Hospital ran several tests over a 3 day stay and did not find anything wrong but could not conclude that it was from the vaccine or not. Upon receiving the second dose on 4/16/21 the same adverse event happened the day following the vaccine again. The patient was transported by ambulance to a different hospital, tests were ran and hospital doctor determined it was due to receiving the vaccine because both incidents were the same. |
| 1220076 | 4/16/2021 | GA | 41 | F | 4/8/2021 | 4/9/2021 | woke up overnight feeling extremely nauseated. She was on the toilet holding the trash can and gagging and thinks she remembers putting the trashcan down but then passed out. Her husband found her on the bathroom floor with her jaw clenched. She says the nausea was so intense it felt like alcohol poisoning when she was younger. She did not go to ER. She felt weak and tired for the next several days. |
| 1220062 | 4/16/2021 | DE | 25 | F | 4/11/2021 | 4/11/2021 | About an hour after her vaccine, patient called and said that she was nauseous, vomiting, had passed out twice, a rash from the injection site up to her throat, and her arm was swollen from the elbow up. I told her to take Benadryl and to go to the ER or to the immediate care. I followed up with her the next day and she went to the ER, she said the Benadryl helped her out significantly and that she was feeling much better that day. She was still inquiring about the second shot but, she was following up with her MD on Wednesday. |

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| 1220053 | 4/16/2021 | MA | 49 | F | 3/21/2021 | 3/21/2021 | <p>Typical symptoms began the evening of the day I got the shot (March 21st): sore arm, achy, headache, dizziness, and just generally beginning to feel "off". Took Aleve. Symptoms worsened the next day and I was extremely fatigued and that carried into Tuesday. Taking Advil as needed. Started vertigo exercises "just in case" to help with the dizziness. By the end of day on Tuesday, all symptoms had cleared except headache, dizziness and fatigue. However, I was beginning to feel a sense of "brain fog"? I was starting to have a really hard time writing a simple email without it being littered with typos or inconsistent thoughts. By Thursday I was in my doctor's office/prescribed meclizine and by Friday he sent me to the ER: EKG, CAT scan and blood work all checked out. No "real" explanation for my symptoms except a weird reaction to the second shot. Over the course of the following three weeks, the headache has subsided but flares up from time to time however the "dizziness", disorientation, brain fog has continued. Sometimes it feels like I have a focus problem too? like it takes me a while to register what it is I am looking at. Then the more I try to live a "normal" day, the more I seem to experience something that I refer to as a "neurological meltdown" starting mid-afternoon and by dinnertime I can barely think my way through dinner preparation. ANY stimulation like children singing, TV noise, dog barking, etc. feels intolerable. It is all I can do to keep myself upright and engaged in the evening routine and then I am passed out on the couch. The other way to describe this is that I feel "concussive"? like I have a concussion. I have to wear sunglasses now. I can't listen to music through my headphones anymore? it is just too much for my brain. It is like by the end of the day my "brain battery" is drained and if I doesn't recharge overnight, I wake up off and dizzy and just can't think clearly or remember much of anything. I saw an ENT on April 12th and am scheduled to see a neurologist on May 3rd. I have NO idea what has happened to me but I was a high energy, multi-tasker, never sit down kind of person who exercised daily until the second shot. NOTE: Prior to the second shot, I was running 6 miles three times a week and swimming 1 1/2 miles three times a week.</p> |

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| 1220049 | 4/16/2021 | MT | 38 | M | 4/13/2021 | 4/13/2021 | Patient experienced near syncope immediately following first dose of vaccine. Patient reports that this is a common occurrence following any procedure involving needles. Patient recovered quickly and refused any further treatment prior to leaving the vaccine POD. |
| 1219983 | 4/16/2021 | MI | 46 | F | 4/13/2021 | 4/14/2021 | At 5:00 AM I woke up and walked to the kitchen to take some Tylenol for my headache. I started feeling dizzy, hot and lightheaded, so I went and sat down. I don't remember, but I must've tried walking back to bed and fainted while walking. I was dizzy after the second dose also for several hours, but never actually fainted. |
| 1219969 | 4/16/2021 | TX | 38 | M | 4/16/2021 | 4/16/2021 | Pt reported feeling lightheaded about 10 minutes after receiving his vaccine dose as well as witnessing another pt have a syncopal event. Pt lost consciousness and was gently lowered down to the floor by a bystander. The patient regained consciousness a few seconds after being aroused. The patient was A&Ox3 and was feeling better after 30 additional minutes of monitoring. The patient declined EMS evaluation when they arrived and felt comfortable going home. He believed his anxiety watching the previous event unfold may have caused his syncope. |
| 1219914 | 4/16/2021 | IN | 37 | F | 4/16/2021 | 4/16/2021 | Patient fainted after receiving the vaccine. She felt light headed immediately before fainting. |
| 1219907 | 4/16/2021 | TN | 73 | F | 4/14/2021 | 4/14/2021 | Patient reports received vaccine 4/14/2021. During evening hours began having nausea that persisted all evening. During the night she was awakened. Upon getting up during the night, reports she "went down to the floor." She thinks she may have fainted but is unsure. Reports she was not injured but was unable to get up from the floor. Her husband called EMS who arrived at their home to assist patient from the floor. Reports no other symptoms other than feeling weak today. |

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| 1219876 | 4/16/2021 | CA | 25 | M | 4/15/2021 | 4/15/2021 | At 1455 client had a vasovagal syncopal reaction following 1st dose of Pfizer vaccine. Client stated he had a history of syncope and anxiety with injections and blood draws. No injuries were sustained and client regained consciousness with sternal rub and verbal prompts. Client was unconscious for less than 20 seconds. Vital signs were obtained and were within normal limits. Client denied shortness of breath, headache, nausea, vomiting, diarrhea, dizziness or blurry vision. Client's pupils were PERRLA. Client complained of feeling stiffness and cramping in hands and arms. Paramedic was able to flex hands and arms without resistance, capillary refill was less than 2 seconds. Client offered 911 evaluation and declined three times. Client left via wheelchair and released to care of significant other following a 60 minute observation time and stated resolution of symptoms. |
| 1219856 | 4/16/2021 | NY | 87 | M | 4/13/2021 | 4/14/2021 | Patient passed out (reported as "blacked out") the day after receiving the vaccine. He was transported by ambulance to hospital. This was the second incident (same incident reported after first dose). He does not have any memory of having passed out. |

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| 1220079 | 4/16/2021 | CA | 61 | M | 4/7/2021 | 4/7/2021 | PT RECEIVED HIS COVID-19 VACCINE AND WAS WAITING IN THE OBSERVATION AREA. AFTER ABOUT 10 MIN MY TECHNICIAN NOTICED HIM SIT ON THE FLOOR FROM HIS CHAIR AND SHE CAME TO GET ME. AS I APPROACED HIM HE LOOKED DAZED AND SUDDENLY BLACKED OUT. IN ABOUT 15-20 SECONDS HE AWOKE AND ABOUT 1 MINUTE LATER HE WAS SPEAKING. ROUGHLY 5 MINUTES LATER, EMS ARRIVED AND CHECKED HIS VITALS, BLOOD SUGAR AND EKG. ALL WERE WITHIN NORMAL LIMITS. WHILE TALKING TO PATIENT AND THE TWO LADIES WITH HIM, WE FOUND OUT HE HAD DRIVEN 3 HOURS FROM HIS HOME TO COME TO OUR PHARMACY FOR THEM TO GET VACCINATED. AND THEY PLANNED TO GET ON THE ROAD AND RETURN. EMS SUGGESTED HE GO TO THE HOSPITAL, BUT AFTER 20 MINUTES HE WAS WALING AND TALKING AND DRINKING WATER. HE AND HIS FRIENDS DECIDED THEY WOULD NOT GO TO THE HOSPITAL. I FOLLOWED UP WITH HIM 2 DAYS LATER ON 4/9 AND HE FELT FINE EXCEPT FOR SORENESS AT THE SITE OF INJECTION. HE ALSO RECALLED A TIME WHEN HE HAD PASSED OUT FROM AN INJECTION WHEN HE WAS A TEENAGER |
| 1219845 | 4/16/2021 | GA | 34 | F | 3/19/2021 | 3/20/2021 | Fainted 13 hours after shot. Low-grade fever (up to 102) for 24 hours, chills, slight headache, loss of appetite, fatigue |
| 1219814 | 4/16/2021 | CT | 47 | F | 3/30/2021 | 3/31/2021 | Lightheaded immediately and almost passed out. Felt a tingling in both hands. Metallic taste in mouth for about an hour. 8 hours later had the chills, body aches, headache, sinus pressure, and blocked ears. I developed tinnitus in both ears 24 hours after the shot and it still hasn't resolved 16 days later. |

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| 1219817 | 4/16/2021 | FL | 23 | F | 4/16/2021 | 4/16/2021 | See below Patient is a 23 yof with history of vasovagal syncope c/o syncope secondary to pfizer vaccine dose 1. Witness states she was pacing back and forth in the hallway when she fell from standing position to the ground hitting her head. She was maintained in the supine position and recovered spontaneously shortly after. Appearance was pale and diaphoretic. V/S were assessed. She was provided gatorade and seated in the green chair. She reported a pressure headache in the occipital region. She denies changes in vision, numbness and tingling in hands and feet, pain in her neck or spine, and history of blood thinners. Boyfriend states she was extremely nervous prior to getting the vaccine. Patient reported |
| 1219806 | 4/16/2021 | | 26 | F | 4/16/2021 | 4/16/2021 | Vasovagal syncope within 5 minutes of dose. Rapid recovery and discharged home after 20 minutes |
| 1219769 | 4/16/2021 | GA | 44 | F | 3/11/2021 | 3/11/2021 | Pt vaccinated at 12:30 with COVID-19 Moderna, 1st dose. While waiting in her car at the observation station of the drive-thru site, pt began to feel like her heart rate was up. Alert and talking, no distress noted. VS Pulse 95 bpm, Respirations 16 per minute, O2 sat 99% and BP 142/98. Random blood glucose 93. Pt given ice pack to apply to neck. Pt reported hx of panic attacks and fainting in the past. Staff stayed with pt until she felt better. Pt was discharged to home via her own car she was driving at 1:15 PM. |
| 1219735 | 4/16/2021 | | 37 | F | 4/13/2021 | 4/13/2021 | Syncope, dizziness; Pt hit her head on the stairs. No open wounds, neuro check wnl. BP 93/69; HR 65 RR 17 SpO2 100% |
| 1219715 | 4/16/2021 | GA | 23 | M | 4/7/2021 | 4/7/2021 | Pt received 1st dose of COVID-19 Moderna vaccine at 1:15 PM. While waiting in observation, pt got up to go to restroom at 1:35 pm and fainted. No injury noted. Pt assisted to sitting while in the restroom area, alert and talking. Upon assisting pt to standing, pt fainted a second time in the hallway. Assisted to wheelchair, noted to be diaphoretic but alert and talking. Taken by wheelchair to ER with mother accompanying. Mother reports that the patient had a phobia of needles as a child and has done this before. Call to dad later that evening when unable to reach pt by phone. Dad reports that pt was released without incident. Diagnosed with syncopal episode. |

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| 1219707 | 4/16/2021 | NY | 33 | F | 4/16/2021 | 4/16/2021 | PATIENT FAINTED WITHIN 2 MIN OF THE SHOT |
| 1219706 | 4/16/2021 | NY | 47 | F | 4/13/2021 | 4/16/2021 | Aches and pains Sore throat Fainted 2 days later |
| 1219698 | 4/16/2021 | | 21 | M | 4/13/2021 | 4/13/2021 | Syncope, flushing/sweating. Another pt witnessed pt fall and hit his head on doorway, no LOC. Pt A&O x3, but dizzy/sweaty/pale. RN assisted pt on wheelchair to obs tent + provider called. VS initially 84/45. BP improved, pt pupils + neuro checked by provider. Given multiple PO fluids + crackers. |
| 1220561 | 4/16/2021 | VA | 32 | M | 4/16/2021 | 4/16/2021 | Patient fainted around the pharmacy area within 1-2 min after receiving his covid 19 vaccination. He hit his head on the floor and started bleeding. I approached the patient immediately, he was alert and talking and confused as to what happened. we called emergency right away and paramedics arrived within 5 minutes and patient was taken to hospital for further evaluation. Initial BP 129/74. |
| 1221192 | 4/16/2021 | OR | 65 | F | 4/16/2021 | 4/16/2021 | Patient experienced syncope approximately 7 minutes after injection. Pulse was checked, which was normal. Provided water and patient felt well enough to walk after about 20 minutes of sitting down and drinking water. Called the patient about 1.5 hours later and they reported feeling okay and recovered. |
| 1219853 | 4/16/2021 | NY | 18 | F | 4/16/2021 | 4/16/2021 | Within 5 minutes of vaccine administration patient began to feel lightheaded and passed out in waiting room. Patient lost consciousness several times for intervals of one minute or less. Patient was very sweaty and urinated on herself. We called EMS who took patient to local hospital. |
| 1220436 | 4/16/2021 | IN | 59 | F | 4/14/2021 | 4/15/2021 | Fainting, headache, stomach ache, nausea, weakness, chills |
| 1220551 | 4/16/2021 | TX | 38 | M | 4/16/2021 | 4/16/2021 | Vasovagal syncope post vaccination, fell from chair in waiting area, vitals stable. Advised to allow EMS to examine, refused. |
| 1220509 | 4/16/2021 | WA | 20 | F | 4/16/2021 | 4/16/2021 | patient passed out about 5 minutes after the vaccine. When i asked her questions, she was responding and was full aware. no rash, no difficulty breathing. Patient reported feeling "nausea and hot~~ |

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| 1219794 | 4/16/2021 | MT | 26 | M | 4/2/2021 | 4/2/2021 | Approximately three minutes after receiving the vaccine the patient fainted. Complained of feeling a little warm, otherwise no other complaints. Recovered quickly and had no sequela. |
| 1220128 | 4/16/2021 | | 33 | M | 4/16/2021 | 4/16/2021 | Patient had dizziness followed by syncope, as well as vomiting. Exact time unconscious was unknown, <5 minutes. Vitals returned to WNL within 15-20 minutes. Patient assessed by FD and declined transport, referred to get checked further by GP. |
| 1220491 | 4/16/2021 | | 16 | M | 4/14/2021 | 4/14/2021 | Syncope; HR 97/50, HR 70, RR 16, Temp 97.5, SpO2 97% |
| 1220481 | 4/16/2021 | CA | 19 | F | 4/16/2021 | 4/16/2021 | RIGHT AFTER PATIENT RECEIVED HER VACCINE AT 9:45 AM, SHE REPORTED HERSELF DIZZY. WE IMMEDIATELY WENT OUT THE PHARMACY TO ASSIST HER. WE WERE ABLE TO BREAK HER FALL WHEN SHE STARTS FAINTING AND SLOWLY LIE HER DOWN THE FLOOR. I IMMEDIATELY ASK MY OTHER TECHNICIAN TO CALL 911. PATIENT STARTED SITTING UP AND REQUESTED SOME COLD WATER WHICH WE GAVE. WE WAITED FOR HER TO FEEL BETTER BEFORE WE ASKED HER TO STAND UP SO SHE CAN SIT PROPERLY WHILE WE WAIT FOR THE PARAMEDIC. |

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| 1220477 | 4/16/2021 | NC | 19 | M | 4/16/2021 | 4/16/2021 | Patient experienced loss of consciousness after administration of vaccine. This happened within 45 seconds of administration. This happened 3 separate times within a 5-10 minute time frame. No signs of anaphylaxis were identified during this time. Patient would "faint" briefly (approximately 10 seconds) and then regain consciousness and confirm that he had no symptoms of anaphylaxis. Symptoms observed were loss of color of the face and lips and some diaphoresis. The patient was monitored for any changes and EMS was called. The patient refused EMS service or hospital service. He stated that the "fainting" happened to him regularly whenever he received a vaccine. The total time of the event was approximately 30 minutes and the patient was advised to stay longer for monitoring if he would refuse EMS service, which he did. The patient has since been called and is currently feeling "normal except for being somewhat tired". He has been advised to follow up with his primary care. |
| 1220459 | 4/16/2021 | NY | 27 | F | 4/9/2021 | 4/9/2021 | fever, rash, hives, palpitations, headache, syncope. Lasting 7 days after vaccination. Evaluated in the ED on 7th day post vaccine. |
| 1220424 | 4/16/2021 | TX | 18 | M | 4/16/2021 | 4/16/2021 | Syncope, lightheadedness. Observation had him walk and he fainted while walking. Ate Crepes for breakfast, lunch he had chips and a small cup of water. |
| 1220408 | 4/16/2021 | NV | 24 | F | 4/10/2021 | 4/12/2021 | Syncope the evening of 4/12, witnessed by family. Woke up sweaty, chills and disoriented. Within 30 minutes overall felt much better. Residual symptoms the following day - chest tightness, anxious, fatigue. |
| 1220406 | 4/16/2021 | CA | 19 | M | 4/16/2021 | 4/16/2021 | Patient had a dizzy spell, fainted twice for about 15 seconds each. appeared to have seizure like activity. Called 911 for further assistance. Patient was pale and cyanotic, became alert by the time paramedics got to the site. |

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| 1220402 | 4/16/2021 | CA | 44 | M | 4/16/2021 | 4/16/2021 | Client got Pfizer COVID vaccine at 1405, started feeling light headed, dizzy, and sweaty with a rapid pulse at around 1410. Client was unresponsive and out of it like he passed out for a few seconds and came out of it and was coherent and responsive again. Client was safe, with three EMTs and lead nurse alongside him. Vital signs taken at 1414, BP 138/88, O2 99%, and P 80. Client started feeling better, no longer sweaty or dizzy at around 1415. Client informed healthcare staff that he had not eaten or had any water since 0800. Vital signs taken again 1425, BP 140/90, O2 100%, and P 72. Client was stabilized and ambulated out of the facility and driven home by his mother at 1430. |
| 1220330 | 4/16/2021 | AL | 24 | F | 4/16/2021 | 4/16/2021 | She felt nauseated, dizzy and hot about 10 minutes after she got her injection. Skin was red. She then felt like she was going to pass out, so we sat in the floor with her and she passed out for about 30 seconds. She then came to and slowly cooled off and started feeling better. She sat with us for 45 minutes and then felt well enough to leave with her mother. |
| 1220213 | 4/16/2021 | OH | 31 | F | 4/10/2021 | 4/10/2021 | 1511 Pt c/o feeling like going to pass out, lightheaded, diaphoretic. C/O right eye being blurry vision. OxSat 97%, HR 92, RR 14 easy and un-labored. States this always happens "when I get a flu shot" Oriented x 4. 1515 OxSat 97%, HR 94, Blood sugar 110, Firefighter continued to monitor patient. @1524 states feels a litter better. Right eye is clearing up. States she is diagnosed with syncope. States had tilt table test alone. Continued to monitor pt. Pt states takes 15 mg Clonazepam for anxiety. Pt states mom died one month ago of COVID. @1545 pt states feels better, right eye is no longer blurry. @1557 pt states ready to go home. States does not need anyone to pick her up and she can drive home. RN walked with patient to exit door. RN stated pt had no complaints/issues. |
| 1220262 | 4/16/2021 | WI | 18 | F | 3/25/2021 | 3/25/2021 | Pt fainted after receiving COVID vaccine injection. Resident physician tended to pt. she was awake when laying down and reported feeling much better when sitting up. |

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| 1220466 | 4/16/2021 | CA | | M | 4/16/2021 | 4/16/2021 | Patient came to observation after receiving first dose of the COVID-19 pfizer vaccine. Patient passed out from his chair to floor after about 5 minutes in observation. Patient placed on mat with 6 liters oxygen. Vital signs of 116/68, HR 78, and oxygen saturation of 98%. Patient remained lying down for about 10 minutes on oxygen to recover. Patient moved to sitting up and then standing with stable vital signs. Oxygen removed. Patient had no other concerns and left in stable condition. |
| 1220369 | 4/16/2021 | AZ | 36 | F | 4/16/2021 | 4/16/2021 | Patient is a 36 y/o F here for her 2nd Moderna vaccine this AM. After being observed for 15 minutes pt c/o N/V and ran to the bathroom. Vitals 140/89, 98% RA, 105. Retook vitals after pt stood up (140/95, 100% RA, 83) and pt still c/o Nausea and dizziness. While exiting the restroom the pt fainted as I was assisting her out. I called for help and guided her to the floor. Dr. was on site and assessed the pt. She was initially tachycardic but improved immediately. cool and clammy to touch. Pt had LOC for approximately 15-20 seconds following episode. Vitals: 135/89, 98%RA, 79. After symptoms improved pt was escorted to an exam room where we monitored her for the next hour. Vitals: 0842-129/89, 99% RA, 84; 0847-134/94, 100% RA, 77 with c/o nausea 7/10. At 0852 Dr. assessed pt again. Pt still c/o nausea; isopropyl alcohol sniff provided and PO water; sx improved, but pt needed to "urinate" and was escorted back to the bathroom by myself and her husband. Pt was able to urinate, upon finishing she stood to walk out; I noticed pallor and clamminess, and she then fainted again. I guided her into the chair I had brought into the bathroom and Dr helped me to guide her to the ground; he auscultated a rapid weak radial pulse; slowed breathing: then she "snapped to". Pt did not have any seizure activity but RUE wrist flexed, pressed against wall. Vitals: 132/84, 100% RA, 71. After the second episode; called 911 to help transport the pt for farther evaluation. FD arrived at 0937 to evaluate the pt. Blood glucose was 80, vitals WNL. Pt still c/o Nausea/dizziness/headache on evaluation. Pt transported by EMS to Hospital. |
| 1220299 | 4/16/2021 | CO | 34 | M | 4/16/2021 | 4/16/2021 | patient fainted minutes after receiving the vaccine. |

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| 1220302 | 4/16/2021 | CA | 61 | F | 4/12/2021 | 4/12/2021 | Patient received first Pfizer Covid-19 immunization on 4/12/2021. The shot was administered at 11:01 am into the left upper deltoid. Approximately 3 minutes later patient complained of faintness and experienced syncope. Patient was able to lie on the ground without assistance and her legs were elevated. Emergency services were placed on standby, and a first responder from the fire department was on hand. Patient was responsive and alert, citing tingling in her left arm and an irritated, scratchy throat. Diaphoresis, but no signs of dyspnea or acute anaphylaxis. Blood pressure elevated. Supine position with elevated legs maintained for about 30 minutes. Patient declined EMT evaluation and was able to leave without assistance. |
| 1220205 | 4/16/2021 | VA | 27 | M | 3/16/2021 | 3/16/2021 | Vasovagal syncope caused by COVID vaccine causing a fall to the ground and hit head on the floor |
| 1220200 | 4/16/2021 | PA | 41 | F | 3/25/2021 | 3/25/2021 | *This description is per the director of this substance treatment recovery facility* Resident was found by her roommate and seemed unresponsive to normal questions. Resident began convulsing and eventually stopped. Resident claimed that she was OK but an ambulance was still called and she was taken to The Hospital. She returned to the recovery home the same night. Diagnosis on hospital discharge paperwork "Syncope.~~ |
| 1220355 | 4/16/2021 | | 40 | M | 4/16/2021 | 4/16/2021 | vasovagal syncope, known reaction to needles, rapid improvement, vital signs stable |
| 1220357 | 4/16/2021 | VA | 40 | F | 4/3/2021 | 4/3/2021 | THE PATIENT WAS VASOVAGAL SYNCOPE WITHIN FIVE MINUTES OF GETTING THE SHOT AND WALKING TO OBSERVATION AREA. THE PATIENT HAD LOW BP/ AND WAS TAKEN IN BY AMBULANCE TO THE ER |

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| 1220361 | 4/16/2021 | MI | 22 | M | 4/16/2021 | 4/16/2021 | While in observation area, patient said he was feeling a little lightheaded and then fell. Patient slightly stabilized his fall by grabbing onto a chair, but still fell on floor, hit his head. Patient was unresponsive for a few seconds as more help arrived, then was asked where he was, what vaccine he got, what his name was, he answered all questions correctly. Blood pressure was taken 3 times with blood pressure cuff pharmacy staff had on hand, readings were 171/76, 166/79, 151/91. EMS arrived took additional blood pressure 141/89, blood glucose 117, performed EKG. EMS said BP, EKG looked good. Patient said he had one time passed out around needles as a kid. Today refused hospital, said he felt okay. He did say his head was a little sore still, EMS said he was looking okay, EMS left. Patient stayed for about a half hour after event, then felt fine and went home. |
| 1220321 | 4/16/2021 | NY | 48 | F | 4/8/2021 | 4/13/2021 | I am not sure if my event was caused by the vaccine I received on April 8, but I have a very strong feeling it is, as never in my life have I experienced anything like it. My day began normally, and I just had returned home from an appointment. I had some lunch, and a few minutes later as I was standing in my kitchen, I began sweating terribly, heart was racing, and I felt like I was going to pass out. I managed to make it to a large living room chair, and once I lay down and put my head back, I passed out. My daughter witnessed everything and said when I passed out, my arms were trembling and my eyes rolled back. This lasted for about 30 seconds. She was unable to arouse me for a bit, but when I came to my speech was slurred. I did not know what had happened. My daughter called 911. By the time medics arrived, I was feeling much better and aware of everything happening. They checked for signs of stroke, vital signs, blood sugar, and everything was normal. I was transported to the ER, and my work up there was normal, including EKG and blood work. The physician that I saw diagnosed me with vasovagal syncope and did not feel the event was related to the vaccine. I completely recovered, and like I said I'm not sure if it was related to the vaccine I received or not. I just feel that it may be worth noting since I've never had an experience like this and I'm pretty healthy with really no medical history. |

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| 1213427 | 4/15/2021 | AZ | 33 | M | 3/25/2021 | 4/3/2021 | While taking a warm Epsom salt bath I started to feel faint. About 1 minute after getting out of the bath my vision became worse and I fainted. I was alone at the time so I dont know if hitting my head on the floor or the fainting caused loss of consciousness. I was out for 20 min to 1 hour. Lost 4-8 oz of blood from bloody nose caused by hitting my head on the floor. |
| 1213180 | 4/15/2021 | | | U | | | Possible vasovagal syncope. She "blacked out" in bathroom and fell. Broke ribs and had pneumothorax due to the fall. Had a couple other episodes of "blacking out" in the next 48 hours. Went to E.D. for injury. Work up was done, she mentioned she had just had the vaccine a few days prior and no VAERS was submitted by ED, they dismissed it. According to patient workup was done to detect embolism or hemorrhage and none was found. |
| 1213378 | 4/15/2021 | NJ | 31 | F | 4/10/2021 | 4/10/2021 | Dizziness,Fainted and a quick tremor for couple minutes |
| 1213451 | 4/15/2021 | NC | 48 | F | 4/10/2021 | 4/11/2021 | Around 2am, I woke up and went to the bathroom. I fainted and hit my head on the floor. I have never fainted before. After my husband woke me up, I threw up multiple times. |
| 1213426 | 4/15/2021 | MI | 54 | F | 4/11/2021 | 4/11/2021 | Patient was scheduled for 2nd dose of covid vaccine. Patient had a severe resp reaction to 1st vaccine shot. Patient was ok to receive seoncd dose per PCP documentation. Upon receving 2nd dose patient had severe allergic reaction to dose. Patient couldnt breathe, throat was swelling. EPI was administstered. EMS was called. Vitals were stable blood pressure148/85, heart rate 81 2liters O2 100%. Patient passed out for 10seconds at 2:08pm. Pt just had a flat affect. Patient abruptly woke up and started to hallucinate. 2:10pm Viltals at this time were blood pressure 168/98, heart rate 79, 2 liters 100%. At 2:15 patients throat was closing and pt was gasping for air. Patient was super anxious and a 2nd dose of EPI was given. EMS arrived at 2:24 BLOOD pressure 157/77 heart rate 87 2 liters O2 100%. EMs took patient to hospital to be further evaluated. Patients husband was at bedside with patient the whole time. Went to ER and was discharged 5 hours later to home. |

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| 1213464 | 4/15/2021 | NY | 67 | F | 4/6/2021 | 4/7/2021 | 24 Hours post vaccination: full body rash for 3 days. Took Benadryl for two days it went away. Both left and right hips hurt so I couldn't walk. Took Tylenol and aspirin for two days. Pain went away. 8 Days later vomiting and diarrhea, Right and left hips hurt again. Fainted. Taking fluids, Tylenol and aspirin. Tired. |
| 1213381 | 4/15/2021 | | 17 | M | 4/13/2021 | 4/13/2021 | After receiving first Pfizer vaccine, patient had a vasovagal episode. Patient states he became dizzy, lightheaded, and became diaphoretic prior to syncope. There were some mild seizure-type activity after the syncope. Patient was transferred to the ED. In the ED, patient experienced no further episodes of seizure activities. Patient was evaluated, observed, and later discharged with PCP and neurology referral. |
| 1213487 | 4/15/2021 | SC | 53 | F | 4/12/2021 | 4/13/2021 | Patient reports they injected Humira on Sunday 4/11, then they got their J&J COVID vaccine on Monday 4/12. Patient reports they developed a fever of 103°F for 2 days and could not get out of bed the first day. Patient has also had a migraine for 3 days that is improving, and today it comes-and-goes. Patient also takes estrogen, so they are concerned for thrombosis risk. Patient denies blurred vision, fainting or loss of consciousness, or other changes in mental status. Patient also denies swollen or redness in their calves and ankles. |
| 1213325 | 4/15/2021 | | 93 | M | 1/25/2021 | 2/15/2021 | K62.89 - Rectal pain R42 - Dizziness R41.0 - Delirium R55 - Syncope R77.8 - Elevated troponin M25.552 - Left hip pain Z86.2 - Hx of thrombocytopenia M79.662 - Pain in left lower leg |

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| 1213268 | 4/15/2021 | MO | 23 | M | 4/13/2021 | 4/13/2021 | Pt received the vaccine at 7:15pm and was told to wait in the observation area for the required 15 minutes. The pharmacist started to walk back to his station when he heard a thud. He turned to look at the patient and they were face down on the ground. The pharmacist put his hand on the patient's shoulder to check if they were okay. Patient had urinated and left a puddle on the ground. When the patient awoke, they stated that they were okay except for a sore head. The pharmacist checked their head for any scrapes, bruises, or bumps. None were found and the patient was asked to wait in a chair for an extra 25 minutes. Personally monitored for 5 minutes for additional syncope then had their companion stay close to them. After waiting for 30 minutes, the patient said they felt fine and asked to leave. |
| 1213183 | 4/15/2021 | CA | 79 | M | 2/3/2021 | 2/4/2021 | Received the vaccine on 2/3/2021 I felt fine that whole day. The following day as I was showering I got lightheaded and fell in the bathroom . I went to the ER and the sent me home because I had no injuries. My blood pressure was high . For a few days I got lightheaded off and on. Then on 2/24/2021 I went for the second dose again i felt fine the whole day. On 2/25/2021 as I was showering I got lightheaded and fainted. My family called the ambulance and I was hospitalized from 2/25/2021 to 2/27/2021. I had facial fractures, fractured septum (nose) and cut upper lip received 10 stitches and teeth and gums were numb and still are a little numb. |
| 1213541 | 4/15/2021 | CO | 26 | F | 4/9/2021 | 4/10/2021 | Extreme headache, lethargy, and fatigue morning after vaccine. Pale clammy skin, cold-sweats, diarrhea, nausea, vertigo, dizziness, fainting, lightheadedness, muffled hearing, and blurred vision, later that afternoon. Pale, clammy skin, cold-sweats, vertigo, fainting, lightheadedness, muffled hearing, and blurred vision spells 1-2x/day since vaccine 1 week ago. |
| 1214291 | 4/15/2021 | CO | 32 | M | 4/15/2021 | 4/15/2021 | Fainted a few mins after receiving the dose. Was sitting for his 30mins post vaccination due to allergy history and fell to the floor. Cut his upper lip during the fall. Will go to PCP to determine if he will need stitches for the lip. Woke within 15 seconds of fall, sweaty forehead and palms. Reported no similar incidents in the past after receiving a vaccine. |

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| 1213132 | 4/15/2021 | NY | 25 | M | 4/15/2021 | 4/15/2021 | About 10 minutes after receiving the first shot of COVID-19 (PFIZER), patient fainted and fell to the floor from the chair he was sitting on. He gained consciousness within seconds and was responsive. Patient reported feeling dizzy but no signs of trouble breathing or any other symptoms. EMS arrived shortly and assessed the patient. According to the EMS, patient's vitals were all normal and patient refused to go to the hospital with them because he was feeling fine. |
| 1213092 | 4/15/2021 | KY | 22 | F | 4/13/2021 | 4/14/2021 | fainted and had decreased HR. has only ever fainted when she was very young. history of only one other episode. |
| 1213088 | 4/15/2021 | DE | 40 | F | 3/19/2021 | 3/19/2021 | Patient (driver of vehicle) passed out shortly after leaving the vaccination lane, while proceeding to the post administration area. Patient was involved in a 5 vehicle in the post administration area. Patient was assessed on scene by emergency unit and transported by emergency unit to local ER for further evaluation. |
| 1213090 | 4/15/2021 | PA | 43 | F | 4/7/2021 | 4/7/2021 | I had multiple side effects, which I will list below, but the one that was most concerning and which I have not seen listed as a typical side effect is that I got very dizzy and fainted, losing consciousness briefly. I got my vaccine around 10am. By 9pm I had severe chills and was achy. Around midnight I got up to use the bathroom and felt dizzy, then I fainted. Thankfully I had called for help beforehand, so my husband caught me and called my name until I regained consciousness. Immediately after coming to I started sweating profusely. My temperature at that time was 100.3. Through the rest of the night and for the following day and night I experienced nausea, chest pains, achy, sore arm, weakness, and fatigue. I felt relief from symptoms by about 48 hours after my vaccination. |

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| 1213221 | 4/15/2021 | CT | 33 | M | 4/12/2021 | 4/12/2021 | PATIENT SAID THAT VACCINE BURNED AFTER ADMINISTRATION. HE GOT REALLY HOT AND NEEDED TO REMOVE HIS MASK TO BREATHE. I ESCORTED HIM TO A SEAT NEXT TO HIS WIFE AND HE FAINTED. HE REGAINED CONSCIOUSNESS AFTER 1 MINUTE. GOT HIM A COLD CLOTH FOR HIS HEAD AND A GLASS OF WATER. ABOUT 15-20 MINUTES LATER HE FAINTED AGAIN. HE REGAINED CONSCIOUSNESS AFTER 30 SECONDS. EMS FINALLY ARRIVED AFTER 2 CALLS TO THEM. EMS CHECKED HIS VITALS AND PERFORMED AN EXAMINATION. HE DECLINED TO BE TAKEN TO THE HOSPITAL. AFTER ABOUT 2HRS HE LEFT ON HIS OWN POWER |
| 1214071 | 4/15/2021 | OK | 27 | F | 3/19/2021 | 3/19/2021 | Passed out and experienced involuntary shaking (possibly tonic-clonic seizure) |
| 1214429 | 4/15/2021 | CA | 64 | M | 4/9/2021 | 4/9/2021 | Patient was found on the floor next to his chair facing forward in observation area. When we attended patient alert, awake and oriented x3. Denied any resp distress. No HA. No n/v. Patient has h/o dvt on coumadin. No h/o DM. recommended further evaluation in ER due to patient had syncope, on coumadin, hit his head to ground. But pt declined and signed AMA. patient reported that he will seek emergency if he feels any worsening symptoms. |
| 1214424 | 4/15/2021 | MA | 19 | F | 4/15/2021 | 4/15/2021 | 19 yro f presented with syncope. loss of consciousness after receiving vaccination. pt was pale cold and clammy. pt was brought to evaluation area and assessed. pt vitals were taken. pt regained consciousness during transport to evaluation area. pt was hypotensive bp 65/43 hr 53 spo2 95% rr 20 pt was provided cold water. pt was placed on ems crew 4 lead ekg. pt appeared to have normal sinus rhythm. pt vitals improved over a short period of time under ems monitoring. fire ems was called to transport patient to er dept. pt final vital set was 116/70 hr 65 spo2 100% ems arrived and pt care was transferred to fire ems. |

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| 1211955 | 4/15/2021 | FL | 31 | M | 4/14/2021 | 4/14/2021 | Patient received vaccine and was asked to move to observation area. Shortly after sitting down the patient came back to pharmacy counter and stated he was feeling dizzy. Just as the pharmacist was telling him to sit back down he fainted and fell on the floor. He recovered rather quickly (matter of seconds?) and tried to sit up right away. Pharmacist asked him to stay on the floor for a moment, the store's first responder (MIC) was called over to pharmacy. After a minute of sitting on floor the patient got up on his own accord and transferred to a nearby chair. His BP was taken twice per emergency protocol of pharmacy. Patient initially appeared calmmy and BP was 132/81, pulse 44, respirations 18 at 12:25p. BP was 142/89, pulse 48, respirations 16 at 12:35. Patient was given both a water and a Gatorade while he was seated. Patient stated he had not eaten anything yet for the day. Patient was repeatedly offered medical services (i.e. "Do you want a medic? Do we need to call an ambulance?") The patient repeatedly refused any further medical treatment. After further observation patient was able to stand, check out at the pharmacy and left the store on his own accord. |
| 1213074 | 4/15/2021 | CA | 20 | M | 4/9/2021 | 4/9/2021 | FAINTING. RECOVERED SOON WHEN WE HAD HIM LYING DOWN. CALLED 911, THEY TALKED HIM AND CONFIRMED THAT HE WAS CONCIOUS AND DIDN'T COME. BP CHECKING (80/42)..REALLY LOW. HE STAYED AT OUR LOCATION FOR 1 HOUR AND LEFT. CHECKED ON HIM ON 4/14/21, HE STATES HE IS FINE. |

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| 1214413 | 4/15/2021 | OK | 27 | F | 4/11/2021 | 4/11/2021 | Pt sts that shortly after her vaccine she became lightheaded and dizzy. She had a similar issue when she gave plasma in the past (she passed out completely). She did not tell staff ahead of time that she passes out with vaccines and was sitting in her chair at the time of administration. Pt sts she immediately got lightheaded and dizzy and she passed out before she even knew what happened. Pt did fall out of her chair and hit her head on the floor. She was responsive within 10 seconds per bystanders and was AOX4. She does have a small amount of swelling to an approximate 1" hematoma to the R side of her head just into her hairline. She was treated and released by EMSA. She refused transport to the hospital. She did have pain at the site of the hematoma. PMS was intact X4 and her neuro function was intact per EMSA during exam. Pt left POV. |
| 1214379 | 4/15/2021 | | 44 | M | 4/1/2021 | 4/2/2021 | Acute kidney failure, unspecified Hypocalcemia Hyperkalemia Syncope ARF (acute renal failure) Abnormal EKG Elevated troponin Elevated LFTs |
| 1214319 | 4/15/2021 | WA | 40 | M | 4/15/2021 | 4/15/2021 | syncope ... patient fainted about 5 minutes after vaccination in lobby of pharmacy under observation. |
| 1214188 | 4/15/2021 | OR | 23 | F | 4/15/2021 | 4/15/2021 | 10:04 Vaccine given 10:20 Pt fainted, mother caught her so she did not injur herself. Pt looked like was briefly seizing. Called 911. Layed pt flat on back while protecting her head and elevated feet. Pt was alert, awake, breathing normal. began to check pulse and BP. EMTs before completion and took over. Pt did not go with EMTs |
| 1214094 | 4/15/2021 | MA | 34 | M | 4/15/2021 | 4/15/2021 | Fainted |

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| 1213944 | 4/15/2021 | CO | 29 | M | 4/12/2021 | 4/12/2021 | Patient was looking pale a minute after the shot, I asked how he was doing, he responded by saying he felt very dizzy. I asked him to take slow deep breaths, gave him some water. About after 1 more minute he passed out (very unresponsive but still breathing, pupils very dilated) pulse was slow but still palpable. Tried ammonium smelling salts, that did not bring patient around. Called 911. Tried patting patient and talking to patient to bring them back to consciousness. After about a minute or two patient was able to respond to me. He knew his name and date of birth and where he was. Asked him to wait for ambulance to check vitals. Patient said he still felt very dizzy. Kept his head down and eyes closed. Once EMS arrived they checked his vitals, determined BP was low (they did not tell me a number). They monitored patient's vitals for 10-15 minutes. BP did not "bounce back" per EMS so they took him to the hospital for IV drip possibly. |
| 1214059 | 4/15/2021 | RI | 21 | M | 4/15/2021 | 4/15/2021 | pt experienced what appeared to be a vaso vagal episode. pt had fainted in his seat and was attended to by ems staff. pt was wheelchaired out to hall way for evaluation. pt vitals were taken at 205pm bp 76/45 hr 55 spo2 96% rr 18. pt admitted to previous experience whengiving blood. pt complained of tension in chest. pt was placed on 4 lead ekg and found to be in what appeared to be normal sinus rhythm. pt vitals wre taken again at 2:15pm bp 105/67 hr 65 rr 18 spo2 100% ra. pt was "feeling better" and was able to walk out of vaccine clinic unassisted. |
| 1214035 | 4/15/2021 | NC | 17 | F | 4/14/2021 | 4/15/2021 | 3 episodes of vasovagal syncope this morning, clustered over approximately 1 hour, on the day following her second dose of Pfizer Covid-19 vaccine. |
| 1214024 | 4/15/2021 | GA | 54 | F | 4/6/2021 | 4/6/2021 | Upon receiving shot pain shot down arm to left hand. When standing up felt faint. Remained in store for 20min until fainting feeling subsided. That night got fever, chills, muscle aching, joint pain, abdominal pain and nausea, diarrhea severe headache. The fever and chills stopped next morning. Continued having moderate muscle aching, nausea and severe headache for 3 days. On the line of severe migraine. It has been 6 days and I still have mild muscle aching, joint pain, nausea, headache, fatigue, and faint. |

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| 1213987 | 4/15/2021 | MI | 61 | M | 4/13/2021 | 4/14/2021 | After receiving my shot around 4:00 pm on April 13, 2021, I was restless and did not sleep well that night. When I woke up on April 14, I was tired but otherwise felt fine except my arm was a bit sore. However, after working at home for a couple of hours, shortly before 10:00 am I began to feel nauseous. I rushed to the bathroom thinking I was going to throw up, and almost immediately fainted. My wife and sons found me on the floor and woke me up. I threw up shortly after and felt pretty lousy the rest of the day with low grade fever, chills, body aches, fatigue, and a headache. I began to feel better at night and had a good night of sleep. Today (April 15), I feel fine except I'm a little tired. |
| 1213960 | 4/15/2021 | TX | 21 | M | 4/13/2021 | 4/13/2021 | Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Hypotension-Mild |
| 1213953 | 4/15/2021 | CA | 34 | M | 4/8/2021 | 4/8/2021 | S: Syncope/vasovagal after COVID vaccine while in observation lot. B: Staff responded to honking horn - pt reported he has just come to from passing out- had been on the phone with partner while event happened and she reported the same. Diaphoretic, lightheaded and out of it. Pt laid flat and treated with ice and supportive care. Vitals stable. History of vagal response around shots previously. A: Syncope after vaccine R: Appropriate care provided. |
| 1213945 | 4/15/2021 | GA | 25 | F | 4/14/2021 | 4/14/2021 | Systemic: Seizure-Severe, Additional Details: pt had seizure approximately 5 minutes after receiving vaccination,was sitting in waiting are,stood up,passed out,hit head,then seized.was short.called 911.pt apparently has history of seizures with vaccination.was cleared by ems. worker called pt at 6 pm and pt was fine.. |

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| 1214208 | 4/15/2021 | KS | 21 | F | 4/13/2021 | 4/13/2021 | The patient received the Pfizer vaccination and had filled out their consent form having everything checked no. After given their immunization they were instructed to sit for the required 15 minutes. AMA the patient got up from chair and approached the counter to ask if they could use a restroom. When the pharmacist approached her, she fainted and bumped her head on the dividing partition on her way down. Pharmacist went out immediately to the patient. 911 was called. The patient was already conscious again. The paramedics to her with them, as they wanted to check her. She was still orthostatic, and they advised to her they felt it would be a good idea. Employee tried to call on 4/14/21 and the patient did not answer. |

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| 1211435 | 4/15/2021 | CA | 41 | F | 3/25/2021 | 3/31/2021 | Immediately after the JANSSEN vaccine I felt tenderness in my jaw that lasted for about two days. My body was sore, my Legs felt like I was having cramps ?growing pains? I also was experiencing allergy/asthma like symptoms that included difficulty breathing and shortness of breath that worsened over time I couldn't speak in full sentences or laugh I was unable to walk 10 steps without gasping for air, after a couple of days of trying to maintain and cope with my theses symptoms. I couldn?t take it anymore, as I was preparing myself to go to the emergency room. I got into the shower the steam from the shower felt like it was suffocating me and I passed out my children took me out of the bathtub and rushed me to the emergency room where I was given several tests that include x-ray, CAT scan, artery bloodwork and vein bloodwork. I was being treated for asthma and given several different breathing treatments and steroids, unable to keep my stats at a decent level and the hard rebound even after continuous treatments, I was admitted because the breathing treatments were not effective. I am still uncertain of the ?actual outcome? the Hospital doctors treated me for an asthmatic episode and gave me directions how to handle my asthma i was prescribed prednisone and referred to my primary that would then refer me to a pulmonologist and cardiologist. At the hospital I was told that there was black spots on my lungs I was told that I was being treated for infection, but then also told it could be pneumonia no certain answer was ever given and i was given and antibiotic and was also told that I needed to see my primary for a way to maintain my asthma. The antibiotics seem to work for a couple of days and again I'm back to having difficulty breathing, shortness of breath, muscle pain soreness and mild lingering headaches. STATUS ASTHMATICUS ASTHMA EXACERBATION ACUTE TRACHEOBRONCHITIS SHORTNESS OF BREATH |

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| 1212066 | 4/15/2021 | CA | 46 | M | 4/10/2021 | 4/14/2021 | Systemic: Body Aches Generalized-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Exhaustion / Lethargy-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: difficulty walking had to call 911-Severe, Systemic: Nausea-Severe, Systemic: Weakness-Severe, Additional Details: per Nurse, pt developed severe vertigo and pt had developed weakness and lead to difficulty walking |
| 1212131 | 4/15/2021 | RI | 56 | M | 4/14/2021 | 4/14/2021 | passed out while using the rest room at 11:30 p.m. family member found me and woke me up. went back to bed. |
| 1212083 | 4/15/2021 | TX | 34 | F | 3/8/2021 | 4/10/2021 | Unsure if related. On April 10 had severe cramp/popping sensation and almost passed out. Was ok after but had mild cramping sensation sense and one day of mild spotting on 4/14. Awaiting to see PCP, about events. |
| 1212067 | 4/15/2021 | NC | 48 | F | 2/10/2021 | 2/10/2021 | fever, syncope |
| 1211965 | 4/15/2021 | CA | 27 | M | 4/14/2021 | 4/14/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: Seizure-Medium, Additional Details: Patient presented with seizure like symptoms for 15 seconds. The health hub concierge noticed and called myself over. He was out of it for maybe 15-20 seconds. I asked him questions to see if he was coherent. He was able to tell me where he was and his name. Patient stated he has history of vasovagal syncope so no EMS was required. BP taken at 101/59 on right arm. He waited an hour before leaving with his mother. |
| 1211928 | 4/15/2021 | FL | 16 | F | 4/14/2021 | 4/14/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild |
| 1211919 | 4/15/2021 | GA | 35 | F | 4/14/2021 | 4/14/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Nausea-Mild, Additional Details: Pt sat in store for 30 minutes after injection (20 minutes after feeling faint). Was feeling well when she left. |

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| 1212256 | 4/15/2021 | | 54 | U | 4/14/2021 | 4/14/2021 | Patient was observed post Covid-19 immunization for 15 minutes . During the observation period, she experienced an adverse reaction with the following symptoms: near syncope, hypotension, diaphoresis. Vaccine was administered at 1510 Assessment : Time of assessment 1524 . Pt stated she began to feel like she was going to pass out. She was diaphoretic, clammy, and hypotensive upon assessment. Vitals at 1525 were; BP 63/40, HR 40, OXYGEN 99%, RR-16. Orthostatic VS were completed upon EMS arrival at 1553; BP 153/88, HR 73, OXYGEN 100%. Actions taken: Vitals sign taken EMS called at 1530. VAERS form obtained and completed by RN. Hand off to EMS upon arrival at 1550. Upon assessment of patient |
| 1211822 | 4/15/2021 | FL | 25 | M | 4/14/2021 | 4/14/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Medium, Systemic: Hyperventilation-Mild, Additional Details: Patient was waiting after getting dose, fainted, ambulance was called. Patient awoke, severe sweating and heavy breathing but responsive. Was monitored by EMT but left without further incident. |
| 1212262 | 4/15/2021 | OK | 20 | F | 4/14/2021 | 4/14/2021 | 5 min after administration pt fainted. head was down and hangs were in a catatonic state. Pt was not responsive and clammy, but within 5 minutes pt was talking and had recovered. |
| 1211424 | 4/15/2021 | CA | 50 | F | 4/13/2021 | 4/13/2021 | blackout or passed out, dizziness, unable to walk, bitter taste in the mouth, dry heaving, rash, shortness of breath, extreme blood pressure immediately upon injection for 1 hour. Continued reactions 48 hours, extreme fatigue, blood pressure, dizziness, metal and bitter taste in the mouth, migraine, stomach upset, red polka dots on hands, itchiness underarms, cough, sore throat, and fever |
| 1211167 | 4/15/2021 | MI | 21 | F | 4/14/2021 | 4/15/2021 | Vomiting and kinda almost fainted. After vomiting I was fine. Lasted roughly 5-10 min. Feeling faint could have been cause by over panicking about vomiting and the vaccine but I though I would share. |

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| 1211008 | 4/15/2021 | | 61 | F | 4/5/2021 | 4/12/2021 | vaccine reaction-passed out. c/o worsening headache and feels tire. states broke out sweat, stomach pain, HA, leg cramping and passed out (for about 30sec according to husband) on Mon. took Advil several days. last Advil 0600. J&J vaccine on 5 Apr. 61 yo f w/spouse c/o ongoing headache w/concerns for single episode of 'passing out' approx 48hrs pta approx 30-45 sec per spouse at bedside; Pt states nighttime episode w/preceding leg crampings, sweating, dizziness, sat on footstool and per spouse passed out but caught by spouse and avoided injury; spontaneous recovery w/o further issue from that episode, spouse denies any post-syncope seizure-like activity/urinary incontinence/tongue biting; Pt and spouse concerned. for cerebral venous thrombosis; Pt has sig hx of prior neurosurgery for posterior/occipital schwannoma around 2017, successfully removed, w/o further findings or complications on f/u (last DEC 2020) to include repeat imaging at that time Pt states has been taking advil OTC for ha but no sig relief at this time; Pt defers need for medications at time of provider evaluation; Pt denies any fevers/ns/chills, cp, SOB, palpitations, dyspnea, abd pain/cramping, current nvd, prior syncope, fam hx of MI/SCD/dysrhythmias. |
| 1210980 | 4/15/2021 | OR | 31 | M | 4/14/2021 | 4/14/2021 | Syncopal: After instructed to sit in the lobby for a 15 minute observation time, the patient walked 20 feet over to my consultation window after a couple minutes reporting lightheadedness/dizziness and requested a seat in my vaccination room. Upon making my way through the pharmacy to open the door the patient collapsed from a standing position to the floor. The patient regained consciousness almost immediately after the fall and reported no injuries. EMS was also on scene by coincidence, shopping. The patient declined their assistance. |
| 1210960 | 4/15/2021 | CA | 34 | F | 4/8/2021 | 4/9/2021 | I woke up the day after my vaccine and felt very dizzy and fainted. (I had other symptoms that I would've expected after the covid shot as well... mild fever, chills, etc.) |

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| 1214469 | 4/15/2021 | NV | 34 | M | 4/13/2021 | 4/13/2021 | PT. PASSED OUT AFTER RECIEVING THE VACCINE. WHEN HE CAME AROUND HE WAS SWEATY AND CLAMY. EMT WAS CALLED. HE ORIGINALLY HAD LOW BLOOD PRESSURE. WEHN THE EMT SHOWED UP ALL VITALS CAME BACK GOOD. |
| 1214629 | 4/15/2021 | PA | 61 | F | 2/6/2021 | 2/7/2021 | Fainted after rising from recumbent position with resultant facial injuries and broken teeth |
| 1211837 | 4/15/2021 | NY | 33 | F | 4/14/2021 | 4/14/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Mild, Systemic: Nausea-Medium |
| 1212691 | 4/15/2021 | NH | 25 | M | 4/15/2021 | 4/15/2021 | Shortly after receiving vaccination patient had a witnessed syncopal event while in a seated position. Pt fell forward from the chair sustaining a nasal injury resulting in epistaxis. EMS was called to the scene. Initial VS prior to EMS arrival was: BP138/80, HR 74, RR 16. When EMS arrived patient was moved into a seated position on the floor. Within 1 minute patient stated that they didn't feel well like they were going to pass out again, became nauseous and pale. Patient placed in supine position and repeat VS of BP: 95/53, HR 72 and RR 16. Patient was placed on EMS stretcher and transported to Hospital Emergency Department for further evaluation/treatment. *Of note, patient stated afterwards that he has passed out with prior lab draws/immunizations.* |
| 1212990 | 4/15/2021 | TX | 26 | M | 4/2/2021 | 4/9/2021 | Fainted on April 9, waking to racing heart and shortness of breath. Chest pain and shortness of breath persisted. Visited Emergency Room evening of April 11. Multiple tests revealed diagnosis of pulmonary embolism. Was immediately transferred to hospital early April 12. Received blood thinning treatment and catheter operation. Discharged April 15, with prescription of Eliquis for continued blood thinning. |

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| 1212973 | 4/15/2021 | DE | 36 | M | 3/19/2021 | 3/19/2021 | According to the witness (driver of the vehicle): The patient received the vaccine and within five seconds was slumped over in the seat, passed out. The driver notified staff and they were instructed to exit the vaccination lane, prior to proceeding to post administration area. Staff requested on scene BLS unit for evaluation. The patient became alert and oriented and allowed BLS to perform an assessment. BLS reported all vitals good. Patient stated that his has never happened before and didn't remember anything beyond receiving the vaccine until he woke up. Patient refused BLS transport. Driver stated they were self transporting to the ER for further evaluation. |
| 1212952 | 4/15/2021 | CA | 46 | F | 4/15/2021 | 4/15/2021 | Patient passed out immediately after receiving vaccine. Pale, diaphoretic, and hypotensive (80 systolic). Patient sent to the ED. |
| 1212947 | 4/15/2021 | PA | 30 | F | 4/9/2021 | 4/9/2021 | 1hr after vaccine: lightheaded + had presyncope when moving around, stretching, or moving from sitting to standing. Injection site sore from arm to shoulder and into neck, unable to lift arm for 3 days. 3hrs after vaccine: developed shortness of breath that is only getting better after day 6, Needed to use asthma inhaler several times. Prior to vaccine, had not needed inhaler for many months. Day after vaccine: developed severe migraine, vomited. Had persistent brain fog and made mistakes at work, didn't start to get better until day 6 post-vaccine. Brain fog and shortness of breath have not fully resolved but do seem better today and more transient rather than constant (day 6 post vaccine). Side effects persisted far longer than expected, and were more severe than my peers, so I feel like it is notable. |
| 1212915 | 4/15/2021 | OH | 42 | M | 4/1/2021 | 4/1/2021 | patient was nervous about getting vaccine. Asked him to wait in out waiting area to be checked on. after couple minutes he came upto register and said feeling dizzy. I brought him in consultation room,he sat on chair ,gave him water to drink. then I let him lay down on floor,he passed out,but was talking to me,answering my question,called 911,EMT came in few minutes,checked everything. They said he might got anxious about getting vaccine,checked BP everthing was fine |
| 1212893 | 4/15/2021 | GA | 29 | F | 4/14/2021 | 4/14/2021 | Near Syncope Episode, Monitor |

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| 1212822 | 4/15/2021 | SC | 47 | M | 4/14/2021 | 4/14/2021 | Patient received Moderna vaccine dose 1 at approximately 2:30 pm on 4/14/21. After about 10 minutes, the patient had a syncopal event. 2 pharmacists quickly rushed over and aided in laying him on the floor. His feet were lifted off the floor and leaned against a chair. He was sweating profusely and his face was red. He has no prior history of fainting. He stated he only had a power bar to eat all day and has severe anxiety from receiving vaccines. After the patient started to feel better, he sat up on his own on the ground. He given a granola bar, chips, a soda, and some candy. After finishing the snacks, the patient sat in the chair and was advised to stay for at least an additional 15 minutes. |
| 1212209 | 4/15/2021 | IN | 49 | F | 4/13/2021 | 4/14/2021 | Felt dizzy and not well- at work. Put head down between legs and next thing I remember is laying on the floor (having passed out for at least one minute). Tried to sit up and passed out again. When I woke up the second time (unknown duration) I was sweating over entire body and remained on the ground. Waited ten minutes until someone found me. EMT was called. Normal heart rate, blood pressure, EKG at scene. All blood work was within normal range. Hematocrit 12.1, blood glucose level 102 1.5 hours after episode. Spent approximately 5 hours under care of either EMT or emergency room care. |
| 1212727 | 4/15/2021 | DE | 42 | M | 4/11/2021 | 4/11/2021 | As described by the patient: Patient (driver) was feeling anxious, received the shot and almost immediately started to see white spots and was dizzy. The patient asked to be directed out of the vaccine lane (prior to proceeding to the post administration area) to just get some air. The patient got out of the car, felt dizzy and fainted. Patient fell to the ground in a sitting position. Patient was assessed by BLS and refused transport. Patient switched positions and allowed his passenger to drive off scene. |
| 1213031 | 4/15/2021 | PA | 22 | F | 4/15/2021 | 4/15/2021 | Warmth, dizziness, temporary loss of hearing shortly after vaccination. No nausea, diaphoresis, or tunnel vision. Near syncope prevented by lying down quickly. Typical vasovagal reaction for her. Rapid recovery with all normal vital signs. No orthostasis. |

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| 1212630 | 4/15/2021 | WI | 34 | M | 4/14/2021 | 4/14/2021 | Description: __On 4/14/2021, Patient arrived for his COVID vaccine. Moderna lot number 047B21A. This was his first dose of Moderna. Patient did not disclose to staff any pre-existing medical issues prior to vaccine administration at screening or to nurse prior to administration of vaccine during screening process. Patient was deemed safe to receive vaccine based on information he provided to both screening nurses and administration nurse. Vaccine administered by RN into left deltoid via IM injection. Patient immediately shared he has a history of ?passing out? after injection was provided, information client did not share during original screening process. Patient then lost consciousness for brief moment. Onsite contracted paramedics called to assess directly as event unfolded. The RNs notified at assisted directly as well. Client regained consciousness within a few seconds of event Privacy screens were placed for patient dignity and privacy. Patient assisted to wheelchair by onsite EMS crew. Patient was then taken to EMS area and further evaluated by onsite EMS crew. Sheriff Detputy outside area for additional backup if needed. RN remained with EMS crew for duration to assure Public Health RN available for assistance. EMS assisted client to cot and had client lay flat. Vitals assessed with machines. B/P 105/60 initially Patient slow to respond but answered questions appropriately. Patient shared he has been seeing a neurologist for fainting spells and other health issues. Additionally shared asthma history and is on lisinpril, Advair and Benadryl for allergies. Took all medications on day of event. Repeat b/b 114/62 pulse ranged from 59-66. O2 sats WNL on room air. EMS placed 12 lead. Patient noted to be in sinus to brady rhythms. EMS then called the hospital for further evaluation due to patient continuing to remain unstable. Patient was agreeable to transfer to hospital for further eval. At time of transfer, patient was alert, orientated, and responding. No IV placed at time o transfer of care to transport. RN updated team that patient was being transferred to local hospital for further eval. |

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| 1212611 | 4/15/2021 | OR | 40 | M | 4/11/2021 | 4/11/2021 | Immediate vasovagal reaction to the vaccine with bradycardia to 30, pale, quickly improved without additional intervention. History of fainting reaction to any shots and blood draw. Family at his side. The patient is not driving today. |
| 1212586 | 4/15/2021 | PA | 30 | M | 4/11/2021 | 4/11/2021 | Patient sitting in observation area, fainted and slid out of the chair landing on left cheek. |
| 1212497 | 4/15/2021 | PA | 36 | M | 4/11/2021 | 4/11/2021 | Patient felt faint, stood up for assistance and lost consciousness and fell to the floor. It was warm at the site and wait time approximately 1 hour. Patient admitted that he was dehydrated. Has a history of fainting. |
| 1212474 | 4/15/2021 | | 71 | F | 2/20/2021 | 2/25/2021 | Death R05 - Cough J96.90 - Respiratory failure R55 - Syncope R41.82 - Altered mental status I95.9 - Hypotension M25.551 - Right hip pain Z79.01 - On apixaban therapy |
| 1212392 | 4/15/2021 | OH | 50 | F | 4/13/2021 | 4/13/2021 | When i took the first does, i passed out the morning after the vaccine and had fever for 2 days. I also had body ache and a light cough. The second dose, i had sever chills starting within 3 hours of the injections. Thru out the night i was freezing but my skin was hot to the touch and i had a fever. The second day i was very sensitive to light and sounds. I couldn't keep my eyes open and had no energy to do anything. I had chills the whole day. I was bundled in 3 blanket and still shivering. The following day i couldn't remember the event of the prior day. It felt as if i was in fog the whole day. Note: I have COVID end of January 2021 |
| 1212304 | 4/15/2021 | OR | 41 | F | 4/13/2021 | 4/13/2021 | About five pm after a nap, I woke up went to the restroom, as I was standing in front of mirror I got a weird feeling and the next thing I knew my boyfriend was waking me up and I had passed out and hit my head. I was so out of it I could not leave the bathroom for about five minutes and i was just sitting on the floor sweating. He then moved me to the bed sitting up, where I was so out of it we didn't know what to do, I have never has episodes like that before in my life. we went straight to the ER for tests |

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| 1212801 | 4/15/2021 | | 27 | F | 4/10/2021 | 4/10/2021 | Patient received vaccine and fainted shortly after administration. Patient was taken to the Emergency Department for further evaluation. Patient stated she has had similar reaction from previous vaccinations. |
| 1215844 | 4/15/2021 | IN | 30 | M | 4/15/2021 | 4/15/2021 | Pt said he felt extremely hot, sweaty, and dizzy. He then fainted, falling and hitting the side of his face. |
| 1215450 | 4/15/2021 | NC | 23 | M | 4/11/2021 | 4/11/2021 | 4/11 vaccination 12:46 12:51 They had us go sit in observation. I felt fine and all of a sudden I felt dizzy and felt near syncope, sweaty. I raised my hand. 2 EMT monitored my HR and BP; both high. Gave me some water, cold compress. Symptoms went away. I went to bed Sunday night, woke up at 230am to chills, shaking, sweats, feverish. That lasted thru till 8/9am and all day Monday I was pretty fatigued. Tuesday symptoms I was pretty much back to normal. I contacted my PCM with recent J&J news. My platelet numbers were normal (blood work done a few weeks before vaccine). Monitored by endocrinologist |
| 1216022 | 4/15/2021 | IL | 23 | F | 4/15/2021 | 4/15/2021 | patient fainted few minutes after administration. was alert and aware after |
| 1216007 | 4/15/2021 | OH | 33 | M | 4/14/2021 | 4/15/2021 | patient reported that he received the dose yesterday and this morning at 10 am passed out while sitting on the toilet. Woke up slumped over the bath tub |
| 1215986 | 4/15/2021 | WA | 22 | M | 4/15/2021 | 4/15/2021 | arrived to post observation after his first dose of Moderna. Pt stated he was dizzy. Pt appeared pale. Pt was A+Ox4. Medics were called and initial BP was 88/40. Pt states hx of syncope after shots. Pt was given juice and water and was able to speak during his entire time in post observation. Pt began to state he was feeling better but just wanted to sit for a while. Pt was clammy and states "I knew this would happen". Pt BP and HR rose to WNL. Pt standing without dizziness. EMTs released Pt at 1650 to continue monitoring a bit longer. 1630 Vitals BP 88/40 HR 50 RR 18 O2 sat on RA 98% 1635 VS BP 90/50 HR 70 O2 on RA 99% 1640 BP 108/62 1645 VS BP 112/60 HR 72 O2 Sat on RA 98% |

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| 1215942 | 4/15/2021 | MI | 22 | M | 4/8/2021 | 4/9/2021 | Seven days of side effects, including fatigue, body aches, headaches, chills, and body temperature issues. After one week, still getting severe headaches on the eighth day which is today 4/15/21. Passed out after vaccine. |
| 1215931 | 4/15/2021 | DE | 58 | F | 3/23/2021 | 3/23/2021 | hot, darkness in eyesight, passed out, urinated |
| 1215872 | 4/15/2021 | PA | 27 | F | 4/15/2021 | 4/15/2021 | Patient received first dose of vaccine and about 5 to 10 minutes later patient fainted and hit her head while waiting in pharmacy area after receiving the shot. She quickly regained consciousness and two pharmacists had her sit on ground to elevate her legs. Also gave her water. Had her stay in pharmacy waiting area until she was ok to leave. |
| 1216033 | 4/15/2021 | OR | 44 | F | 4/11/2021 | 4/11/2021 | Reports fainted in the car. When clinical staff arrived, the patient is alert and oriented. Reports fainting, nausea, and weak. HR 48-50 and BP 90/60 initially. Improved in a few minutes to HR 60 and BP 120/60 and remained stable, symptoms eventually resolved before leaving the site. The patient is the driver today and here alone. Advised her to have someone drive her to her second appointment and tell the vaccinator that she had a reaction to the first dose so she will be directed to 30 minutes observation line. |

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| 1215858 | 4/15/2021 | TX | 21 | M | 4/15/2021 | 4/15/2021 | At the pre-counsel stage, the patient said that he was a little nervous about getting this immunization, but wanted to go ahead and do it. I counseled him on the immunization and sent him into the booth to get the shot. Technician administered the vaccine and then told Technician that he felt a little nauseous. Technician told him to stay seated. A few seconds later the patient passed out and started slipping down the chair. Technician grabbed him from behind and called me over to assist. I yelled for Staff to call 9-1-1 and a code white. I held him from the front and Technician held him from the back and we slowly lowered the patient to the floor. Technician sat behind the patient to hold him up while I assessed the patient and tried see if he was responsive. The patient was breathing and had a pulse, so I patted him on the face and chest to see if he would become responsive. After about 15 seconds, the patient became responsive and confused. He asked what happened and if he got the shot yet or not. After talking to the patient for a moment he said he was fine, but needed to vomit. I gave him a trash can and he vomited. We gave the patient some water and sat with him on the ground for a few minutes until the paramedics arrived. The paramedics took the patient's vitals and the patient said he felt fine and declined going to the hospital. We had the patient sit in the observation area for another 30 minutes. He said he felt totally fine and was ready to go home. |
| 1216039 | 4/15/2021 | TX | 18 | F | 3/13/2021 | 3/25/2021 | 12 days after COVID vaccine, patient had episode of syncope, preceded by dizziness and confusion. |
| 1215817 | 4/15/2021 | OR | 50 | M | 4/9/2021 | 4/9/2021 | Patient presents with a potential reaction to the COVID19 vaccine. I was called to evaluate the patient in the car lineup into the monitoring area. The patient had a moderate vasovagal episode without syncope. He was given oral hydration, placed supine, and moved to the monitoring area. He improved rapidly. With close monitoring and hydration, he improved to baseline and was returned home with his wife as the driver. |

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| 1215577 | 4/15/2021 | PA | 36 | F | 4/15/2021 | 4/15/2021 | Pt felt light headed and warm several minutes after the vaccine. She has passed out with blood draws in the past and says her symptoms now are similar to previous episodes. Transported to med obs at 1500. Pt given water and crackers and almost immediately feels better. Pt released to home by self via public transportation at 1522. Vitals as follows: 1500 BP 135/91 HR 85 SPO2 98 1505 BP 125/80 HR 91 SPO2 98 1510 BP 125/80 HR 82 SPO2 99 1515 SITTING BP 125/84 HR 85 SPO2 100 1520 STANDING BP 150/88, 124/79 HR 93 SPO2 100 |
| 1215570 | 4/15/2021 | CA | 16 | F | | 4/15/2021 | Patient became clammy and fainted after vaccine administration. Episode lasted about 10-15 minutes. Patient became alert and oriented and felt fine. |
| 1215565 | 4/15/2021 | WA | 23 | M | 4/9/2021 | 4/9/2021 | Patient presented with a potential reaction to the COVID19 vaccine. I was called to his vehicle in the vaccination tent. The patient had a witness vasovagal with true syncope. The patient was roused within 2 seconds and was responsive. He was moved to the monitoring area, placed in the supine position, and closely observed. He was given aggressive oral hydration. |
| 1215553 | 4/15/2021 | CA | 28 | M | 4/15/2021 | 4/15/2021 | At about 1520 during observation period, Pt reported feeling dizzy, light headed, clammy and sweaty followed by syncope while in the passenger seat of car. RN crushed ammonia inhalant and placed under Pt's nose and he immediately regained consciousness. Pt became alert and oriented x4. Instructed to recline seat, elevate legs and do PLB. Pt reported feeling better after a few minutes. Water given and observed for total of 30 min. Pt reported symptoms resolved and ED precautions given. Pt verbalized understanding and left in stable condition in passenger seat of car. |

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| 1215519 | 4/15/2021 | CA | 35 | M | 4/15/2021 | 4/15/2021 | At 1520 staff was notified by another patient in the court yard that patient not feeling well; assessed patient- noted to be nauseated was oriented to person and time; not oriented to place. Denies chest pain/SOB/tightening of throat/ voice is unchanged./ breathing well 1525 VS checked; 140-92 1526O O2 saturation auration noted to be 97%; noted to orient to person, place and time now (pt stated he has history of getting dizzy and almost fainting after blood draws) 1531 Patient verbalizes that he is feels better 11538 Patient stable for discharge |
| 1215481 | 4/15/2021 | PA | 62 | U | 4/15/2021 | 4/15/2021 | s/p vaccine 10 min, patient began to feel lightheaded and faint. She was safely lowered to the floor at which time sx improved. She was transported via litter to observation 1. No syncope, CP, SOB, paresthesia. Observed patient while supine with some improvement of sx. Positive h/o similar sx that lasted "all day: Pt drove self here from work. Mild HA Vitals: @ 1507 lying HR 101, BP 157/81, O2 97, @1519 lying HR 90, BP 136/81, O2 98, @1529 sitting HR 93, BP 150/89, O2 99 Pt feeling better with minimal dizziness |
| 1215871 | 4/15/2021 | PA | 27 | F | 4/15/2021 | 4/15/2021 | Pt received Moderna dose #1. Pt experienced what looked to be seizure and temporary loss of consciousness about 8-10 mins. into 15 min post-vaccine observe time. Pt was gently placed on floor and legs elevated by staff 911 called. EpiPen on hand, but not used as patient regained consciousness within 1 min or so and no c/o SOB, airway constriction - could verbalize same. Pt lucid and conversational, but did ask "why am I on the floor" - no recollection of syncope or seizure. No hx of seizure disorder, diabetes, or needle phobia, but states she did feel similar when naval piercing took place. |
| 1216326 | 4/15/2021 | MN | 30 | M | 4/14/2021 | 4/14/2021 | Patient received vaccine and walked out of the vaccination room to sit down in the waiting area. Patient passed out and fell out of his chair. The nurse, pharmacist and physician's assistant working in the clinic attended to patient. Patient had low blood pressure and was disoriented. PA put patient's leg up on chair for a few minutes until the ambulance arrived. EMT's checked patient out and he then was picked up. |

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| 1214599 | 4/15/2021 | MA | 23 | F | 4/15/2021 | 4/15/2021 | PT received COVID vaccine. PT was accompanied by her mother. PT stated she had a history of fainting post receiving vaccines. PT immediately felt dizzy and experienced syncope. PT was laid down on the ground and EMS immediately responded. Foxborough fire/rescue also arrived on scene to evaluate and treat PT. PT regained alertness and was assisted on to a wheelchair so that she may be moved to an area for further evaluation. PTs condition improved. PT decline transport and was released to her mother after. |
| 1214528 | 4/15/2021 | CA | 42 | F | 4/15/2021 | 4/15/2021 | Near syncope slight tachycardic-90's sudden episode of shaking |
| 1216567 | 4/15/2021 | MO | 51 | F | 4/8/2021 | 4/9/2021 | Fainted without warning while attempting to take second dose of Extra Strength Tylenol. Had a fever and chills and severe arm soreness. |
| 1216548 | 4/15/2021 | CA | 19 | F | 4/14/2021 | 4/14/2021 | Parient fainted after receiving Pfizer vaccine. |
| 1216525 | 4/15/2021 | CA | 58 | F | 1/4/2021 | 2/5/2021 | I feel well for 7-10 days and then feel ill for 1-3 days. Low-grade fever, feverish, body and muscle aches, severe headache, fatigue, fainting, weak. I had my first vaccine on 1/14/2021 and my second vaccine on 2/4/2021. I felt ill after my first vaccine, however symptoms wee not severe. After my second vaccine, I became very ill. Vaccine was administered by pharmacy at my place of work. |
| 1216458 | 4/15/2021 | CA | 47 | F | 3/14/2021 | 3/23/2021 | I go to work but I can breathe. I said to my manager I can't work. I need to come back home. I drove my car very difficult. After I come home, I can't breathe so my husband called 911. I was fainting. I check everything. I have a problem, I can't breathe when I read or phone. Now I am better than old. I don't know what happened. I think it is the problem when I take the vaccine. |
| 1216438 | 4/15/2021 | MD | 19 | M | 4/11/2021 | 4/11/2021 | Lightheadedness and headache about 8 hours after vaccination, restless sleep during the night. Next morning before taking a shower felt lightheaded and sick to stomach. After my shower I fainted and had an ankle contusion due to fall. |

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| 1216029 | 4/15/2021 | CA | 25 | F | 4/8/2021 | 4/8/2021 | Syncope 10 minutes after administration while in waiting area. In and out of consciousness for 10 minutes. Severe hypotension per EMS. Once laid supine patient recovered fully and was not transported to hospital. No interventions or studies done. |
| 1216383 | 4/15/2021 | | | U | | | At 1855 observation nurse assessed patient. Patient fainted in observation line per wife statement, presented with cyanosis of the lips, pale in skin color, diaphoretic and incontinent. Vitals upon assessment: BP- 76/48, HR: 68, Temp: 35.1, O2 Sat: 75%. Wife reported that patient took 0.25 mg of Xanax at 1400 and then again at 1615 to calm nerves. Second set of vitals obtained: BP- 86/50, HR: 69, O2 Sat: 97%. 911 called, they arrived around 1600 where patient left AMA. |
| 1216054 | 4/15/2021 | GA | 31 | M | 4/15/2021 | 4/15/2021 | Today 4/15/21, patient was administered the Moderna COVID-19 vaccine. Prior to the vaccination, his wife mentioned to us that he has a severe phobia of needles and has passed out previously to other shots. He had no other issues on his PQCF preventing him from receiving the vaccine. The PQCF was reviewed with the patient by pharmacist. Tech administered the vaccine under supervision of both pharmacist and other technician due to his phobia. Patient received the vaccine with no issues except obvious nerves and a few minutes later while still in the booth, he reported not feeling well. We got him a bottle of water and he went to the post-vaccination waiting area with his wife. We were monitoring him closely and noted that his head was slumping into his wife's stomach when he was sitting down, and he appeared ill. Immediately, we got patient in supine position on the floor with his feet on a chair elevated. Cold ice packs were put on his head, neck, and wrists. Within 5-10 minutes, he was feeling much better. He sat back up in the chair, still with ice packs, and drank water. Patient was asked to stay for 30 minutes so we could continue to monitor him. After 30 minutes, he left with no issues. |

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| 1216270 | 4/15/2021 | OH | 74 | M | 3/13/2021 | 3/14/2021 | Patient received vaccine on Saturday morning. On Sunday morning, he experienced chest tightness that resolved with no treatment. On Monday evening, he fainted walking to the bathroom. Wife states that patient regained consciousness within a few seconds. EMS was called and arrived about 2 minutes after the episode. Wife reports all vitals and EKG were normal when paramedics checked patient out. |
| 1216224 | 4/15/2021 | CA | 33 | M | 4/15/2021 | 4/15/2021 | Pt had an episode of syncope. He was sitting in his car at the time and did not fall or hit his head. He momentarily lost consciousness but came to after being physically tapped on shoulder. He reported having similar episodes when he has had his blood drawn. EMS was contacted and his blood pressure was 70/40 and pulse was 90. EMS was unable to get a blood glucose reading, Pt fully recovered and was picked up by his wife. |
| 1216199 | 4/15/2021 | IL | 17 | F | 4/15/2021 | 4/15/2021 | 1705- Pt passed out right after vaccine. Pt regained consciousness about 3-5 seconds later, stated that she couldn't hear anything. Pt moved to the observation area in a wheel chair. 1715- Pt passed out again, ammonia inhalants used. Regained consciousness 3 seconds later. Pt sweaty. Ice placed to back of neck. Pt moved to cart. First set of vitals @ 1717: Spo2: 100% HR: 53 BP: 83/42 Water and snack given to pt. Second set of vitals @ 1720: Spo2: 95% HR: 54 BP: 88/48 Third set of vitals @ 1726: Spo2: 97% HR: 64 BP: 102/64 Pt sitting up and talking with staff an mother, color in face improving. Pt states she is starting to feel better. Fourth set of vitals @1732: Spo2: 99% HR: 67 BP: 103/66 Pt sitting at 90 degrees, eating and drinking. States she does not feel nauseous. Last set of vitals @ 1537: Spo2: 100% HR: 62 BP: 94/63 Per mother she normally faints with vaccines. Pt states she is feeling much better. Reminded pt and mother to keep up with fluids. |
| 1216197 | 4/15/2021 | WA | 66 | F | 3/24/2021 | 3/25/2021 | sudden nausea, lightheadedness, passed out, severe chills, all over body aches; lasted several hours; recovered at home |
| 1216131 | 4/15/2021 | FL | 26 | M | 4/5/2021 | 4/10/2021 | Passed out after stretching once, heart palpitations multiple times, light headedness |

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| 1216100 | 4/15/2021 | NC | 30 | F | 4/14/2021 | 4/14/2021 | At approximately 7:30 pm (almost 9 hours after receiving the second Moderna vaccine), I began to have chills and a low grade fever of 100.4. My neck also became extremely stiff. The chills continued to persist and each hour my temperature increased. At 10:00pm my fever was 103 in the ear and I took 1000mg Acetaminophen. The fever went down to 101 overnight and eventually the chills subsided. The morning after the vaccine at 6:20am, I went to take a shower and nearly passed out in the shower - experiencing tunnel vision, ringing in ears, and extreme nausea. The rest of the day, I continued to have a low grade fever between 100.0-100.4, muscle and joint pain, bad neck stiffness, headache, occasional eye pressure, intermittent nausea, and fatigue. The symptoms improved by 8:00 pm (about 33 hours after the vaccine). |
| 1216056 | 4/15/2021 | VA | 23 | F | 4/10/2021 | 4/10/2021 | Syncope |
| 1216432 | 4/15/2021 | CA | 34 | M | 4/15/2021 | 4/15/2021 | RN assessed patient. Pt presented cyanosis of lips, diaphoretic, incontinent, bp: 76/48, hr: 68, temp 35.1, o2 sat: 75% wife of patient reported pt passed out in observation and that patient took Xanax 0.25 mg at 1400 and again at 1615. fire dept arrived around 1800- pt left ama per fire dept . |
| 1214640 | 4/15/2021 | RI | 46 | M | 4/11/2021 | 4/12/2021 | After receiving the J&J vaccine on Sunday afternoon, when my husband got up on Monday morning he passed out in the bathroom and was unresponsive. The EMTs arrived and were able to revive him in the ambulance. When they reached the hospital he was put on life support. After he coded again in the Emergency room they told me he was without oxygen for too long and was taken off the respirator. He passed away at 4:10 PM. |
| 1214838 | 4/15/2021 | VT | 41 | F | 4/11/2021 | 4/13/2021 | Patient has been unable to take a deep breath - has sensation of dizziness - has sensation of fainting |
| 1214824 | 4/15/2021 | TX | 29 | M | 4/15/2021 | 4/15/2021 | Vasovagal syncope. States hadn't had anything to eat or drink, snack and water provided. Vitals taken/stable, rested on cot for an hour before leaving. |

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| 1214816 | 4/15/2021 | FL | 52 | F | 4/15/2021 | 4/15/2021 | Patient was sitting in observation, post injection. Patient states that she got dizzy and fainted. Nursing staff saw the patient fall over and hit her head on the wall as she was falling to the floor. Patient was turned on her back and assessment was started. Patient was hooked up to a 12 lead EKG, vitals were obtained BP was low at 91/58 and pulse was 51, R:22 and O2:98%. Patients head was assessed for any trauma and none was noted, patient did report that she bit her tongue and a small laceration was noted on the tip. 911 was called and patient was transported via EMS. |
| 1214812 | 4/15/2021 | CT | 55 | F | 4/13/2021 | 4/13/2021 | Started with dizziness, then nausea, tingling sensation, lump in throat. Then racing heart and heart palpitations. Blood pressure dangerously high. Then extreme tiredness and passed out. Then ambulance was called |
| 1214784 | 4/15/2021 | UT | 25 | F | 4/6/2021 | 4/6/2021 | As I was given the shot, I passed out. I stayed for 15 minutes and went home, Then, I threw up. |
| 1214737 | 4/15/2021 | CA | 32 | M | 4/8/2021 | 4/8/2021 | syncope. collapsed from sitting position. emergency services called and arrived. administered aid. stabilized patient but he and wife refused further emergency services. left on his own recognizance |
| 1214840 | 4/15/2021 | | 62 | F | 3/6/2021 | 4/10/2021 | N17.9 - AKI (acute kidney injury) R19.5 - Occult blood positive stool E87.6 - Hypokalemia R55 - Syncope |
| 1214663 | 4/15/2021 | MI | 27 | F | 4/11/2021 | 4/11/2021 | Patient came into the pharmacy with her mother to receive the JANSSEN COVID-19 vaccine. Per technician that witnessed the event the patient passed out while next to her mother while walking over to the chair to wait 15 minutes after immunization. The mother started yelling and the patient ended up in the chair, did not fall onto the floor. At this time the senior technician called 911. The patient regained consciousness, was breathing but appeared pale in complexion. The patient verbalized that her heart was racing. EMS arrived, patient was put on oxygen and transported to the hospital. |

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| 1214673 | 4/15/2021 | | 25 | M | 4/15/2021 | 4/15/2021 | Pt had a syncopal episode 5 minutes after receiving the vaccine. He stood up to notify a staff member when he passed out and fell, hitting his head and sustaining abrasions to his right hand. Pt recalls what happened prior to the syncopal event. He experienced a similar event in the past after receiving the flu shot. Pt also did not eat or drink anything prior to coming here. EMS was notified and pt was brought to a ER. |
| 1214607 | 4/15/2021 | NV | 39 | M | 4/14/2021 | 4/14/2021 | Patient passed out while receiving the vaccine. |
| 1214592 | 4/15/2021 | | 19 | M | 4/15/2021 | 4/15/2021 | dizzy/syncope BP 152/117 P 70 Spo2 99% Reoeat BP 60/P 90/P |
| 1214546 | 4/15/2021 | | 25 | F | 4/15/2021 | 4/15/2021 | Syncope |
| 1215447 | 4/15/2021 | NE | 31 | M | 4/15/2021 | 4/15/2021 | PT PASSED OUT AND FELL OUT OF HIS CHAIR HITTING HIS HEAD ON THE CONCRETE FLOOR. |
| 1216083 | 4/15/2021 | MD | 53 | F | 3/21/2021 | 4/8/2021 | About a week ago: frontal and occipital head pain, lightheadedness, syncope for seconds, right calf pain, shortness of breath |
| 1214542 | 4/15/2021 | MN | 36 | F | 3/28/2021 | 3/28/2021 | Lightheaded then passed out, woke up with chest pain, gradually very low pressure and seizure |
| 1214540 | 4/15/2021 | MN | 46 | F | 4/14/2021 | 4/14/2021 | After 20 minutes the following happened... Dizzy, high,, very hot, labored breathing. I then fainted. I then had blurred vision and need to go to bathroom. Made it to bathroom and had loose stools. I later got very. Cold. This entire episode lasted 30 minutes |
| 1214690 | 4/15/2021 | CA | 31 | M | 3/29/2021 | 4/13/2021 | Idiopathic Syncope |

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| 1215093 | 4/15/2021 | KY | 18 | M | 4/7/2021 | 4/7/2021 | This patient had some dizziness after the shot and was apprehensive in receiving it. He claimed he felt dizzy and in seconds had slumped off of his chair. He was unresponsive for a few seconds only about 5-10 seconds and we gave him an IM Benadryl as a precaution. He awoke complaining of a funny feeling in the mouth and tongue but had no rash or redness or swelling to indicate an allergic reaction. We decide to monitor closely for an escalation of symptoms but to have a EpiPen handy, and call an EMT unit. His blood pressure was low at first at around 107/68 then quickly come up in about 10 minutes to 130/80. With no other issues we believe he had a vasovagal syncope but wanted the ER to make sure we were correct. I called and checked on him after he was at the ER. and the nurse stated that he was doing very well and that they had seen this happen with the vaccine at other site locations. |
| 1215406 | 4/15/2021 | | 27 | F | 4/15/2021 | 4/15/2021 | Reported being light headed exit monitor walking client to the cot. Client fainted assisted to the floor. Client quickly came responsive and was assisted to get in wheelchair. Taken to a private monitoring room. b/p 118/50 PSO2 100% pulse 84. Respirations even and unlabored. Skin pink warm and dry. 3:53 Given water and a snack. Stated she felt 80% better. 3:57 stated she was ready to go, no further symptoms. informed to seek medical attention with any further problems. |
| 1215403 | 4/15/2021 | OR | 49 | M | 4/7/2021 | 4/14/2021 | 1 week post vaccination - patient, not responding to albuterol HFA, called 911, he passed out, was unresponsive, pronounced dead. |
| 1215393 | 4/15/2021 | CA | 40 | F | 4/15/2021 | 4/15/2021 | Patient started experience syncope symptom after the vaccine administration and during the waiting period (15 minutes). She started feeling light headedness on her chair and tipping over to the floor. Her father who arrived with her to the vaccination had come to the rescue, and together with the pharmacist on duty, helped situating her on the floor. Paramedic was also called to ensure the patient safety but left shortly after since the patient had recovered nicely. |
| 1214652 | 4/15/2021 | CO | 59 | M | 4/15/2021 | 4/15/2021 | Pt fainted after getting vaccinated and afterwords told us that he had not had food that morning due to being nervous. |

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| 1214854 | 4/15/2021 | TX | 38 | M | 4/15/2021 | 4/15/2021 | FAINTING, REPORTS HISTORY OF SYNCOPE; B/P- 115/78, HR-66, PULSR OX- % |
| 1215325 | 4/15/2021 | OK | 73 | F | 3/18/2021 | 3/18/2021 | Patient complained of diarrhea and vomiting the evening of 03/18. She tried to treat the symptoms. On 03/20/2021 patient got light headed and fainted. Husband took her to the ER. She was admitted for 2 days and treated for dehydration. They also did a cardiac evaluation and adjusted some of her meds. Upon discharge Dr recommended that she may consider not taking the 2nd covid dose. |
| 1215122 | 4/15/2021 | WA | 42 | F | 4/12/2021 | 4/12/2021 | Pt was seated in observation area after vaccine administration. She started to get dizzy and walked up to pharmacy counter and fainted/passed out. She fell and hit her head on the ground. She had a gash on her forehead, so we called 911 and had paramedics notified. Fire Department arrived and assessed her. BP and HR wnl, bleeding under control, no further medical attention needed. Pt was feeling better, and was able to stand up. Pt was able to go home, no hospital necessary. I contacted her later that evening and she was feeling better, no further adverse effects. |
| 1215094 | 4/15/2021 | MN | 27 | F | 4/12/2021 | 4/12/2021 | Patient received Janssen COVID19 vaccine at 10:15am. Upon receiving vaccine she sat down on chair to wait for 15 minutes post-vaccination. Just minutes after sitting down patient lost consciousness, fell from chair, hit her head on the floor, seize for a short moment, only to momentarily regain consciousness, and faint for a second time. EMS were called and patient was transported to Emergency Department for testing and observation. Patient believes she fainted the first time due to not having eaten much by that point in the day and due to anxiety about receiving the vaccine, and she was told she fainted a second time due to hypotension. She states she has a history of previously fainting during other medical procedures, though no similar previous reactions she can recall after vaccines. |
| 1215348 | 4/15/2021 | TX | 38 | M | 4/15/2021 | 4/15/2021 | Fainted 10min post injection. History of same symptom with venipuncture. No acute distress BP: 115/78 HR: 66 SpO2: 98% Seen and cleared by EMS |

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| 1215079 | 4/15/2021 | CA | 48 | F | 4/10/2021 | 4/11/2021 | 4/11/2021 3:00am Dizzy when got up from bed 8:01am - dizzy and nauseous had to crawl, fainted - hit head, injection site very sore Slept rest of day low blood pressure - 102/67 4/12/2021 - High blood pressure, dizzy and nauseous 4/13/2021 High blood pressure - went to ER - 177/111 - ER doctor was not aware that J&J was being paused and told me results had nothing to do with vaccine. 4/15 - Followup phone call with different Dr to review symptoms encouraged me to submit symptoms |
| 1214931 | 4/15/2021 | | 72 | M | 3/4/2021 | 3/4/2021 | Rectal bleeding abdominal pain R55 - Syncope and collapse K92.2 - Lower GI bleeding |
| 1214873 | 4/15/2021 | | 41 | M | 4/15/2021 | 4/15/2021 | Full syncopal episode lasting 15 seconds per vaccinator. Awake, alert and oriented upon med response arrival. Pt states hx of syncope with blood draws and injections. denies having breakfast today. Denies any food or drink from medical staff. Symptoms resolved and pt left. |
| 1214904 | 4/15/2021 | MT | 36 | M | 4/15/2021 | 4/15/2021 | After patient received his shot, while sitting during the 15 min waiting period. The patient began getting lightheaded and hot, his color went out of him and his eyes began rolling back in his head. His eyelids turned a purple color and he appeared to momentarily stop breathing. Myself and another pharmacist got him on the ground and supported his head with a coat. When he "came to" and was talking to us. He described feeling better on the cold floor and his color began coming back. I was speaking with him the entire time. While we were out with his 9-1-1 was called and paramedics arrived 15 min later. by the time paramedics had arrived the patient had gotten up and back into the chair himself, was lucid and had color back in his face. Paramedics arrived and took over. He was given the green light from them and remained in the pharmacy area for a total of about 30 minutes before heading home. The patient was admittedly nervous for the shot and had not eaten or had anything to drink the whole day to that point. I believe he passed out from a variety of factors not related to the actual ingredients in the vaccine but cannot confirm this. |

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| 1214913 | 4/15/2021 | | 38 | F | 4/15/2021 | 4/15/2021 | Pt received her 1st dose of Pfizer on 4/15/2021. Five minutes after receiving her vaccine, she passed out. Pt hit her left shoulder, which led to a bruise. The pt passed out an additional two times within five minutes of each other. Pt was alert and oriented afterwards. She has a history of syncope episodes post-injections. Vitals were stable and had transportation home. Pt was advised to seek emergency care in the event of any additional episodes. Pt will follow up at pharmacy in the morning. |
| 1214955 | 4/15/2021 | PA | 40 | F | 4/6/2021 | 4/6/2021 | Tunnel vision, near syncope, rapid heartbeat, rapid increase in blood pressure. Lasted at least 30 minutes while I waited at the clinic. Was given one Benadryl. Symptoms cleared but was still not symptom free when I drove home. |
| 1215002 | 4/15/2021 | TX | 20 | F | 4/15/2021 | 4/15/2021 | Patient her first dose of the vaccine and 15 minutes after vaccination she fainted for a few minutes. She was responsive, but had a low blood pressure of 90/70. She was observed over a period, her blood pressure up to normal. She was counseled on signs and symptoms to watch out for and if so seek medical attention. |
| 1215045 | 4/15/2021 | MN | 22 | M | 4/15/2021 | 4/15/2021 | pt was here to get his Covid-19 vaccination. He fainted about 2 minutes after administration. Pt notified associate, associate and pharmacist moved pt from the seat to the floor. He then sat on floor for a few moments until he was feeling better. He was given water and then was waiting for his fiance to come drive him home |
| 1207924 | 4/14/2021 | KS | 45 | M | 4/12/2021 | 4/12/2021 | few minutes after patient got vaccine, he fainted, he was pale, dizzy. we laid him down on the floor and after 1-2 minutes he open his eyes and start talking. we observed him for 30 more minutes. |
| 1207812 | 4/14/2021 | PA | 17 | M | 4/9/2021 | 4/9/2021 | patient fainted after receiving the vaccine. was fine after resting and rehydrating |
| 1208030 | 4/14/2021 | NH | 50 | M | 4/14/2021 | 4/14/2021 | Pt developed dizziness and nearly passed out after injection. BP 100/60, HR 64, SPo2 99%. Symptoms improved without intervention. PT's wife drove him home. |

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| 1207953 | 4/14/2021 | FL | 23 | M | 4/10/2021 | 4/10/2021 | Pt received the vaccine sat in our waiting area and then passed out a couple minutes after receiving the vaccine. He came to in a minute or so. We called 911 and the paramedics came and took him to the local hospital. Per his report he had not had anything to eat that day and when he came to he felt nauseated and clammy. |
| 1208056 | 4/14/2021 | CA | 24 | M | 4/13/2021 | 4/13/2021 | A 24 year old male who has completed a 15-minute observation period with the following signs and symptoms of an adverse reaction: loss of consciousness and other - dizziness. Pt endorsed he is very anxious about the vaccination. Had a hx of fainting spells during vaccinations. Pt endorsed that while he was on the chair, he felt anxious and dizzy, then tried to take deep breath and passed out. Pt was found on the ground for 5 seconds but regained consciousness right away. No headache, chest pain, SOB, swelling of lips/tongue/throat. Denies any urinary/bowel incontinence. PMHx: none Pt was sent to examination via wheelchair. Vital signs check. Given water for hydration and apple juice. Felt better. vital signs stable Have abrasion on right knee and left dorsal wrist. Physical exam unremarkable. No hematoma or laceration on the head Observed for additional 30 minutes More likely syncopal episode vasovagal This is not an allergic reaction to the vaccine |
| 1207843 | 4/14/2021 | UT | 25 | F | 4/12/2021 | 4/13/2021 | While sitting in a chair waiting 15 minutes after the shot she was fine one minute and then passed out. When she came to the pharmacist gave her some orange juice. It didn't help and she was very nauseous. When she got up to leave she was totally incoherent, was unable to walk on her own. When she got home she was no better so I first called our family doctor which both said take her to the ER. There they did many tests and they all came back fine so they sent her home. By that evening she was able to walk on her own and talking right. She was terribly tired and still today 4/14 she is feeling worse but still not 100%. With the pause today for this vaccine we are very worried about this. |

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| 1208072 | 4/14/2021 | NY | 69 | F | 3/10/2021 | 3/10/2021 | Within 10 minutes: lightheaded, whole body weak like before fainting; by 15 minutes - lump in throat/indication of throat tightening, sore throat - took first Benadryl; within 20 minutes - noticeable 'lump' in throat when swallowing - took second Benadryl; symptoms reducing until about 45 minutes, then started increasing again; at 50 minutes took third Benadryl; at 1 hr. 5 minutes - improving and left the pharmacy (my husband drove although the 3 Benadryl did not make me drowsy - while one at bedtime would normally put me to sleep.) I am very aware of my body's reaction to things and told the pharmacist up front of my reaction to the 2020 flu shot, as well as my preparedness with the Benadryl and my epipen. I |
| 1207815 | 4/14/2021 | AR | 27 | M | 4/13/2021 | 4/13/2021 | Syncope with seizure like activity. Bradycardia and hypotension, HR 30-40 BMP |
| 1208004 | 4/14/2021 | OR | 51 | F | 3/30/2021 | 4/10/2021 | Patient received Covid 19 vaccine on 3/25/21 in Oregon city. 10 days later she had a syncope episode and another syncope episode on 4/11/21 |
| 1207881 | 4/14/2021 | NJ | 20 | F | 4/10/2021 | 4/11/2021 | patient recieved J& J vaccine on saturday at 2 pm following am patient woke up walked to bathroom told mom she wasnt feeling well, mom noticed she was going to pass out and assisted patient to ground, syncope lasted < 30 sec. Patient drank water/ginger ale, patient returned to sleep and woke up and reported feeling normal Patient took an adderrall 15 mg saturday night around 6 pm after vaccine to do school work Patient ate and drank normally saturday night patient has period currently- normal bleeding normal cramping patient on tri lo marzia BC and on spirinolactone for acne Of note patient does report hx of syncope in the am 1 year ago- never seeked treatment it was non recurrent Patient also states that a couple times a week she wakes up feeling dizzy- last about < 1 min and goes away. |
| 1207780 | 4/14/2021 | MI | 38 | M | 4/14/2021 | 4/14/2021 | Patient received vaccine. Walked up front and passed out by front wall |

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| 1207779 | 4/14/2021 | IL | 26 | F | 4/13/2021 | 4/13/2021 | Vasovagal syncope after three minutes of receiving first vaccine dose. Paleness, nausea, sweating, dizziness, and vision blackout. Treated by lying down, applying ice packs, and hydrating with water. Symptoms subsided within five minutes. |
| 1207778 | 4/14/2021 | TN | 33 | F | 4/9/2021 | 4/9/2021 | PATIENT RECEIVED JANSSEN VACCINE ON 4/9/21. 10 HOURS POST-DOSE PATIENT REPORTS FLU LIKE SYMPTOMS AND 4 EPISODES OF SYNCOPE. SHE THEN REPORTS PAIN IN LEGS AND ABDOMEN. ULTRASOUND OF LEGS WERE NEGATIVE FOR BLOOD CLOTS. TODAY 4/14/21 SHORTNESS OF BREATH HAS NOT IMPROVED AND PAIN IN LEGS IN ABDOMEN HAS NOT IMPROVED. PATIENT IS GOING TO ER FOR EVALUATION. |
| 1207765 | 4/14/2021 | OH | 19 | M | 4/14/2021 | 4/14/2021 | Moderna COVID-19 Vaccine EUA Passed out immediately after receiving vaccine. |
| 1207758 | 4/14/2021 | RI | 24 | F | 4/10/2021 | 4/10/2021 | Patient fainted shortly after vaccination and hit head causing a lesion on eyebrow. Patient regained consciousness shortly after and appeared very pale and disoriented. Doctor and EMTs on site immediately responded instructing patient to remain on the ground for about 30 mins and monitored her pulse and blood pressure. Patient reported feeling well enough to sit up on the floor after about 30 minutes after which she remained sitting for several more minutes before finally standing up and being picked up by relative to drive back home. |
| 1207721 | 4/14/2021 | CT | 59 | F | 4/12/2021 | 4/13/2021 | prolonged headache, dizziness, nausea, body aches, chills, extreme fatigue. 36 hours after vaccine, I fainted. Oxygen dropped to 83 (I have an oximeter.) |

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| 1207592 | 4/14/2021 | NY | 27 | F | 4/14/2021 | 4/14/2021 | 9:20 Pt reported to individual not feeling well. FNP and EMS to pt--pale, diaphoretic and sitting in chair. Unresponsive-breathing without difficulty. Pt aroused in appx 10 sec and assisted to WC and wheeled to medical eval tent. Pt A&O, no SOB/CP. Pt reports she "does this (syncope) once in awhile-the doctors don't know why" The pt also reports she has " done this" (syncope) in the Dr.s office before as well. They just laid my down". Denies no treatment or dx given for episodes. EMS evaluated with VS-Stable. Pt drinking water bottle without complications. Pt declined to be transported to hospital for further evaluation.9:50 apprx pt independently amb to OBS area with supervision. escorted pt husband to her in. After a few minutes-pt reported doing well when asked. Color evaluated and WNL-no paleness and/or sweating noted. Discussed with pt and husband at next appt for vaccine: 1-eat something prior-pt reported she did not eat today 2-let someone at medical area of today's episode and to lay down prior to vaccination 3-Husband may come with pt at next appt 4-next appt is location change and will be at Pt also instructed to contact her PCP and report today incident. Both individuals verbalized understanding and ambulated independently to exit steady and without difficulties. |
| 1208101 | 4/14/2021 | FL | 64 | M | 4/10/2021 | 4/10/2021 | Patient experienced syncope approx. 5 minutes after receiving dose. Hypotensive with approx. BP of 80/40. Was transported to hospital by emergency first responders |
| 1208601 | 4/14/2021 | CA | 19 | F | 4/9/2021 | 4/10/2021 | Dizziness, nausea, passed out, hit head, had seizure |
| 1207587 | 4/14/2021 | PA | 62 | F | 4/9/2021 | 4/9/2021 | Severe nausea, syncope, flushing of face and upper body |
| 1207581 | 4/14/2021 | CA | 21 | M | 4/13/2021 | | Patient fainted 5 minutes after receiving first dose of Moderna COVID-19 vaccine. Experienced low heart rate (96/53 100) and shortness of breath. Patient given water and monitored for an hour checking oxygen levels and blood pressure. EKG given, showing slight abnormality. Patient felt better, recommended to contact PCP and see cardiologist for follow up. |

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| 1207761 | 4/14/2021 | MA | 25 | F | 3/4/2021 | 3/21/2021 | Multiple episodes of recurrent syncope on Saturday with fall. 4-6 episodes of LOC lasting minutes at a time, 2-3 minutes between episodes. Each episode of LOC followed by several seconds of confusion, then immediately back to baseline. One episode associated with urinary incontinence |
| 1208445 | 4/14/2021 | CO | 20 | M | 4/14/2021 | 4/14/2021 | Patient fainted, lost consciousness momentarily, became responsive right away when RPh went to administer care. Patient complained of dizziness. Patient sat with head down for approximately 20 minutes at which time he stated he was feeling better. |

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| 1206906 | 4/14/2021 | WA | | F | 3/29/2021 | 3/30/2021 | <p>passed out 24 hours after the first shot; heartrate went to 99; freezing; chills off and on; wiped out; freezing ,chills off and on; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (passed out 24 hours after the first shot) in an 87-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 025A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event. Concomitant products included ASCORBIC ACID, ERGOCALCIFEROL, NICOTINAMIDE, RETINOL, RIBOFLAVIN, THIAMINE HYDROCHLORIDE (VITAMINS [ASCORBIC ACID;ERGOCALCIFEROL;NICOTINAMIDE;RETINOL;RIBOFLAVIN;THIAMINE HYDROCHLORIDE]) for an unknown indication, TRIAMCINOLONE ACETONIDE (NASACORT), FLUTICASONE PROPIONATE (FLOVENT), LISINOPRIL and PRAVASTATIN. On 29-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 30-Mar-2021, the patient experienced LOSS OF CONSCIOUSNESS (passed out 24 hours after the first shot) (seriousness criterion medically significant), HEART RATE INCREASED (heartrate went to 99), FEELING COLD (freezing; chills off and on), FATIGUE (wiped out) and CHILLS (freezing ,chills off and on). On 30-Mar-2021, LOSS OF CONSCIOUSNESS (passed out 24 hours after the first shot) had resolved. On 06-Apr-2021, FEELING COLD (freezing; chills off and on), FATIGUE (wiped out) and CHILLS (freezing ,chills off and on) had resolved. At the time of the report, HEART RATE INCREASED (heartrate went to 99) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Electrocardiogram: (Inconclusive) result not mentioned. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. Treatment included as EKG and discontinued Glipizide. Company comment:This case concerns an 87-year-old female with a serious unexpected event of loss of consciousness, and nonserious unexpected heart rate increased, feeling cold, and expected fatigue, chills. Based on current available information and temporal association between the use of</p> |

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| 1207578 | 4/14/2021 | NC | 41 | F | 4/12/2021 | 4/12/2021 | the product and the start date of the event, a causal relationship cannot be excluded. This case was linked to MOD21-070319, US-MODERNATX, INC.-MOD-2021-068543 (E2B Linked Report).; Sender's Comments: This case concerns an 87-year-old female with a serious unexpected event of loss of consciousness, and nonserious unexpected heart rate increased, feeling cold, and expected fatigue, chills. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. MOD21-070319: US-MODERNATX, INC.-MOD-2021-068543:wife case |
| 1208620 | 4/14/2021 | | 23 | M | 4/14/2021 | 4/14/2021 | I immediately got a headache after the shot and became dizzy several hours later. I went to bed around 9 pm and then woke up around 10 am and was very dizzy and my arm was in severe pain. I had to vomit so I got out of bed and fainted and fell to the floor. I got up again and then fainted and hit the floor. My husband then called 911 and I was transported to the hospital. |
| 1208686 | 4/14/2021 | PA | 37 | M | 4/6/2021 | 4/14/2021 | syncope for 2-3 seconds, hit head on ground. symptoms improved after laying down. |
| 1208617 | 4/14/2021 | FL | 19 | F | 4/14/2021 | 4/14/2021 | I woke up 7 days after receiving the vaccine with shooting sharp pains across my abdominal / midsection. While attempting to go to the bathroom, I must have passed out because I woke up some time later on the floor with a busted face and nose, and a severe headache. Initially the day after the shot, I had sharp shooting pains down my right leg. I have also had a headache on more days since getting the vaccine. Mental fog and tiredness is also occurring a few days after the initial shot. |
| | | | | | | | Patient was very nervous upon receiving vaccine and told immunizing tech that she had previously fainted upon donating blood. Immediately after receiving the shot, she said she felt like fainting. Her mother walked her to the observation chair for monitoring. She fainted and her mother along with two grocery associates went to hold her from falling off the chair. Two paramedics who happened to be a few feet away came to assist and took her vitals. Other medics arrived and took her to the hospital. |

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| 1208602 | 4/14/2021 | FL | 26 | F | 4/11/2021 | 4/11/2021 | Rush throughout body, then passed out. Immediate recovery. Paramedics @ side. Refused transport to hospital. |
| 1208580 | 4/14/2021 | CA | 36 | F | 3/8/2021 | 3/9/2021 | I got the vaccine at 4pm at the pharmacy where I work. I had no symptoms except for very mild local injection discomfort but was able to do my usual normal activities. At 2 am that evening, I woke up with a lot of pain in my legs, I felt they were so heavy to move around in bed. My lower back was extremely painful too, I tried to stand up to walk a bit, the pain was very severe and I couldn't stand straight, it was very hard to drag my feet, they felt very heavy and my muscles were painful to the touch even. So went back to bed, and was in agony. I had to go to work in the morning to open the store I work at until they find me coverage. Driving was very hard with my painful legs. I reached the store and I was walking very slowly, I couldn't have a full control over my legs, they were painful waist down, and felt very heavy, when I sat down my muscles were painful wherever pressure was applied to them (from the chair). Lightheadedness: I felt lightheaded when I woke up from bed at night to try to walk and ease the pain. So decided to go back to bed to prevent falls. At work, while walking and sitting, I had episodes of very light headidness and sat often on the floor and lifted my legs. Measured my blood pressure on 3 occasions it was 90/50 then 100/50 then 110/60. One time only I fainted where my colleagues put me down and lifted my legs. At 8am (morning of 3/9/2021) I had a feeling of heavy breathing. Needed to take deep breath as if my lung muscles were tired and needed to take deep breath to fill them with enough air. At work and because of the increased intensity of muscles pain, I started to breath faster and deeper coz I was in agony Headache: severe and excruciating headache started from 6am to 12pm on 3/9/21. Throughout the symptoms, I refused to take medications to let the vaccine run its course. My family drove me back from work coz I was weak and lightheaded and in severe pain at 10.30am. Came home, took one Advil 200mg at 11am. I was completely pain free at 12pm. Lungs still felt weak, needed to breath deeper for two days but then got better. |

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| 1208514 | 4/14/2021 | | 23 | M | 4/14/2021 | 4/14/2021 | On call to car, pt fainted. Quickly aroused but diaphoretic and pale. Laid back in seat. Given cool air and compress. Color improved. Responded appropriately to questions. Briefly nauseated. Vss throughout. After about 20 minutes patient reported well enough to leave. Driven by girlfriend. |
| 1208565 | 4/14/2021 | NY | 70 | F | 1/11/2021 | 3/8/2021 | Pt developed severe hypotension and two episodes of syncope at onset of hypotension. Since that date we have struggled to maintain her blood pressure over a systolic of 100. She frequently runs 75/55 sitting down. She is not orthostatic. Resting P has increased from 80 to 95. She is currently taking Droxidopa 400mg tid prn and Midodrine 10mg prn. Additionally, when these do not raise her systolic to 100, she takes 100 Hydrocortisone. The presumed diagnosis is dysautonomia, and she has been referred to a specialty center. |
| 1208447 | 4/14/2021 | NE | 22 | M | 4/14/2021 | 4/14/2021 | Vasovagal reaction, patient was sitting and fainted shortly after receiving vaccine. Did not eat much before vaccine. He immediately knew his name, where he was, etc. |
| 1208103 | 4/14/2021 | IN | 62 | F | 4/12/2021 | 4/13/2021 | Passed out dizzy nausea body aches and very bad headache for 24 hrs |
| 1208435 | 4/14/2021 | PA | 50 | F | 4/9/2021 | 4/9/2021 | pt fainted |
| 1208421 | 4/14/2021 | MA | 60 | M | 4/12/2021 | 4/13/2021 | Reaction to first dose was nil. Below is reaction to the second dose: Same evening: slight fever and chills Next day: Stomach upset, dizziness, mild headache, nausea. One fainting episode at 8PM followed by vomiting. Heartrate: 55-63. The day after: Another fainting episode at 11:AM, followed by vomiting. Heartrate: 55-60. |

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| 1208416 | 4/14/2021 | WA | 33 | M | 3/25/2021 | 3/25/2021 | I received my first dose of the pfizer vaccine at 11am at the safeway pharmacy. I had consumed several glasses of water in the morning before the event, a cup of yerba mate tea, and a piece of toast. I smoke, and had smoked one cigarette in the morning before my appointment. Just after receiving the vaccine I ate a few pieces of jerky and maybe 15 Jojo potatoes from the safeway deli. I was advised to wait 15 minutes before leaving. I set an alarm. I bought some food to eat (jojo potatoes and jerky) and waited to leave the site until 11:22am. I felt strange/weird, but this isn't an unusual feeling after receiving any kind of shot/vaccine for me. I was driving to work and I started to feel just a little bit strange after smoking another cigarette. I got a little nauseous but nothing too bad. Thirty seconds later I started to get dizzy, my ears rang, I felt my blood pressure drop, and I passed out on the interstate going freeway speeds. I woke up around a minute and half later according to my brother who was on the phone. I was treated for injuries at emergency room. |
| 1208372 | 4/14/2021 | CO | 41 | F | 3/22/2021 | 3/22/2021 | Approximately 5 minutes after receiving the shot, got light headed and fainted |
| 1208357 | 4/14/2021 | FL | 38 | F | 4/10/2021 | 4/10/2021 | Fainted after 30 minutes |
| 1208239 | 4/14/2021 | TX | 20 | M | 4/13/2021 | 4/13/2021 | Pt received vaccine and was seated. I went back to pharmacy and realized the patient had fainted. By the time I got to the patient he had regained consciousness. I gave the patient 2 cold packs and told him to take off his mask. I also gave him a bottle of water and a glucose tablet. |
| 1208185 | 4/14/2021 | NH | 64 | F | 4/11/2021 | 4/12/2021 | During the night I felt like I had a fever, chills and body aches. And the next morning after I woke up needing to use the restroom, got up but started feeling dizzy and fainted for about 2minutes. EMT was called and once they arrived I began vomiting and my BP was super low. During the transport to the hospital I vomited again and was given antinausea meds. At the ER I was given IV fluids, chest xray, EKG and blood was drawn and I was released after a few hours of monitoring |

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| 1208153 | 4/14/2021 | NE | 22 | F | 4/5/2021 | 4/5/2021 | Right after the nurse administrated the vaccine to my daughter, she complained about having numbness on her feet, flurry eyes, was not able to hear very well, dizziness and fainted for a short time. |
| 1208149 | 4/14/2021 | TX | 45 | M | 4/12/2021 | 4/12/2021 | 5 minutes after receiving the injection, my husband passed out, starting sweating profusely, and was out cold for a minute. EMS were called and he was seen in ER due to low heart rate and sweating to rule out any heart conditions. He had 2 EKGs - one in the ambulance and one in the ER. He also had to have a CT for falling and bumping his head to rule out that injury. The DX was listed as a vagal response, but we are not so sure we agree given that he is 45 years old, has no priory history or anxiety about shots. |
| 1208478 | 4/14/2021 | KS | 50 | M | 4/1/2021 | 4/12/2021 | History of Present Illness The patient presents with 50-year-old male with a history of hypertension and diabetes who presents via private vehicle with complaints of atraumatic left calf pain x4 hours. Symptoms started while typing on computer at work sitting in chair. Described as mild soreness to his left medial calf rating behind his knee. No frank tenderness with palpation. No fall, trauma, injury, or overuse syndrome including gym. No swelling, edema, or asymmetry. No associated motor/sensory disturbance able to wiggle and feel all digits with good pulses. No chest pain, shortness breath, palpitation, lightheadedness, or syncope. No spasms, cramps, or charley horses. Patient denies any history or DVT/ PE, hypercoaguable disorder, recent immobilization or surgery, recent long trips or travel, or active malignancy (w/ treatment in last 6 months) but does take prescribed clomiphene for androgen replacement/stimulation. Discomfort scribed as soreness, minimal intensity, 2 out of 10 without provocative or palliative factors. |

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| 1206918 | 4/14/2021 | FL | | F | | | <p>passed out twice; was very weak; dizzy; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (passed out twice) in a female patient of an unknown age who received COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No medical history was reported.). On an unknown date, the patient received second dose of Vaccine (Intramuscular) 1 dosage form. On an unknown date, received first dose (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient experienced LOSS OF CONSCIOUSNESS (passed out twice) (seriousness criterion medically significant), ASTHENIA (was very weak) and DIZZINESS (dizzy). At the time of the report, LOSS OF CONSCIOUSNESS (passed out twice), ASTHENIA (was very weak) and DIZZINESS (dizzy) outcome was unknown. Concomitant product use was not provided. Treatment information was not provided. Reportedly, two days after experiencing the events, the patient was able to walk five miles a day like she used to do in the mornings. Company Comment: Very limited information regarding these events has been provided at this time. Further information is required.</p> |

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| 1206910 | 4/14/2021 | MI | 61 | F | 3/13/2021 | 3/13/2021 | Pneumonia; Fainting; Vomiting; Fever; Muscle aches and pains; This spontaneous case was reported by a consumer and describes the occurrence of PNEUMONIA (Pneumonia) and SYNCOPES (Fainting) in a 61-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 038A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No reported medical history). On 13-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 13-Mar-2021, the patient experienced SYNCOPES (Fainting) (seriousness criterion medically significant), VOMITING (Vomiting), PYREXIA (Fever) and MYALGIA (Muscle aches and pains). On 23-Mar-2021, the patient experienced PNEUMONIA (Pneumonia) (seriousness criterion medically significant). On 18-Mar-2021, PYREXIA (Fever) had resolved. At the time of the report, PNEUMONIA (Pneumonia) had not resolved and SYNCOPES (Fainting), VOMITING (Vomiting) and MYALGIA (Muscle aches and pains) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 23-Mar-2021, Chest X-ray: revealed pneumonia (Inconclusive) Revealed pneumonia. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. |
| 1207053 | 4/14/2021 | GA | 23 | F | 4/7/2021 | 4/7/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient fainted after receiving her first dose of the Pfizer vaccine for covid 19. She was laid down on her back. Fainting spell lasted about 2-3 minutes. She said it was usual for her to faint after immunization as a child. She didn't mention this because she thought she had outgrown it. She complained about quizziness in her stomach after the fainting spell. She was given 1 tablet of 25mg Benadryl. |

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| 1207052 | 4/14/2021 | MD | 21 | M | 4/10/2021 | 4/10/2021 | The patient presented to the pharmacy to receive his Covid-19 vaccination. He was accompanied with his mother, who stated that she was there for support. It was not made clear to the vaccinator that the patient had a history of fainting with vaccines or blood draws. The vaccine was administered, and the patient immediately lost consciousness. The patient was placed in a chair with arms, and was caught before falling to the ground. The patient did not come in contact with the floor or any surfaces to cause further damage. The patient with quickly assessed by the pharmacist on duty and 911 was called by the other pharmacist. The patient quickly regained consciousness and was aware that he had "done it again". Neither the patient nor the mother were particularly concerned about the event, but we called the paramedics to be safe. The paramedics came and took vitals, everything checked out okay and the patient declined transport to the hospital. The patient's mother then drove the patient home. |
| 1207050 | 4/14/2021 | NY | 25 | M | 4/13/2021 | 4/13/2021 | Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Severe, Systemic: Headache-Severe, Additional Details: Within 5 minutes of receiving COVID vaccine, patient just collapsed to the floor. For about 30 seconds patient was unresponsive to name. Upon awakening, patient was very confused and reported severe headache and dizziness. 911 was called and patient was escorted |
| 1207045 | 4/14/2021 | NY | 22 | F | 4/13/2021 | 4/13/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Additional Details: pt was dizzy and light headed after vaccine and lost conciousness for a couple of seconds. she was sweaty and a little confused for a couple of seconds. she ate and drank something after and was feeling better and we phoned 911 to check her out. she was released and doing much better. |
| 1207024 | 4/14/2021 | CA | 21 | F | 4/13/2021 | 4/13/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe |

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| 1207016 | 4/14/2021 | NY | 28 | M | 4/13/2021 | 4/13/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: patient confirmed didnt eat today and was dehydrated-Severe, Systemic: Hypotension-Severe, Additional Details: patient was up in front store by cash register and collapsed, employee notified another employee who notified another employee. got patient into a chair gave water, patient declined all help except almonds and water. patient refused medical treatment, refused to have emt or medics called. will follow up with patinet in am |
| 1206995 | 4/14/2021 | WI | 25 | F | 4/8/2021 | 4/8/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: Tingling (specify: facial area, extremities)-Medium, Systemic: Weakness-Medium, Additional Details: Patient fainted briefly and was weak and had tingling in both arms and hands-tried hydration and fan cooled air circulation-revived within 10-15 min-kept for observation for 30 -45 minutes and had mother pick her up so she didnt drive |
| 1207072 | 4/14/2021 | SC | 17 | F | 4/13/2021 | 4/13/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Additional Details: Patient fainted in waiting are 5 minutes after shot. Patient's muscles stiffened up and she hit back of head on shelf. Pharmacists lowered patient to recovery position on floor, where pt recovered consciousness and relaxed. Patient's mother said that patient has vaso-vagal responses to shots and that she was having one of those. Patient was well and was able to leave without further assistance. |

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| 1206954 | 4/14/2021 | TX | 34 | M | 3/29/2021 | 3/30/2021 | Patient active-duty military on deployment at time of vaccination. Patient to return to later this week. Dr. and I remains on deployment and are best reached via e-mail or above phone number. 34 y/o active-duty male received the Jannsen COVID 19 vaccination on 29-Mar-2021. He describes expected symptoms of fatigue and body aches overnight, but reports development of melena the next morning, 30-Mar. On 31-Mar-2021, he developed nausea/vomiting and persistent diarrhea/melena. He presented for care after an episode of syncope with extreme pallor and hypotension (BP 70s/40s). Hypotension and pallor resolved with 2L NS bolus and patient felt well and was dispositioned to quarters without further workup. On the night of 01-Apr, patient had a recurrent episode of syncope with recurrent hypotension. He was transferred to the ED and found to have a Hgb 5.0 secondary to GI bleeding due x3 peptic ulcers in different stages of healing. He received x4 units PRBCs and started on a proton-pump inhibitor. He continues omeprazole and iron supplementation. Hgb is now stable at 11.6. H. pylori pending. He will follow-up with GI physician. Of note, patient has had a voluntary weight loss of 30 pounds over the past x3 months. He has aggressive supplement use as above and reports exercising twice daily. |
| 1207084 | 4/14/2021 | NH | 34 | M | 4/13/2021 | 4/13/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Additional Details: After the first dose of the Pfizer COVID19 vaccine, patient felt faint while sitting. When patient stood up to report dizziness, the patient ended up fainting and falling. Patient reported that he did not hit his head. He regained consciousness quickly after and was able to sit for 30 minutes before leaving the facility. |

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| 1206912 | 4/14/2021 | | 71 | F | 3/17/2021 | 3/17/2021 | <p>Passed out; Hit her head 3 times; White Blood Cell Increased; Bloody nose that would not stop; Felt nauseated; This spontaneous case was reported by a health care professional (subsequently medically confirmed) and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out) and HEAD INJURY (Hit her head 3 times) in a 71-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Diabetes since an unknown date. Concomitant products included POTASSIUM, VITAMIN D3, TRAMADOL, LEVOTHYROXINE, METOLAZONE, SPIRONOLACTONE and ACETYLSALICYLIC ACID (BABY ASPIRIN) for an unknown indication. On 17-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 17-Mar-2021, the patient experienced LOSS OF CONSCIOUSNESS (Passed out) (seriousness criterion hospitalization), HEAD INJURY (Hit her head 3 times) (seriousness criterion hospitalization), EPISTAXIS (Bloody nose that would not stop) and NAUSEA (Felt nauseated). On an unknown date, the patient experienced WHITE BLOOD CELL COUNT INCREASED (White Blood Cell Increased). The patient was hospitalized from 17-Mar-2021 to 24-Mar-2021 due to HEAD INJURY and LOSS OF CONSCIOUSNESS. On 17-Mar-2021, LOSS OF CONSCIOUSNESS (Passed out), HEAD INJURY (Hit her head 3 times), EPISTAXIS (Bloody nose that would not stop) and NAUSEA (Felt nauseated) had resolved. At the time of the report, WHITE BLOOD CELL COUNT INCREASED (White Blood Cell Increased) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Action taken with mRNA-1273 in response to the events was not Applicable. After hospitalization patient was started with Januvia, Pregabalin, Potassium chloride, Torsemibe, Metoprolol, Levemir insulin Company comment:Based on the current available information and the temporal association between the product and the start date of the events a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and the temporal association</p> |

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between the product and the start date of the events a causal relationship cannot be excluded.

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| 1206908 | 4/14/2021 | | | F | 3/28/2021 | 3/29/2021 | <p>passed out because she was feeling that the world was revolving; shortness of breath when she moves; fast heart beat when she moves; swelling in right leg; Numbness in right leg; body ache; fever; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (passed out because she was feeling that the world was revolving) and DYSPNOEA EXERTIONAL (shortness of breath when she moves) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event. On 28-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 29-Mar-2021, the patient experienced PAIN (body ache) and PYREXIA (fever). On an unknown date, the patient experienced LOSS OF CONSCIOUSNESS (passed out because she was feeling that the world was revolving) (seriousness criterion medically significant), DYSPNOEA EXERTIONAL (shortness of breath when she moves) (seriousness criterion medically significant), HEART RATE INCREASED (fast heart beat when she moves), PERIPHERAL SWELLING (swelling in right leg) and HYPOAESTHESIA (Numbness in right leg). On 29-Mar-2021, PAIN (body ache) and PYREXIA (fever) had resolved. At the time of the report, LOSS OF CONSCIOUSNESS (passed out because she was feeling that the world was revolving), DYSPNOEA EXERTIONAL (shortness of breath when she moves), HEART RATE INCREASED (fast heart beat when she moves), PERIPHERAL SWELLING (swelling in right leg) and HYPOAESTHESIA (Numbness in right leg) outcome was unknown. No concomitant medication were not provided. The patient was treated with PARACETAMOL (TYLENOL) and METOPROLOL. Action taken with mRNA-1273 in response to the event was not applicable. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be</p> |

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| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1206901 | 4/14/2021 | | | F | 4/2/2021 | 4/3/2021 | <p>excluded.</p> <p>clogged ears; injection site rash; She almost fainted; She was nauseated and wanted to vomit; Sweating; blood pressure went low/down; pale; Fever; Headache; Body ache; This spontaneous case was reported by a consumer and describes the occurrence of SYNCOP (She almost fainted) in a 29-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 011A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No reported medical history). On 02-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 03-Apr-2021, the patient experienced PAIN (Body ache), PYREXIA (Fever) and HEADACHE (Headache). On 04-Apr-2021, the patient experienced SYNCOP (She almost fainted) (seriousness criterion medically significant), HYPERHIDROSIS (Sweating), HYPOTENSION (blood pressure went low/down), PALLOR (pale) and NAUSEA (She was nauseated and wanted to vomit). On an unknown date, the patient experienced EAR DISCOMFORT (clogged ears) and VACCINATION SITE RASH (injection site rash). At the time of the report, SYNCOP (She almost fainted), PAIN (Body ache), HYPERHIDROSIS (Sweating), HYPOTENSION (blood pressure went low/down), PALLOR (pale), PYREXIA (Fever), HEADACHE (Headache) and NAUSEA (She was nauseated and wanted to vomit) outcome was unknown and EAR DISCOMFORT (clogged ears) and VACCINATION SITE RASH (injection site rash) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 04-Apr-2021, Blood pressure measurement: Low. Tylenol was used as treatment medication. Concomitant medications was not reported. This case was linked to MOD-2021-067463, US-MODERNATX, INC.-MOD-2021-067463 (E2B Linked Report).; Sender's Comments: MOD-2021-067463:First Dose Case US-MODERNATX, INC.-MOD-2021-067463:Second dose case</p> |

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| 1206510 | 4/14/2021 | TX | | F | | 4/8/2021 | DIZZY AND LIGHT HEADED; BAD HEADACHE; HURT IN NECK MUSCLES VERY BAD; FACE WAS RED; DRY MOUTH; FACE WAS HOT; BREAKING OUT IN A COLD SWEAT CLOTHES WERE SOAKED; LITERALLY ALMOST FAINTED; SHAKES; CHILLS; NAUSEA; This spontaneous report received from a patient concerned a female of unspecified age. The patient's height, and weight were not reported. The patient's past medical history included had surgery from the meds. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, administered on 08-APR-2021 14:30 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 08-APR-2021, the subject experienced face was red. On 08-APR-2021, the subject experienced dry mouth. On 08-APR-2021, the subject experienced face was hot. On 08-APR-2021, the subject experienced breaking out in a cold sweat clothes were soaked. On 08-APR-2021, the subject experienced literally almost fainted. On 08-APR-2021, the subject experienced shakes. On 08-APR-2021, the subject experienced chills. On 08-APR-2021, the subject experienced nausea. On 08-APR-2021 15:00, the subject experienced dizzy and light headed. On 08-APR-2021 15:00, the subject experienced bad headache. On 08-APR-2021 15:00, the subject experienced hurt in neck muscles very bad. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from dizzy and light headed, face was red, dry mouth, face was hot, breaking out in a cold sweat clothes were soaked, literally almost fainted, shakes, chills, nausea, bad headache, and hurt in neck muscles very bad on APR-2021. This report was non-serious. |
| 1206361 | 4/14/2021 | CA | 27 | M | 4/12/2021 | 4/12/2021 | Syncope; BP 101/55; HR 67 improved to 121/72; HR 80. RR stable at 18 |

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| 1206319 | 4/14/2021 | TX | 42 | M | 4/13/2021 | 4/13/2021 | vaccine adm at 2:33, , 2:40pm pt had fainting episode vs:129/67, P44-54, T96.2, R18, O2 sat 98%, EMS called R/T syncope and bradycardia. 2:44 vs:116/72, T96.2, R18, O2 97%, in and out of consciousness. lowered to ground by clinical staff, turned on side. 2:50 vs: P70, 112/64, R18. 2:53 EMS onsite, 126/79, P66, R18 3pm EMS cleared pt, declined to go to hospital. 3:10 VS 126/79, P66, R 18, A/O x 4, friend present. Medical director informed, ok to leave. Left in no acute distress. |
| 1206297 | 4/14/2021 | MO | 61 | F | 4/10/2021 | 4/11/2021 | Passed out. Heart palipatations & vomiting lasted 7 hours, |
| 1210521 | 4/14/2021 | UT | 23 | M | 4/9/2021 | 4/9/2021 | AFTER PATIENT RECEIVED THE DOSE OF COVID VACCINE JOHNSON AND JOHNSON HE WAITED FOR 15 MINUTES AND WHEN HE STOOD UP, HE COLLAPSED BUT HE WAS CONSCIOUS, WE HELPED HIM AND PUT HIM BACK ON A CHAIR AND HE PASSED OUT FOR 3 TO 5 SECONDS AFTER THAT HE STARTED FEELING BETTER BUT STILL VERY COLD AND PALE. WE ASKED HIM TO WAIT FOR OTHER 30 MINUTES AND AFTER THAT HE FELT OK. |
| 1208881 | 4/14/2021 | | 64 | F | 4/8/2021 | 4/8/2021 | Did not realize I had a reaction until I came home from the hospital... started with a grey out that progressed to a functioning black out... shortly after the black out I passed out... it had effected my heart and pacemaker... I went into a functioning grey out... |
| 1206968 | 4/14/2021 | TX | 46 | F | 4/13/2021 | 4/13/2021 | Systemic: Fainting / Unresponsive-Severe, Systemic: Seizure-Mild, Systemic: Shakiness-Mild, Additional Details: patient passed out and fell over and hit the floor face forward. bruised face and chipped tooth.911 was called and patient was taken to er. Not sure on final outcome. Called husband to check on patient and have not received a call back. will call again. |

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| 1207186 | 4/14/2021 | IL | 20 | F | 4/13/2021 | 4/13/2021 | Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Exhaustion / Lethargy-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Headache-Mild, Systemic: Hypotension-Mild, Systemic: Shakiness-Mild, Systemic: Tachycardia-Mild, Additional Details: Patient refused Benadryl, was monitored for 30 minutes. Patient felt dizzy and faint, we monitored, gave water, an ice pack. Patient's symptoms resolved after 30 minutes. |
| 1207541 | 4/14/2021 | PA | 18 | F | 4/8/2021 | 4/8/2021 | Fainting, Syncope for less than a minute |
| 1207537 | 4/14/2021 | NY | 40 | F | 3/31/2021 | 3/31/2021 | Dizziness about 3-4hrs after injection Heart rate between 114-138 about 6hrs after injection to 4/5 Fainting about 14-16hrs after injection Extreme SOB and palpitations upon exertion about 6hrs after injection to present |
| 1207536 | 4/14/2021 | CO | 30 | F | 4/8/2021 | 4/8/2021 | syncope, dizzy, lightheaded, nausea, low grade fever, slight chills, shivering, slight headache |
| 1207524 | 4/14/2021 | OK | 20 | M | 4/12/2021 | 4/13/2021 | RINGING EARS, RIGHT SIDE WENT NUMB, PASSED OUT, HIT HEAD HAS CONCUSSION |

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| 1207446 | 4/14/2021 | TX | 21 | M | 4/13/2021 | 4/13/2021 | Client passed out while seated in observation falling to the right side of the chair and onto the ground Client landed face down on the floor and was turned over onto his side first before being flipped onto his back Client's head did hit the ground Client reportedly appeared to be having a seizure when he was turned over Multiple people were present to assist client including nurse and EMT At 12:09, LVN called 911 and relayed information to the dispatch While on the phone, nurse went to get an Ambu-bag because staff present reported that the Client stopped breathing but had a pulse Upon bringing the Ambu-bag, the Client had already regained normal breathing pattern and no longer needed assistance breathing . Ambu-bag was present but was not used Client was assisted into a wheelchair and taken to the private recovery area. Physician, nurse, and EMT were present Client was alert enough to answer questions Client began to vomit / dry-heave for a short moment Client asked EMT about transport billing and was informed that he might possibly get a bill but that he had the option to choose not to pay it At 12:20, Vitals taken BP 155/112, Pulse 64 Client informed of the need to be further evaluated at the hospital Client verbalized multiple times that he did not want to be transported even after speaking with the physician Physician suspected that the client had some underlining reason that he did not want to disclose regarding his refusal to be transported At 12:25, Vitals taken BP 135/83, Pulse 58, O Sat 97% Blood sugar reading 104 Client reports no pain in the head, no nausea Client reports that he did not eat anything prior to coming At 12:31, Ambulance arrives EMT briefs paramedic regarding the incident and the client's history Paramedics questioned client Client signed form and verbalized that he did not want to be transported and felt well enough to leave Client called his brother to drive him home At 12:41 Client was wheeled in the wheelchair to the car Client informed of selfcare and instructed to go to the hospital / ER if symptoms worsen or headaches develop Client informed to let further vaccine administrators know that he passed out in the past and needs to have the injection lying down Client verbalized understanding Client's brother drove him home |

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| 1207379 | 4/14/2021 | OH | 40 | F | 4/13/2021 | 4/13/2021 | 3:41PM PT STATES SHE FEELS LIKE 'SHE MAY PASS OUT'. PLACED IN WHEEL CHAIR - SYNCOPED X30-60 SEC. MOVED TO COT; NOW RESPONSIVE. BP 150/90, HR 96, R 16, O2 SAT 99%. PT CALLED HUSBAND TO COME PICK HER UP. 3:46PM PT STATES 'THIS IS HER TYPICAL POTS EPISODE'. STATES SHE WAS WORKING ON HER KITCHEN AND PROBABLY JUST OVER DID IT. BP 128/80. STATES SHE FEELS BETTER NOW. 3:50PM A/O, PINK, W/D, RESP WITH EASE. BP 132/78, HR 77. 4PM SITTING UP - DRINKING WATER. STATES 'FEELS PRETTY GOOD'. 4:08PM TO EXIT PER WHEEL CHAIR; ASSISTED INTO AUTO TO BE TAKEN HOME PER HUSBAND. A/O, PINK, W/D, RESP WITH EASE. 4-14-21 9:30AM TC: PT STATES SHE 'FEELS SO MUCH BETTER NOW'. |
| 1207314 | 4/14/2021 | OH | 27 | M | 4/14/2021 | 4/14/2021 | Patient arrived for his vaccine. Vaccine was administered by nurse. Patient then stated that he does not do well with shots and then he passed out. The nurse attempted to break his fall. He fell out of the chair and onto the floor hitting his head on the ground. He was passed out for about 20-30 seconds. His legs were elevated and he woke up. VS were taken BP 137/80 HR 68 O2 sat 100% Squad was called. VS retaken BP 141 HR 70 O2 sat 100% Squad arrived. Patient feels lightheaded. Assisted to chair. VS retaken BP 114/93 HR 60 O2 sat 98 % Patient taken to hospital. |
| 1207235 | 4/14/2021 | NY | 45 | M | 4/10/2021 | 4/10/2021 | Patient experienced vasovagal syncope x4. Blood pressure 90/60, skin clammy and pale. Patient was laid down with feet elevated and provided a cool compress. Patient's blood pressure reached 118/72 and reported feeling better. Patient was transported via ambulance to the Hospital for further evaluation. Patient required no treatment at the hospital and was discharged home to care of self. |
| 1207057 | 4/14/2021 | NY | 17 | M | 4/13/2021 | 4/13/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Headache-Mild, Systemic: Hypotension-Mild, Systemic: Weakness-Mild |
| 1207189 | 4/14/2021 | TX | 42 | F | 3/19/2021 | 3/20/2021 | Felt ill and fainted the day after the vaccine. Had persistent headaches and went to the ER on 3/27/21. Feeling better now. Reported to me, her PCP on 4/13/21. |

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| 1207547 | 4/14/2021 | NH | 46 | F | 4/9/2021 | 4/9/2021 | Metallic taste filling mouth within first two minutes of injection, lasting for three hours. Cold sweat and the feeling of possible fainting lasted ten minutes. Nausea occurred for 24 hours. Swelling of lymph node in the armpit of the left arm (non-injection) arm as well as a feeling of burning near the underside of the arm just above left elbow lasting 48 hours. When the metallic taste resolved, it was replaced by an indescribable taste lasting for two hours. Within 24 hours, a strong smell of "plastic" for two hours was replaced by the strong smell of "burnt toast/burning" for several hours. The lymph node in the left arm still feels swollen but less so, and it six days past the injection date. Menstruation began a week early, which has not been off schedule for ten years, so it feels related. I hope this helps; feel free to reach out if you have additional questions. |
| 1207185 | 4/14/2021 | NC | 26 | F | 4/8/2021 | 4/8/2021 | passed out |
| 1207170 | 4/14/2021 | IL | 17 | F | 4/13/2021 | 4/13/2021 | Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Nausea-Mild, Additional Details: Patient was close to vomiting, benadryl was given, patient recovered. |
| 1207148 | 4/14/2021 | OR | 50 | M | 4/7/2021 | 4/7/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild |
| 1207134 | 4/14/2021 | DE | 51 | F | 3/31/2021 | 4/6/2021 | Systemic: Dizziness / Light headiness-Severe, Systemic: Fainting / Unresponsive-Severe, Additional Details: 6 days after dose patient had a syncopal attack and severe palpitations. Daughter called ambulance after finding mother had fainted. |

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| 1207127 | 4/14/2021 | IL | 42 | F | 4/13/2021 | 4/13/2021 | Systemic: Chills-Mild, Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Exhaustion / Lethargy-Mild, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Mild, Systemic: Hypotension-Mild, Systemic: Shakiness-Mild, Systemic: Tachycardia-Mild, Systemic: Tingling (specify: facial area, extremities)-Mild, Additional Details: Patient reported anxiety with needles, blood work, vaccines. She experienced lightheadedness, dizziness, and needed to lie down. Bendaryl was given 50 mg and patient recovered. Cold packs applied to back of neck, water given. Likely an anxiety induced response. |
| 1207107 | 4/14/2021 | TX | 25 | M | 4/13/2021 | 4/13/2021 | Systemic: Fainting / Unresponsive-Severe, Systemic: Hypotension-Severe, Systemic: Vomiting-Medium, Additional Details: Syncope; normal bp; hr 80; hx of syncope from dental procedure. No hx of seizure. |
| 1207100 | 4/14/2021 | NJ | 53 | F | 4/9/2021 | 4/12/2021 | Symptoms: On Monday April 12 while at work, I felt dizi, like fainting and when walking I felt like I was not walking straight. It was intermittent, sometimes I was feeling fine, and later on, I started feeling as described (dizi, feel like things around me were moving). It was very strange. When to see the nurse at work and my blood pressure was 122/87. On April 13, went so see my doctor, I was feeling fine, but my blood pressure was 120/90. It is kind of high for me, as I have a history of low blood pressure . Janssen COVID-19 Vaccine EUA |
| 1207098 | 4/14/2021 | NY | 20 | F | 4/13/2021 | 4/13/2021 | Systemic: Chest Tightness / Heaviness / Pain-Mild, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Severe, Systemic: Shakiness-Mild, Additional Details: Pt stated that she was nervous that she would "pass out from vaccine!", recommended she stay 30 min instead of 15 min for monitoring. Has hx of anxiety d/o & panic attacks (3x/month). Stated she felt dizzy after getting vaccine and she contributed it to that. Gave 12oz OJ, 1 protein pack (nuts & chocolate berries) and water. Only had ramen noodle soup today & was dehydrated. Checked in after 30 minutes, felt fine and was back to normal. |
| 1207087 | 4/14/2021 | MA | 18 | F | 4/13/2021 | 4/13/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild |

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| 1207213 | 4/14/2021 | NC | 57 | F | 4/11/2021 | 4/12/2021 | The symptoms started a few hours after the shot, feeling tired and fatigued. About 16 hrs after the injection, 4/12/2021 at approximately 3:30 AM I woke up feverish, chills, nauseous and with a bad headache. When I got out of bed I felt dizzy. I was so dizzy I must have fainted on our bathroom floor as I was returning to my bed. My husband had to carry me to bed. I had these symptoms for approximately 24hrs. On 4/13/2021 I still felt fatigues and dizzy. Today, 4/14/2021 I am still fatigued and dizzy. |
| 1210215 | 4/14/2021 | MD | 19 | F | 4/8/2021 | 4/8/2021 | A few hours after I got home from getting the shot, my lower body started to ache super bad. My skin started to hurt like I had rug burn, but I wasn't surprised because that happens to me when I get the flu. My legs and groin region started to hurt more and more and I got the chills. It was extremely bad and I was sort of writhing but I told myself I was overreacting. At around 8 or 9, I decided I would sleep it off and went to bed. At 1:00 am, I got up to use the bathroom and I began feeling lightheaded. I thought I had just stood up to fast so I continued. As I walked, i got more and more dizzy and I couldn't hear well. When I sat on the toilet, I realized I wasn't going to be able to get back up, so I sat and waited. I started to get super hot so I took my shirt off. I finally was able to get up and walked towards the sink but I collapsed before I got there. I started drinking the sink water and ran my shirt under the water and put it on my head to cool off. This really helped so I went back to my room to call my mom. I have never fainted before or come this close to fainting. For the rest of the night I had the worst migraine of my life that gave me aura in my left eye and made my left arm and left side of my face go numb, as well as pulsing in my head. The pain on my skin, and in my legs and head was still there for two days after but it was manageable enough for me to go about my day. I tried to exercize to ease the muscle pain but this did not work. |

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| 1210553 | 4/14/2021 | CO | 54 | M | 3/25/2021 | 4/6/2021 | 4/6/21 - got bloody nose at 10:00 A.M, which would not stop. Nose still bleeding 2 hours later, got dizzy, so lied down. Vomited blood and could not stop the bleeding. Went to the ER at 2:00 PM, to have them stop the bleeding 4/6/21- E.R. - Fainted n the lobby while waiting. Taken back to room and given IV and gave multiple tests. E.R. doctor put packing in nose to slow bleeding. Still The Diagnosis was Epistaxis and Vasovagal syncope, and advised to follow up with my doctor and otalaryngologist. 4/8/21- Nose bleeding finally cam to stop in the evening, but had fatigue, weakness, irregular heartbeat, and shortness of breath 4/9/21- ENT and Allergy removed packing, completed nasal scope. Nose still felt like it was stuffed with blood clots until 4/13/21 |
| 1210523 | 4/14/2021 | CO | 27 | M | 4/14/2021 | 4/14/2021 | Pt fainted after 2nd Pfizer injection. Pt fell from chair, resulting in a minor injury to his right knee. BP was taken and found to be low (96/54). He was given ice packs until symptoms resolved. |
| 1210503 | 4/14/2021 | CA | 61 | M | 4/12/2021 | 4/12/2021 | Lightheadedness, felt like he was going to black out, he did not faint. He was evaluated by a MD and due to the distance of his drive home was advised to go to ER via ambulance. Seen in ER- no chest pain, nausea, or vomiting. He did have some diaphoresis. Has a history of vasovagal syncope associated with needles. Seen and released without further interventions. |
| 1210487 | 4/14/2021 | TX | 21 | F | 4/13/2021 | 4/13/2021 | The patient received her Moderna Covid-19 vaccine and was sitting in the waiting area with her companion. Approximately 12 minutes after receiving the vaccine, the patient fainted. The pharmacist was alerted and immediately went to assist. The patient was unconscious 1 minute or less, never fell out of her chair and recovered quickly. |

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| 1210471 | 4/14/2021 | MI | 35 | F | 4/9/2021 | 4/9/2021 | After receiving the vaccine I went and sat in a chair for the 15 minutes following the vaccine. Approximately 4-5 minutes later I started feeling really hot. Then I started getting nauseous and dizzy. I tried to get up and walk to the pharmacy desk (vaccine occurred at pharmacy) but fainted midway there. I was out less than one minute and after sitting down and having some water and putting ice packs on my face I felt better. I have never in my life fainted before. I wasn't nervous or scared to have the vaccine. I followed up with my regular doctor on the Monday following the vaccine and had an EKG and bloodwork done all of which came back normal. |
| 1210459 | 4/14/2021 | TX | 29 | F | 4/9/2021 | 4/9/2021 | patient fainted, loss of hearing in ear, had a brief seizure |
| 1210457 | 4/14/2021 | MA | 35 | M | 4/6/2021 | 4/6/2021 | Vasovagal syncope with ragged breathing and lingering feeling of nausea and fatigue |
| 1210379 | 4/14/2021 | CA | 52 | F | 4/6/2021 | 4/6/2021 | Syncope 10 min after vaccine for past 7 days short of breath, palpitations (with PVS on EKG that were not a prior known condition), weakness, fatigue |
| 1209905 | 4/14/2021 | IL | 19 | F | 4/14/2021 | 4/14/2021 | Patient was walking to observation room when she began to feel dizziness, vision changes and tinnitus resulting in syncope 1-2 minutes. Patient was on floor in sitting position supported by staff member. Diaphoretic. Pale. Unresponsive <1 minute. No head or face injury noted. No bleeding, swelling or ecchymosis noted. Full ROM to neck, LE and UE. Denies pain, CP, SOB, HA, palpitation or vision changes. BP 94/53 HR 99 O2 99% Patient was assisted to chair. A&O x 4. Reports that she was fasting x 1 month, reports eating small amount of granola bar and small amount of water. Patient was observed for 30 minutes. d/c home in stable condition w/ dad. ED warning s/s discussed. Patient and father repeated instructions w/ good understanding. |

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| 1210284 | 4/14/2021 | IA | 28 | M | 4/14/2021 | 4/14/2021 | Patient within 5 minutes started to feel funny and then passed out/blacked out. According to wife he did shake for less than 15 seconds in his arm and a bit in his head. They were in the car, so she tilted the seat back for him and came in to get us. Within the 30 seconds that she was gone he was awake and sweating profusely. We gave him an ice pack, 25mg of liquid benadryl, and kept him laying back in the seat. At 5 and 15 minutes mark the patient was checked on and he was completely fine. After 20 minutes the patient had stopped sweating and reported to be feeling 98% better. |
| 1210648 | 4/14/2021 | CA | 58 | M | 4/14/2021 | 4/14/2021 | Patient received pfizer vaccine, sitting for observation for 15min and observed by next patient, who alerted pharmacist, that he passed out, dropped phone/papers, and shakes. Pharmacist about to administer epipen but he regained consciousness in seconds, alert and stated dizzy, drank water given to him. 911 called and paramedic came to check him. BP is low, he's brought out in stretcher to hospital(?) for evaluation. Wife came to pharmacy later to inquire since she got call from him being in hospital for observation. Wife stated that he is nervous about needles, vaccination |
| 1210056 | 4/14/2021 | CA | 18 | M | 4/14/2021 | 4/14/2021 | After administration of the COVID-19 1st dose, patient fainted and was caught by his father. Patient then sat on a chair while pharmacy staff monitored patient. Approximately 5 minutes after the incident, patient continue to experience sweating and weakness. |
| 1210047 | 4/14/2021 | TX | 45 | M | 4/14/2021 | 4/14/2021 | Patient reports feeling dizzy, lightheaded, passed out 3 times, clammy, anxious. EMS assessed patient, BP:84/63, pulse 41, spo2 97-99%, BS 154, second set of v/s; BP: 99/66, pulse: 52, third set of v/s; BP: 105/68, pulse: 63-75. Patient reports he has history of passing out with needles , he reports feeling better, symptoms improved, refused transport to ER, he was cleared by EMS. |

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| 1210025 | 4/14/2021 | MI | 17 | F | 4/14/2021 | 4/14/2021 | Patient arrived with mom for Covid vaccine at 12:48 pm. Mom reports a history of fainting so nurse decided to administer vaccine with client lying down. Vaccine was administered and client immediately stiffened arms and appeared to seize while her eyes rolled back. Nurse reported she turned the client onto her side and she "came to within 20-30 seconds." She reported blurry vision but could read when asked to do so. She quickly became alert and oriented. Her mother reported that she had a previous episode one time in the past year with painful menses. Her vitals remained stable but each time she attempted to stand up, she reported feeling "sick." She developed a headache within minutes of the vaccine and took 2 Tylenol while still there. Client left with parent to follow up at hospital. |
| 1209957 | 4/14/2021 | FL | 27 | F | 4/14/2021 | 4/14/2021 | PT FAINTED ABOUT 10 MINUTES AFTER VACCINE WAS ADMINISTERED, FELL FORWARD FROM SEATED, HIT HEAD ON GROUND, HUSBAND CALLED EMT, PARAMEDICS ARRIVED TO TAKE PT TO EMERGENCY ROOM, PT HAD SUFFERED FROM POSSIBLE SEIZURE AND CONCUSSION |
| 1209945 | 4/14/2021 | CA | 39 | F | 4/5/2021 | 4/5/2021 | The minute after the vaccination I had fainted, vision went, low blood pressure, after laying down became better. Rested almost an hour in order to be able to walk. next day, I had severe headache, with nausea, and a day later I had bleeding. Bleeding became severe, I had miscarriage. I was 7 weeks pregnant. |
| 1209934 | 4/14/2021 | FL | 52 | F | 4/11/2021 | 4/11/2021 | Within minutes vaso vagal syncope. May not be related. Has occurred before with other injections or drawing blood. Next day, injection site soreness. Fatigue. Everything normal by day 2 |
| 1209924 | 4/14/2021 | TX | 29 | M | 4/14/2021 | 4/14/2021 | patient fainted |
| 1209917 | 4/14/2021 | | 18 | F | 4/14/2021 | 4/14/2021 | Patient reports dizziness and fainting. Upon assessment, pt. was diaphoretic and pallor. Put pt. on oxygen at 10 LPM. Took vitals BP: 76/46, O2 at 99% on 10L of oxygen, HR 45. Placed patient down on the ground with legs elevated. After 15 minutes, pt. reports feeling better. Retook vitals: BP: 129/82, 97% on room air, and HR 73. Informed patient to monitor for worsening symptoms at home and drink plenty fluids at home. |

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| 1210292 | 4/14/2021 | OH | 61 | F | 3/10/2021 | 3/10/2021 | Swelling, tenderness at site. Headache within 5 hours. Muscle aches. Abdominal cramping and back pain all within 5 days (3/10-3/14)of vaccine.Passed out on 4/10/21 while walking, noted fatigue on 4/8 until 4/13. |
| 1210826 | 4/14/2021 | | 23 | F | 4/13/2021 | 4/13/2021 | Patient fainted and had a short seizure roughly 5 minutes after the injection. EMT came and drove patient to hospital for further evaluation. Outcome - unknown. |
| 1210499 | 4/14/2021 | OK | 35 | F | 4/14/2021 | 4/14/2021 | pt was given her 1st dose ~9:33am on 4/14/21. while sitting and waiting for the observance period, pt became hot, sweaty, dizzy and fainted at 9:45am. pt came to and was trying to get up right as we were coming to her aid. pt was given an ice pack and placed in upright position and monitored for another 15 to 20 mins until family could come pick her up. |
| 1208891 | 4/14/2021 | NJ | 54 | F | 4/3/2021 | 4/8/2021 | Hemmoraged and passed many clots from my reared. Lost a lot of blood. Fainted and threw up. Was in ICU for 2 nights. Had 2 blood transfusions. They clamped area where polyp was removed on March 30th. |

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| 1211314 | 4/14/2021 | MA | 60 | F | 4/8/2021 | 4/9/2021 | Developed heart palpitations approximately 10 hours after receiving vaccine. Also insomnia making it impossible to sleep. Palpitations seemed to get better by 11 am the next morning but my heart rate was still elevated (pulse 106-112). Shortly after that (around 11:45 am) I became extremely light headed and dizzy and felt like I was going to pass out. I also started to feel nauseous and sweaty. I rested lying down for two hours before hearing back from my doctor's office. I was able to control the lightheadedness and dizziness by lying down. The feeling of passing out / nearly fainting went away. I continued to feel nauseous and my heartrate was still elevated. I started to get a headache as well. On the advise of a nurse at my doctor's office, my husband took me to the ER. My EKG was normal . My heartrate was elevated. Due to the overcrowding at the ER that day I was made to wait at least an hour and half for further evaluation. I continued to feel light headed and slightly dizzy. My nausea and headache got much worse . I was finally taken back to a treatment room and received IV fluids, Zofran and Tylenol. My heartrate went back to normal and my headache and nausea improved with treatment and I was discharged around 7pm. I continued to feel very tired and slightly lightheaded that evening. The next morning I was much more nauseous again and still very weak feeling and slightly lightheaded. I have continued to feel weak, very fatigued , unwell and nauseous on and off until today, April 14, which is 6 days after I was vaccinated. |
| 1211309 | 4/14/2021 | NC | 21 | M | 4/7/2021 | 4/7/2021 | Syncope at 1033 am, recovered while lying down, cool compress, water. Observed with vitals for 30 mins. Discharged asymptomatic at 1103 |
| 1211269 | 4/14/2021 | KS | 18 | F | 4/14/2021 | 4/14/2021 | approximately 2 minutes after vaccination patient began to have light headed sensation- near syncope without long term disability or injury |
| 1211101 | 4/14/2021 | MO | 63 | F | 4/9/2021 | 4/12/2021 | Nauseous, sharp pain in upper abdomen, sweating, passed out. Spouse called ambulance |
| 1211083 | 4/14/2021 | NY | 53 | F | 3/9/2021 | 4/7/2021 | Passing out at work.. Syncope... high heart rate... extremely low blood pressure.... dizziness... headaches... fatigue |

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| 1211046 | 4/14/2021 | NC | 21 | F | 4/7/2021 | 4/7/2021 | Pt with syncope a few minutes after event. Pt laid in recumbent position, recovered, continued observation with vitals, water, and cool compress. Symptoms resolves after 15-20 mins, discharged home. after 30 mins. |
| 1210577 | 4/14/2021 | MA | 49 | M | 3/21/2021 | 3/27/2021 | Nausea and abdominal pain building over several hours leading to syncope. Patient was unconscious for at least 10 minutes. Nausea dissipated then built again for several more hours. Observation and lab tests at Emergency room. No treatment. Symptoms resolved. |
| 1210841 | 4/14/2021 | FL | 52 | M | 4/8/2021 | 4/13/2021 | Diarrhea since 04/06/2021 everyday two times per day. On April 8th developed heavy abdominal pains and fainted became rigid, clenched fists, and shook like a seizure. My wife stood by my side and witness me waking up pale and confused after about 10 seconds of episode. I continue to have diarrhea. |
| 1210630 | 4/14/2021 | OH | 59 | M | 3/4/2021 | 3/6/2021 | Mother called health department today, 4/14/21, to report reactions son experienced after receiving vaccine 3/4/21. She stated that on 3/6/21 he started having headaches, weakness and leg cramps. He went to the hospital two times with complaints. On 3/15/21 he was unable to walk/drive because headaches were severe. On 3/30/21 he passed out, squad was called. He was not responsive and was put on a vent at the hospital. A "scan" showed blood clots in brain and heart. This individual passed away on 4/4/21. |
| 1210815 | 4/14/2021 | VA | 22 | F | 4/6/2021 | 4/6/2021 | Almost passed out about 6 minutes after injection 5 days later I developed a face rash - still have face rash today |
| 1210773 | 4/14/2021 | OR | 18 | M | 4/13/2021 | 4/13/2021 | 5 minutes after getting the shot I fainted / had a seizure. I heard from people around me that my face had turned pale and that my hands were cramping up. I woke up not knowing what had happened, or where I was for a good 30 seconds. They had to call an ambulance and take me to the hospital to get checked on. |

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| 1210747 | 4/14/2021 | MI | 21 | F | 3/16/2021 | 3/16/2021 | Patient passed out and we could not get her to come to. She was taken to the hospital by ambulance. Her blood pressure was very low. She became very weak. She had a horrible and very scary reaction to the vaccine. She was in the hall face down when we found her and we could not get her to wake up. When she did come to, we could not calm her. Patient normally lives by herself and luckily was with us when this happened. We can't imagine what would have happened if she was alone. |
| 1210726 | 4/14/2021 | OH | 16 | F | 4/13/2021 | 4/13/2021 | Patient stated in evaluation form that she had passed out once before after giving blood for labwork. She and her mother decided to continue with the vaccination as it had never occurred before after getting a vaccine. A few minutes after the vaccine the patient lost consciousness. Mom stated that her face tensed up right before hand. The patient remained in her chair for the duration of the event. She regained consciousness about 30 to 60 seconds later, and within a few minutes she was conscious but still very shaky, pale, and hot. She was able to sip some water and we put a cool, wet paper towel on the back of her neck. The patient and her mother remained seated and under observation for an additional 15 to 20 minutes with no further issues, at which point they left the store. I followed up with the patients mother the next day and she said her daughter was exhausted last night, but this morning she woke up feeling well and went to school like normal. |
| 1210694 | 4/14/2021 | | 32 | F | 3/30/2021 | 4/7/2021 | Fatigue for 2 days after shot. Headache starting 8 days post vaccination. Lasted 2-3 days (4/7-4/9/21) Dizziness, blurred vision, almost fainted on 4/9/21 |

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| 1210692 | 4/14/2021 | MN | 70 | F | 2/18/2021 | 2/19/2021 | I woke up at 3:30 a.m. lightheaded. I went to the bathroom and on the way back to the bedroom I fainted. I regained consciousness and realized that I was on my knees on the bedroom floor. I felt as though the room was whirling and fainted again. I woke up to find that I was laying down on the bedroom floor. At that point, I heard my husband asking me what happened. I felt him pick me up and put me back in bed. He didn't sleep the rest of the night listening to me to make sure I was breathing. I woke up in the morning feeling fine, no more symptoms. While my episode was going on, I never thought to call for help from my husband. Very unusual for me not to do that. I just didn't think about talking, strange for me. |
| 1210686 | 4/14/2021 | | 20 | F | 4/13/2021 | 4/13/2021 | The patient felt dizzy when after the vaccine was administered and then fainted. The patient was given crackers and juice and recovered on their own. |
| 1210685 | 4/14/2021 | MI | 51 | F | 4/10/2021 | 4/11/2021 | Approximately 3:00am I woke up with severe chills & severe headache. After not being able to fall back to sleep due to headache I decided to take medication for headache. Walked to kitchen for water and before I could take medication I passed out and fell to the floor hitting head on cupboard door. After realizing I passed out and fell I got up to take meds and passed out again. I woke up on the floor some time later and was able to get to the couch. |
| 1210704 | 4/14/2021 | | 24 | F | 4/14/2021 | 4/14/2021 | The patient experience syncope after administration of the vaccine. The patient was given juice and resolved. The patient was released on their own accord. |
| 1211020 | 4/14/2021 | NC | 19 | F | 4/7/2021 | 4/7/2021 | Pt with syncope about 3 minutes after her injection. Pt placed in recumbent position, returned to full consciousness after about 20-30 seconds. Vitals monitored x 20 mins, offered cool water and ice packs, pt discharged after observation period feeling well. |

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| 1209062 | 4/14/2021 | NJ | 36 | F | 4/14/2021 | 4/14/2021 | patient received unconscious, syncope episode noted. Post vaccination stated site felt nauseous , lightheadedness and falling to floor. patient unconscious x 3. Assisted to wheelchair Ax3. At 1108am vitals monitored Pulse 59 BP 77/50 RESP 20. Fluids administered A&O x3. Verbally responsive speech clear. Injury to left eye and head noted. pain 2/10. Ice administered. 1116am Pulse 70 BP 91/67. Patient refused to go to the ER, family notified, patient is released from facility accompanied by sister. |
| 1209385 | 4/14/2021 | NY | 23 | F | 4/12/2021 | 4/12/2021 | i received the vaccine at 3pm on monday april 12th. i started shaking less than 5 minutes after i received the dose and my throat started to swell and i couldn't swallow. they placed me under observation for 30 minutes and gave me water?saying that ?i might just be afraid of the needle and not to worry, this is an abnormally normal reaction to a new vaccine.? after 30 minutes a man walked over to me and said ?oh you?re still here?? and chuckled. they then told me i would be fine after a while and to leave. i started walking down the sidewalk and almost passed out so i called an uber to take me to the nearest urgent care. i arrived at urgent care around 4pm unable to swallow and having a reaction to the vaccine. they saw me immediately and gave me 3 50mg of prednisone and a benadryl and placed me under observation for 45 minutes. he said i looked better and i even felt marginally better. i called another uber and when i was almost home my tongue started to go numb as well as my lips and my breathing was becoming constricted. i had the uber driver pull over as i had to sit on the sidewalk and get some air. i then called another uber to the hospital because my symptoms were becoming increasingly more alarming. Hospital admitted me and gave me a shot of epinephrine and IV fluids and kept me under observation for 6 hours. they discharged me a little after midnight with a prescription for prednisone, epinephrine, and benadryl. if i had been administered epinephrine at the vaccine site on monday and not been told i was just squeamish by the male air force cadets?i probably wouldn't still be short of breath, painfully swallowing, and bedridden. |

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| 1209311 | 4/14/2021 | GA | 85 | M | 4/14/2021 | 4/14/2021 | Fainting after vaccine, patient had not eaten breakfast, no chronic diseases reported, blood pressure at onset of episode 110/60, heart rate 62, pale, clammy, after approximately 10 seconds patient responded to verbal commands, cool clothes to forehead and back of neck, gave patient coke and peanut butter crackers and monitored 30 minutes after episode, patient did not change planes or fall, moved to sitting position with assistance at onset of episode, niece with patient and drove patient home. Patient left clinic in no distress. |
| 1209293 | 4/14/2021 | AZ | 17 | F | 4/9/2021 | 4/9/2021 | The shot was given on Friday around 1 pm. Blurry Vision immediately after vaccination, then felt fine until 7 pm. At 7 pm she fainted at Lacrosse practice. The following day, Saturday, she fainted at work and was sent home. Sunday, she slept most of the day. Monday, she fainted at school and was sent home. Symptoms have been feeling of her heart racing, blurry vision, fainting, weakness, and major fatigue. No fever. |
| 1209288 | 4/14/2021 | PA | 32 | M | 3/31/2021 | 3/31/2021 | At approximately 4:58 PM on 03/31/2021 patient during 30 minute observation developed dizziness, general itchiness and urticaria to his hands. Pt administered in RA IM 50mg Benadryl at 5:00pm. Pt AA&Ox4, airway patent, breathing normal and non-labored. Pulse strong and regular with adequate perfusion. Pt lung sounds clear upper and lower lobes. Pt stated improvement, and intially refused transport to the ED, when upon sitting patient felt profound dizziness without syncope and patient was consulted again about emergency transport, who consented. Pt transported via emergency services to Hospital. First and last vitals as follows: 4:50pm 160/100bp, 122p, 22r, 98% O2 5:20pm 152/92bp, 110p, 20r, 98% O2 |
| 1209263 | 4/14/2021 | GA | 54 | F | 3/26/2021 | 3/31/2021 | hives, dizzy, nausea, fainting-this lasted 24 hours -the reaction was 5 days after the vaccine-I did get a B12 mic shot on the Monday after getting vaccine on Friday. Felt fine until Wednesday then broke out in hives and later that day fainted. Still to this day I am breaking out almost every day and I think it is tied to heat. Met with doctor today and she put me on steroid to try to calm down the break outs and then re-evaluate. |

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| 1209251 | 4/14/2021 | TX | 30 | M | 4/14/2021 | 4/14/2021 | Pt had vaccine and said he fainted and fell down. When asked if he hit his head he said yes. His head was assessed for laceration or bumps, none were observed at the time of assessment. He was under observation until he felt he was okay to go home. He was a&ox4 after vital signs were locations. |
| 1209248 | 4/14/2021 | OH | 41 | M | 3/6/2021 | 3/6/2021 | I received the dose at 5:35am on 3/6/21 went home slept most of the day woke up and felt tired, 8:00pm on 3/6/21 I left for work drove a few miles up the road and fainted and crashed my vehicle. |
| 1209241 | 4/14/2021 | NC | 55 | F | 3/10/2021 | 3/25/2021 | next day extreme fatigue, fever lethargy. Got better but never got energy back and had some body aches and trouble sleeping. On Wed. March 25th an EXTREME headache began and I could find no relief with High doses of Tylenol or Ibuprophin or a mixture of both. It was my whole head. Stayed on the couch all day Saturday and Sunday 27th and 28th unable to move because of the pain and extreme fatigue. Monday the 29th made myself go to work but was not able to function or get much relief. On Tuesday the 30th went to see physician who said he thought it was Occipital Neuralgia and gave me prednisone and said use hot compresses. Told him I thought it was more due to other symptoms like hallucinations (shadows I would see) Mind not clear and made me worry about driving. Asked if the shot could be a possibility. He just said he couldn't rule it out. The doctor also mentioned I felt very hot but never took my temperature. I Took the prednisone. Headache did start to clear on Wed the 31st in the evening but my neck seized up where I could no longer turn it to the left and was very painful. Also felt like my lymphnodes were swollen. I called on call doctor and they prescribed a muscle relaxer. I did not start to get better until Sunday April 11th. Experience a couple ocular migranes as well during this, Still experiencing some fatigue and almost to a fainting point in the mornings |

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| 1209237 | 4/14/2021 | PA | 47 | M | 4/14/2021 | 4/14/2021 | Patient fainted, but patient mentioned that he does faint after needle exposure. Patient also ended up vomiting. Laid patient on floor and observed for 40 minutes took blood pressure and patient stated that it was normal for him. After 15 more minutes we let patient leave and wife drove him home. Called at 2:40 and confirmed that patient made it home safe. |
| 1209418 | 4/14/2021 | NY | 35 | M | 4/12/2021 | 4/12/2021 | Patient experienced extended episode of syncope and temporary discontinuation of respiration approximately 8 minutes after vaccination. |
| 1209101 | 4/14/2021 | OH | 26 | M | 4/6/2021 | 4/7/2021 | Within 12 hours of injection: Body aches, fever, severe chills (convulsions), headache, nausea, threw up three times, passed out. |
| 1209148 | 4/14/2021 | WA | 20 | M | 4/9/2021 | 4/9/2021 | The patient had a needle phobia and was very anxious prior to the vaccine. Once the patient received the vaccine, he waited in the waiting area for 15 minutes post-vaccine. About 5 minutes after the vaccine, he notified the pharmacy staff that he wasn't feeling well and he was feeling faint. The pharmacy staff provided him with a glass of water and was monitoring him. He said he felt like he fainted and wasn't feeling well. He said he felt warm and sweaty. The pharmacy staff provided him with an ice pack. He then notified the pharmacy staff that he urinated in his chair while waiting post-vaccine. He wanted to be checked out and wanted us to call 911 . The patient began to feel better after about 20 minutes. The EMT arrived and checked the patient. Even though, the patient was feeling better, the EMT recommended the patient be checked further anyways. He was brought to the Triage center and was there for about 1 hour, according to the patient, and was feeling better. He said he felt slightly fatigued that day and the following day, but other than that he was feeling back to normal and no issues. He stated he has severe needle phobia and has experienced these fainting spells and anxiousness in the past. We followed up with the patient and he provided this information to us. He stated he was feeling good and back to normal. He had no further questions or concerns. We told him to follow up with us if questions or concerns came up. |
| 1209041 | 4/14/2021 | CT | 18 | F | 4/12/2021 | 4/12/2021 | Mild seizure, passed out |

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| 1209023 | 4/14/2021 | TX | 33 | M | 4/14/2021 | 4/14/2021 | Passed out with snoring respirations |
| 1209012 | 4/14/2021 | TN | 48 | F | 4/6/2021 | 4/14/2021 | A week after shot, arm became sore again. The next morning, more soreness developed with a rash at injection site. It was also hot to the touch. I also became queasy, sweaty and close to fainting. |
| 1209011 | 4/14/2021 | MI | 47 | M | 4/7/2021 | 4/11/2021 | On 4-11-21 at approximately 5 pm, I fainted while in the bathroom at home. |
| 1208996 | 4/14/2021 | FL | 51 | M | 4/11/2021 | 4/11/2021 | Approximately 4-5 after receiving the Covid Vaccination, my heart rate dropped, the top of my body was shaking and I passed out. The ambulance arrived and took me to the ER. My heart rate was at 40 . I was in the hospital for observation for 3+ hours. |
| 1209897 | 4/14/2021 | OH | 55 | F | 4/8/2021 | 4/8/2021 | I fainted with no warning signs, fell down broke my elbow. |
| 1210733 | 4/14/2021 | NM | 34 | F | 3/25/2021 | 3/25/2021 | patient felt dizzy, possible fainting, possibly anxiety, paramedic observed. |
| 1208974 | 4/14/2021 | PA | 69 | F | 3/30/2021 | 3/30/2021 | AT APPROXIMATELY 1:59PM 03/30/2021, PATIENT UNDER 15 MINUTE OBSERVATION STARTED TO DEVELOP LIGHT-HEADEDNESS AND DIZZINESS WITHOUT EVENT OR HISTORY OF SYNCOPE. PT UPON ASSESSMENT WAS AA&OX4, AIRWAY PATENT, BREATHING NORMAL AND NON-LABORED. PULSE STRONG AND REGULAR WITH ADEQUATE PERFUSION. PT SELF-ADMINISTERED 1L WATER ORALLY AND FELT IMPROVEMENT TO CONDITION, AND WALKED WITHOUT EVENT TO VEHICLE AND TO HYDRATE AS RECOMMENDED. VITALS: 1400 (160/100, 87p, 18r, 97%) 1415 (132/60, 79p, 16R, 97%) 1427 (128/92, 78p, 18r, 97%) |

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| 1208926 | 4/14/2021 | FL | 19 | F | 4/14/2021 | 4/14/2021 | <p>This is a 19 y.o. female status post 1st dose of Moderna vaccination on 04/14/21 at 130PM. Patient was outside under the tent waiting 15 minutes post vaccination when she fell out of her chair and onto the ground. Upon arrival, patient was lying face down and unresponsive. 10 seconds later patient regained consciousness, but was lethargic, clammy and pale. Patient is nauseous and vomiting. With assistance, patient was transported via wheelchair inside the modular unit in the parking lot. Reports eating a cookie this morning. Last meal was last night and it was a bowl of spaghetti. Patient reports having a syncopal episode and seizure 5 months ago after getting a COVID-19 nasal testing. Denies any medical history, no NKDA, no medications, no recent illness. Initial VS at 1400 was 90/56 HR 52, O2 sats 98% on room air. Denies SOB, denies difficulty breathing, denies chest pain, denies HA, denies dizziness. VS 1408- 90/56 HR: 57 BPM, RR: 12 BPM, O2 Sats: 98% Room Air VS 1425-91/57 HR 50 BPM, RR: 12 BPM O2 Sats 98% Room Air VS 1440- 94/57 HR: 54 BPM, RR: 12 BPM, O2 Sats: 98% RA Plan: Syncope and collapse- Patient was evaluated for 1 hour. Patient reports that she was feeling much better and was eager to go back to her room. Her pallor improved, she was AOx3 and speaking in clear sentences. , RN was advised to try patient with sips of clear liquids and provide her some crackers and have patient ambulate prior to discharge. When the nurse was repeating her VS and providing the patient the crackers, patient experienced another syncopal episode, but regained consciousness immediately. VS at 1450: HR 49 BPM, O2 Sats 99%, BP 82/50. Because patient experienced another syncopal episode, 911 was dispatched for ER evaluation. Patient asked that I speak to her mother, mother updated on patient's condition and that she needs to go the ER for further evaluation. Mother agrees and verbalizes understanding of care. Spoke to with the local health department and she reports that this case will need to be reported to VAERS. Patient is being transported by stretcher to the hospital. Will follow up with the patient. Nausea and Vomiting- Patient refusing Zofran IM, prefers PO. Zofran 4 mg SL given once at 1400 for nausea and vomiting. Nausea and Vomiting improved within 20 minutes. No nausea or vomiting upon discharge from the health center.</p> |

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| 1209202 | 4/14/2021 | TX | 27 | M | 4/14/2021 | 4/14/2021 | Fainted (hx of similar symptom with venipuncture) and tingling sensation to bilateral fingers Seen and cleared by EMS |
| 1209663 | 4/14/2021 | CO | 55 | F | 3/6/2021 | 3/6/2021 | Sorry for delay in reporting. I didn't realize I should report the adverse effects. I had the vaccine at 11:30 am and felt fine. But around 6pm, I was sitting outside on a cool night with a jacket and scarf on and I suddenly very very hot and had to take off my layers. I felt nauseous. I got up to go inside because I thought I would throw up and then fainted. I came to a second later (some friends where with me) and felt extremely nauseous. My friends brought me a bucket and I got sick. I felt immediately better. But later that night I had a headache, and chills. I didn't get sick again, but I left as if I had the flu. I felt better in the morning. |
| 1209794 | 4/14/2021 | IA | 32 | M | 4/7/2021 | 4/7/2021 | On Wed, April 7, 2021, Kurtis received the first dose of Pfizer COVID vaccine. About 14 minutes after receiving the shot, he passed out while sitting on a chair and was found on the floor (5:45pm). He regained consciousness almost immediately and he stated he was dizzy and lightheaded. He also stated he only ate one spinach salad during the day and is trying to lose weight. We gave him water and a protein bar to eat. He slowly sat up on the floor, sat in a chair, and then stood. His fiance came to pick him up and drive him home. When called on 4/9, he stated that he was doing well and having no adverse reactions. |
| 1209855 | 4/14/2021 | MA | 23 | F | 4/14/2021 | 4/14/2021 | PT received Covid19 vaccine at 16:30. PT experienced sudden weakness and dizziness at the site of her own blood that occurred at the vaccination site of her L arm. PT also stated she felt close to fainting. EMS responded to the vaccination table and assisted the PT to sit in a wheelchair where she could be moved to another location for further evaluation. PT condition improved and refused transport. |

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| 1209749 | 4/14/2021 | CA | 32 | F | 4/14/2021 | 4/14/2021 | Patient had an episode of fainting (possible syncope ?) approximately 5 minutes after receiving vaccination. She was sitting on a chair while waiting for the 15 minutes post-vaccination observation. She fainted and fell on the ground. But she was conscious and was able to respond normally. At the end, she was feeling fine. She explained it has happened to her a few times in the past when she had blood drawn. |
| 1209063 | 4/14/2021 | MA | 28 | M | 4/8/2021 | 4/8/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Additional Details: while observing the patient after administering the vaccine, he temporarily fainted. He came to immediately and felt better within the following 5 minutes. |
| 1209856 | 4/14/2021 | | 66 | M | 4/14/2021 | 4/14/2021 | received 2nd dose today and approximately 2 minutes after receiving vaccine, became unresponsive. I was present and carried behind the curtain and placed the on the floor. began to posture and have tonic clonic movement. Pupils were fixed and dilated. This lasted nearly 3 minutes during which time his airway and C spine was protected and an ambulance was called. regained consciousness and stated that he has passed out from vaccines several years ago. does not have a history of seizure. A complete neuro exam was performed: intact as tested, cerebellar exam is intact, speech is of a regular and steady cadence, transported to ED |
| 1209431 | 4/14/2021 | NC | 25 | F | 4/7/2021 | 4/7/2021 | Initial injection site pain and almost passed out but did not. All body chills and shaking at 11, followed by fever, all over aching through 8Apr with focus on lower back. Injection site soreness through 8 Apr. |
| 1209743 | 4/14/2021 | | 39 | M | 4/14/2021 | 4/14/2021 | Patient passed out after receiving his first Pfizer covid19 vaccination. He fell to the ground, but does not believe he hit his head. He came to not too long after and stated that this has happened before when he has dealt with needles. Other symptoms include patient feeling clammy. His BP was taken three times and read 97/59. 156/108, and 134/94. |

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| 1209734 | 4/14/2021 | FL | 23 | M | 4/14/2021 | 4/14/2021 | Numbing of tongue, cannot see or hear for a minute, fainted. He fell to ground and regain hearing and sight, and started to feel better. |
| 1209711 | 4/14/2021 | CA | 58 | F | 4/12/2021 | 4/13/2021 | Thirty four hours after my vaccine all of a sudden it felt as though someone gave me a tranquilizer. Everything started spinning, I felt nauseous and could not keep conscience. I felt paralyzed. I could not lift any part of my body. I passed out! I remember this morning that I could faintly hear my husband on the phone trying to get help. I feel much better today, but still dizzy and nauseous, but nothing like what hit me last night. It was as if someone had given me anesthesia. I could not find anyone on line that had this reaction? |
| 1209678 | 4/14/2021 | NJ | 29 | F | 3/10/2021 | 3/11/2021 | Nausea, vomiting, fever, dizziness, headache, body ache, fainting |
| 1209632 | 4/14/2021 | NY | 66 | F | 1/14/2021 | 1/25/2021 | FIRST EVENT: I fainted while walking my dog on 01/25/2021, 11 days after first dose of the Moderna vaccine. I fell on the ground and hit my head. I had never previously fainted before. I injured my forehead, my nose, my knees and hands. I do not remember falling to the ground and I did NOT brace when falling. While fainting, I didn't realize I was falling. SECOND EVENT: In February, after the second dose of Moderna, I started getting strong pain and cramps in both legs in the calf muscles and my toes. I couldn't walk. Starting on 03/09/2021, the pain in the left left intensified and I went to the doctor. The doctor performed ultrasound and told me that I have inflammation of the veins in the calf muscle. I started blood thinner medication (Eliquis) on 03/10/2021 for four days. I also took Ibuprofen (3x600 mg daily) for 12 days and Celebrex for 10 days. Once the inflammation decreased, I stopped taking the medication. I had residual pain for three weeks. I no longer have pain. |

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| 1209576 | 4/14/2021 | CA | 36 | M | 4/14/2021 | 4/14/2021 | Patient received 2nd vaccine on left deltoid muscle at 01:05PM. Patient advise the need to wait 15 minutes for any adverse reaction. Patient verbalized understanding. Patient asked if history of fainting patient stated when he was younger and has not fainted in a while, and his first COVID-19 vaccine was done in a drive-thru and he was fine. Patient was monitor for 5 mins after vaccine was given inside the room, when patient stated is was feeling dizzy and patient fainted at 01:10PM. Provider was called and made aware. Patient was move to provider room to be laid down with help of other nursing staff. Vital sign taken at 01:15 PM BP 108/81 HR 75 SpO2 99% RR 18 patient stated he was feeling a bit better. Vital sign taken at 01:25 PM BP 106/79 HR 71 RR 16 SpO2 98%. Patient stated he was better but was going to call Partner to come and pick him up. Vital sign at 01:35PM 123/81 HR 72 SpO2 98 % RR 16, patient stated he was much better. Patient was asked to sit on chair and stated he felt fine vital sign taken at 01:45 PM BP 128/87 RR 16 SPO2 97% HR 71. Vaccination record card and Fact sheet for vaccine provided to patient. Patient monitor for 30 minutes no adverse reaction noted. Patient left clinic stable with steady gait with Partner. |
| 1209466 | 4/14/2021 | NY | 21 | F | 4/10/2021 | 4/11/2021 | 4/10 at night - lightheaded, fever, chills, sweating, headaches -- > took Tylenol 4/11 in morning- fever, headaches, dizziness, severe dehydration, fainting/passing out -- > taken to ER after passing out, treated with saline, other fluids, and rest |
| 1209574 | 4/14/2021 | CA | 24 | M | 4/14/2021 | 4/14/2021 | MINUTES AFTER RECEIVING VACCINE, PATIENT FELL AND WOKE UP CONFUSED. POSSIBLE SLIGHT SYNCOPE. PATIENT SEEMED FINE AFTER SITTING DOWN AGAIN. PATIENT TOLD TO WAIT 30 MINUTES LONGER AND TO CONTACT SOMEONE ELSE TO DRIVE HIM HOME. OFFERED TO CALL 911, BUT PATIENT DECLINED AND SAID HE FELT FINE. |
| 1209491 | 4/14/2021 | AL | 43 | M | 4/13/2021 | 4/13/2021 | Severe chills, headache, body ache, dizziness. Low fever. Almost passed out. |

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| 1209533 | 4/14/2021 | WA | 22 | M | 4/6/2021 | 4/6/2021 | PT RECEIVED THE VACCINE AFTER COMPLETING THE SCREENING QUESTIONNAIRE AND CONSENT FORM. PT THEN WALKED AROUND IN THE STORE AFTER RECEIVING THE VACCINE AND ENDED UP FAINTING. THIS OCCURRED WITHIN 10 MINUTES OF RECEIVING VACCINATION. |
| 1209593 | 4/14/2021 | NM | 34 | F | 3/25/2021 | 3/25/2021 | dizziness, chills, possible fainting |
| 1209703 | 4/14/2021 | AZ | 78 | F | 3/16/2021 | 3/16/2021 | pt had 2nd dose of covid vaccine on 03/16 went home got something to eat laid down- does not remember anything else for 2 days was found on the floor by her bed must have fell off of the bed has lost urine neighbor found her- call paramedics declined to go to hosp thinks she passed out for 1.5-2 days daughter came to take care of her had to drink from straw couldn't eat brain fog feeling better now |
| 1209529 | 4/14/2021 | IL | 42 | F | 4/8/2021 | 4/8/2021 | 15 minutes after injection: out of nowhere became extremely dizzy, nauseous, and fainted. stayed on floor, drank water, juice, crackers, tried to get up but was too weak and almost fainted again. sweating profusely and cloudy vision so lied back down. After 1+ hour felt mostly better so left . 30 minutes into my drive home felt sudden onset of nausea, left fingers tingling & numbing with save wave of extreme dizziness. Pulled onto median and called 911. My face started stiffening into a pucker like position and my muscles all through my body stiffened, but weakened with sharp tingling. I couldn't stand so they carried me out of car and took me to Hospital. The rooms were full so I was in wheelchair waiting for room, shaking profusely, blue fingers, nauseous, dizzy and couldn't stand on my own. I was able to go to restroom w/assistance but My muscles were stiffened for 1 hour+ and over and i felt awful. over the course of 5 hours I gained strength back and started to feel better with just mild headache and nausea. They did EKG, blood panel and chest xray which looked ok. Diagnoses as allergic reaction and told me to come back if more issues. The day after shot and every day since have had a headache at base of neck and pressure in cheek/forehead + nauseau + dizziness and extreme tired. Today is 14th and no headache today. |

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| 1209508 | 4/14/2021 | WA | 26 | M | 4/10/2021 | 4/10/2021 | The patient was nervous prior to vaccine and had a needle phobia. About 5 minutes post-vaccine, the patient stated he was not feeling well and feeling warm and sweaty. The pharmacy staff provided the patient with water and an ice pack. The patient stated he was feeling faint. The patient fainted for about 20 seconds and then became conscious again. The patient didn't have any injuries and didn't fall down. The patient was okay and he laid down and elevated his feet on a chair. He then stated that he has severe needle phobia and has fainted several times in the past with vaccine administration and blood draws. He had experienced this in the past. He was still slightly faint and requested that he be checked out. The EMT arrived and they took his vitals and checked him. By the time the EMT arrived, he was beginning to feel better and had sat up and drinking water. There were no further issues. The EMT stated he was good to head home. We followed up with patient and the patient was feeling good with no further issues. |
| 1202447 | 4/13/2021 | OK | 64 | F | 4/11/2021 | 4/12/2021 | Woke up feeling VERY sick and weak with headache. I honestly can't describe better how I felt except I was very ill, more so than I recall feeling my entire life. Got up and used scooter to get to bathroom, as I was non-weight bearing from an ankle from a reconstruction surgery March 2. 70 mins later, I found myself on the bathroom floor after, I assume, I fainted. I have no memory of falling onto the tile and blacking out. My scooter was on the floor near me. The good news is that I no longer felt sick, but was instead sore from slamming into the tile. My coccyx area was hurting, but not enough for me to feel like I needed x-rays. I also had a very sore left shoulder and neck area. I see my ankle surgeon April 15 and will have the ankle x-rayed. I'm hoping to see if I damaged the ankle with the fall. (My ankle hurts a great deal and causes lack of sleep and nausea since the surgery, so I don't know if the fall made the ankle worse or not.) |
| 1202244 | 4/13/2021 | AR | 55 | F | 4/12/2021 | 4/12/2021 | Nausea with Syncope lasted longer than 10 seconds |
| 1202258 | 4/13/2021 | | 27 | M | 4/13/2021 | 4/13/2021 | Syncope |

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| 1202594 | 4/13/2021 | GA | 34 | F | 3/27/2021 | 3/27/2021 | 11:15 am began getting dizzy and disoriented. Went home and went to bed. Saturday03/27/2021 remained dizzy and a bit disoriented throughout the day, at approx 5:50 pm passed out and fell when she got up. Continued to be dizzy and went back to bed. 03/28/2019 still dizzy and passed out again. Took her to the ER at 11:00 am. She was treated and discharged 03/28/2021. Diagnoses: Dizzy Spells & Syncope. It is not in the documentation, but the doctor said he thought it was probably a reaction to the Covid Immunization. She is scheduled to receive the second dose on 04/17/2021 but we can't find anyone to tell us for sure if she should proceed. HELP!!!! |
| 1202323 | 4/13/2021 | IN | 19 | F | 4/11/2021 | 4/11/2021 | low blood pressure (99/71), low heart rate (40-70 bpm), fainting, palpitations |
| 1202574 | 4/13/2021 | TN | 21 | M | 4/13/2021 | 4/13/2021 | 5 minutes post vaccine, patient became dizzy and experienced syncope. Patient was brought to ER. Patient had not eaten any food that day. |
| 1202382 | 4/13/2021 | GA | 24 | F | 3/30/2021 | 3/30/2021 | Syncope while waiting in the waiting period for the 15 minutes. I felt weird and nauseous and started having tunnel vision. |

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| 1202547 | 4/13/2021 | NC | 33 | M | 4/10/2021 | 4/10/2021 | 33yr old patient with unknown PMH and allergies, presented to office for COVID-19 injection on 4/10. CMA administered JANSSEN COVID19 VACC (LOT # 207A21A, exp 6/23/21) IM to patient's right deltoid at 0841. Immediately following injection, patient's arm began to shake which continued past 5min. Patient endorsed seeing black spots, then nausea. Patient denied shortness of breath, difficulty swallowing, chest pain or other symptoms. Patient noted to be pale, diaphoretic, and fainted upon sitting down. Reporter observed patient shaking. Patient admitted to urgent care for further follow up. At 0904, BP 136/82, HR 79, 98% RA. At 0947, BP 93/61. Patient given NS 500mL bolus IV. At 1025, patient denied dizziness, weakness, or nausea. Patient changed to sitting position with mild nausea. VS remained stable. At 1035, patient ambulating without issues. Patient discharged home in stable condition. Patient noted he had not eaten prior to injection. Urgent care provider indicated per physical exam consistent with vasovagal reaction to vaccine. POC = 142, given crackers and water x 2. |
| 1202512 | 4/13/2021 | TX | 34 | F | 4/10/2021 | 4/10/2021 | Dizziness, headache, fainting during 15 minute waiting period |
| 1202229 | 4/13/2021 | AZ | 19 | F | 4/12/2021 | 4/12/2021 | Nearly fainted after the injection. I was very close to passing out, though I soon regained consciousness. My heart rate dropped to 40bpm with the blood pressure being 71/40. After 10 minutes of laying down in front of the pharmacy I felt better with my feet elevated, though I was tired for the rest of the day with an acute headache. |

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| 1201937 | 4/13/2021 | MD | 40 | M | 4/13/2021 | 4/13/2021 | Pt experienced fleeting moment of syncope 5secs while sitting on a chair in the recovery hall. He was aroused to consciousness when his name was called and chest rub applied. V/s bp 103/64, res 12, temp 94.8, hr 83, o2 97% RA. He was taken to a cubicle in a wheelchair and made to lay down on a cot for further observation. Pt was noted to be perspiring profusely. 2pkts of small apple juice and a bottle of water were offered, Pt drank all. At 10:15 a m v/s obtained read - bp 116/84, rr14,hr75, temp 96.6, O2 97% RA. Pt. verbalized feeling well, denied any pain. He was advised to see his caregiver for further medical evaluation .He walked away from the room unassisted at 10:28 a m. |
| 1202453 | 4/13/2021 | | 29 | F | 4/13/2021 | 4/13/2021 | ~~hot", presyncope, lightheadedness. Evaluated by EMS-Refusal to transport. |
| 1202454 | 4/13/2021 | CT | 57 | F | 4/11/2021 | 4/12/2021 | Fainted twice after receiving second shot. Fainted on bathroom floor and hit head and back. Achy, tired and sore afterwards. |
| 1202348 | 4/13/2021 | NC | 19 | F | 4/12/2021 | 4/12/2021 | About 4 hours after the injection I began to feel extremely tired and took a nap for a couple of hours. When I woke up at 5 pm I noticed body aches and chills, and a migraine that would get substantially worse and became throbbing when I would sit up or stand. After taking some Tylenol (300 mg) I thought I was able to walk for small periods or time (aka walk to the bathroom) but I fainted on the way back |
| 1201884 | 4/13/2021 | NC | 36 | F | 4/13/2021 | 4/13/2021 | Patient became extremely dizzy and had to sit immediately on the floor. A check of her blood pressure showed very low results. Patient spoke of history of anxiety, but had never experienced dizziness/near fainting as a symptom. EMS was called and took over caring for the patient. |

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| 1201753 | 4/13/2021 | MI | 30 | M | 4/13/2021 | 4/13/2021 | He has a history of fainting with vaccines and blood draws. He passed out about 10-15 seconds after it was complete. He came to temporarily and went back out. We got him down to the floor and raised his feet above his head. We used ice packs under his neck and wrists. He came to again while on the floor and wanted to lower his legs a minute or two after. He stayed laying down for about 5 minutes, then he sat up on the floor for another 4-5 minutes. He then stood up on his own with out assistance. He then sat for the remainder of his 30 minutes and was much better upon leaving. |
| 1201734 | 4/13/2021 | NY | 22 | F | 2/25/2021 | 2/25/2021 | -3 hours after my first shot I felt very disoriented and nauseated. I immediately fainted and I lost consciousness for 5 minutes, while unconscious I also was incontinent and peed myself. When I came to, I was disoriented for about 2 minutes and very cold. -For a week after I fainted I was very weak and couldn't stand up without feeling that I was going to faint. -The second week after my shot I also felt pressure on my chest for 5 days that has since then gone away. -Since I fainted 3 hours after my shot I have experienced constant ringing in both ears that have not stopped for the past 30 days since I got the vaccine. I also experience blurry vision and vertigo that hasn't gone away. -I have also developed headaches and recently I have an itchy rash on my neck. -Since then it has been hard for me to focus and sometimes I feel like the world is in slow motion. |

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| 1201778 | 4/13/2021 | WA | 39 | F | 4/6/2021 | 4/6/2021 | About 2:30pm on 4/6/2021, same day as vaccine, began to have saline/metallic taste in mouth, about 1 hour later started to get cotton mouth and began getting tired; by 5pm same day I was fatigued and had a hard time keeping my eyes open, started getting chills about 7:30pm and took 2 ibuprofen and fell asleep, woke up some time before midnight because my heart was pounding in my chest, was so tired that I'm not sure if I passed out or just fell back asleep but woke up around 3:00am on 4/7/2021 with a fever and headache. The cotton mouth, fatigue, headache and fever of 99.9 to 101 lasted until about 8:00am on 4/8/2021., where I had a second set of chills and the fever broke. On 4/9/2021 I still had fatigue and had to leave work early as I couldn't multi-task and had a hard time staying focused. The inability to focus and fatigue lasted 4/10/2021 and 4/11/2021, just walking up and down my stairs at home exhausted me. On 4/12/2021 I went back to work, my focus is better but still not back to where it should be, I still get exhausted easily and everything is a bit too bright. On 4/12/2021 about 7:30am, I had a bloody nose that took a while to stop (about 30 minutes), that is not normal as I rarely have a bloody nose; I was late to work due to it and had another one while at work around 11:40am; it was not as bad as the first and stopped after approximately 10 minutes. Today is 4/13/2021- Things are still a little too bright and my energy level is not quite back to normal, I also have a slight headache. |
| 1201796 | 4/13/2021 | AZ | 22 | M | 4/9/2021 | 4/9/2021 | Patient fainted while sitting in chair. Started sweating profusely, felt clammy and cold. Elevated legs, checked pulse and pulse oximeter. Was awake and talking within a couple minutes. Gave him cold water and crackers and he was feeling much better. Paramedics arrived and confirmed all was good. |
| 1203507 | 4/13/2021 | AZ | 54 | F | 4/2/2021 | 4/2/2021 | Patient fainted after getting her vaccine. EMS (was present on-site) observed patient for 30 minutes; she felt better after 15 minutes. Patient denied any additional medical attention and she felt okay afterwards. Later patient said that she has needle phobia. Patient has no symptoms or any additional issues as of 4/13/2021, when followed up with patient. |

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| 1202614 | 4/13/2021 | FL | 71 | F | 4/2/2021 | 4/3/2021 | Chills with shaking , the next morning my husband found me passed out on the tile floor,bruised ribs |
| 1201957 | 4/13/2021 | CO | 18 | F | 4/12/2021 | 4/12/2021 | Feeling nauseous at 7 pm, started to feel dizzy at 10 pm and passed out briefly, friend witnessed. Had 1/2 dinner at 7 pm and 3 water bottles between vaccination and 10 pm. Took shower next morning and felt dizzy getting out, tried to lay down and passed out briefly. |
| 1201820 | 4/13/2021 | MI | 28 | F | 4/9/2021 | 4/9/2021 | Extremely high fever, light-headed, fainting, muscle aches, chills, nausea. Symptoms began at about 4 pm. By 8 pm, they were unbearable and fainting began. Fever broke at 11:30 pm after laying under cold towels and taking aspirin at 8 pm. Headache and fatigue lasted until noon Saturday (April 10) |
| 1202183 | 4/13/2021 | NC | 44 | F | 4/7/2021 | 4/7/2021 | Light headed and passed out/fainted. Tingly fingers after and jittery for a while after. |

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| 1201944 | 4/13/2021 | MA | 33 | F | 4/5/2021 | 4/6/2021 | The night of my first shot, I went to bed but woke up at 3am to use the restroom. Upon washing my hands, I started seeing stars and completely blacked out. I had chills but was sweating profusely. I thought I could make it back to my bed but apparently lost consciousness and passed out on my way out of the bathroom, fall forward onto my knees and smashing my head on my bedroom floor. My boyfriend woke up from the bang and found me unconscious for ~10 seconds before he got me to come to. I was extremely disoriented once I came to and he was able to get me back into bed. Since that date (4/6/21 3am), I have experienced a headache like never before. 4/7 and 4/11 were the worst headaches I've ever had in my life. I was hysterically crying with ice packs on my head in the dark, as light was very bothersome. Taking Tylenol every 4 hrs during daytime while awake barely shook this headache. I had a good day on 4/10, but then had the set back with the worst headache ever on 4/11. I spoke with my doctor's office on 4/7 and they decided I most likely had a concussion and could recover at home. I called again 4/12 in the AM after having the worst headache of my life on 4/11 and they could not get me in for a visit until 4/13. I just left that appointment and while I passed their "neuro" physical exam, I am still experiencing these headaches along with dizziness and shortness of breath when doing the smallest task or bending down and getting back up. I've requested a CT Scan to ensure there isn't a brain bleed causing these issues from my fall which occurred due to the dizziness from receiving this Covid vaccine. |
| 1201984 | 4/13/2021 | IN | 34 | M | 4/8/2021 | 4/8/2021 | Directly after giving the vaccine the patient fainted. Patient "came to" and paramedics were called. When they got here, he fainted again and they took him to the hospital. |
| 1202026 | 4/13/2021 | MO | 56 | F | 4/8/2021 | 4/8/2021 | Rash all over, redness, fever, chest pain and heaviness, fainting, severe itching, sore throat with blisters in mouth, Migraine, and HBP. Treatment: ER-IV Solu-medrol X1, Pepcid x1, Fiorcet x1, Toradol x1, Caffeine pill by mouth. |

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| 1202033 | 4/13/2021 | GA | 22 | F | 3/23/2021 | 3/23/2021 | <p>March 5, 2021: 1st dose of Pfizer vaccine. Severe site pain. March 23, 2021: 2nd dose of Pfizer vaccine. Felt very restless and sick during night, by the next morning symptoms really sat in. March 24, 2021: Went to Urgent Care due to fever. Had COVID-19 test (negative). Very close to passing out there (put head between knees and did not). Was sent to emergency room immediately due to heart rate (high 140s-150s. Highest known was 152 BPM). ER performed following: portable chest x-ray, blood tests, urine tests, EKG. Was told results were all normal with the exception of EKG (not told anything about it, form listed as abnormal). Passed out 2x at hospital. Was given one IV rehydration solution and released that night. Symptoms below lasted for several days: Headache Aches Nausea Aggressive shakes Shortness of breath Confusion Dizziness Site pain (also developed bump under arm) Fever - 103.8 (after 2 Advil, 2 Tylenol, 3 ice packs and eating frozen grapes) Heavy sweats Racing heart Restless March 30, 2021: Still having frequent heart palpitations (they come and go but happen several times during the day. Keep having very high heart rates). Went to doctor. While there, nurse noted irregular heartbeat that sounded like it was ?skipping a beat? and heart rate was also jumping all over the place (high pace, low pace, high, etc.). It was clear something was abnormal. Doctor gave EKG approximately 20 minutes later, EKG looked normal. Was told to come back next morning for blood work and to cut out caffeine. March 31, 2021: Came in for blood work to check thyroid. April 6, 2021: Thyroid results were normal. Still having palpitations among other symptoms (see April 12 for more info) so was told to come in. Was given ?work from home? note and referred to cardiologist. April 12, 2021: Appointment at cardiologist. Still having severe palpitations, occasional dizziness/ lightheadedness, nausea, shortness of breath, exhaustion and chest pain. Heart rate was recorded this day to have gotten up to 139 BPM-- was very high majority of the day. EKG was normal (with exception of high heart rate) but 30 mins later doctor observed high heart rate and abnormal rhythm. Was told to come back in a week and one day for a heart ultrasound and heart monitoring for three days. Still no caffeine intake since 3/30/21. Previous heart rates taken at doctor's visits over the years for comparison below. Never had any prior</p> |

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| | | | | | | | heart problems whatsoever: 8/29/18: 70 BPM 9/17/18: 88 BPM 10/17/18: 64 BPM 10/31/18: 73 BPM 1/21/19: 78 BPM Note: At this point, I have missed over a week and a half of work, and worked from home for over a week. I'm not any better heart wise at all over the course of three weeks post vaccine. |
| 1202054 | 4/13/2021 | WI | 34 | F | 4/8/2021 | 4/8/2021 | Upon receiving vaccine pt immediately stated she felt lightheaded, then stated it was becoming worse and passed out in chair in vaccine booth. Assistance called pt lowered to floor and then assisted to w/c when fully awake a few moments later. Pt stated she immediately felt better. Pt escorted to back recovery area and vitals taken by staff and monitored. VS were as follows HR 88, Resp 20 and BP 92/70. No injuries or abnormalities noted |
| 1202162 | 4/13/2021 | LA | 39 | F | 3/6/2021 | 4/8/2021 | Syncopal, seizure like activity. Negative scans and blood work in the Emergency Room on April 8. Fatigue presently |
| 1201799 | 4/13/2021 | | 28 | M | 4/13/2021 | 4/13/2021 | Syncopal |
| 1203448 | 4/13/2021 | CT | 24 | F | 4/8/2021 | 4/8/2021 | Received vaccination around 10:15 AM and began experiencing soreness in left arm around 1 PM. Consumed regular diet and drank about 2 L of fluids until 6 PM. Laid in bed around 5 PM and got up at 6 PM to urinate. Felt fine, just a bit tired and sore arm. While urinating, experienced slight nausea. When washing hands, experienced dizziness and lightheadedness. Attempted to stabilize self on doorway of bathroom and quickly after exiting bathroom, lost consciousness and fainted. Remained unconscious for a couple of minutes and returned with full clarity and processing, but weakness. Checked bp about 3 hrs later and was very low, with orthostatic numbers even lower. Fever measured at 100.5 F. Took 250 mg Tylenol and hydrated. Days later, bp remains low -- Friday, one day after: standing - 81/57 with temperature of 101.4 F, remaining entire day, with fatigue, joint pain, muscle cramps. on Monday: 86/64, with fatigue, no fever Bp is usually on lower side of healthy range, but no history of clinically low blood pressure, nor orthostatic bp. |

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| 1203644 | 4/13/2021 | CT | 24 | F | 4/7/2021 | 4/7/2021 | Trouble breathing as the shot was administered. Vision began to black out after 3 minutes. Urge to vomit, extreme nausea. Passed out, unconscious within 5 minutes of receiving the shot. Could not sit up/dizzy for 30 minutes. Nausea, weakness, dizzy, poor mental acuity/memory. Later that night, and through the night for 10 hours, severe back pain. Nausea, severe weakness, dizzy, poor mental acuity and memory, sweats and chills. The next day (day immediately after receiving vaccine) symptoms continued but lessened by 5 pm. Each day since then, the symptoms have ALL remained in a more mild form. Today is day 6 and I still have moderate back pain and occasional sweats, weakness and fatigue. |
| 1203610 | 4/13/2021 | CO | 19 | M | 3/31/2021 | 3/31/2021 | Patient had syncope shortly after the Janssen vaccine was given while he was waiting in the medical monitoring area of the vaccine clinic. Patient was unconscious for less than a minute, vitals signs were taken onsite, BP 102/60, O2 96, HR 72, RR 15. Pt was observed and assessed at the time by Dr. Patient reported not eating that afternoon, he was given water and a snack and monitored for 40 min after event. Patient instructed to f/u with primary care doctor the following day and go to the ER/Urgent care if any other changes occur. |
| 1200469 | 4/13/2021 | MD | 29 | F | 4/8/2021 | 4/8/2021 | Pt complained of burning when vaccine injected. Within 2 minutes pt put her head down; stated she was dizzy and then her eyes rolled back and she started to slump over in her chair and then fainted. Moved pt to the floor. She was unconscious for only 1 minute. Vitals: BP: 110/62, Pulse 48, R: 12, T: 98.1, Pulse ox: 99%, Finger stick for blood sugar: 92. Pt had not eaten for almost 24 hours and has a fear of needles. Within 10 minutes vitals improved: BP: 125/90, P: 67, R: 18, Pulse ox: 99%. Pt is a smoker and had worked all night. |
| 1201706 | 4/13/2021 | CA | 32 | F | 3/14/2021 | 3/19/2021 | 7:00 pm Friday started getting left arm: numbness on whole left side of body, left side of face swelling and droopy. Felt a sharp pain in left arm near basilic vein and started swelling like a ball. Felt shortness of breath and dizzy with blurry vision. Almost passed out when stood up. Was rushed to the ER. Had Sharp pains shooting through left leg. |

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| 1203594 | 4/13/2021 | VA | 21 | M | 4/8/2021 | 4/8/2021 | Patient fainted and fell to the floor within 15 minutes of vaccination. He was observed to have seizure-like activity for approximately 20 seconds. Patient was transported to ER by EMS. |
| 1203584 | 4/13/2021 | TX | 52 | F | 4/1/2021 | 4/1/2021 | nausea/ vomiting /syncope |
| 1203530 | 4/13/2021 | CA | 39 | F | 4/10/2021 | 4/10/2021 | All fine after shot until about 9 hours after shot cold aches in back and the fever all body sweating nausea, no vomiting, in bed got up to go to bathroom and passed out falling have lots of bruising multiple areas from fall. felt better after came to. No seeing medical prof for this treatment has been bed rest. |
| 1203527 | 4/13/2021 | IA | 50 | F | 3/17/2021 | 3/25/2021 | Vasovagal syncope. Had vaccine on the 17th on the 25th in the early morning hours I got out of my bed, passed out or had a seizure in my kitchen. Went to doctor 4 days later because I was in pain mainly in feet, was told I broke my foot. I asked if vaccine could have caused it and was blown off by 3 different healthcare providers, I thought by law they were supposed t report adverse effects like this. |
| 1203519 | 4/13/2021 | TX | 50 | F | 4/12/2021 | 4/12/2021 | near syncope, dizziness |
| 1203517 | 4/13/2021 | PA | 29 | F | 4/6/2021 | 4/6/2021 | within 30 seconds from vaccine parient became very light headed cold and clammy. and passed out blood pressure was very low 82/54. patient was awaken and immedietly started asking lots of questions stating that it felt like a dream a 2nd bp was taken and was 100/78. 3minutes later patient passed out again with what appeared to look like seizures.. Patient was lied on the ground a vitals continuously watched ambulance was called. Patients vitals were stabilizing and was decided to move patient out of way when having patient to walk patients pressure once again dropped patient was sent to er for further evaluation. It was later passed on to us by patient that er stated that patient has such a low tolerance for pain that this caused this occurance as the same thing happened the next day when patient got out of bed and arm hurt from the vaccine. Patient passed out. |
| 1203512 | 4/13/2021 | TX | 29 | M | 4/12/2021 | 4/12/2021 | Near Syncope |

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| 1203505 | 4/13/2021 | IA | 21 | F | 4/9/2021 | 4/9/2021 | fainted |
| 1203485 | 4/13/2021 | | 35 | F | 4/7/2021 | 4/7/2021 | History of anxiety around injectables Symptoms: diaphoretic, pale, light headed, husband stated she had first syncope episode after receiving the vaccine. As EMT arrived to assess the patient she had a second syncope episode that presented as seizure activity that lasted for 40-50 seconds. After the second episode patient came alert stated she felt much better, which she state she didn't feel well after the first syncope episode. We witnessed patient ambulate to the stretcher and loaded into ambulance for further assessment and transport then patient refused transport. VS: BP 140/95, RR, 18, pulse 70, Oxygen 98% |
| 1203487 | 4/13/2021 | PA | 29 | M | 4/12/2021 | 4/12/2021 | Almost passed out, blood pressure had dropped |
| 1203181 | 4/13/2021 | NJ | 19 | F | 4/13/2021 | 4/13/2021 | Site: Pain at Injection Site-Mild, Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Mild, Additional Details: a few minutes after the patient took the vaccine she started getting lightheaded and she came to the pharmacy counter and passed out there. i carried the patient and sat her straight in a chair. i gave her water and orange juice. patient was confused and not aware of her surrounding and said she barely could hear. once she drank the OJ she felt better. took her vitals everything was fine. pt said she felt all good |
| 1202686 | 4/13/2021 | FL | 60 | F | 4/11/2021 | 4/11/2021 | Patient was seated. Patient passed out had shallow rapid breathing, weak pulse |

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| 1202770 | 4/13/2021 | CT | 24 | F | 4/12/2021 | 4/12/2021 | Prior to administration of Janssen Covid-19 vaccine the patient was anxious but was completely fine once the procedure commenced and concluded. After finishing explaining the possible side effects of the vaccine and handing the patient the V-Safe handout, she got up slowly and proceeded to our designated post vaccination monitoring seating arrangement. Upon concluding the vaccination process with the patient's partner, she alerted the pharmacist that she does not feel well. To which he asked her to further elaborate on what she is experiencing. She began to say she thinks she's going to faint as she is attempting to drink water. As she was having a drink of water she fainted. To which he responded by running over and catching her before she hit the ground, cradling her upper torso, specifically the head and laid her down on the floor with the assistance of pharmacist and her partner. In the midst of everything he instructed another pharmacy technician to call 911 for the paramedics. As she was in the process of drinking water I saw her other hand go to the region of the neck, thinking it was also an allergic reaction and administered a dose of Epi-Pen. He administered the Epi-Pen on the upper side of her thigh, directly to the skin not through clothing. There was a very brief moment where the patient began to convulse but gradually regain consciousness. The patient became lucid and was conversing with him, apologizing for the incident. He assured her there was nothing to apologize for and to which she told me she had similar incidents from vaccinations as a child. She did not mention this prior to administration of the vaccine and through conversation we believe the incident may be caused from high anxiety of needles / vaccinations. When the paramedics arrived, they assisted the patient from the floor and gave a warning that she believed she was going to faint again, and fainted in the arms of the paramedics. |
| 1202803 | 4/13/2021 | MA | 22 | M | 4/13/2021 | 4/13/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild |

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| 1202987 | 4/13/2021 | MN | | F | | 4/1/2021 | PASSED OUT; TERRIBLE FEVER; SMALL ANEURYSM IN BRAIN; This spontaneous report received from a patient concerned a female of unspecified age. The patient's height, and weight were not reported. The patient's past medical history included hormone therapy, and IVF (In-Vitro Fertilization). The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, 1 total administered on 03-APR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. Concomitant medications included hormone therapy. On 03-APR-2021, the patient experienced terrible fever and headache after vaccination at night. On 04-APR-2021, the patient passed out which had never happened to her before. She was taken to the emergency room and was diagnosed with a small aneurysm in her brain. The patient was very fearful, this was new and would be getting larger/rupture sooner. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the terrible fever, passed out and small aneurysm in brain was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0- 20210412164-covid-19 vaccine ad26.cov2.s -Small aneurysm in brain, Passed out. This event(s) is considered not related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: MEDICAL HISTORY |

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| 1203088 | 4/13/2021 | CO | | U | 4/7/2021 | | <p>FAINTING; DIZZINESS; VOMITING; NAUSEA; This spontaneous multiple patient report was received from physicians, consumer, media, and press release and concerned 11-13 adult male and female patients. Initial information received from a consumer on 07-APR-2021 was processed with additional information received from media and then obtained via follow up with physicians on 08-APR-2021, and from the physician and Department of Public Health and Environment press release on 09-APR-2021. The patients' height and weight were not reported. The patients' concurrent conditions included anxiety and fainting. The patients received COVID-19 VACCINE AD26.COV2.S (suspension for injection, route of administration, dose, and site of vaccination not reported, batch number: 18008980 and 201A21A) administered on 07-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On 07-APR-2021, within 15 minutes of vaccination, 11-13 patients out of about 1700 who were vaccinated that day experienced varying symptoms including fainting, dizziness, vomiting, and nausea. The patients received vaccine at a "drive-up" vaccination event, then drove to a parking lot to wait for about 15 minutes with instructions to honk if they felt ill. Two or three patients were transported by EMS to the local hospital for observation. They were later released from the emergency department and were not admitted. Two patients were recommended to go to the hospital, but declined, and were observed and treated with juice and water along with other 7 patients at the site. The reporting physician did not feel that the reactions were due to the lot or the specific vaccine, but were rather due to vasovagal reactions. The press release stated that "the Food and Drug Administration has run the two lot numbers used at the site and found no worrying pattern of similar events with these lots." The action taken with COVID-19 VACCINE AD26.COV2.S was not applicable. The outcome of the fainting, nausea, dizziness, and vomiting was not reported. This case is associated to product complaint PQMS# 90000175639. This case is linked as same patient to 20210415071. This report was serious (Other Medically Important Condition).; Sender's Comments: V0 This report concerns multiple patients who experienced adverse events after receiving an injection at a "drive-up" vaccination site. On 07-APR-</p> |

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| | | | | | | | 2021, within 15 minutes of vaccination, 11-13 patients out of about 1700 who were vaccinated that day experienced varying symptoms including fainting, dizziness, vomiting, and nausea. Two (or three) patients were transported to the hospital for observation. It was reported that some patients had concurrent anxiety and fainting. Given the close temporal relationship and the nature of the events, the events are considered possibly related to the vaccination, the "Drive-up" circumstance likely were a significant contributory factor. |
| 1203461 | 4/13/2021 | TX | 28 | M | 4/11/2021 | 4/11/2021 | I got the Covid 19 Vaccine Pfizer at the pharmacy. After I got the Vaccine I was waiting in the waiting room for 15 minutes but before my time was up and it was my time to leave I felt really dizzy & light headed as I was sitting down on a chair. Then I just felt some one tell me to wake up because I had fainted, fell face down to the floor & convulsed for 5 seconds. |
| 1203173 | 4/13/2021 | KS | 28 | M | 4/13/2021 | 4/13/2021 | Patient alerted me he had trouble with passing out or dizziness in the past. I gave the vaccine and patient immediately laid on the floor with legs up. He felt better, then dizzy again. Then better. When he went to stand up a third time he got dizzy and passed out in the chair. Another helped me lay him on the ground and he immediately came to. We stayed another 25 minutes in room and another 20 minutes out front. Gave a bottle of water but no medications. Patient felt good after that and left. |
| 1203454 | 4/13/2021 | PA | 53 | F | 4/13/2021 | 4/13/2021 | pt felt lightheaded several minutes after vaccination. felt better after lying down and drinking water. pulse in the 70s throughout. lungs ctab and heart rrr. was able to ambulate without assistance. pulse did not change after standing. counseled on syncope precautions. |
| 1203270 | 4/13/2021 | UT | 57 | M | 4/8/2021 | 4/9/2021 | Fainted twice, some body shakes when waking up, glazed over eyes |

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| 1203347 | 4/13/2021 | FL | 82 | M | 3/25/2021 | 3/28/2021 | PATIENT WAS ADMINISTERED THE JANSSEN COVID VACCINE AT APPROXIMATELY 10:30AM. IMMEDIATELY FOLLOWING REMOVAL OF NEEDLE AFTER INJECTION, THE PATIENT APPEARED TO FAINT FALLING FORWARD IN HIS OWN LAP. AFTER ABOUT 15 TO 30 SECONDS, HE REGAINED CONSCIOUS. WE ASSESSED THE PATIENT TO ASK IF HE HAD EVER EXPERIENCED FAINTING BEFORE OR SPECIFICALLY DURING VACCINATION. HE HAD NO PREVIOUS EPISODES. WE QUICKLY OFFERED THE PATIENT SOME WATER AND CRACKERS WHILE HE REMAINED SEATED. THE PATIENT FELL FORWARD AGAIN AND APPEARED TO BE CONVULSING. ONCE HE STABILIZED, MY PARTNER STEPPED AWAY TO RETRIEVE WATER, AND THE PATIENT ONCE AGAIN FELL FORWARD AND BEGAN CONVULSING. ONCE HE STABILIZED, HE DRANK SOME WATER AND ATE SOME CRACKERS. HE MENTIONED THAT HE FELT EXTREMELY TIRED. WE INSISTED TO CALL THE PARAMEDICS FOR HELP, BUT HE DECLINED SAYING THAT HE WAS OK AND MAYBE THE NEEDLE TRIGGERED THE EVENT. AFTER WE OBSERVED THE PATIENT FOR 30 MINUTES AND HE ASSURED US HE WAS IN STABLE CONDITION, HE LEFT WITH HIS GIRLFRIEND. PATIENT WAS CALLED TWICE AFTER THE EVENT TO FOLLOW-UP BUT WE HAVE NOT HAD SUCCESS IN FOLLOW-UP. |
| 1203411 | 4/13/2021 | NJ | 52 | F | 4/7/2021 | 4/7/2021 | Pt stated she was shaking, sharp abdominal pain, eyes burning, temperature of 100.4 F, nauseous, weak, near fainting, difficulty breathing, and burning knees. |
| 1203413 | 4/13/2021 | VA | 22 | M | 4/7/2021 | 4/7/2021 | Patient fainted and fell on the floor within 15 minutes of vaccination. Patient felt nauseous and was transported to the ER by EMS. |
| 1203431 | 4/13/2021 | CO | 57 | F | 4/7/2021 | 4/7/2021 | Light headed, nausea, syncope, vomited, Level of consciousness was diminished prior to leaving after receiving her vaccine. > First VS: 140/83, Pulse 88, RR 18, Oxygen 97% > Second VS: 123/74, pulse 76, RR 18, Oxygen 93% Transport checked VS in the ambulance and she refused transportation. |

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| 1202651 | 4/13/2021 | CA | 27 | F | 4/7/2021 | 4/7/2021 | All administration of vaccine was done properly, however, patient soon developed sudden syncope. Had patient sit in upright chair, legs not crossed, had BP readings done (113/68, HR 67), patient states light headiness and dizzy. Patient had to be in administered chair for 10 minutes before transitioning to another post vaccination chair to be monitor for additional 20 minutes. Patient regained consciousness within a few minutes and was cleared to leave facility after patient was properly monitored in facility. |
| 1203144 | 4/13/2021 | FL | 70 | F | 3/18/2021 | 3/19/2021 | Congestion in lungs; Upper respiratory infection; Felt passed out; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PULMONARY CONGESTION (Congestion in lungs) in a 70-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 047A24A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event. On 18-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 19-Mar-2021, the patient experienced PULMONARY CONGESTION (Congestion in lungs) (seriousness criterion medically significant), UPPER RESPIRATORY TRACT INFECTION (Upper respiratory infection) and PRESYNCOPE (Felt passed out). At the time of the report, PULMONARY CONGESTION (Congestion in lungs), UPPER RESPIRATORY TRACT INFECTION (Upper respiratory infection) and PRESYNCOPE (Felt passed out) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Concomitant product use was not provided by the reporter. Patient had fever, chills, headache and sore throat. Then later she developed cough with mucus and shortness of breath. She still had congestion in lungs and at one time almost felt passed out. She has been to emergency 4 times for this and they told her that it was upper respiratory infection. Treatment medications included Loratadine, Dexamethasone and Albuterol. |

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| 1200276 | 4/13/2021 | RI | 23 | M | 4/11/2021 | 4/11/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Medium, Additional Details: felt unwell, fell out of recovery chair and hit head. Patient monitored on floor with feet elevated until rescue came and took patient to ER and was monitored. Went home same day and returned to work the next day, feeling better |
| 1200682 | 4/13/2021 | NY | 30 | M | 4/7/2021 | 4/11/2021 | I received the vaccine on Wednesday, April 7th. I was told I had an anaphylactic reaction at the time of injection: I started sweating upon receiving the vaccine, my blood pressure dropped, and I almost passed out. I was monitored for 30 mins before being sent home. Other than some fatigue, I was fine the rest of the day. On Thursday, April 8th, I was tired but felt fine otherwise. Friday and Saturday, April 9th and 10th, I felt like I was back to normal and even did some light exercise. On Sunday morning, April 10th, the left side of my body (side of injection) went numb, I had extreme vertigo, shortness of breath, and blotches that appeared in random places. It didn't look like hives, but rather looked like strips of red. I didn't feel like I was having an allergic reaction, but something did not feel right. I consider myself a pretty healthy guy with a healthy lifestyle. I did not feel the need to go to the ER quite yet, but I did have a friend come over to monitor me. My friend did some acupuncture which helped resolve the numbness and dizziness and some of the blotches, and also mentioned concerns regarding blood circulation and potential clotting issues she thought I was having. |
| 1200657 | 4/13/2021 | CA | 17 | F | 4/12/2021 | 4/12/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Additional Details: she was sitting for 15 minutes observation she fainted and fell from the chair. She wa unconscious for about few seconds. called 911 for her. she looked pale. paramedics took her in. checked all her vital sign she was fine , her dad took her home. Spoke to dad at 6 pm in the afternoon. she is home resting and having dinner. |
| 1200654 | 4/13/2021 | NC | 18 | F | 4/6/2021 | 4/6/2021 | Passed out, hives, throat felt like it was swollen, right arm swelling, headache, stomach pains, chills, fever. Was given EPI pen, benadryl, antihistamine blockers, and steroids. |

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| 1200653 | 4/13/2021 | | 24 | M | 4/13/2021 | 4/13/2021 | Dizziness followed by syncope |
| 1200636 | 4/13/2021 | CA | 33 | M | 4/11/2021 | 4/11/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient fainted and was passed out for ~30 seconds but resumed consciousness soon after. 911 was called and firefighters arrived to the scene and assessed patient. His vitals were normal. Patient declined further medical attention. |
| 1200614 | 4/13/2021 | PA | 59 | F | 4/13/2021 | 4/13/2021 | HTN crisis, dx as near syncope @ Hospital |
| 1200609 | 4/13/2021 | NY | 23 | M | 4/9/2021 | 4/9/2021 | Patient passed out while waiting the 15 minutes after the injection |
| 1200595 | 4/13/2021 | MN | 20 | F | 4/9/2021 | 4/9/2021 | Systemic: Fainting / Unresponsive-Medium, Additional Details: Regained consciousness quickly (less than 30 seconds) |
| 1200594 | 4/13/2021 | | 54 | F | 4/7/2021 | 4/11/2021 | Woke 4 am to use bathroom. While using bathroom, got dizzy and nauseous and broke out in a full body sweat, then passed out, falling to the floor. |
| 1200530 | 4/13/2021 | CA | 25 | F | 4/12/2021 | 4/12/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Seizure-Mild, Additional Details: Patient fainted after getting her first dose of the vaccine. Patient fainted while sitting in the chair, the immunizer led her down to the floor. Patient was alert in 20 seconds of fainting, she was not aware of what had happen. Patient was asked if she was having difficulty breathing. Patient was having hard time resposing, epinephrin was adminstered and 911 was called at 11:29am. |
| 1200465 | 4/13/2021 | NY | 38 | M | 4/12/2021 | 4/12/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Headache-Medium, Systemic: Nausea-Medium, Systemic: Vomiting-Medium, Additional Details: Patient experienced fainting for 2-3 seconds followed by 10 minutes of nausea/vomiting/flushing. Patient returned to baseline |
| 1200296 | 4/13/2021 | | 19 | M | 4/12/2021 | 4/12/2021 | syncope, history of syncope due to vaccinations. monitored for 30 mins and symptoms resolved. |

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| 1200286 | 4/13/2021 | TN | 62 | M | 4/12/2021 | 4/12/2021 | About 10 minutes after getting the shot, while waiting in the Doctor's waiting room, I began to feel dizzy and began sweating. They moved me into an exam room, and which time I passed out. I was awoken by the doctor standing over me, rubbing my chest. I was subsequently transferred to the ER. |
| 1200565 | 4/13/2021 | CA | 25 | F | 4/12/2021 | 4/12/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Mild, Systemic: Hypotension-Medium, Systemic: Nausea-Mild, Systemic: Shakiness-Mild, Additional Details: patient fainted immediately after vaccinated. patient speaking within 15 seconds of fainting spell. Epi administered to right thigh. patient put supine on floor with knees up and c/o nausea. patient reported she had previously fainted after ob/gyn visit. Patient reports hx of low BP. |
| 1200010 | 4/13/2021 | OK | 16 | F | 4/10/2021 | 4/10/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Syncope with twitch, fully awake and oriented within a minute. |
| 1203655 | 4/13/2021 | IN | 46 | F | 4/8/2021 | 4/9/2021 | Started to feel badly (headache, slight fever, typical side effects) around 10-11pm Thursday... Was very thirsty so got out of bed to go the bathroom and get more water around 3am. On the way back, fainted. Not sure how long was out, but came to and was able to get up and back to bed after lying on the floor for ~10 minutes. The rest of Friday, just felt feverish, headachy and fatigued. |
| 1202785 | 4/13/2021 | CT | 17 | U | 4/13/2021 | 4/13/2021 | Systemic: Chills-Mild, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Mild, Systemic: Nausea-Mild, Systemic: Weakness-Mild |
| 1199700 | 4/13/2021 | FL | 31 | F | 4/9/2021 | 4/10/2021 | Redness/swelling at injection sight. Soreness at injection sight. Dizzy, migraine, nauseous, fainting spell, and body aches. |

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| 1199719 | 4/13/2021 | VA | 45 | F | 4/9/2021 | 4/10/2021 | Patient received second Pfizer dose on 4/9 at 9:15 am. That evening she developed fever of 102.5 F with body aches and chills. On 4/10 at about noon, she developed squeezing chest tightness for about 20-30 minutes. 7/10 with back and neck tightness as well. she developed an urgent need to have diarrhea and had a momentarily loss of consciousness consistent with presyncope. Afterwards, the chest tightness went away and she felt better. All other symptoms resolved. The patient came to the clinic. Vitals: BP 97/63, P90, T36.6C, D-dimer 7140 ng/ml EKG- NSR, rate 83 bpm, no acute ST-T changes, Troponins negative, CBC - normal Chest CT with contrast negative for PE B/L LE Venous ultrasound- Right posterior tibial thrombus |
| 1199824 | 4/13/2021 | OK | 47 | F | 4/12/2021 | 4/13/2021 | Body aches, fainted followed by a Seizure |
| 1200284 | 4/13/2021 | VA | 48 | M | 4/12/2021 | 4/12/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe |
| 1200007 | 4/13/2021 | OH | 18 | M | 4/12/2021 | 4/12/2021 | Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Seizure-Mild |
| 1200281 | 4/13/2021 | NY | 23 | M | 4/12/2021 | 4/12/2021 | Systemic: Chills-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Exhaustion / Lethargy-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Seizure-Severe |
| 1200011 | 4/13/2021 | VT | 18 | F | 4/9/2021 | 4/9/2021 | Systemic: Fainting / Unresponsive-Mild |
| 1200019 | 4/13/2021 | FL | 23 | F | 4/10/2021 | 4/10/2021 | Systemic: Confusion-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Weakness-Mild |
| 1200249 | 4/13/2021 | FL | 24 | F | 4/12/2021 | 4/12/2021 | Site: Itching at Injection Site-Mild, Systemic: Fainting / Unresponsive-Severe, Systemic: patient has severe anxiety -Mild, Systemic: Shakiness-Mild, Additional Details: patient suffers from severe anxiety. Patient reported it has happened before with other vaccinations |
| 1200256 | 4/13/2021 | MD | 34 | M | 4/12/2021 | 4/12/2021 | Systemic: Chest Tightness / Heaviness / Pain-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium |

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| 1200268 | 4/13/2021 | CA | 18 | F | 4/11/2021 | 4/11/2021 | Site: Pain at Injection Site-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Nausea-Mild, Additional Details: Pt experienced a brief syncope episode. Nurse, the immunizer, was there with her and her mother the entire time. We observed pt for over 30minutes and they left the pharmacy with no other symptoms. I called pt the next morning and she stated that fainting was a \"normal reaction...I get it everytime I get a shot\". She is in between doctors right now and does not feel like we need to contact him. Will talk to her new doctor next time she is seen |
| 1200796 | 4/13/2021 | MI | 28 | M | 4/12/2021 | 4/12/2021 | patient fainted immediately after receiving the vaccine, but they came too a couple minutes later |
| 1199828 | 4/13/2021 | NC | 26 | F | 4/9/2021 | 4/9/2021 | Dizziness and fainting for few seconds Provided support so that patient does not fall. Monitored airway and breathing. Once patient got conscious , provided water and gatorade. Monitored her for 45 minutes and kept checking how alert and oriented she was. |
| 1201628 | 4/13/2021 | CO | 18 | F | 4/9/2021 | 4/9/2021 | Patient arrived to clinic to receive Janssen COVID-19 vaccine. Patient was accompanied by father. After consenting to receive vaccine, vaccine was given to left deltoid muscle. After about eight minutes, patient started to express feeling strange, reporting that she felt like she was going to pass out. Patient became clammy and pale. Clinic MD was called for assistance. After a few minutes, patient started yawn, with head nodding back. Patient was slow to respond for approximately 30 seconds during syncope. There was no loss of pulse or no s/s of trouble breathing. In clinic emergency response called, along with 911. Paramedics arrived to clinic, received report from MD and nurse about situation. Patient was assessed by paramedics, EKG done and was NSR, blood glucose done, and VS several times throughout incident. Patient was initially hypotensive with BP 80s/60s, with BP returning to 116/62 within a few minutes. Patient was taken home by parents following incident, electing not to go to hospital with paramedics. Patient was in good condition when leaving clinic with directions from clinic staff and paramedics to seek emergent care if needed. |

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| 1200707 | 4/13/2021 | NJ | 39 | U | 4/6/2021 | 4/10/2021 | I started having chest pain palpitation Tuesday night and wasnt able to sleep. Wednesday, body ache, and headache all day. Thursday headache still there but manageable. Friday no problem. Saturday, felt differently but ok... Sat around 5:50pm started to feel lightheaded, I tried to walk to my bed to lay down and fainted and hit the floor. I woke up on the floor confused and realized on what had happened. Chest tightness continues and back of the head still hurts as of today and exhaustion persists, Tuesday 4/13. |
| 1201346 | 4/13/2021 | CO | 18 | F | 4/7/2021 | 4/7/2021 | Fainted and hit head, fever, threw up, bad headache, nausea, body aches so bad that it hurt her to touch her anywhere, chest heavy, mouth felt like something in it Lasted for about 36 hours and then weak for another 12 hours Took Tylenol and Motrin after calling Doctor |
| 1201383 | 4/13/2021 | SC | 22 | F | 4/8/2021 | 4/8/2021 | PT WAS FINE IMMEDIATELY AFTER VACCINATION. PT GOT UP AND WALKED TOWARD THE SEATING AREA WHILE WAITING FOR HER HUSBAND AND SAT DOWN. WITHIN 2 MINUTES, SHE PASSED OUT AND FELL INTO THE FLOOR. RPHS IMMEDIATELY ATTENDED TO PT AND SHE STARTED TO COME TO. BP WAS NOT DETECTABLE AND PULSE WAS 54. RESPIRATIONS WERE 40. EMS ARRIVED AND BP WAS 80/60, HR 80 AND RESPIRATIONS 20. THEY STRONGLY ENCOURAGED HER TO GO TO THE ED TO GET CHECKED OUT AND SHE AGREED. NO MEDS NEEDED OR ADMINISTERED. PT RETURNED TO CLINIC FROM ED AT 4:40 PM TO SET UP 2ND APPOINTMENT AND STATED THE ED TOLD HER IT WAS JUST A REACTION TO THE NEEDLE STICK. |

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| 1201405 | 4/13/2021 | TX | 45 | F | 4/5/2021 | 4/5/2021 | I received my COVID Vaccine Johnson & Johnson on April 5, 2021 about 3:45 p.m at Walgreens location listed above. Immediate dizziness and pain on my left arm after receiving vaccine. Next day woke up sick as if I had the flu. Third day I was ok but I have numbness on the left side of my body and felt very nauseous. I have been taking Dramamine to help. I can feel it from my head to my toes as far as the numbness is concern. The left side of my face is still numb. I have been very lightheaded and on Thursday 8, 2021 I had lunch with co workers and felt like fainting. Today is April 13, 2021 I am still lightheaded, and my face and left side of my body still numb and shaky. I feel is has been affecting my thinking. I have not gone to ER, been tolerating it with Dramamine and rest. |
| 1201489 | 4/13/2021 | NY | 37 | M | 4/7/2021 | 4/7/2021 | 4/7/21 12:25 PM B/P 150/98, P 97, 12:40 PM Pulse 78. Chief Complaint syncope and cold sweats, history of syncopal events associated with needles, patient briefly lost consciousness and fell to the ground from standing without hitting his head, regained consciousness and rested. |
| 1201305 | 4/13/2021 | MN | 42 | F | 4/5/2021 | 4/6/2021 | Shot received on 4/5 at 9:30am. On 4/6 at 7:45am (approximately 22 hours later), I fainted, injuring myself. I also vomited and experienced chills, fever, and fatigue. |
| 1201574 | 4/13/2021 | NY | 51 | F | 3/26/2021 | 3/26/2021 | Waited 15 minutes, felt ok, went to car, almost passed out. Went back in to Dr. because thought I might pass out, very dizzy and shaking. My blood pressure & heart rate were high. Dr. believes I had anti-bodies and my body reacted. However, it is 2 1/2 weeks later and I am still dizzy if I move too fast, lean forward, scroll on phone etc. Also, fell out of bed 4-5 days after shot because very dizzy and couldn't catch my balance. |
| 1201237 | 4/13/2021 | CT | 61 | F | 3/9/2021 | 3/10/2021 | Chills, muscle aches, fever of 102 for 6 hours from 2AM 3/9/2021-, fever of 101 and headache/ muscle aches afterwards to 2AM 3/10/21 -fever broke. Fatigue, muscle aches continued for 3 days. (maybe not associated with vaccine... but hip/leg pain flared and continues as well as sudden fainting and flare of diverticulitis (ER-CTscan 3/28/21) |

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| 1201649 | 4/13/2021 | FL | 61 | F | 4/6/2021 | 4/7/2021 | Beginning approximately 10 PM (about 8 hours post-injection), I started to have chills (feet were freezing) and was exhausted. Went to bed, and slept most of the night, only waking once to urinate and to drink a small amount (approx 2 oz) of Coca Cola -- I was very nauseous and thought it would help settle my stomach. During the night I sweated profusely. At 8 AM, I woke again and went to urinate. At that time I felt very nauseous, dizzy, and light headed. When I walked about 2 -3 feet to my bedroom, I collapsed on the floor - unconscious. My partner called EMS, they arrived minutes later. By then I was conscious. They transported me to Medical Center Emergency Room, where I remained for several hours. They indicated that my SYNCOPE was a result of dehydration. TODAY, 4/13, news of BLOOD CLOTS has compelled me to report my adverse reaction. |

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| 1201664 | 4/13/2021 | NY | 45 | M | 4/11/2021 | 4/12/2021 | Soon after injection I developed soreness at injection site, and about an hour later it travelled down my arm and to my hand, with also arm stiffness. On Monday, 4/12/2021 at 12:15am (about 6 hours after injection) I developed chills and body aches. Throughout the night I also developed a headache, muscle aches, nausea and started sweating. At 9am (4/12/2021) when I woke up, all the symptoms continued (chills, body aches, muscle aches, arm soreness and stiffness, headache, nausea) and also felt extreme tiredness. My temperature at 9:15am was 100.4 degrees F. I basically stayed in bed and slept most of the day. I got up at 2:30pm to get something to eat and had a temperature of 101 degrees F. After eating, which made me feel even more nauseous, I went back to bed and continued to sleep. I woke up at 7:30pm to feed the cats. I felt the same as I did at 2:30pm--listed above--and was up and about for 20 minutes. I started to prepare a quick meal and fainted twice (around 8pm) within a minute from each other. The first time I fell to my knees and the second time I felt onto my back. I was unconscious for only a few seconds each time. I went into bed after and placed an ice pack on my forehead. I took my temperature after the ice pack at 8:15am and my temperature was 101.4 degrees F. I ate soup around 8:45am and took Tylenol (1000mg) at 9:30am. I went back to bed and slept all through the night. This morning (4/13/2021--2 days after injection) I feel much better--only have some slight chills and arm soreness. My temperature at 9:15am (4/13/21) was 95.7 degrees F. |
| 1201668 | 4/13/2021 | NY | 20 | M | 4/10/2021 | 4/10/2021 | 1-2 minutes after receiving vaccine patient was sitting in chair and asked for water. Upon evaluation, patient's head fell forward and he passed out. Once Paramedic and NP responded, patient became responsive, was transferred to wheelchair. VS 122/72, 98%, 82 HR. Client was discharge after 30 min monitoring. |
| 1201677 | 4/13/2021 | | 28 | F | 4/13/2021 | 4/13/2021 | Flushed dizzy pre syncope |

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| 1201686 | 4/13/2021 | FL | 23 | M | 4/10/2021 | 4/10/2021 | Administrated JJ covid shot about 145pm. while having patient wait for 15 minutes, the patient started to feel faint & dizzy. His blood pressure was taken, the meter produced error. upon re trying blood pressure was measured at 70/60mmhg. The patient never lost conscious or passed out. Had patient remained sitting while continuing to monitor. I suggested that the patient allow us to call EMS, The patient declined. Chose to leave store against my medical advice. I suggested the patient follow up with emergency medicine or urgent care for assessment. |
| 1201692 | 4/13/2021 | PA | 62 | M | 4/11/2021 | 4/11/2021 | Patient received vaccine at mass vaccination clinic. Proceeded to observation area and fainting sitting in chair. Patient protected in chair from fall but loss consciousness 2 more times. Episode lasted 46 minutes. Patient given ginger ale and recovered. |
| 1201522 | 4/13/2021 | KY | 23 | M | 4/11/2021 | 4/11/2021 | Pt was observed to be slumped over in chair approximately 7min into waiting post vaccine in waiting room. np alerted. Breathing , appeared to have fainted. Pt started to have jerking entire body movements as staff trying to get pt to wake up.... pt noted to have spit in mouth on lips and was making grunting noises as jerking . Staff assisted pt safely to floor. Epi retrieved but as came back to pt. And pharmacist also present w NP pt was breathing , slowly coming to , no swelling noted so then it became more clear poss vasovagal response ... in the beg it was unclear so Ems was activated . Pt continue to stay w clinic for an hour waiting on ride . Pt had declined Ems . Pt vitals pulse 55-65.... coloring better initially very pale . Mother came and reports that it gets nervous and has passed out before after blood draw but not a shot. |
| 1200978 | 4/13/2021 | CT | 28 | F | 4/12/2021 | 4/12/2021 | Immediately upon getting the dose, I fainted and felt as though my ears were popping. This feeling has only gotten worse and it feels as though my ears have too much pressure in them (like I?m underwater) |

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| 1201699 | 4/13/2021 | FL | 49 | F | 4/2/2021 | 4/2/2021 | symptoms started with nausea and worsened greatly over an hour period. Had projectile vomiting and diarrhea which last ~4 hours. later in the evening had dizziness and fainted 2 times. extreme exhaustion lasted approximately 60 hours . symptoms started around 6 hours after injection dose was given at a mobile site |
| 1200845 | 4/13/2021 | NY | 56 | M | 4/11/2021 | 4/11/2021 | Patient was given IM dose of Moderna COVID-19 vaccine. Within 2-3 minutes the patient collapsed in his seat and fainted. Patient was non-responsive for 1-2 minutes then became responsive before intervention was given. 9-1-1- was called and EMS took patient to hospital. |
| 1200873 | 4/13/2021 | NJ | 20 | M | 4/2/2021 | 4/2/2021 | At 10 pm pt. started feeling unwell so he went to lie down. About 10 minutes later he had chills, body aches and was shaking. After a couple of hours he started feeling hot and flushed but did not have a fever. He had body aches and a headache. At 4am he went to the bathroom and started feeling faint so he tried to go back to his bed but fainted in the bathroom. His Mom helped him back to his bedroom, he had no injuries just a headache at that time. He stayed in bed until approx. 5pm when he felt better. No other injuries, or doctor visits. |
| 1200901 | 4/13/2021 | DC | 23 | F | 4/8/2021 | 4/8/2021 | Fainted after receiving shot. |
| 1200936 | 4/13/2021 | FL | 39 | F | 4/12/2021 | 4/12/2021 | Syncope without loss of consciousness |
| 1201328 | 4/13/2021 | MN | 38 | M | 4/8/2021 | 4/8/2021 | Patient felt extremely light-headed and fainted for a few seconds---came to when rph felt for pulse and patted him on shoulder. Rph had reviewed information on consent form including whether he had had any adverse effects to a vaccine that required immediate medical care. His notation on the consent form and verbal information provided to rph prior to injection was no. Immediately after the injection is when he said he should have mentioned that he has fainted in the past when receiving an immunization. EMS was contacted to assess patient and whether it was safe for him to leave pharmacy. EPS monitored blood pressure and other vitals and patient said he felt well enough to leave on his own after 30 minutes observation by rph |

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| 1200961 | 4/13/2021 | NH | 23 | M | 4/12/2021 | 4/12/2021 | Patient fainted |
| 1200709 | 4/13/2021 | MO | 24 | F | 4/13/2021 | 4/13/2021 | pt fainted immediately after administration for approx 5 seconds, called 911, pat came to and was ok. she was checked out by EMS and pronounced OK |
| 1201039 | 4/13/2021 | NH | 52 | F | 4/12/2021 | 4/12/2021 | Patient reported history of fainting after vaccines and pharmacist instructed the patient to sit be monitored for 15 minutes or longer after receiving the vaccine. Patient refused to wait and left immediately after the vaccine and fainted in the front entrance of our facility. She was awake and breathing but disoriented and needed assistance to get up. Patient husband and patient both refused to have EMTs evaluate the patient before leaving. |
| 1201049 | 4/13/2021 | NE | 25 | F | 4/10/2021 | 4/10/2021 | Within 5-7 minutes of receiving shot i fainted/passed out. Onsite paramedics stated blood sugar, blood pressure, and pulse were within normal range after sitting on stretcher for 15 minutes. I signed a release refusing transport to hospital as i was feeling better. Throughout the first day I started feeling tired and sore but that was to be expected. Following day 4/11, extremely nauseous, headache, body aches and typical flu like symptoms, low grade fever of 100-101. At roughly 9:45 am and again at 11:25 am started throwing up bile/stomach acid. Flu like symptoms did not subside until morning of 4/13. |
| 1201061 | 4/13/2021 | CO | 41 | F | 4/10/2021 | 4/10/2021 | Client became light headed and dizzy and had an episode of syncope. EMS alerted, Client regained consciousness. client laid down for 30 mins. Client escorted to car with no evidence of shakiness or lightheadedness |
| 1201069 | 4/13/2021 | MN | 23 | M | 4/12/2021 | 4/12/2021 | Patient fainted about 5 to 10 minute after receiving dose of COVID-19 vaccine. He was very rigid and not responsive to commands. This went on for a few minutes, patient was placed on the ground where he gained consciousness and responsive to commands. Upon coming to patient did say this had happened in the past but he was sorry he failed to mention it. |

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| 1201082 | 4/13/2021 | FL | 18 | F | 4/7/2021 | 4/7/2021 | WITHIN 30 SECONDS OF VACCINE GOING IN HER ARM SHE STARTED TO SWEAT AND GET VERY HOT. SHE SAT IN A CHAIR AND SAID SHE DIDN'T FEEL WELL AND IMMEDIATELY PASSED OUT. HER COLOR DRAINED AND SHE THEN GOT VERY COLD AND SWEATY. THE MAN WHO ADMINISTERED THE VACCINE AND I RUBBED HER FACE, NECK AND CHEST WITH RUBBING ALCOHOL AND A LADY HELD VAPOR BEADS UNDER HER NOSE SHE WAS UNRESPONSIVE AND COMPLETELY OUT ALMOST 4 MINUTES. PHARMACY STAFF CALLED 911. PARAMEDICS CAME RIGHT AFTER SHE WOKE UP AND TOOK BLOOD PRESSURE AND SAID IT WAS VERY LOW AND TRANSPORTED HER TO HOSPITAL TO BE EVALUATED. SHE WAS GIVEN AN IV, HAD BLOODWORK AND AN EKG, HAD A URINALYSIS. WAS DISCHARGED LATER THAT AM. STARTED FEVER & CHILLS SAME DAY 5PM, DID NOT FEEL |
| 1201190 | 4/13/2021 | CO | 28 | M | 4/10/2021 | 4/10/2021 | entered clinic with red bull energy drink, spouse reported Patient drank a soda earlier, skin appeared pale, reported he did not do well with vaccines as a child in the past, still wanted to proceed with vaccine. Had seizure for 2 mins, family reported past history of fainting. EMS attended, responded to questions appropriately, fainted a second time, monitored, pt was released home with spouse |
| 1200956 | 4/13/2021 | CT | 47 | F | 4/1/2021 | 4/3/2021 | 55 hrs after vaccination, I was doubled over with severe abdominal pain. Continuous waves of severe pain. Shortly after severe pain started, tremors/teeth chattering chills even under seven heavy blankets, lasted for hours. Headache (which had been there since 6 hrs after vaccination). Pain was so severe that I was getting ready to go to ER and then vomited. Felt a tad better only to vomit again three hours later, body in a pool of sweat but no fever. Aches, tingling hot prickly sensation running from toes to head, almost passed out. Diarrhea every hour after second vomit, stomach pain started to subside then but never went away completely until 3 days after. |

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| 1205235 | 4/13/2021 | DC | 0 | M | 3/29/2021 | 3/29/2021 | He passed out, he couldn't stay awake/ passing out; This is a spontaneous report from a contactable consumer. An 80-year-old male patient received the 1st dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration administered in arm left on 29Mar2021 10:45 (Batch/Lot Number: ER8132) as SINGLE DOSE for COVID-19 immunization at the hospital. Medical history reported as none. Concomitant medications were not reported. The patient also had no prior vaccinations (within 4 weeks). On 29Mar2021 around 6:30 or 7 PM, the was at the house when the passing out began where he couldn't stay awake. The patient was brought to emergency room and was admitted in the hospital on that same day of 29Mar2021. Outcome of the event was not recovered. No follow-up attempts are possible. No further information is expected. |
| 1205461 | 4/13/2021 | AZ | 40 | M | 4/13/2021 | 4/13/2021 | Patient experienced lightheadedness, dizziness, nausea, syncope within the first 15 minutes of moderna administration. Patient left the observation area prior to the 15 minutes. Paramedics were called and evaluated patient. Determined patient was okay and needed no further medical attention and told patient to stay in the pharmacy waiting area for 15 more minutes for observation. patient left without further incidents. |
| 1205453 | 4/13/2021 | NC | 24 | F | 4/12/2021 | 4/12/2021 | Fainted once approximately 8 hours after receiving the vaccine. No other adverse reaction afterwards other than fever and chills. I have no prior history of fainting. |
| 1205451 | 4/13/2021 | TX | 20 | M | 4/10/2021 | 4/10/2021 | The patient fainted at around 1:10pm (for less than<5 sec.). Per father, son has a history of fainting with vaccines. The patient was reclined on chair and I waited until the patient was completely responsive. No treatment necessary. Symptoms subsided, and patient left the store/pharmacy after more than 30 minutes of wait time. |

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| 1205382 | 4/13/2021 | CA | 20 | F | 4/7/2021 | 4/7/2021 | ABOUT 10 MINUTES AFTER RECEIVING THE VACCINE, PATIENT WAS SITTING WITH HER MOTHER AND BECAME LIGHT HEADED AND BEGAN SWEATING. SHE NEVER LOST CONSCIOUSNESS AND WAS ABLE TO FOLLOW DIRECTIONS DURING THAT TIME. EMS WAS ALREADY ON SITE ATTENDING TO A PREVIOUS PATIENT WHO HAD FAINTED. THEY RENDERED AID TO PATIENT BY CHECKING HER VITAL SIGNS. SHE WAS HYPOTENSIVE ON A MONITOR. THEY DID NOT CHECK BLOOD SUGAR. UPON GETTING HER HISTORY, IT WAS DISCOVERED SHE HAD DRIVEN 3 HOURS FROM HER HOME TO FIND A LOCATION WITH THE VACCINE AND HAD ONLY EATEN LITTLE DURING THE DAY. AND PRIOR TO HER VACCINE, ANOTHER PATIENT FAINTED. |
| 1205380 | 4/13/2021 | MD | 17 | F | 4/13/2021 | 4/13/2021 | patient fainted after receiving vaccine - her dad was with her here in the pharmacy and stated that this was typical of her when getting blood drawn/needles |
| 1205367 | 4/13/2021 | KS | 19 | F | 4/10/2021 | 4/11/2021 | 4/11/21 fatigue weakness slept 5 hours 4/12/21 chfs pain, clammy dizzy, fainted Headache 4/13/21 trouble tracking, time. Clammy, dizzy, fainted, headache, vomit, body aches, fatigue, tingling, shaking, cheats pain |
| 1205344 | 4/13/2021 | | 36 | F | 4/12/2021 | 4/12/2021 | vasovagal syncope |

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| 1205333 | 4/13/2021 | HI | 42 | M | 4/13/2021 | 4/13/2021 | Participant fell off chair on his right side at 11:04 AM. He hit his right temple area. He fainted without warning. He has an abrasion on his right temple and left knee. Syncope episode lasted between 15 seconds. He responded to voice. Vital signs were taken immediately and were stable 118/60 pulse 80 respirations 18 chest clear temperature 97, O2 sat was 98% at 11:04 AM. Participant was accompanied by his partner. He denies blurry vision headache or nausea vomiting his skin was clammy and cool pale in color he has a history of fainting. He denied other health conditions. His blood pressure at 11:24 was 120/90 pulse 71 respirations 16 breath sounds clear temperature 97.3 and O2 sat was 99% His vital signs at 11:39 were 119/75 pulse 72 respirations 16 breath sounds clear 97.5 temperature. he was alert and oriented once he recovered from his fainting. We placed a participant flat on the ground allowed him to rest until he felt able to sit up. We dressed his abrasions in right temple and left knee, monitored his vital signs which were stable. participant drank water and Powerade. he declined a snack he rested in cot when able to be moved. we informed to notify his primary care doctor of the fall and inform to tell vaccinator he has a history of fainting when he comes back for vaccine number two. he was accompanied By his partner off the premises once he felt better was able to ambulate safely his partner will drive him home his vital signs were stable |

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| 1205329 | 4/13/2021 | TX | 21 | M | 4/13/2021 | 4/13/2021 | Patient said he felt light-headed after his shot. He was advised to continue sitting in the vaccine area. Since he was feeling light-headed, the immunizing pharmacist told me to get the blood pressure cuff. When I got back, the patient passed out. The pharmacist and I moved the chair from underneath him and he gently put him on the floor. He quickly woke up and the pharmacist began to ask him questions such as his name and where he was to make sure he was ok. He was able to answer those questions fine and we placed him in a chair so he can rest. When he was in the chair, he began to pass out again. He quickly woke up again but wasn't feeling good. The pharmacist checked his blood pressure and it was low. His temperature was at 93F. The pharmacist continued to stay with him and he made sure that someone else was able to come and pick him up. Once he felt ok, he had the patient go sit in the post-vaccination waiting area until he had his ride pick him up. |
| 1205322 | 4/13/2021 | | 64 | F | 4/13/2021 | 4/13/2021 | Female caucasian client 64 years old in a wheelchair came with husband at 2:00 PM to get her 1st dose of the Covid 19 Vaccine. Husband reported patient passed out before when they were drawing her blood out years ago. LVN called on site MD to the table to consult with patient and husband on the best way on how to prevent client for passing out. MD advice client to drink fluids first and position patient head leaning down to prevent from passing out. At 2:14 PM Covid 19 Vaccine EW0158 administered to patient left arm Intramuscularly by LVN. Client reported she was having chest pain at around 2:24 PM. Immediately 911 was called and on site EMT's. Patient vitals signs are stable |
| 1205312 | 4/13/2021 | TX | 30 | M | 4/13/2021 | 4/13/2021 | PATIENT STATED DIZZINESS EYES GLAZED OVER PALE AND PASSED OUT FOR 2 SECONDS DID STERNAL RUB DIAPHORETIC BP:83/40 HR:93 (2ND) BP:97/59 HR:71 |
| 1205302 | 4/13/2021 | PA | 18 | F | 4/13/2021 | 4/13/2021 | Patient fainted about 10 minutes after shot. Laid patient down got her to raise legs, drink water, ice pack after about 10 minutes patient felt well was coherent. Left pharmacy with mom. |

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| 1205301 | 4/13/2021 | MD | 32 | F | 4/2/2021 | 4/3/2021 | 8 hours after vaccination I had a fever, vomiting, body aches, chills, I fainted, and had extreme leg pains. The symptoms went away after 24 hours. I took acetaminophen when the symptoms started and for the next 48 hours after. |
| 1204951 | 4/13/2021 | CA | 34 | F | 3/25/2021 | 3/25/2021 | Twenty minutes after injection, tongue and throat started tingling. Tingling grew in intensity quickly. The sensation can be compared to having Pop Rocks candy in the mouth. Face became flushed red and paramedics were called. Faint redness on underside of arms. Sensation of heat felt in scalp and neck. Fainting occurred. Paramedics determined reactions were not life-threatening. Tongue and throat were not swollen. Tingling sensation slowly diminished over the next eight hours. About an hour after injection, diarrhea occurred. |
| 1205071 | 4/13/2021 | OH | 85 | U | 2/11/2021 | 2/18/2021 | On February 18, 2021 between hours 18:20-18:40 and a week after taking the second shot, patient lost balance (fainting) at home, fell, bruised a rib and fractured skull, causing subdural hematoma (bleeding outside of the brain). Bleeding stopped and several CT scans were performed. Under medical supervision, an anticoagulant medication was stopped to allow for healing. On February 20, 2021, moved from ICU to regular hospital room and on February 23 moved to another hospital for intense rehabilitation. Within days a thrombus developed causing a minor Cerebrovascular Accident, which was immediately identified by a medical doctor and nursing staff. On March 2, 2021 at 10:30 am moved to a Medical Center for further treatment. An endovascular thrombectomy for the removal of a thrombus was performed by a doctor. After recovery in the Neurosciences Critical Care ICU, under amazing care by the doctors, further thrombi developed on patient's lungs and around the bowel. Patient expired at 8:01 on March 4, 2021 due to Ischemic Complications of Thrombi/Thromboemoli. |
| 1204964 | 4/13/2021 | NC | 54 | M | 4/1/2021 | 4/8/2021 | Dizziness, almost fainting, loss of appetite...headaches all day 3-5 after shot....loss off appetite, over 7 days |

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| 1205009 | 4/13/2021 | NY | 67 | F | 3/23/2021 | 3/23/2021 | Patient was administered vaccine, as per protocol moved to the vaccination wait area for 15 minute observation. She passed out about 5 minutes later, she came to and said she was fine, then passed out again. I called 911 when she passed out the second time, I also administered an Epi-pen injection just in case she was having an allergic reaction. Shortly after the injection she came to and by then the paramedics had arrived. They took her BP it was 130/80 they also said they see this a lot with injections and that it was syncope and that it is pretty common. We followed up with her the next day and she was fine, she feels she didn't eat that day and she a little frightened and that is why she passed out. |
| 1205013 | 4/13/2021 | FL | 27 | M | 4/13/2021 | 4/13/2021 | Patient had vaso-vagal reaction from the vaccine. Within 2 minutes of getting the vaccine the patient became flushed and very pale. He as sweating profusely and had vision loss. He was sitting while this all happened which I think prevented him from fainting. I got him water, an ice pack and called ems. By the time EMS arrived the patient was starting to feel better. EMS did their evaluation on site and the patient was able to go home 20 minutes later. |
| 1205016 | 4/13/2021 | CA | 19 | F | 4/13/2021 | 4/13/2021 | A few Minutes after getting the vaccine, patient stood up, felt dizzy light headed and nauseas and then passed out. Patient was unconscious for approximately 5 seconds before waking up. Patient was then assisted to a supine position before getting a set of vital signs, all WNL except for a low blood pressure. Patient was then assisted to a cot where she explained how she felt before hand and another set of vital signs was taken, all WNL and an improved blood pressure. Patient was then asked to wait at least 30 minutes and until all symptoms had subsided before having someone assist her in getting home. |
| 1205051 | 4/13/2021 | CA | 24 | F | 4/13/2021 | 4/13/2021 | After patient received the vaccine, she went to wait in the waiting room for 15 minutes. Though after 5 minutes she fainted and a customer helped her to the ground. The patient was very pale and was sweating. We called 911 and the EMT took her to a nearby hospital. |
| 1205273 | 4/13/2021 | NH | 28 | M | 4/13/2021 | 4/13/2021 | Pt passed out momentarily after vaccination. He recovered quickly without intervention. BP 136/64, HR 60, SP02 99%. His significant other drove him home. He recovered completely at time of departure. |

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| 1205060 | 4/13/2021 | AZ | 58 | F | 4/12/2021 | 4/13/2021 | Woke up at 3 am, felt a little off and walked to the restroom. While sitting on toilet, with no warning completely passed out and apparently fell on my face. Woke up in a pool of blood from a nose bleed and cut on my nose. I don't know how long I was out. Was disoriented and lay down on the hallway floor and was shaking for quite some time. My partner cleaned the wounds and helped me to bed. Was in pretty bad pain from the fall - knee, nose and neck. Tried to sleep and finally did about an hour later then woke to profuse sweating and nausea. Didn't throw up, but then finally went back to sleep. Have had a 100.1 degree temperature most of today. |

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| 1205243 | 4/13/2021 | | 31 | F | 4/4/2021 | 4/4/2021 | fainted; having an odd taste in my mouth; shortness of breath/breathing took 40 minutes to return to normal; vasovagal syncope response; the expected sore injection site; headache; felt overheated; could quite literally only see stars; This is a spontaneous report from a non-contactable consumer (patient). A 31-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in Arm Right on 04Apr2021 10:45 (Lot Number: ER8732) as single dose for covid-19 immunisation. Medical history included hypoglycaemia (she ate before the injection) and fainting. Concomitant medication(s) included Birth control and prednisolone acetate ophthalmic sus. The patient did not receive other vaccines within 4 weeks prior to the COVID vaccine. 5 minutes after the injection, the patient began having an odd taste in mouth, shortness of breath, and she fainted. She had a history of fainting, but it took longer for her to recover than usual (50 minutes instead of 15). When she regained consciousness a few minutes after, she had a headache, felt overheated, and could quite literally only see stars. Her breathing took 40 minutes to return to normal, and her body temperature took 2 hours to feel normal. She assumed this was mostly a vasovagal syncope response, but she wasn't anxious or in pain beforehand. After 6 hours, she still have the odd taste, a headache, and the expected sore injection site. The events resulted in Doctor or other healthcare professional office/clinic visit. Therapeutic measures were taken as a result of the events included Paramedic took vitals and monitored for an hour. The outcome of the events was recovered with sequelae. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. No follow-up attempts are possible. No further information is expected. |

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| 1205142 | 4/13/2021 | NC | 51 | F | 3/12/2021 | 3/18/2021 | sudden severe onset of vertigo; dizziness; syncope; vomiting; This is a spontaneous report from a contactable consumer (patient, self-reported). A 51-Year-old female patient (who was not pregnant at the time of vaccination) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, formulation: Solution for injection, Lot number: EN6204 and expiry date was not provided) via an unspecified route of administration, in left arm on 12Mar2021 at 13:30 as a single dose for COVID-19 immunisation. Medical history included rheumatoid arthritis and immunotherapy. The patient had allergies to penicillin, sulfa drugs and peanuts. The patient's concomitant medications were not reported. The patient previously took ibuprofen and had allergy. The patient stated that On 18Mar2021 at 12:30, the patient experienced sudden severe onset of vertigo and dizziness with syncope and vomiting. The patient was hospitalized for 3 days. On an unknown date in Mar2021, the patient was hospitalized, and a week and a half later still had dizziness which prevents patient from performing daily tasks. Patient received unspecified treatment for the adverse event. Seriousness of the events was reported as hospitalization. Outcome of the events vertigo, syncope, vomiting and loss of personal information was recovering, and for the events dizziness it was not recovered. |

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| 1205150 | 4/13/2021 | | | F | 3/6/2021 | | <p>Passed out; Cannot make it on the second dose schedule; missed from receiving her second dose; She has vomitted; she is still sick; can't keep her head up and has headaches; Feeling sick; She cannot eat; This is a spontaneous report from a contactable consumer (reported for herself). The female patient (80 unit not reported) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Lot no: not reported) on an unknown route of administration on 06Mar2021 as SINGLE DOSE for COVID-19 immunization. Patient's medical history included Diabetes. Concomitant medications were not reported. It was reported that the patient had the first dose of the vaccine on 06Mar2021 and now can't keep up with herself. The patient has vomited and can't keep her head up and has headaches. and stated she knew the vomiting goes on for 14 days but today was 23 days and she was still feeling the same. Patient was due for her second dose of the vaccine and wanted to know if she should still get her second dose or if she should wait a couple weeks until she feels better. Upon follow-up (29Mar2021, on an unknown date the patient had passed out, cannot make it on the second dose schedule; missed from receiving her second dose, cannot eat, vomiting, Feeling sick. The patient reported that she experienced different symptoms like she passed out and was in IV fluid (as treatment) after the first dose. Now the patient cannot make it on the second dose schedule. The patient was reported that the treatment was advised by her physician because the patient passed out and missed from receiving her second dose. The patient cannot eat, vomiting and she was still sick, up until now, that is why she cannot go to get the second dose of vaccine. Limited information was available over the call. The outcome of the events was unknown. Information about lot/batch number has been requested. Follow-up attempts are completed. No further information is expected.</p> |

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| 1205174 | 4/13/2021 | TN | 40 | M | 3/25/2021 | 3/25/2021 | passed out/stopped breathing for 15-20 seconds.; passed out/stopped breathing for 15-20 seconds.; Felt faint; trouble breathing; This is a spontaneous report from a contactable consumer (patient). A 40-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) dose 2 via an unspecified route of administration, administered in left arm on 25Mar2021 11:00 (Lot Number: EN6205) as single dose for covid-19 immunisation at age 40 years old. The patient's medical history was not reported. No known allergies. No covid prior to vaccination and was not tested for covid post vaccination. Concomitant medication included loratadine (CLARITIN) taken for an unspecified indication, start and stop date were not reported. The patient previously received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) on 03Mar2021 14:00 (lot no: EN6200) in left arm for COVID-19 immunization at age 40 years old. On 25Mar2021 11:15, the patient felt faint, had trouble breathing, and passed out/stopped breathing for 15-20 seconds. The adverse events resulted in emergency room/department or urgent care. Treatment for the events included EMT monitoring onsite, saline and other meds (unspecified). The patient recovered from the event passed out/stopped breathing on 25Mar2021; while recovered from other events on an unspecified date in Mar2021. |

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| 1205179 | 4/13/2021 | OH | 78 | F | 3/17/2021 | 3/1/2021 | <p>passed out for a very short period of time; was awakened by total body shaking and it was not just shivers but was uncontrollable shaking; her body felt warm but then she was freezing; her body felt warm but then she was freezing; was sick and was different and very weak; muscles were sore; This is a spontaneous report from a contactable consumer. A 78-year-old female patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE)), via an unspecified route of administration, administered in the left arm on 17Mar2021 12:10 (Batch/Lot Number: EN6207; Expiration Date: 31May2021) as a single dose for covid-19 immunization. The patient's medical history was not reported. There were no concomitant medications. The patient received her first dose of the Pfizer BioNTech COVID19 vaccine on 23Feb2021 (lot number: EN6198 with expiry date 31May2021) for Covid-19 immunization. The patient experienced passed out for a very short period of time and awakened by total body shaking and it was not just shivers but was uncontrollable shaking on 18Mar2021; her body felt warm but then she was freezing, she was sick and was different and very weak, and muscles were sore in Mar2021. It was further reported that the patient got the 2nd dose of the Pfizer BioNTech vaccine that day on 17Mar2021 and about 12:45am or 1:30am the next morning she was awakened by total body shaking and it was not just shivers but was uncontrollable shaking; the shaking has resolved completely but she is not sure when it resolved but she was shaking for a good while because she can remember being so uncomfortable with her body moving so much which went on for maybe 20 minutes or so when her husband woke up. Patient's husband then woke up and got Ibuprofen and gave it to her and that stopped the shaking which surprised her and she did not know the Ibuprofen would work to stop the shaking that well and the Ibuprofen did work in stopping the shaking. The Ibuprofen stopped the shaking and she can remember to touch her body felt warm but then she was freezing and she does not know what this means but this was not ongoing and resolved when her husband gave her the ibuprofen and she stopped shaking right away which always amazed her that the Ibuprofen worked. She stated fortunately the Ibuprofen stopped her from shaking and she was able to sleep until early morning when she</p> |

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woke up and knew she was sick and was different and very weak; states the weakness was not ongoing and the approximate time the weakness resolved was unknown but she was down the rest of the day and after that she passed out for a very short period of time and held her head up and stood up and thought wow something was going on and asked where was this coming from and it was not nausea but she was just weak. She has not passed out for a huge amount of time but fortunately she had some towels laying close by and was able to use a towel; states after that she stopped for the rest of the day and only got up to go to the potty and was just so weak and heard that from many people that they just slept afterwards. Caller states her muscles were sore and she realized that was just normal and after the 2nd dose of the vaccine she knew her muscles would probably be sore and this was resolved. She came downstairs and was sitting on a chair and then stood and no longer sat in the chair and her husband knew things were not right with her and her eyes looked funny and she passed out and that never happened to her before and she was passed out for a few moments. Other than the Ibuprofen she did not have treatment and did not go to the emergency room or the HCP office. Patient only took one Ibuprofen and she has a very small body and her husband sometimes takes 2-3 Ibuprofen and she thinks wow that is so many but she herself does not have any medication and she just took one Ibuprofen and it worked; She took the Ibuprofen on 18Mar2021 in the early morning. Fortunately she was in good health. Outcome of the event passed out for a very short period of time, was awakened by total body shaking and it was not just shivers but was uncontrollable shaking and muscles were sore was recovered in Mar2021, and unknown outcome for the remaining events.

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| 1205208 | 4/13/2021 | IL | 18 | F | 3/24/2021 | 3/24/2021 | acute sinus infection; bilateral cerumen impaction; Bilateral otitis media; Had a syncopal episode; Dizzy; This is a spontaneous report from a contactable physician. A 18-years-old female non-pregnant patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Formulation: Solution for injection, Batch/Lot Number: ER8730), dose 1 intramuscular, administered in right arm on 24Mar2021 as single dose for covid-19 immunisation. Medical history included dysmenorrhoea, menometrorrhagia, obesity, guillain-barre syndrome. Concomitant medication's included ethinylestradiol, levonorgestrel (LUTERA) taken for an unspecified indication, start and stop date were not reported. The patient previously took fluconazole (known allergies). Patient had not received any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination. The patient was tested for Covid test post vaccination on 25Mar2021 show the negative result. Patient claimed she became dizzy within 15 minutes of the vaccine and had a syncopal episode. She stated that it occurred twice since the vaccine. This MD conducted physical exam on 30Mar2021 and found bilateral cerumen impaction that was cleared. She reported that this revealed bilateral otitis media and she was diagnosed with acute sinus infection and treated. Although her symptoms can be explained by these findings, this MD was continuing work up for Guillain-Barre. The adverse event result in Emergency room/department or urgent care. Treatment received for the adverse event are supportive care, antibiotic for sinus infection and clearance of impacted cerumen. The outcome of the events were recovered with lasting effects. No follow-up attempts are needed. No further information is expected.; Sender's Comments: The event syncope is assessed as possibly related to the suspect vaccine BNT162B2 based on strong temporal association, but consider also possible contributory effects from patient's medical history and/or concomitant medications. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics |

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| | | | | | | | Committees, and Investigators, as appropriate. |
| 1205525 | 4/13/2021 | VA | 27 | M | 4/13/2021 | 4/13/2021 | Patient walked to waiting area and when he sat down he fainted, hit his head, and started having seizure-like activity (jerky, twitchy). Patient was down about 15 seconds and when he sat back down his blood pressure was 74/48 and his vision was black. Called EMT, patient refused to go with EMT, because he felt better after 30 minutes of sitting |
| 1205054 | 4/13/2021 | TN | 22 | F | 4/13/2021 | 4/13/2021 | Patient started feeling lightheaded, dizzy, SOB, hot a few minutes after vaccination then fainted. A couple of minutes later she felt fine and after staying in the pharmacy for 30 minutes left. |
| 1205998 | 4/13/2021 | OH | 34 | M | 3/28/2021 | 3/28/2021 | Pt fell at 1458 and hit the head. Pt looked sweaty. The paramedic advised to F/U with PCP. Pt agreed to be taken to the hospital for further evaluation. Pt left the center with the paramedics at 1522. Past history of syncope and family cardiac history (specially when flying). |
| 1205471 | 4/13/2021 | CO | 16 | M | 4/13/2021 | 4/13/2021 | patient fainted, |
| 1205887 | 4/13/2021 | OH | 18 | F | 4/11/2021 | 4/12/2021 | I experienced 4 syncopes in a span of 5 minutes. I was taken to the E.R. and given fluids before they sent me home. |
| 1205928 | 4/13/2021 | | 16 | M | 4/12/2021 | 4/12/2021 | Syncope and dizziness, BP 125/75, HR73, RR16. Patient experienced syncope and fell to floor from chair. Regained consciousness after ~3 seconds. Vital signs stable, released in stable condition |
| 1205947 | 4/13/2021 | NY | 45 | F | 3/1/2021 | 3/13/2021 | When I got the vaccine I fainted. I never fainted before with vaccines. The real problem started a week after I got the vaccine I felt extremely exhausted, and I'm having a hard time getting up from bed in the morning. My symptom is that all my joint hurt so much, my ankles, my wrist, my knees, my hips, my elbows anywhere is a joint its hurts. If im sitting it hurts, if I'm standing it hurts, if im laying down it hurts. Besides that I feel nervous, like I'm shaking in the inside, but I'm not shaking. |

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| 1205962 | 4/13/2021 | NY | 17 | F | 4/12/2021 | 4/12/2021 | While waiting during the 15 minute monitoring period patient (17 year old female) fainted in her chair. Mom noticed that patient's arms went rigid right before she passed out. Patient was still breathing and was laid on the ground to her side and 911 was called immediately. Mom was massaging her thighs and arms to increase blood flow and she regained consciousness within a few minutes. She was very pale and felt weak. She was given water and remained laying on the ground for another 10 minutes before EMS arrived. She explained she gets anxiety about any medical procedure, has had history of fainting after shots/blood draw/blood pressure reading. EMS took fingerstick reading and gave her oxygen to ensure she doesn't faint again from blood glucose fingerstick. Vitals came out to be normal. Mom explained this is very normal and she doesn't see the need to take her to the hospital. EMS offered to have patient with them in the ambulance for another 15-20 minutes before she's free to leave. |
| 1205858 | 4/13/2021 | MD | 60 | F | 4/7/2021 | 4/7/2021 | Shortly after the vaccine I fainted which came on quite quickly and upon waking within a minute I felt sick and vomited. |
| 1205991 | 4/13/2021 | FL | 65 | F | 4/12/2021 | 4/12/2021 | The patient experienced an unknown taste after receiving Moderna as well as dizziness and fainting. She also had periods of feeling faint. The store management was called and alerted EMS which arrived after 20 minutes approximately. Basic vitals were taken and the patient was taken to the hospital. |
| 1205784 | 4/13/2021 | OH | 20 | F | 4/11/2021 | 4/11/2021 | At 10PM (8 hours after getting the JnJ vaccine) pt developed chills and pulsate headache. Pt was able to sleep. Next day in the morning by 7:40AM she went downstairs and got dizzy and fall gradually on the floor. Pt got help, but when she was trying to get up she got lightheaded/passed out again bumping her head on the wall. Pt reacted, fluids were given. Pt slept all morning. At 2PM she got up from bed. No pulsate headache, just "mild headache." Today, 48 hours later, pt reported light headache. Denies abdominal pain or pain in extremities. Pt and parents of pt were encouraged to report to patient's PCP. |

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| 1206015 | 4/13/2021 | OH | 25 | M | 3/28/2021 | 3/28/2021 | Pt went to stand and fainted hitting the floor face down. @ 2:30PM pt was picked up by friend from the vaccination center. |
| 1206068 | 4/13/2021 | WA | 44 | F | 4/7/2021 | 4/7/2021 | Was not instructed to wait after shot so I went to my car. Drove for a couple of hours. Got out of car, walked forward and passed out with a seizure then throwing up when I came to. Received concussion. Taken to ER and admitted for 5 days. Still experiencing vertigo and nausea |
| 1206183 | 4/13/2021 | FL | 30 | F | 4/7/2021 | 4/7/2021 | Fainted for a few seconds within 10 to 15 minutes of the shot, dizziness, nausea (but I also hate needles and have a history of almost fainting with shots); chills 30 minutes after shot and off and on for two days after shot, itchy hives on my stomach and chest two days later that took a couple days to fully disappear but no rash at the vaccination site; extreme fatigue and brain fog for five days; arm soreness for two days. |
| 1206223 | 4/13/2021 | WA | 41 | M | 4/13/2021 | 4/13/2021 | PATIENT LOST CONSCIOUSNESS FOR 10 SECONDS , 10 MINUTES AFTER RECEIVING VACCINATION. AFTER HE REGAINED CONSCIOUSNESS HE SAID HE HAD NOT EATEN BREAKFAST AND HAD NICOTINE GUM 10 MINUTES BEFORE GETTING THE VACCINE. ALSO HE MENTIONED THAT IT HAD HAPPENED TO HIM BEFORE WHEN HE GOT A VACCINATION. HE FAINTED WHILE THE NEEDLE WAS STILL IN HIS ARM. HIS BLOOD PRESSURE WAS 142/68. EMT ARRIVED AFTER 5 MINUTES AND TOOK HIM TO THE HOSPITAL |
| 1202737 | 4/13/2021 | IA | 24 | F | 4/7/2021 | 4/7/2021 | Patient felt dizzy/light headed about 5 minutes after receiving Moderna vaccine and then fainted. She was unconscious for around 1 minute before regaining consciousness. Patient reported that she had a severe fear of needles and believes that was what caused her to faint. |

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| 1203657 | 4/13/2021 | VA | 27 | M | 3/31/2021 | 3/31/2021 | Client was waiting in his car post vaccination when he felt dizzy, sweaty and was walking back to the vaccination area when he fainted. Client was assisted by a flow worker and client did not suffer any injuries from fainting. BP was 139/89, client is able to speak and is oriented X3. 911 was called, Medic 209 arrived and evaluated client. Client's glucose was 92, an EKG was performed. Client declined transport to the hospital and asked his wife to pick him up. Client stated that he was feeling better and that understand to call EMS if symptoms worsen on the way home. |
| 1205964 | 4/13/2021 | GA | 32 | F | 4/8/2021 | 4/9/2021 | Received vaccine at 3pm on 4/8 and adverse event happened the morning of 4/9. Leg cramps/pains, dizziness, shortness of breath, weakness, and fatigue. I passed out in the morning at a doctors appointment and took a couple minutes to get back consciousness. All color was drained from my face for hours and had to receive 2 bags of fluid. Still getting dizzy/light headed 5 days out from the vaccine. |

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| 1205686 | 4/13/2021 | PA | 26 | M | 4/13/2021 | 4/13/2021 | Patient noted on form that he had a severe reaction to peanuts which causes him to have anaphylaxis. He stated that he does carry an EpiPen and any time anything with peanuts touches his mouth/lips he immediately notices his throat starting to close. He also is allergic to cats. Before administering the vaccine, the patient noted that he does not like needles and was not going to look. I administered the vaccine and the patient and I exited the vaccination room. I explained that he should sit in the waiting area for about 30 minutes due to his severe allergic reaction in the past. By the time that I walked back into the pharmacy, the patient's wife shouted "He's not breathing!". My technicians called 911 while I grabbed an EpiPen and rushed to the patient. I immediately administered a 0.3 mg dose of epinephrine and observed that the patient had passed out, was not breathing, but had a pulse. A few seconds later he regained consciousness and his breathing was erratic. I gave him water and he stated that he felt very lightheaded and dizzy. I instructed him to remain seated. He also noted that his vision was blurry and he saw a black dot. His wife was fanning him to cool him down while I tried to obtain the patient's blood pressure, but could not get a reading. The paramedics came and evaluated him thoroughly. His blood pressure, heart rate, EKG, and blood sugar were all within normal limits. They determined that the syncope was most likely due to the patient not eating during the day and not liking needles. The patient was feeling much better and declined further medical treatment, including going to the hospital. He was instructed to go home and relax. |
| 1206059 | 4/13/2021 | AZ | 61 | F | 3/27/2021 | 3/28/2021 | Fainted and fell face first on my kitchen floor out for about 2 minutes. Bruised face. |
| 1205555 | 4/13/2021 | CO | 18 | M | 4/13/2021 | 4/13/2021 | patient fainted but has history of fainting with vaccines |
| 1205557 | 4/13/2021 | KS | 22 | M | 4/13/2021 | 4/13/2021 | Patient felt light headed and had brief episode on syncope in observation area post vaccination- did not require intervention |
| 1205559 | 4/13/2021 | NY | 25 | F | 3/31/2021 | 3/31/2021 | Vasovagal Reaction with no previous history of fainting, vaccine anxiety |

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| 1205575 | 4/13/2021 | NY | 38 | M | 4/13/2021 | 4/13/2021 | About 20 minutes after receiving the shot, patient fainted. He gained consciousness after few seconds and was responsive. He reported no trouble breathing or any other reaction. he reported that he feels dizzy occasionally. EMS was activated, Patient was able to stand up and walk on his own out of the store. He reported feeling completely fine and did not want to go to ER but just went with EMS to their van to get evaluated |
| 1205882 | 4/13/2021 | OR | 67 | F | 4/2/2021 | 4/3/2021 | On 2nd day: Very bad headache, almost fainted, took Tylenol (6/day of 500mg), drank fluids, blood pressure low. Better on day3, only slight headache. On 9th day: felt soreness in right calf muscle, no swelling or redness. Thought it was due to low physical activity. No stamina. Tire very easily and get sweaty upon little exertion On 10th day: felt sharp jabbing pain in chest when taking deep breath or yawning. No actual shortness of breath. On 11th day (today): decided to start taking full strength aspirin in case it is a blood clot. Took 1 in a.m. 1 in p.m. |
| 1205663 | 4/13/2021 | MA | 31 | M | 4/10/2021 | 4/10/2021 | Vasovagal reaction. Has a history of fainting with blood draws. Patient alert, oriented and left event on own accord. VS stable |
| 1205522 | 4/13/2021 | CO | 21 | F | 4/13/2021 | 4/13/2021 | patient fainted but usually faints with vaccines |
| 1205701 | 4/13/2021 | NJ | 33 | M | 4/9/2021 | 4/11/2021 | I PASSED OUT ON DAY 2 WHILE OUTSIDE AND REQUIRED STITCHES. WHILE AT A MEDICAL FACILITY GETTING X-RAYS, I PASSED OUT A SECOND TIME AND WAS RUSHED TO THE EMERGENCY ROOM. |
| 1205712 | 4/13/2021 | IL | 24 | F | 4/13/2021 | 4/1/2021 | after vaccine, pt sat 15 minutes and tried to get up and passed out. cashier went out to help check on her when she was going down. she came too. pt was talking and alert and remained sitting while paramedics were coming |
| 1205714 | 4/13/2021 | VA | 86 | F | 4/8/2021 | 4/11/2021 | She was found unresponsive by her husband on 4/11/2021 and pronounced dead at the scene. She had been to the emergency room for recurrent syncope several weeks prior to any vaccinations. No cause was determined. |
| 1205739 | 4/13/2021 | CA | 26 | F | 4/13/2021 | 4/13/2021 | Shortness of breath, nausea, syncope. Called 911. Transported to Emergency Room. |

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| 1205742 | 4/13/2021 | MI | 24 | M | 4/13/2021 | 4/13/2021 | I received dose #1 of COVID and planned to walk through the store to shop. While walking passed the observation chair, I began to feel dizzy and decided to sit down. After I took a seat, I immediately began to feel numbness in my arm which spread to my entire body. I was also feeling a piercing headache with ringing in my ears and my dizziness was extreme. At this point I called for help to the individual who had administered my shot as I had feared I would have fainted. I was in this extreme state for approximately 3-5 minutes. The individual at the pharmacy then checked in on me, gave me a bottle of water and after drinking it I began to feel better. I was then able to walk around and buy some food. Approximately 20 minutes after that event and eating and drinking some food, I felt like I was back to normal. I am writing this 5 hours later, and I currently feel normal, with some soreness in my arm I received the vaccine in. |
| 1205751 | 4/13/2021 | KY | 23 | F | 3/23/2021 | 3/24/2021 | I fainted twice the following day after my vaccine shot and hit my head against the hardwood floor. I first fainted at around 4:00 AM on March 24, 2021 after waking up. My parents carried me down the stairs and I fainted again after that. I didn't receive any treatment afterwards. I had a fever for the entire day and was feeling dizzy and nauseous for most of that day. I haven't fainted since then but still feel a little bit dizzy every once in a while. |
| 1205626 | 4/13/2021 | NJ | 28 | F | 4/5/2021 | 4/5/2021 | After the vaccination was given the patient started to wait her 15 minutes. After 5 minutes of waiting the patient slumped over and passed out onto the floor. Her color was very pale and her eyes were rolling in the back of her head. She regained consciousness but her color was still poor and we called and ambulance because she was still feeling faint. The EMT's immediately took her blood pressure and it was extremely low. She acknowledged that she did not eat or drink anything at all that morning. The EMT's recommended she go to the hospital but she refused. After 30 minutes with emergency personnel she felt better and well enough to leave with her family member who was with her. |

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| 1204076 | 4/13/2021 | TN | 48 | F | 4/13/2021 | 4/13/2021 | Patient became light headed after receiving vaccine and passed out briefly. She was complaining of being dizzy and nauseous. After several minutes of laying in the floor and not feeling better, EMS was called. While waiting for the EMS she complained of trouble breathing. EMS took her to the hospital. |
| 1204276 | 4/13/2021 | KY | 25 | F | 4/9/2021 | 4/9/2021 | Client passed out upon reaching vehicle. Her eyes were dilated approx. 1 to 1.5 cm. unresponsive. Was able to get small response out of patient. O2 at 4L placed BP taken 160/98 pulse 66. but was weak and thready. Patient passed out once again and did sternal rub while calling her name. Patient came slowly to and pupils returned to normal. Patient confused on what had happened. States she has passed out before from shots but states this was different. States when she was out she had dreams but couldn't remember them. Patient remained extremely pale but was communicating normally. Stayed with patient another 20 minutes. Paleness getting better. Patient did not want to go to ER. Encouraged her to f/u with PCP ASAP. Ver Patient verbalizes understanding. She was with her parents so did not have to drive. Parents verbalized patient would not be alone. Patient called early evening of that same day. Patient states she is feeling fine denying any left over symptoms. Called patient Sunday 04/11/2021 and she verbalized doing fine. |
| 1203952 | 4/13/2021 | OH | 18 | F | 4/13/2021 | 4/13/2021 | Pt had vagel response. Due to high anxiety about the shoot pt , passed out after shot for 2 to 3 s ,and was helped to get down on floor with her legs elevated. Patient was in shock, this her BP was high, but was alter and oriented, helped to get stable. with in five minutes of the response pt was at her base line but we kept her at vaccine site for 30 minutes to monitor her response. |
| 1204008 | 4/13/2021 | NY | 45 | F | 4/13/2021 | 4/13/2021 | ABOUT 15 MINUTES POST VACCINATION, PATIENT FAINTED IN THE WAITING AREA OF THE PHARMACY. HER BLOOD SUGAR AND BLOOD PRESSURE WERE CHECKED AND WERE NORMAL. SHE HAS A PHOBIA OF NEEDLES AND IT MAKES HER DIZZY AND LIGHTHEADED. |

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| 1204015 | 4/13/2021 | FL | 48 | F | 4/6/2021 | 4/6/2021 | Extreme Nausea, Leg aches, fever, chills, Fatigue and weakness, extreme headache, vomiting, fainting, pressure in head, bleeding/nosebleed, cough and congestion |
| 1204034 | 4/13/2021 | TX | 25 | M | 4/11/2021 | 4/11/2021 | Dizziness and syncope |
| 1203940 | 4/13/2021 | TX | 43 | M | 4/11/2021 | 4/11/2021 | Syncope |
| 1204049 | 4/13/2021 | IL | 22 | F | 4/10/2021 | 4/10/2021 | Patient fainted in the immunization room after immunization had been provided. Patient claimed to always faint after vaccines. Patient also vomited after fainting and having a drink of water. |
| 1203926 | 4/13/2021 | VA | 27 | M | 4/11/2021 | 4/11/2021 | Patient fainted and exhibited seizure-like activity within 15 minutes of vaccination. Patient was transported to ER by EMS. |

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| 1204105 | 4/13/2021 | GA | 66 | F | 3/25/2021 | 3/25/2021 | at about 4 hours after vaccine I thought I was having a stroke. The right side of my face went numb and felt like it was drooping, my right arm went numb, my right leg and foot went numb. But I could still talk and make a smile face so I did not go to ER. Gradually both of my legs became very weak and then my hands became very weak. This lasted for over a week/ten days. By the first night I couldn't sleep because my brain could not seem to get into a deep sleep pattern, had body aches and sore arm but not dreadful, and by the next day had a fever which maxed at 101 degrees (my normal is 97.2-97.4). Had a low grade fever for 10 days! Also by the 2nd day I had swollen glands in my right neck and armpit, and pain from my right elbow to my neck. My usual level of unstable balance was MUCH worse for at least a week and my usual tinnitus was MUCH louder than usual for about 10 days! Night 3 I had a very bad episode of something like restless leg which also extended not just in my legs but also into my head! Very bizarre! By day 4 I was having episodes of near fainting, often. This lasted for about another week. All in all it was a dreadful experience, which I believe was related to issues with my already compromised nervous system due to the Parkinson's/MSA. I will NEVER have another one fetes vaccines or booster shots if those become available. I am quite frightened that the next vaccine could result in me actually having a stroke or other serious consequence. |
| 1204179 | 4/13/2021 | MI | 21 | M | 4/13/2021 | 4/13/2021 | The patient passed out after 10 minutes after feeling really hot and sweating. He became conscious in less than a minute and was feeling okay. |
| 1204229 | 4/13/2021 | | 30 | M | 4/13/2021 | 4/13/2021 | Syncope post vaccine. Dizziness, nausea, jerking motions upon event last few seconds, incontinence, Vomited. Pt left with girlfriend at 2:45. symptoms resolved |

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| 1204235 | 4/13/2021 | TX | 50 | M | 4/13/2021 | 4/13/2021 | P.T suffered from a syncope as he was receiving injection. PT states that this is not an uncommon event for him when he receives IM injections due to anxiety. PT stated that he began feeling light headed and dizzy just after inection. LOC was less than 30's . Subjects vitals were monitored continuously for 30 minutes. First set of vital were BP- 79/54, HR 45, SPO2 99% on room air. Last set of vitals BP- 112/78, HR 76, SPO2 100 on room air. PT declined transport to a hospital and was advised to follow up with his primary care physician |
| 1206249 | 4/13/2021 | MI | 54 | F | 4/1/2021 | 4/2/2021 | severe headache, followed by syncope |
| 1204247 | 4/13/2021 | FL | 18 | F | 4/13/2021 | 4/13/2021 | Patient felt tingling in her left arm after receiving the Covid vaccination. While patient was sitting down to wait her 15 minutes observation time, she felt faint and passed out while sitting in the chair. Her mother who was sitting next to her was able to help her to the ground. Patient knew where she was and who she was but felt dizzy and had arm pain. |
| 1204042 | 4/13/2021 | CO | 29 | M | 3/31/2021 | 3/31/2021 | Patient had a syncope episode along with urinary incomitance shortly after receiving the Janssen vaccine. Pt was sitting in the medical monitor area when the event happened. Pt was unconscious for less than a minute and EMS was called. EMS evaluated pt, he was pale but fully verbal and functioning. vitals were stable, BP 110/69, HR 74, O2 97. Pt refused transport but was monitored at the site by doctor for an hr before being released. Pt was instructed to go to UC/ER if he had another episode or new s/s and follow up with his primary care provider. The following day, the patient's primary care provider tried multiple times to reach out and follow up with pt. Pt did not respond to his PCP. |

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| 1203806 | 4/13/2021 | PA | 43 | M | 4/13/2021 | 4/13/2021 | without warning and approximately 5 minutes after patient received vaccine patient passed out and fell face first onto floor. patient was approached lying face down on floor bleeding and sounds of gurgling coming from patient patient was unresponsive. When patient was brought around and returned to consciousness patient did not know where he was or what had happened. Patients pulse was very low at 58 and dropping to as low as 39. Patient pulse did not stabilize the entire time patient was under our care. Patient had about a inch and a half laceration about eye and possible facial fracture. It was noticed that patients face was swollen when leaving with ambulance to be transported to er. |
| 1203671 | 4/13/2021 | ID | 18 | M | 4/10/2021 | 4/10/2021 | Patient had fever/chills/sore muscles. Patient reports going to take shower to help with flu-like symptoms and fainting in the shower. Patient's parents helped patient and had him hydrate. He has recovered now, with a lingering Head Ache. |

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| 1206163 | 4/13/2021 | WA | 23 | F | 4/6/2021 | 4/6/2021 | I received the shot at 14:30, in which medical staff in the jail's medical center watched me for 20 minutes to ensure there were no immediate reactions. I went about my day afterward with no symptoms. At 21:30 when I went to sleep, I got some aches in my joints and took 1 dose of liquid capsule NyQuil to help with the pain and went to sleep. At 00:30, the 7th, I woke up groaning in my sleep to the extreme pain in my joints and feeling hot internally. I decided to get up and take a warm bath to ease the aches. I went and ran the bath and all of a sudden while it was running, I had a severe need to throw up, but could not naturally. Since this was concerning, I got up and walked out of the bathroom and all of a sudden in the hall I got a feeling of impending doom and that something was not right and I fainted. I laid on the floor for what I would approximate to be 5 minutes going in and out of consciousness waiting for the blood to fully return to the brain. After this, I instantly felt like I needed to survive and that I felt like I could be dying so I slowly crawled down the stairs to get to my military ID so I could call the military's nurse advice line. I had to take a break and lay on the concrete in my garage because I felt so dizzy and so hot and began to feel my vision disappear like I was going to faint again. I waited a few minutes before getting back up the stairs crawling to my phone to call. When I called them 00:58, they told me to call 911 because they believed I would be having a severe reaction, though I noted to them I did not have a rash or hives. I then called 911 at 01:08. They sent EMT's to my home which took my vitals. I had normal blood pressure, SPo2, and temp, but an elevated heart rate of just under 100 and a high respiration rate. EMT's made the decision for me to stay home since the hospital did not seem immediate in their opinion. After this I stayed on the couch for a few minutes and then felt very tired so I walked slowly to my room and fell asleep. I woke up at 06:00 for work, and arrived at 07:00. In the hour after waking up I was achy, sweating, and felt light headed. I got to work and my Sergeant told me to go home and sleep. I slept another 5 hours at 08:00 and when I woke up most of my symptoms went away other than aches and getting flush very easily for 5 days. At this current time all I notice is some random light headedness that quickly resolves and comes a few times a day at random and without cause. |

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| 1204910 | 4/13/2021 | PA | 26 | F | 4/13/2021 | 4/13/2021 | Pt fainted after receiving Pfizer COVID vaccine. It was standing and began swaying and not verbally responding to pharmacist. Pharmacist was able to catch her before she fell and he slowly lowered her to the ground. Pharmacist had her lay on her back. Another Pharmacist assisted and had pt put her feet up on a chair to improve blood flow to pts head. PT laid on the ground for about 10 minutes and was conversing with Pharmacist. She was able to sit in a chair and stated she was feeling better, but had a warm sensation. We provided her with an orange juice and she had her own water. Pt hadn't eaten for a few hours and had a history of fainting after giving blood. Her dad came and drove her home after 45 minutes as a safety precaution. |
| 1203706 | 4/13/2021 | IL | 19 | M | 4/12/2021 | 4/12/2021 | Patient received shot and went to the bathroom. When returning from the bathroom he felt dizzy and fainted while walking back from the bathroom. |
| 1203710 | 4/13/2021 | TX | 61 | F | 3/8/2021 | 3/8/2021 | syncope |
| 1203947 | 4/13/2021 | NC | 43 | F | 4/9/2021 | 4/9/2021 | Profuse sweating, light headed, hard to hear, almost fainted within minutes of receiving the shot. Was fanned, given orange juice and a cool towel. After 30 minutes I felt okay to leave the pharmacy. Felt lightheaded the rest of the day and really out of it. Developed a fever later that evening that ran throughout the night. Loss of appetite for 3-4 days. Diarrhea on day 4. Pain in arm at injection site for 4 days. |
| 1203804 | 4/13/2021 | TX | 31 | F | 4/6/2021 | 4/6/2021 | After I gave the her the vaccine in the passenger seat, she was fine. Then a couple of minutes later we could not distinguish what kind of reaction was occurring and had another patient call 9-1-1. The patient jerked at that moment, but the paramedics arrived within 8 minutes and checked her out, she is fine. It turned out that she has a history of fainting when needles are administered with blood draws or vaccines. She drank some juice and recovered without incident. The paramedics released her home and no other concerns arose. |

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| 1203749 | 4/13/2021 | CO | 20 | M | 3/31/2021 | 3/31/2021 | Patient had a syncope episode along with urinary incontinence shortly after receiving the Janssen vaccine. Pt was sitting in the medical monitor area when the event happened. Pt was unconscious for less than a minute and EMS was called. EMS evaluated pt, he was pale but fully verbal and functioning. vitals were stable, BP 110/69, HR 74, O2 97. Pt refused transport but was monitored at the site by Dr, for an hr before being released. Pt was instructed to go to UC/ER if he had another episode or new s/s and follow up with his primary care provider. The following day, the patient's primary care provider, NP tried multiple times to reach out and follow up with pt. Pt did not respond to his PCP. |
| 1203820 | 4/13/2021 | PA | 21 | F | 4/12/2021 | 4/12/2021 | Patient fainted and, upon waking, was hot/sweaty and generally felt unwell with several random spells of nausea for about 45 minutes afterwards. |
| 1203848 | 4/13/2021 | VA | 42 | M | 4/9/2021 | 4/9/2021 | Patient fainted onto the floor within 15 minutes of vaccination. Patient transported to ER by EMS. |
| 1203873 | 4/13/2021 | NY | 21 | M | 4/11/2021 | 4/12/2021 | Intense headache, fatigue, chills, body aches beginning the morning after vaccination. These symptoms have persisted for 48 hours after vaccination. On Monday, April 12th at 2:45PM, I experience a full-body fainting and collapse onto the floor when attempting to stand upright. |
| 1203903 | 4/13/2021 | TX | 23 | F | 3/8/2021 | 3/8/2021 | syncope |
| 1203907 | 4/13/2021 | MO | 19 | F | 4/13/2021 | 4/13/2021 | I administered Moderna COVID-19 vaccination to patient. I advised patient to wait 15 minutes post vaccination. Patient was sitting in post vaccination waiting area chair. Approximately 10 minutes after vaccination, patient's mother alerted us for assistance. Patient was slumped over in chair and had fainted. Patient was pale and had complained of dizziness to her mother prior to passing out. Responded to patient and helped patient to the floor to avoid hitting her head. Called 911. Patient responded and woke up. Had patient continue laying on floor until EMS arrived. EMS took patient's blood pressure and blood sugar. No significant medical history or known allergies. No history of passing out after vaccinations. Patient said she had not eaten yet today. Patient's blood pressure was low and EMS indicated that patient was dehydrated. |

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| 1203915 | 4/13/2021 | CO | 27 | F | 4/7/2021 | 4/7/2021 | symptoms: light headed & syncope episode in which patient hit head on pavement Vitals: BP 93/51 RR 16, Pulse 115 O2 67% Intervention/treatment: Oxygen at 6L/minute by non-rebreather , re-assessed vitals, called for EMS transport O2 Sats after oxygen was 100%. Paramedics assessed patient and took a blood glucose which was 118. Patient denied drug and alcohol usage and denied pregnancy NKDA NDMedical Condition other than anxiety and fear of needles. Patient refused medical transport and signed waiver with Paramedics |
| 1203789 | 4/13/2021 | PA | 36 | M | 4/13/2021 | 4/13/2021 | patient was given the vaccine,he was fine until he started walking around the store then he felt faint and returned to the pharmacy. we sat him in a chair,he was sweaty.white and started to slowly faint to the floor. His face got very red and his breathing sounded labored ,we placed him on the floor and he passed out briefly but came back to in about 3 minutes,very quickly he came back and his color returned and he knew where he was and answered all of our questions.We called 911 for an ambulance and when the ambulance crew arrived he was talking and feeling better.He had a gatoraid and sat up and answered all the questions everyone asked and his color was restored and he stood up and was feeling well enough to leave |
| 1204821 | 4/13/2021 | CA | 18 | F | 4/13/2021 | 4/13/2021 | Appx 15 minutes after vaccination, patient began feeling "faint", history of fainting, patient with syncopal episode and "passed out" for appx 90 seconds, hypotensive and bradycardic upon arrival to ER gurney, 1L NS given and NC O2 placed, patient dispositioned to Emergency Department via MR. |
| 1204649 | 4/13/2021 | WI | 41 | F | 4/1/2021 | 4/1/2021 | Within 6 hours of the injection, I experienced a severe headache, 101-degree fever, chills, severe leg pain, and fainting spells when attempting to walk. The symptoms lasted approximately 24-hours. |

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| 1204753 | 4/13/2021 | PA | 77 | F | | 2/1/2021 | <p>put on 30 pounds of water weight; Fainted; blood pressure dropped so low that she fainted; Moderna COVID-19 Vaccine reaction; This spontaneous case was reported by an other health care professional and describes the occurrence of VACCINATION COMPLICATION (Moderna COVID-19 Vaccine reaction) in a 78-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Primary pulmonary hypertension. Concomitant products included MACITENTAN for Primary pulmonary hypertension, WARFARIN, TADALAFIL and DILTIAZEM for an unknown indication. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. In February 2021, the patient experienced VACCINATION COMPLICATION (Moderna COVID-19 Vaccine reaction). The patient was hospitalized on sometime in February 2021 due to SYNCOPE. At the time of the report, VACCINATION COMPLICATION (Moderna COVID-19 Vaccine reaction) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. On an unspecified date in Feb-2021, the patient reported that she became very ill and hospitalized for 12 days after receiving the Moderna vaccination. She reported that her blood pressure dropped so low that she fainted. She also had had put on 30 pounds of water weight, which she is trying to get off. She reported that her doctor was aware of the hospitalization. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Reporter did not allow further contact; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p> |

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| 1204770 | 4/13/2021 | FL | 81 | F | 3/8/2021 | 3/8/2021 | fainting spells; Chills; Pain at site of the injection; itchiness at the site of the injection; rash at the site of the injection; This spontaneous case was reported by a consumer and describes the occurrence of SYNCOP (fainting spells) in an 81-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Autoimmune disorder. On 08-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 08-Mar-2021, the patient experienced VACCINATION SITE PAIN (Pain at site of the injection), VACCINATION SITE PRURITUS (itchiness at the site of the injection) and VACCINATION SITE RASH (rash at the site of the injection). On 02-Apr-2021, the patient experienced SYNCOP (fainting spells) (seriousness criterion medically significant) and CHILLS (Chills). The patient was treated with PARACETAMOL (TYLENOL) ongoing since an unknown date at an unspecified dose and frequency. At the time of the report, SYNCOP (fainting spells), CHILLS (Chills), VACCINATION SITE PAIN (Pain at site of the injection), VACCINATION SITE PRURITUS (itchiness at the site of the injection) and VACCINATION SITE RASH (rash at the site of the injection) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Concomitant medication not reported. Treatment included Tylenol. Company comment:Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |

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| 1204773 | 4/13/2021 | FL | 43 | M | 3/9/2021 | 4/7/2021 | Fainting for about 30 seconds to a minute in the bathroom; Feeling dizzy; Could not stand for a while when fell; This spontaneous case was reported by a consumer and describes the occurrence of SYNCOPE (Fainting for about 30 seconds to a minute in the bathroom) in a 43-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 026B21A and 003A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event. On 09-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 2 dosage form. On 06-Apr-2021 at 5:00 PM, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 2 dosage form. On 07-Apr-2021, the patient experienced DIZZINESS (Feeling dizzy) and DYSSTASIA (Could not stand for a while when fell). On 07-Apr-2021 at 4:00 AM, the patient experienced SYNCOPE (Fainting for about 30 seconds to a minute in the bathroom) (seriousness criterion medically significant). On 07-Apr-2021, DIZZINESS (Feeling dizzy) and DYSSTASIA (Could not stand for a while when fell) had resolved. On 07-Apr-2021 at 4:01 AM, SYNCOPE (Fainting for about 30 seconds to a minute in the bathroom) had resolved. No concomitant medications were reported. Treatment included for the events was acetaminophen. Patient reported that he felt dizzy and fainted for about 30 seconds to 1 minute in his bathroom at around 4:00 am this morning after receiving his second dose of the vaccine yesterday on 6 April 2021. Also, he could not stand for a while when fell. The patient took energy drink. Patient confirmed that the symptom was one time and it has not come back.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |

| <u>VAERS_ID</u> | <u>RECVDATE</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1204781 | 4/13/2021 | NY | 79 | F | 2/9/2021 | 3/9/2021 | <p>head injury/head trauma; eye infection; syncope/passed out; felling bad; has no balance; felt dizzyed; irritated; This spontaneous case was reported by a consumer and describes the occurrence of HEAD INJURY (head injury/head trauma) and SYNCOPPE (syncope/passed out) in a 79-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 028L20A and 012M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Glaucoma. Concomitant products included CLONAZEPAM (KLONOPIN) for Glaucoma. On 09-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 08-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 09-Mar-2021, the patient experienced HEAD INJURY (head injury/head trauma) (seriousness criterion hospitalization), SYNCOPPE (syncope/passed out) (seriousness criterion medically significant), FEELING ABNORMAL (felling bad), BALANCE DISORDER (has no balance), DIZZINESS (felt dizzyed) and IRRITABILITY (irritated). On 25-Mar-2021, the patient experienced EYE INFECTION (eye infection). The patient was hospitalized from 09-Mar-2021 to 11-Mar-2021 due to HEAD INJURY. At the time of the report, HEAD INJURY (head injury/head trauma), SYNCOPPE (syncope/passed out), FEELING ABNORMAL (felling bad), BALANCE DISORDER (has no balance), DIZZINESS (felt dizzyed), IRRITABILITY (irritated) and EYE INFECTION (eye infection) outcome was unknown. No treatment medication was included. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. This case was linked to US-MODERNATX, INC.-MOD-2021-071179 (E2B Linked Report). This case was linked to MOD-2021-071179 (Patient Link).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. US-MODERNATX, INC.-MOD-2021-071179:Case for first dose</p> |

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| 1204643 | 4/13/2021 | NM | 19 | F | 3/16/2021 | 3/16/2021 | Weakness/Fatigue starting the evening of the injection and persisting for about 48 hours. Chills/fever, nausea, and lightheadedness starting the next morning. Loss of consciousness (Uncertain if it was vasovagal syncope or seizure) 10:30 pm the next day. |
| 1204819 | 4/13/2021 | CA | 45 | F | 3/26/2021 | 3/26/2021 | Johnson and Jonson vaccine given in my left arm. Within 5 minutes I passed out cold. When I came too I almost passed out again. The strange thing was that I was having a hard time not passing out for at least 10 minutes after this shot. I have never experienced this before. I had no energy for the rest of the night. By the next day I had a fever and felt like i had the flu for over 24 hours. My husband did as well but he did not pass out. |
| 1204851 | 4/13/2021 | TX | 24 | F | 4/13/2021 | 4/13/2021 | 440pm Client with syncope episode. Provided cold compress and snacks. |
| 1204883 | 4/13/2021 | CA | 31 | M | 4/9/2021 | 4/9/2021 | Patient appeared to be fainted for 1-2 seconds. After having water and snack, he became ok. Patient was asked to wait for 45 minutes. Family members said that he did not have breakfast and he is scared of seeing needles or blood. |
| 1204850 | 4/13/2021 | TX | 20 | F | 4/6/2021 | 4/6/2021 | At 5:30 PM she was feeling nauseous and weak. She passed out, had a headache, chills, and intermittently experienced profuse sweating. She had a fever at 12:30 AM that evening (next day). She was a little nauseous and took it easy the next day and was fine after a day passed. |
| 1204858 | 4/13/2021 | PA | 24 | F | 4/13/2021 | 4/13/2021 | PATIENT FAINTED ABOUT 10-15 MINUTES AFTER RECEIVING HER FIRST DOSE OF THE MODERNA VACCINE |

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| 1204875 | 4/13/2021 | CA | 36 | F | 4/10/2021 | 4/10/2021 | Patient got dizzy and fainted and fall down the chair. She did come back alert within a minute. Patient said that she fainted once time before when she got her blood draw. She admitted that she did not eat anything in the morning before the vaccine appointment. We did call 911 and the firemen responded within 5-10 minutes and verified that all her vitals signs are normal . Patient declined to go to the hospital. We have patient sit on the floor, drink some water and eat some Skittles and she did reported she was feeling better. We had patient call her family to pick her up. |
| 1204277 | 4/13/2021 | PA | 64 | M | 4/13/2021 | 4/13/2021 | Near syncope, revived immediately with and amonia inhalant. |
| 1204881 | 4/13/2021 | CA | 18 | F | 4/13/2021 | 4/13/2021 | Appx 20 minutes post vaccination, pt reported "feeling faint", guided to floor by family, pt "passed out" for appx 90 seconds, pt to on site triage, hypotensive and bradycardic, 1L NS and 02 started, pt dispositioned to ER. |

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| 1204786 | 4/13/2021 | CA | 67 | M | 2/21/2021 | 3/9/2021 | <p>Passed out every time he stood up; Gallbladder infection; This spontaneous case was reported by a non-health professional (subsequently medically confirmed) and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out every time he stood up) and CHOLECYSTITIS INFECTIVE (Gallbladder infection) in a 67-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included No adverse event (No reported medical history). On 21-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 09-Mar-2021, the patient experienced LOSS OF CONSCIOUSNESS (Passed out every time he stood up) (seriousness criterion hospitalization) and CHOLECYSTITIS INFECTIVE (Gallbladder infection) (seriousness criteria hospitalization and medically significant). The patient was hospitalized on 09-Mar-2021 due to CHOLECYSTITIS INFECTIVE and LOSS OF CONSCIOUSNESS. The patient was treated with Surgery for Cholecystitis infective. At the time of the report, LOSS OF CONSCIOUSNESS (Passed out every time he stood up) and CHOLECYSTITIS INFECTIVE (Gallbladder infection) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 09-Mar-2021, Laboratory test: abnormal (abnormal) Gallbladder infection. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No relevant concomitant medications were provided. This case concerns a 67-year-old male hospitalized with serious unexpected events of loss of consciousness and cholecystitis infective. Event onset 17 days after first dose mRNA-1273. Underwent surgery. Events resolved. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.; Sender's Comments: This case concerns a 67-year-old male hospitalized with serious unexpected events of loss of consciousness and cholecystitis infective. Event onset 17 days after first dose mRNA-1273. Underwent surgery. Events resolved. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be</p> |

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| | | | | | | | excluded. |
| 1204351 | 4/13/2021 | TX | 31 | U | 4/13/2021 | 4/13/2021 | PT passed out but came out of it |
| 1204638 | 4/13/2021 | KY | 29 | F | 4/12/2021 | 4/12/2021 | DIZZINESS NEARLY PASSED OUT AND LOW BLOOD PRESSURE |
| 1204303 | 4/13/2021 | NC | 20 | F | 4/10/2021 | 4/10/2021 | I was in the passenger seat while my mom was driving me home after vaccination, and I began to feel nauseous a few minutes into the drive. About ten to fifteen minutes after we left (in total, about 25-30 minutes post-vaccination) I felt so sick (nausea, sweating, chills) that I couldn't keep my head up. I briefly fainted, but I woke up about two minutes later. My mom finished driving me home, and my condition improved with rest over the following hours. |
| 1204317 | 4/13/2021 | GA | 20 | F | 4/13/2021 | 4/13/2021 | Patient fainted a few minutes after receiving the vaccine. She was fine after a couple minutes and declined to have ambulance |
| 1204375 | 4/13/2021 | MD | 25 | M | 4/13/2021 | 4/13/2021 | The patient fainted about 5 minutes after administration of the vaccine. He mentioned before the vaccine that this also happened before his last vaccine (M-M-R) and said it was related to anxiety associated with getting vaccines/needlephobia. I asked him if he felt comfortable getting the vaccine today and he said to go ahead and give him the shot. At the time of injection he started breathing a little heavier but looked relatively well. After about 5 minutes in our waiting area, he started to look pale and fainted. The pharmacy manager and technician went to check on him. He was not responsive for about 30 minutes before he came to. |

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| 1204427 | 4/13/2021 | AZ | 41 | F | 4/12/2021 | 4/12/2021 | Vaccine shot at 9:15am immediately after shot (within 30 mins) - muscles twitching under left rib cage. This comes and goes every few hours. Sore arm 4:00pm same day 10:30pm same day:arm pain increased dramatically, blood pressure blood sugar dropped, almost passed out. chills, involuntary twitches, confusion, HEART PALPITATIONS, extremely weak, Next day (today 4/13/21) - early morning: fatigue, heart palpitations, lack of appetite, weak, brain fog. body aches. arm still hurts but not as bad. no bruising or swelling or redness at all where injection site is at. Pain is all inside shoulder area. same day 4/13/21: stomach cramps and nausea in addition to other symptoms mentioned above. continued heart palpitations. Although I am not allergic to anything that I know of, I am highly sensitive to any kind of medication. I very very rarely take any kind of medication. Even for pain. have not taken any medication to assist with the Moderna vaccine side effects. |
| 1204453 | 4/13/2021 | MO | 31 | F | 4/13/2021 | 4/13/2021 | Vaccine was given to patient. Patient was moved to observation area and sat down. After approx. 5 min the patient was feeling light headed. Propped up her feet to rest and gave her water. Patient passed out and was unresponsive though she still had a pulse and was breathing. EMS was called. Before EMS arrived patient was alert and responsive again. Once EMS arrived pt BP 107/90. Pt was not taken to ER, she recovered and left on her own. |
| 1204484 | 4/13/2021 | NY | 34 | M | 4/3/2021 | 4/4/2021 | Symptoms starting roughly 10 hours after vaccine, and lasting for 18-24 hours: High fever, chills, intense body ache, joint pain (to the point of not being able to move), fatigue, headache, vomiting, diarrhea, abdominal pain, weakness/fainting |
| 1204497 | 4/13/2021 | AL | 19 | M | 4/12/2021 | 4/13/2021 | Patient reports having fever and chills overnight. At approximately 6am he had a fainting episode followed by two other fainting episodes later in the morning. At approximately 3pm when I talked to him, he was still fatigued but feeling better. |

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| 1204528 | 4/13/2021 | FL | 43 | M | 4/13/2021 | 4/13/2021 | 1:44PM. Patient noted to be diaphoretic, and sliding out of his chair (slowly). EMS and nursing staff assisted him to stretcher. Eval by NP and EMS. 1:50 pm BP 114/78; P 61; BS 163; Sat 97%. R. 16 and easy. Patient oriented x 3. No loss of consciousness. Offered water, cereal bar. Patient returned to normal facial color. Diaphoresis decreased. Asked to go home. He arrived and will depart, he discussed his prior history of fainting, etc after injections. Discharged at 2:39 pm |
| 1204544 | 4/13/2021 | NJ | 31 | M | 4/13/2021 | 4/13/2021 | pt was in and out of fainting was given water and a granola bar. pt had white lips and vision blurry hasn't eaten since breakfast no hx of fainting in the past |
| 1204551 | 4/13/2021 | NY | 23 | M | 4/13/2021 | 4/13/2021 | Patient fainted, Blood pressure of 90/50, heart rate 50, patient sweating, very sleepy, feeling cold |
| 1204565 | 4/13/2021 | CA | 22 | F | 4/13/2021 | 4/13/2021 | 22 yo female without pmh, presented to USC vaccine site for 2nd dose of Moderna covid vaccine today. She arrived with boyfriend feeling well. Shortly after administration of vaccine, pt felt lightheaded and nauseated and passed out. Syncope was witnessed by medical staff. Pt was sitting in chair at the time and lowered carefully to the ground in supine position with legs elevated. She responded to name and sternal rub within seconds. Now feels sleepy. Denies SOB, CP, HA, numbness/tingling, pruritus or rash, abd pain. Nausea improving. No hx of syncopal reaction to vaccines or other. Denies being pregnant, not on menses. No meds pta. Vitals BP 110/70, HR 59bpm, RR 14, SpO2 100% ra, no thermometer available Heart and lung sounds normal, oropharynx benign, abd non-tender, no obvious rash or swelling or angioedema. No signs of anaphylaxis. Appears vasovagal. Within minutes, pt improving, skin color returning to normal. Able to respond verbally with understanding. A&Ox4. Sxs improved. Monitored full 30 minutes. Able to go home with boyfriend, educated on precautions, recommended rest and hydration. |
| 1204493 | 4/13/2021 | FL | 27 | M | 4/13/2021 | 4/13/2021 | patient passed out several minutes after receiving vaccine. he was very anxious before and during the vaccination. He came to in under a minute, waited in the store for approx. 20 minutes before leaving. |

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| 1204594 | 4/13/2021 | CA | 22 | F | 4/8/2021 | 4/8/2021 | Syncope post vaccine, fell out of chair. Pt had been NPO, has been known to syncope with blood draws. Pt came back within seconds. |
| 1197034 | 4/12/2021 | MA | 23 | M | 4/12/2021 | 4/12/2021 | Patient lost consciousness during the 15 minute waiting period after receiving the vaccine. He was pale and sweating, and lacerated his nose as he fell to the to floor. It appears that he fainted. |
| 1196866 | 4/12/2021 | ME | 24 | M | 4/6/2021 | 4/6/2021 | NEAR SYNCOPE/VASOVAGAL- Treatment cold packs - laid supine with feet elevated - hydration 20 fl oz water. |
| 1196901 | 4/12/2021 | NY | 63 | M | 4/8/2021 | 4/9/2021 | around 3 AM patient got dizzy and passed out. When I talked to patient at 6:30 AM, he stated to me that he was dizzy and fell during the night, his voice was very slurred and I could hardly understand him, he was also very disoriented. Took him to hospital ER around 7 AM |
| 1196917 | 4/12/2021 | VA | 26 | M | 4/12/2021 | 4/12/2021 | patient fainted in post vaccination waiting area, quickly regained consciousness |
| 1196920 | 4/12/2021 | IA | 33 | M | 4/10/2021 | 4/10/2021 | Around 5-10 minutes after the injection, patient began to feel faint. Patient turned pale and diaphoretic and passed out. Patient was lethargic and confused when coming back. Patient then began to remember where he was and started to feel better for about 2 minutes. Patient then fainted again and was able to regain consciousness with tactile and verbal stimulation. Medics were called for the patient. Patient's blood pressure was 80/55. When medics arrived, the patient had started to feel better and refused ER treatment. Medics left patient without doing vitals or assessments. Patient stayed at the vaccine clinic for another hour and then left after feeling better. |
| 1196942 | 4/12/2021 | FL | 66 | F | 4/8/2021 | 4/9/2021 | Patient went to the bathroom and when she got back to the couch, she fainted and could not get back up. Patient called her husband and he came home and helped her to lay down on the couch. Patient reports she was very weak. Patient has not told her doctor. |
| 1196955 | 4/12/2021 | MD | 28 | F | 4/10/2021 | 4/12/2021 | Fainted 36 hours after the vaccination. My fiancé found me unconscious and shaking. |
| 1196959 | 4/12/2021 | NJ | 53 | F | 4/4/2021 | 4/5/2021 | Passed Out Nauseous Dizzy Loss Sense of Smell |

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| 1197046 | 4/12/2021 | SC | 57 | M | 4/11/2021 | 4/11/2021 | Patient representative called pharmacy 4/12/21 stating husband, fainted while at dinner about 5 hours after receiving vaccination on 4/11/21. 911 was called and patient was cleared by EMS at home. |
| 1197028 | 4/12/2021 | MA | 39 | F | 4/11/2021 | 4/11/2021 | Patient fainted immediately after receiving the vaccine |
| 1197040 | 4/12/2021 | IL | 24 | F | 4/10/2021 | 4/10/2021 | Patient began to feel dizzy around 10 minutes of waiting after the vaccine administration. Patient then began to vomit but could not get all of the vomit out of her throat. She then passed out. Patient was lethargic and difficult to arouse. Patient's blood pressure was 122/80. Medics were called and arrived on scene and took patient to the ER. |
| 1196786 | 4/12/2021 | MN | 59 | M | 4/9/2021 | 4/9/2021 | Client reported prior to vaccination, that it is common for him to become faint and possibly "pass out" when receiving injections, having blood draws completed, and IVs started. Verified that client was feeling well and had eaten breakfast and was hydrated prior to injection. Client sitting in chair and tolerated injection well. About 5 minutes after injection given, client reported that he was feeling faint. Client was clammy and pale, and lost consciousness for about 30 seconds. Wife present and held his head and stood next to him in the chair. Client did not fall, and stayed seated in the chair. He slowly regained consciousness, and when able to sit and speak, client was offered water, which he accepted. VS collected - BP sitting in RUE - 108/78, P - 64, R - 16, O2 sats - 96%. Client started to regain color, and report that he was feeling better. Granola bar offered and client ate. Wife reported that this is a common event for client, when having blood drawn, IVs started, or injections given. Client states that he has "passed out many times before." Client stayed seated in chair, with RN and wife in room with him. By 0945, client states that he was feeling "back to normal." No s/s of allergic reaction. Wife to drive home and stay with husband for the rest of the day. Discussed s/s of allergic reaction, and other s/s that require immediate medical attention. Wife and client verbalized understanding. |

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| 1196655 | 4/12/2021 | NJ | 26 | F | 4/12/2021 | 4/12/2021 | pt fainted shortly after the vaccine was given, we tapped her shoulder and called her name and she came to and she was given water.. called 911 she denied going to the hospital...her friend drove her home after 30 minutes. |
| 1197005 | 4/12/2021 | NC | 60 | F | 4/9/2021 | 4/10/2021 | 18 hours after receiving shot, experienced extreme sweating, chills, diarrhea, dizziness, passed out in my husbands arms. Husband shook me awake, applied cold compresses, and took two Ibuprofen tablets. Chills and sweating continued for several hours. The following day I was very weak and had a head ache. Next day was better. |
| 1196848 | 4/12/2021 | CA | 30 | F | 4/9/2021 | 4/9/2021 | nausea, chills, lightheadedness/near-syncope, tremors, myalgias, fever, diarrhea |
| 1196832 | 4/12/2021 | IL | 61 | F | 3/17/2021 | 4/12/2021 | 61 y.o. female who presents with chest pain and syncope. Patient reports she began feeling ill around 6:00 p.m. last night. Patient reports she was having nausea, vomiting, and diarrhea. She denies any hematemesis or hematochezia. Patient states she awoke around 11:00 p.m. and felt like she was needing to vomit so she went to the bathroom. Patient reports that upon getting up she noticed pain across her chest. She described her pain as a midsternal pain with radiation across the chest. She described as a dull pressure. She currently reports no chest pain upon arrival to ER. Patient reports associated shortness of breath, lightheadedness, nausea, vomiting, and diaphoresis with the pain. Patient's cardiac risk factors include hypertension, smoking, age, obesity, and family history. Once patient was in to bathroom, she states she began having nausea, vomiting, and diarrhea. Patient subsequently passed out and hit her head on the bathtub. Patient had slight nose bleed. Patient's family found her lying in the floor and call 911. Patient was unsure of how long she was out during her syncopal episode. admitted to hospital Observation dx chst pain, vasovagal syncope |

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| 1196831 | 4/12/2021 | IL | 18 | F | 4/12/2021 | 4/12/2021 | Approx 5 minutes after receiving the vaccine, the patient experienced syncope and slid out of her chair. She was unconscious for approx 10 seconds. After lying down for approx 10 minutes and using a cold compress on her forehead, she felt better and was able to walk unassisted. Her mother is taking her to Care to be checked. |
| 1196829 | 4/12/2021 | OH | 45 | F | 4/9/2021 | 4/9/2021 | Patient became lightheaded and passed out temporarily. She was coherent and aware, but began to feel tingle in throat. EMS was called and patient was taken to the hospital for observation. Per the patient, she was administered epinephrine, diphenhydramine and steroids at arrival to hospital. Upon follow-up with patient later that evening, she was home and comfortable. |
| 1196826 | 4/12/2021 | NY | 27 | M | 4/11/2021 | 4/11/2021 | vasovagal episode / syncope with subsequent fall to ground, striking head. lightheaded, clammy, loss of vision prior to episode. Brought to Emergency Department, discharged to home in stable condition within 5 hours. |
| 1196688 | 4/12/2021 | GA | 35 | M | 4/10/2021 | 4/10/2021 | Customer said he is feeling dizzy and fainted and lost conscious for few minutes. |
| 1196788 | 4/12/2021 | OH | 19 | F | 4/10/2021 | 4/10/2021 | Syncope 1 minute witnessed by clinic staff in monitoring area approximately 10 minutes after vaccine administered. Patient denied chest pain, shortness of breath, abdominal pain and dizziness. Patient's skin assessment: pale, cool, diaphoretic. Vital signs obtained: BP 110/60, HR 84, Pulse Ox: 99%, RR 18. Patient remained in medical monitoring area for 30 minutes with no further reaction. Patient given fruit snacks and juice. Patient's skin color returned to normal, stated she felt better after lying down and eating. |
| 1196756 | 4/12/2021 | NC | 26 | M | 4/9/2021 | 4/9/2021 | Syncope |
| 1196747 | 4/12/2021 | ME | 23 | F | 4/6/2021 | 4/6/2021 | SYNCOPE/VASOVAGAL- Treatment cold packs - laid supine with feet elevated - hydration 20 fl oz water. |
| 1196717 | 4/12/2021 | OH | 19 | F | 4/12/2021 | 4/12/2021 | Vasovagal syncope within 10 minutes following administration of vaccine |

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| 1196698 | 4/12/2021 | NY | 42 | M | 4/11/2021 | 4/11/2021 | Vasovagal / syncope with subsequent fall to the ground, striking head; transferred to Emergency Department - stated lightheaded, dizziness, clammy prior to syncope and fall. Patient discharged to home in stable condition from facility within 3 hours. |
| 1196695 | 4/12/2021 | NJ | 21 | M | 4/7/2021 | 4/7/2021 | Pfizer-BioNTech COVID- 19 Vaccine EUA: Vaccine recipient experienced near syncope post vaccination. He was attended to by the medic and was NOT transferred to the emergency department. |
| 1197247 | 4/12/2021 | IL | 67 | F | 4/2/2021 | 4/3/2021 | Patient passed out and unresponsive and brought to hospital > 24 hours after vaccine given |
| 1196797 | 4/12/2021 | PA | 24 | M | 4/12/2021 | 4/12/2021 | patient fainted, then came to, had nausea, then vomited. Had patient sit and drink water afterwards ~30 minutes. |
| 1197287 | 4/12/2021 | FL | 16 | F | 4/12/2021 | 4/12/2021 | Patient felt dizzy and passed out for a minute. Patient also urinated while passed out |
| 1197651 | 4/12/2021 | OH | 42 | F | 4/9/2021 | 4/10/2021 | pain, tenderness, swelling, hardness, redness and sore under arm pit in lymph nodes. fatigue, body aches, chills, nausea and slight fever. I almost passed out while driving. |
| 1197637 | 4/12/2021 | PA | 28 | M | 4/10/2021 | 4/10/2021 | PATIENT FAINTED AFTER LEAVING IMMUNIZATION ROOM |
| 1195956 | 4/12/2021 | OH | 29 | M | 4/10/2021 | 4/10/2021 | Patient had symptoms of vasovagal syncope 10 - 30 seconds after receiving the shot. Felt dizzy, hot, and passed out. EMS was called and patient stayed an hour on site and received water. Patients girlfriend reported this had happened before with other vaccines. |
| 1197624 | 4/12/2021 | NY | 33 | F | 4/12/2021 | 4/12/2021 | Approx 6 mins after vaccination pt fainted. She recovered on her own within a minute and was very diaphoretic and pale, but was alert and oriented x 3. Pt then stated she was feeling very nauseous and proceeded to vomit. 911 was called and B/P 87/58, HR 91 and O2 99. EMS arrived B/P was fluctuating and pt was brought to ED for evaluation |

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| 1197619 | 4/12/2021 | WI | 29 | F | 3/27/2021 | 3/27/2021 | syncope and collapse (most likely vasovagal); hypoglycemia; got hot; This is a spontaneous report from a contactable consumer (patient). A 29-year-old female patient received bnt162b2 (Pfizer-BioNTech COVID-19 Vaccine, Batch/Lot number was not reported), dose 2 via an unspecified route of administration, administered in left arm on 27Mar2021 10:15 (at the age of 29 years) as single dose for covid-19 immunization. The vaccination facility was Pharmacy/drug store. The patient has no medical history and no known allergies. The patient was not pregnant. No vaccines were given 4 weeks prior. No prior issues with vaccines, no health issues, had cereal and juice two hours before vaccine and was not hungry. The patient has no COVID-19 prior to vaccination. The patient was not tested post vaccination. Concomitant medications included ethinylestradiol, norgestimate (SPRINTEC). Historical vaccine includes dose 1 of bnt162b2, on 25Feb2021 (05:15 PM) at the left arm for COVID-19 immunization at the age of 29 years. On 27Mar2021 at 1030 AM, 10 minutes (as reported) after receiving vaccine and during wait period, got hot and passed out. Ambulance was called and transported to hospital. CMP, serum pregnancy test, troponin (ekg), urinalysis with reflex culture, CBC/auto differential, Glucose WH-BLD lab tests performed on 27Mar2021. Monitored pulse and oxygen on 27Mar2021. Diagnosis-syncope and collapse (most likely vasovagal) and hypoglycemia (unspecified). The events resulted in Emergency room/department or urgent care visit and did not receive treatment. The outcome of the events was unknown. Information on about lot/batch number has been requested. |

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| 1197612 | 4/12/2021 | CA | | F | | 2/26/2021 | <p>Collapsed; Lost her vision; Exhausted; This spontaneous case was reported by a consumer and describes the occurrence of SYNCOP (Collapsed), BLINDNESS (Lost her vision) and FATIGUE (Exhausted) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Hypertension and Diabetes. On 26-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced SYNCOP (Collapsed) (seriousness criterion hospitalization), BLINDNESS (Lost her vision) (seriousness criterion hospitalization) and FATIGUE (Exhausted) (seriousness criterion hospitalization). At the time of the report, SYNCOP (Collapsed) and FATIGUE (Exhausted) outcome was unknown and BLINDNESS (Lost her vision) had not resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. Concomitant product use was not provided by the reporter. No treatment information was provided. Based on the current available information and temporal association between the use of the product and the events though start date was not provided- reporter indicated event occurred after the first dose), a causal relationship with the events cannot be excluded; Sender's Comments: Based on the current available information and temporal association between the use of the product and the events though start date was not provided- reporter indicated event occurred after the first dose), a causal relationship with the events cannot be excluded</p> |

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| 1197500 | 4/12/2021 | NY | 44 | M | | 4/2/2021 | SYNCOPE/PASSED OUT FOR A COUPLE OF HOURS; SEVERELY DEHYDRATED; FLU; INJECTION SITE WAS SORE; This spontaneous report received from a pharmacist concerned a 44 year old. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 042A21A, and expiry: 06-JUN-2021) dose was not reported, frequency 1 total administered on 02-APR-2021 to right arm for prophylactic vaccination. No concomitant medications were reported. On 02-APR-2021, the patient was severely dehydrated a couple of hours after receiving the vaccine, syncope/passed out for a couple of hours (unsure how long), and injection site was sore. On same day, it felt like the patient had the flu, which was described as chills, fever and the patient's throat being sore at the same time. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from syncope/passed out for a couple of hours, severely dehydrated, injection site was sore, and felt like patient had the flu on 04-APR-2021. This report was serious (Other Medically Important Condition).; Sender's Comments: V0;20210411188-covid-19 vaccine ad26.cov2. s-syncope/passed out, severely dehydrated. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s). |
| 1197392 | 4/12/2021 | NY | 39 | F | | 4/2/2021 | 4/2/2021 Vomiting, diarrhea, fainting, tingling in arms and fingers, severe chills (uncontrollable shaking), intense muscle and body, intense headache |
| 1197388 | 4/12/2021 | OR | 30 | F | | 4/10/2021 | 4/10/2021 Patient was nervous about the vaccination. About 5 minutes after vaccination patient got up from waiting area to ask for water and fainted, fell and hit her head. EMS was immediately called, arrived shortly and transported patient. |

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| 1197377 | 4/12/2021 | MO | 19 | F | 4/12/2021 | 4/12/2021 | PATIENT STARTED TO FEEL DIZZY/LIGHT HEADED ABOUT 5 MINUTES AFTER HER VACCINATION. WE LAID HER DOWN AND RAISED HER FEET AND SHE STARTED TO FEEL BETTER. PATIENT RECOVERED. SHE DID STATE SHE HAS HAD REACTIONS TO VACCINE (FAINTING) IN THE PAST PRIOR TO RECEIVING HER COVID SHOT. |
| 1197370 | 4/12/2021 | FL | 38 | M | 4/12/2021 | 4/12/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Nausea-Medium, Systemic: Vomiting-Medium |
| 1197355 | 4/12/2021 | GA | 29 | M | 4/12/2021 | 4/12/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient fainted in store after receiving first dose of Pfizer Covid vaccine. Patient regained consciousness within a minute and reported no other injuries. Patient was guided by pharmacist on duty to lie down with feet propped up. Patient remained in room for approximately 30 minutes after which patient confirmed that he was feeling fine. Patient will call pharmacy if any new symptoms develop |
| 1197326 | 4/12/2021 | FL | 18 | F | 4/7/2021 | 4/7/2021 | Per the NP: 1:20pm: While in observation, patient had an episode of syncope/ hypotension. It was unclear at the time if this was a reaction to the vaccination or not. Was treated immediately by NP and EMT/Paramedic staff. 911 was called and pt was transferred to the ER via monitored stretcher for further evaluation. Prior to leaving, and as pt was being transferred from one stretcher to the transport stretcher, pt experienced another syncopal episode. No arrhythmia noted on monitor, BP running 70's/50's. Awake, sluggish but oriented to person and place upon leaving. Transported via monitored stretcher to the ER. |
| 1197217 | 4/12/2021 | FL | 61 | F | 3/20/2021 | 3/20/2021 | Lightheadedness, almost passed out so they kept me longer & it happened again. Had to pull over side of road on way home as I almost blacked out. Happened throughout the day and then my blood pressure went to 160/90. That has lowered but still has not returned to normal. |

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| 1197113 | 4/12/2021 | MT | 54 | F | 4/9/2021 | 4/9/2021 | Patient is a 54 y.o. female who presents with concern for allergic reaction. Patient received her second Covid vaccine today. Shortly after this she felt very faint and almost passed out. She then developed a rash over her chest and felt like had a scratchy throat that was slightly swollen to her. She was given 1 dose of IM epinephrine with significant improvement in symptoms. She states he does have a history of allergy to strawberries as well as bees. Last time she had very she developed hives and vomited. She is feeling significantly better now no significant shortness of breath and her throat feels better. No nausea or vomiting or diarrhea at this time. Patient otherwise fairly healthy with no major medical problems. |
| 1197060 | 4/12/2021 | NY | 49 | F | 4/12/2021 | 4/12/2021 | First dose at 12:15pm arrived observation, at 12:20pm c/o feeling unwell, nausea, felt anxious, appeared pale and diaphoretic. Patient place in WC, placed in supine position in Med Eval area, drank water. Patient recovered well, BP 110/78, P 82, R 20. Left with husband clinically well. Likely vasovagal reaction without syncope. CSyta NP |
| 1197065 | 4/12/2021 | | 49 | M | 4/8/2021 | 4/9/2021 | Beyond initial flu-like symptoms, patient initially experienced bouts of light-headedness at around 10:30 a.m. the day after the 2nd shot - which was Apr 9, 2021. After laying down for a couple of hours, the patient tried to have lunch, but experienced syncope at around 12:45 p.m. Patient's spouse could not revive them initially, so called 9-1-1. |
| 1197072 | 4/12/2021 | ME | 27 | F | 4/7/2021 | 4/7/2021 | DELAYED SYNCOPED IN OBSERVATION - LAYED PATIENT SUPINE ELAVATED LEGS GAVE WATER - AND APPLIED ICE PACKS LEFT ON OWN RECONNAISSANCE 30 MINUTE LATER. |

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| 1197087 | 4/12/2021 | MT | 25 | F | 4/7/2021 | 4/7/2021 | 1 minute after receiving vaccine, patient was seated in a chair. Large sigh, then head went back. Staff immediately by her side, full grand mal seizure lasting 90 seconds. During this time assist of two to floor. After seizure assisted to side for rescue position. Public health attached to hospital and MD and PA arrived quickly. Patient transported to ER for further follow up. When patient regained consciousness she stated she had "passed out several times before and has felt more stress in this past year.~~ |
| 1197091 | 4/12/2021 | IL | 71 | F | 4/5/2021 | 4/5/2021 | about a half hour after getting the vax she became light headed, had nausea, some chills. By the time she got home she was very dizzy and almost fainting. She said her heart was racing and pounding then she vomiting. These symptoms lasted a couple of hours before dissipating. |

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| 1197325 | 4/12/2021 | MN | 21 | F | 4/12/2021 | 4/12/2021 | Patient reported a history of nervousness around needles and had passed out after an immunization in the past. I walked her through the immunization process and after administering her vaccine, I asked her if she was feeling ok before allowing her to leave the clinical room. She stated she was feeling ok so I instructed her to have a seat in the post-vaccination waiting area just outside the pharmacy for 30 minutes so we could observe her as a safety precaution. Shortly after sitting down, the patient fell off her chair. I ran out to check on her and found her unconscious and lying face down on the floor. As soon as I touched her shoulders she began to wake up and tried to get up. I asked her to remain laying down and offered to help her roll over onto her back. I asked her if she could tell me her name - she responded correctly. I asked if she knew where she was and she correctly stated she was at store. I had her take some deep breaths until her color came back and when she asked if she could please sit up, I assisted her into her chair and asked a technician to get a bottle of water for her. She felt a little shaky so I continued to hold onto her shoulders until she felt completely stable. She was able to take a few sips of water which helped her feel more steady. EMS arrived and checked her blood pressure and blood glucose levels. She was cleared by EMS and chose not to go to the hospital for further care. I had her call a friend to drive her home and stay with her for a while to make sure she was ok. |
| 1197101 | 4/12/2021 | | 23 | M | 4/12/2021 | 4/12/2021 | syncope. Evaluated by EMS-Refusal to transport. |
| 1197320 | 4/12/2021 | NY | 43 | M | 4/12/2021 | 4/12/2021 | Patient received dose at 1:19pm walked to OBs area, sat in chair. Started texting, noted weakness, c/o sweaty feeling, alerted staff. Placed in WC, back to Med Eval tent where he was diaphoretic, pale. Did not lose consciousness. Patient admits to not eating or drinking today at all, very stressed about vaccine. Drank a bottle of water, and gatorade, fan for air circulation. Patient recovered well on cot in supine position, walked out without incident. Likely vasovagal response without syncope. NP |
| 1197124 | 4/12/2021 | | 25 | M | 4/12/2021 | 4/12/2021 | SYNCOPE. Evaluated by EMS-Refusal to transport. |

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| 1197127 | 4/12/2021 | MD | 44 | F | 4/12/2021 | 4/12/2021 | Shortness of breath, tightening of throat, near syncope. PT had a Hx asthma and allergic reactions to antibiotics. 0.3 mg EPI via autoinjector left medical thigh. 8 doses of albuterol MDI PT improved after treatment. Evaluated, treated by EMS. Transported to ED for further evaluation and treatment. |
| 1197157 | 4/12/2021 | | 32 | M | 4/12/2021 | 4/12/2021 | LIGHTHEADED, PRESYNCOPE. Evaluated by EMS-Cleared |
| 1197632 | 4/12/2021 | VA | 53 | F | 4/8/2021 | 4/8/2021 | Extreme nausea and vomiting Fever Dizziness Fatigue Diarrhea Fainting No appetite Symptoms listed above lasted 56 hours. Treated at home, no visit to doctor. Injection site was sore 24 hours. |
| 1197231 | 4/12/2021 | | 31 | M | 4/12/2021 | 4/12/2021 | presyncope, nausea, black spots in vision. Evaluated by EMS-Cleared |
| 1197050 | 4/12/2021 | TX | 19 | M | 1/30/2021 | 1/31/2021 | The day following the vaccine at 2:30 AM, I had terrible chills, headache, shaking, and full-body weakness. 9:30 AM, I got out of bed and fainted soon after (reason for filing this report). The next day at 2:30 AM, every symptom went away. |
| 1197092 | 4/12/2021 | PA | 41 | F | 4/11/2021 | 4/11/2021 | Patient with self-reported history of anxiety, syncope and near syncope with medical procedures/needles. Complained of feeling anxious, light-headed, jittery after vaccination. Became pale, placed in a supine position, provided oral fluids, including fluids with sugar, VS stable, hypotensive to 77/57, pulse ox 99%, blood glucose 185, NSR on monitor reported by EMT on site. Husband called, patient declined EMS transport, was able to ambulate with supervision to husband's car, husband transport to local ER in private vehicle. Follow up with patient <24 hrs post vaccination: patient reported feeling better. Admitted she was anxious about receiving vaccination since appointment was made one week ago. |

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| 1195714 | 4/12/2021 | NY | 17 | F | 4/11/2021 | 4/11/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: pt passed out several minutes after receiving vaccine. BP was measured at 144/82 and the patients father stated she had passed out in the past when giving blood or seeing needles after a vaccine. no allergic response or history of allergy reported prior to administration outside of mild shellfish allergy. pt was monitored for 30 minutes before being allowed to leave with her father |
| 1196057 | 4/12/2021 | MN | 35 | F | 3/17/2021 | 3/18/2021 | at 1:30 am I started with the chills and feeling that i was going to vomit when i got up to go to the bathroom i because very dizzy and laid down and passed out this time i am not sure how long i was out for at approximately 4:30 am I had the same feeling went to the bathroom and yelled for my husband as i was very dizzy again when i got into the bathroom he said i was passed out and was doing some convulsing I was out for over a minute and he was trying to get me to wake up. Prior to waking i could feel him touching me and i could hear noise but i could not make out the noise or open my eyes and was unaware at that moment what was going on after I woke i threw up and then went back and laid down. then again about 7:30 am I had to use the restroom so walked into the bathroom I went to the bathroom after I felt very dizzy again and laid down on the floor at this point i passed out again and this time i could feel myself shaking see bright light but couldnt stop the shaking or see anything else. I am unsure how long this lasted. After that I went and laid down again and felt better I then was only tired. After resting I felt good and didnt feel i should go in since i was feeling better I did call my dr a few days after and inform her on what happend. ** I had also started my period during this morning. |

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| 1195834 | 4/12/2021 | MA | 27 | M | 4/11/2021 | 4/11/2021 | Systemic: Fainting / Unresponsive-Severe, Systemic: Nausea-Severe, Additional Details: Patient felt light headness, gave patient water, he ate sour patch kids then he said hes ok but will sit for 30 minutes, but he lost consciouness for about 20 seconds, woke up then started vomitting, we called 911 and EMT came took his vital signs bp 117/91 seems ok but patient refuse to go to emergency room, Patient stayed for another 30 mins, his family came and picked him up. Patient said he will call his PCP if still nausea problem, patient said he fainted with injections before but never violently vomit |
| 1195828 | 4/12/2021 | CA | 20 | M | 4/11/2021 | 4/11/2021 | Systemic: Confusion-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe |
| 1195818 | 4/12/2021 | GA | 21 | M | 4/7/2021 | 4/7/2021 | Systemic: Body Aches Generalized-Severe, Systemic: Confusion-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Severe, Systemic: Headache-Severe, Systemic: Hypotension-Severe, Systemic: Visual Changes/Disturbances-Severe, Additional Details: patient experienced temporary blindness, sweating ,syncope- which is ultimately why we call the ambulance |
| 1195774 | 4/12/2021 | DE | 50 | F | 4/11/2021 | 4/11/2021 | Systemic: Fainting / Unresponsive-Severe, Additional Details: IMMUNIZERS WITNESSED PATIENT FALL OUT OF HER CHAIR AND LOSE CONSCIOUSNESS. THEY CALLED 911 AND MONITORED HER. LETTING HER STAY LAYING THEN HELP UP SLOWLY TO SEATED POSITION. TRIED TO MONITOR BP, BUT AMBULANCE ARRIVED BEFORE THEY COULD GET CUFF ON. PATIENT DECLINED GOING TO HOSPITAL. FOLLOWED UP VIA PHONE CALL. |
| 1195767 | 4/12/2021 | GA | 55 | F | 4/7/2021 | 4/7/2021 | Systemic: Chills-Severe, Systemic: Confusion-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Severe, Systemic: Hypotension-Severe, Systemic: Weakness-Severe |

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| 1195760 | 4/12/2021 | MA | 27 | M | 4/11/2021 | 4/11/2021 | Systemic: Fainting / Unresponsive-Severe, Systemic: Nausea-Severe, Additional Details: Patient felt light headness, gave patient water, he ate sour patch kids then he said hes ok but will sit for 30 minutes, but he lost consciouness for about 20 seconds, woke up then started vomitting, we called 911 and Paramedic came took his vital signs bp 117/91 seems ok but patient refuse to go to emergency room, patient stayed for another 30 mins, his family came and picked him up. Patient said he will call his PCP if still nausea problem, patient said he fainted with injections before but never violently vomt |
| 1195734 | 4/12/2021 | CT | 19 | F | 4/11/2021 | 4/11/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Hypotension-Medium, Systemic: Numbness (specify: facial area, extremities)-Medium, Systemic: Visual Changes/Disturbances-Medium |
| 1195733 | 4/12/2021 | SC | 24 | F | 4/11/2021 | 4/11/2021 | Systemic: Fainting / Unresponsive-Severe, Additional Details: While resting after injection, patient fainted and fell out of chair and hit head on the ground. Paramedics responded and patient did not want to go with the as she felt better. WE gave ice and water and monitored until patient left under her own power. |
| 1195729 | 4/12/2021 | IL | 16 | F | 4/11/2021 | 4/11/2021 | Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Hyperventilation-Medium, Systemic: Hypotension-Medium |
| 1195724 | 4/12/2021 | CO | 18 | F | 4/8/2021 | 4/8/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe |
| 1195720 | 4/12/2021 | PA | 33 | F | 4/11/2021 | 4/11/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Seizure-Mild, Additional Details: Patient felt dizzy for 5 minutes after getting the vaccine, she got on her knees, and then passed completely out. Her body was rigid and was unresponsive for about 30 secs. The patient woke back up and thought she has urinated. We took her vitals and her BP came up 141/131 Pulse 88. The paramedics arrive ad when they took her BP it was 137/82. She refused transport to the hospital. When she left the store she was feeling normal. |

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| 1195896 | 4/12/2021 | IL | 39 | F | 4/11/2021 | 4/11/2021 | Patient fainted in pharmacist's arms, was lowered to ground and came back to pretty quickly, called 911 to come and make sure she was ok, could not indicate her surroundings for a bit, shaking, sweating, tingling in extremities |
| 1195717 | 4/12/2021 | TX | 25 | M | 4/11/2021 | 4/11/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Additional Details: Patient appeared pale prior to administration, however told immunizer that she was fine and wanted to receive the vaccine today. Appox 10min after receiving, pt was sitting down and slumped over. The immunizer out of abundance of caution administered an epi-pen. She did regain consciousness immediately. 911 was called and she was taken locally to be observed temporarily since she did not have anyone with her. |
| 1195954 | 4/12/2021 | IL | 60 | F | 4/8/2021 | 4/9/2021 | Arm pain immediately afterwards. Beginning at 18 hours after vaccination: excruciating headache, nausea, diarrhea, elevated temperature/flushing, chills, fatigue, swelling and redness at injection site. Unable to eat or drink anything for 12 hours. Symptoms started to ameliorate after taking 1,000mg of acetaminophen around 28 hours after injection. 48 hours after vaccination, most symptoms had passed except for some residual headache and fatigue. Short fainting spell at 49 hours but did not pass out. |
| 1195710 | 4/12/2021 | NY | 24 | M | 4/10/2021 | 4/10/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Hypotension-Medium, Systemic: Tingling (specify: facial area, extremities)-Medium, Systemic: Visual Changes/Disturbances-Medium |
| 1195707 | 4/12/2021 | CA | 21 | F | 4/11/2021 | 4/11/2021 | Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Mild, Systemic: Hyperventilation-Mild, Systemic: Shakiness-Mild |
| 1195706 | 4/12/2021 | MA | 40 | M | 4/11/2021 | 4/11/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Hypotension-Mild |
| 1195703 | 4/12/2021 | OK | 25 | M | 4/8/2021 | 4/8/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: PT DID NOT LOOSE CONSCIOUSNESS, BUT FELT LIGHT HEADED AND FELL TO FLOOR, BLOOD PRESSURE AND PULSE WERE NORMAL, NO FEVER. |

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| 1195696 | 4/12/2021 | CA | 24 | F | 4/10/2021 | 4/10/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient fainted due to low blood sugar having skipped breakfast. Recovered within minutes after sitting down and drinking water. |
| 1195646 | 4/12/2021 | IN | 36 | F | 4/7/2021 | 4/8/2021 | Syncope, vertigo, nausea, fever- started approx 24 hrs post vaccine. Syncope, vertigo, and nausea lasted approx 6 hours. Low grade fever was gone by morning. Headache off and on for 3 days, last time Saturday morning. Severe arm pain- swollen, red, hot to the touch, knot in arm and bruising. Sharp pains from area, hurts to raise arm, currently ongoing. Have been treating with ice and ib profen, little relief. |
| 1195641 | 4/12/2021 | OH | 27 | F | 4/9/2021 | 4/10/2021 | I was fine with dose number one I only had some pain in my arm. With dose number two I had fainted the next morning. Had cold chills. Body aches. A severe headache and nausea. |
| 1195563 | 4/12/2021 | | 26 | F | 4/10/2021 | 4/10/2021 | Patient passed out, states it happens on occasion. BP 114/73 HR71 RR16, then 5 minutes later 124/75, HR72, RR16. Patient came up to provider, asked to lay down, then passed out. States she has fainted in the past when she saw others past out. Left in stable condition |
| 1195558 | 4/12/2021 | | 17 | M | 4/10/2021 | 4/10/2021 | Patient fainted and fell while standing, hit head on floor, brief loss of consciousness, pupils PERRLA. Minor head pain, BP hypotensive (80/54) in wheelchair. Gave juice and crackers (hadn't eaten that day), glucose 91. Patient stable upon leaving, recommended ER visit for head evaluation. |
| 1195536 | 4/12/2021 | CA | 41 | F | 4/11/2021 | 4/11/2021 | Dizzy, fainting, nausea |
| 1197679 | 4/12/2021 | NY | 31 | M | 4/12/2021 | 4/12/2021 | After receiving vaccine, patient sat down then fainted/collapse, hand and knees first to floor |
| 1196661 | 4/12/2021 | VA | 32 | M | 4/5/2021 | 4/5/2021 | pt was in observation room, felt hot, passed out around 13:12, took patient to the recliner lifted legs, ice pack, head back. Patient alert and oriented times 3, bp 126/71, 93 pulse, 97% o2 on room air. |
| 1195534 | 4/12/2021 | CO | 21 | F | 4/7/2021 | 4/7/2021 | Light headed. Very hot, over heating. Had to lay down with feet in the air to not pass out. 3 people in line behind me passed out. |

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| 1195719 | 4/12/2021 | FL | 31 | F | 4/8/2021 | 4/8/2021 | Site: Bruising at Injection Site-Mild, Systemic: Allergic: Difficulty Breathing-Mild, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Mild, Systemic: Allergic: Itch (specify: facial area, extremities)-Mild, Systemic: Body Aches Generalized-Severe, Systemic: Chest Tightness / Heaviness / Pain-Severe, Systemic: Chills-Medium, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Nausea-Medium, Systemic: Shakiness-Severe |
| 1196359 | 4/12/2021 | MN | 45 | F | 4/9/2021 | 4/9/2021 | nausea, fainted; monitored and recovered in 30 min. |
| 1196616 | 4/12/2021 | NY | 42 | M | 4/11/2021 | 4/11/2021 | Vasovagal / syncope episode with subsequent fall to the ground, striking head; taken to the Emergency Department, stated prior to syncopal episode felt lightheaded, sweaty, clammy. Patient discharged to home within 3 hours of ED admission. |
| 1196609 | 4/12/2021 | TX | 24 | F | 3/27/2021 | 3/27/2021 | Patient said she is scared of needles and has fainted after injections. Immediately after injection she said she felt dizzy then she slumped in her chair and closed her eyes was unresponsive and pale for about a minute. When she responded she was slightly confused for about 30 minutes sat up drank water and put cold paper on her forehead and her back of her neck. Rested for half an hour. Then walked assessed to observation area. |
| 1196604 | 4/12/2021 | OH | 23 | F | 4/11/2021 | 4/11/2021 | Pt. passed out, hit floor 5 minutes after vaccine. Vs 130/78, HR 68, OxSat. 98%. Pt on floor, legs elevated, water offered. Pt is now able to sit down in chair unassisted. |
| 1196586 | 4/12/2021 | TX | 28 | F | 4/5/2021 | 4/12/2021 | Patient recived Janssen COVID 19 vaccine. After receiving the shot, patient went stiff and fainted with rolling of the eyes. Team member was able to help patient to ground. EMS service was called. EMS checked BP and blood glucose which was in normal range and recommended to have caregiver come pick patient up and rest. Patients fiancé came and took home. Team member escorted patient out |
| 1196578 | 4/12/2021 | NY | 54 | M | 4/10/2021 | 4/10/2021 | Reported an episode of syncope. Transferred to the ED and will follow up with PCP. |

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| 1196559 | 4/12/2021 | DC | 26 | F | 4/7/2021 | 4/8/2021 | Fever of 101.1+ lasting 10 hours, on-and-off low-grade fever for 48 hours Headache, including eye and jaw pain, lasting 3+ days Dizziness; inability to stand or walk due to head pain and fear of fainting (dizziness lasted ~24 hours) Nausea and loss of appetite (ongoing) Body aches, including spinal pain and hip pain lasting 48 hours |
| 1196547 | 4/12/2021 | NJ | 21 | F | 4/3/2021 | 4/3/2021 | Pfizer-BioNTech COVID- 19 Vaccine EUA: Vaccine recipient had syncope with fall post vaccination. They refused transport to the emergency room. |
| 1196526 | 4/12/2021 | ME | 25 | M | 4/10/2021 | 4/10/2021 | Pt. fainted while vaccine was in arm. I called a CODE 100 and put a cold water bottle on the patient's neck. Pt. came to within seconds. Pt. came to profusely sweating, pale, and feeling dizzy. We took his BP and kept monitoring it for 45 minutes after we had him lay down. His BP continued to rise and was normal. Pt. was nervous before vaccine administration (shaking). After event, Pt. stated this has happened in the past with donating blood. Pt.'s girlfriend picked him up, so he did not drive home. |
| 1196502 | 4/12/2021 | MN | 51 | F | 4/9/2021 | 4/9/2021 | light headed, sleepy, muscle twitching, fainted. Monitored and resolved in 60 min. |
| 1196465 | 4/12/2021 | NJ | 16 | F | 4/3/2021 | 4/3/2021 | Pfizer-BioNTech COVID- 19 Vaccine EUA: Vaccine recipient experience vasovagal syncope post vaccination |
| 1196445 | 4/12/2021 | OK | 21 | F | 4/8/2021 | 4/8/2021 | Immediately (a minute or two) after receiving the vaccine: lightheadedness, nausea, nearly fainted, vision started going blurry/black, sweating for about 5-10 minutes. Stayed seated until it mostly passed, then went outside for fresh air and to cool down. Put a cold rag on forehead/back of neck for half hour following symptoms. Drank water at soon as possible. For the next 36 hours after receiving the vaccine: sensitive skin, muscle weakness, tiredness, headache, body aches (including the sight of injection), chills, hot flashes. Took Advil every few hours to reduce pain, kept lights off, laid in bed to rest. |

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| 1196420 | 4/12/2021 | KS | 44 | M | 4/9/2021 | 4/9/2021 | Left arm felt thick and stiff; fingers on same side began to tingle; became dizzy; sweaty; got up to ask for help as instructed, fainted and hit the top on my head on the counter, I believe; came to; threw up; laid on the floor for a while; moved to a chair; wife came to pick me up; slept for 2 1/2 hours after that; felt better in the evening; typical sore arm |
| 1195888 | 4/12/2021 | OH | 62 | F | | | Started out the day with a fever of around 100.8, had body aches, chills then that night I started having bad stomach cramps and diahreach and I fainted. Had to call 911 and ended up with an overnight stay in the hospital. |
| 1196363 | 4/12/2021 | FL | 24 | F | 4/10/2021 | 4/12/2021 | Patient fainted shortly after receiving dose on 4/10. Patient did respond shortly afterwards and was given juice and a ice pack. Continued to monitor for some 30 plus minutes prior to releasing. Called patient around 5PM same day, patient sounded great and was doing well. Note: Patient has a history of fainting upon vaccine admin. but did not indicate to provider prior to administering vaccine. Patent called at moms request on 4/12 at 9:54 am and indicated she noted upon waking 2 hives in crevasse of arm which spread to all over body. Advised patient to call MD office for guidance and speak to live person. Spoke to doctor's office whom indicated they would address hives condition and then advise provider this provider. |
| 1196621 | 4/12/2021 | MI | 39 | M | 4/7/2021 | 4/8/2021 | In the Morning after my shot, I was getting breakfast ready for my kids. Everything seemed fine at the time and I started getting an odd feeling. Not really a dizzy or lightheaded feeling, but an odd feeling. The next thing I know, I came to on the floor. My security camera in the living room caught part of it from down a hall. I fell strait forward, onto my stomach with a large crash. The rest of the day, I did feel fatigue, joint pain in my knees and then chills/hot flashes later in the day/evening. The next morning (Friday) I woke up with a scratchy throat but felt fine the rest of the day. I have never fainted in the past. I don't know what would bring that on. I also have not had that feeling or any fainting spells since that incident. My wife came home about 8am out of concern. |

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| 1196347 | 4/12/2021 | WI | 55 | F | 4/9/2021 | 4/9/2021 | Patient passed out immediately following injection of vaccine. Her eyes rolled back and she was not able to speak. The vaccinator got help immediately, and patient's husband was in the room. She remained in a seated position with her husband holding her head up while standing behind her. Her blood pressure dropped to 78/80, heart rate was 45 bpm. She was unconscious for approximately one minute and 30 seconds. 911 was called immediately and she was transported to medical center. When I called the patient today, she did say that she was feeling better. She mostly felt nauseous and dizzy following her vaccination. She reports that her arm still feel itchy and that she has been taking Benedry |
| 1196321 | 4/12/2021 | GA | 23 | M | 4/10/2021 | 4/10/2021 | Patient fainted shortly after receiving covid vaccination. He was seated. 911 was called. He revived quickly and consulted with emergency personnel . He stated he was feeling better but he did not want to drive. He remained at the pharmacy until he transportation arrived. |
| 1196295 | 4/12/2021 | AR | 59 | M | 3/31/2021 | 3/31/2021 | Johnson-Johnson Covid 19 vaccine EUA- patient arrived 0845 completed paperwork and taken back guard, at 0858 client stated he was not feeling well and asked if he could lay down. Guard held his hands on shoulder to support client. Client became unconscious , code blue called , laid client to floor, client, pale, skin clammy and cold. Vital taken 0900 BP 92/60 pulse 52 resp. 20. As soon as client placed on floor he became responsive. He stated his pulse runs 52 and that was normal for him. He stated he has no medical history or medications, not diabetic. He stated he usually faints when he gets shots but it had been 20 years ago since he fainted so he thought he was over it. Stated he has fainted multiple times after shots. EMT arrived at 0904 client awake, alert and oriented, VS 112/68. EMT checked client over well. 0910 BP 147-86 HR 54. Client refused to go to hospital staff stayed with client approx. 15-20 more minutes in break room, he had beverage and snack. He stated he was much better and felt comfortable to leave, |

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| 1196289 | 4/12/2021 | MI | 65 | M | 3/10/2021 | 3/16/2021 | Patient presented to ED on 3/16/21 with cough and shortness of breath. He was found to be COVID-19 positive on 3/16/21 at PCP office. Was treated and admitted from 3/16/21 to 3/20/21. Returned to ED on 3/21/21 following a syncope and collapse episode at home that results in a head wound and suturing. Presented to ED on 3/24/21 with hypoxia and was transferred to medical facility where he was admitted from 3/24/21 to 4/1/21. |
| 1196286 | 4/12/2021 | NY | 28 | M | 4/5/2021 | 4/10/2021 | Extreme fatigue (starting day after shot) Nausea (starting immediately after shot) Ear ache (approximately 36 hours after shot) Chest pain/dizziness (5 days after shot) Trouble breathing (5 days after shot) Artery damage (discovered in ER) Fainting (1 day and 5 days after shot) Treated at hospital ER - hospitalized for observation |
| 1196251 | 4/12/2021 | CA | 18 | F | 4/10/2021 | 4/10/2021 | passed out after vaccine was given moved to EMS room BP: 108/61 HR:77 O2 98% |
| 1196240 | 4/12/2021 | GA | 33 | M | 4/10/2021 | 4/10/2021 | Patient he has a history of feeling faint after having blood drawn. Shortly after administration of the covid vaccination, the patient fainted. He had been seated. 911 was called. The patient revived quickly. Emergency personnel consulted with him. Patient remained at the pharmacy and left independently once he felt better. |
| 1196238 | 4/12/2021 | MI | 63 | M | 3/22/2021 | 4/10/2021 | Pt complained of dizziness for 2 weeks prior to hospitalization 4/10/2021, and passed out 6 times in the 2 days prior to admission. Upon admission was found to have acute pulmonary embolism. Physician requested VAERS report. |
| 1196207 | 4/12/2021 | FL | 18 | F | 4/11/2021 | | Patient collapsed 2-3 minutes after vaccination. The whole body was pale and unresponsive. She was laid down on the floor. 911 was called. Within a minute, her skin color became pinkish, and breathing was detected. She became aware of her environment. While we waited for the paramedics, her breathing and skin came back to normal. She reported of no breakfast or lunch before getting the vaccine. We gave her some chocolate and water. Her family later reported that she passed out after a flu shot a few years back. Her family refused to take her to hospital after the paramedic's advice. |

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| 1196143 | 4/12/2021 | MN | 18 | F | 4/9/2021 | 4/9/2021 | fainted/fell, BP 117/71, pulse 80. Resolved within minutes following monitoring |
| 1196119 | 4/12/2021 | VA | 33 | F | 4/9/2021 | 4/9/2021 | patient fainted after receiving vaccine (1st dose of pfizer). arousable, no loss of consciousness, no trauma, able to place in chair, 13:25 111/75, 100, 59, patient states "this is how she reacts to shots, piercings and tatoos. |
| 1196110 | 4/12/2021 | GA | 36 | M | 4/7/2021 | 4/7/2021 | Patient received first dose at the Vaccine Drive-Through. Patient appeared curious and asked multiple questions regarding the vaccine. However, the decision was made by the patient to proceed to receive the first dose of Pfizer vaccine. Patient received vaccine at approximately 02:00 pm. Shortly after administration of the vaccine and while in the reaction waiting area, he experienced ?dizziness and difficulty breathing? and requested assistance. Onsite medics state patient leaned his head back and his eyes rolled back in his head. No sign of swelling, itchy, or rash. Vital signs were within normal limit. Paramedic was immediately called at 02:08 pm. EMS arrived at 02:15 pm and departed at 02:20 pm. Paramedics transported non-emergent patient to ED. ED DX: vasovagal syncope; no signs of anaphylaxis or severe vaccine reaction. Patient released from emergency department at 03:15 pm with without activity restrictions. |
| 1196046 | 4/12/2021 | NY | 50 | F | 4/7/2021 | 4/9/2021 | Syncope, Arm swelling size of football |
| 1196364 | 4/12/2021 | NY | 58 | F | 4/6/2021 | 4/6/2021 | Fainted in the observation area after 1-2 minutes of vaccine |

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| 1198919 | 4/12/2021 | CA | 54 | F | 4/12/2021 | 4/12/2021 | Pt was administered the vaccine approximately 10:30 am. She reported feeling fine immediately after receiving the vaccine. She said she was walking around the store when she suddenly felt hot. She began searching for a place to sit down, but was unable to locate a seat. She stood by the refrigerated items in order to cool down when she semi fainted. She was caught by a front store employee. She reported no physical injuries at the time. She was carried to a chair and was able to sit upright on her own. She was able to speak in full complete sentences. She was alert and somewhat oriented. She said she felt very hot and dizzy. Her blood pressure @10:50 am was 108/81, pulse: 62, respiratory rate: 20. Vitals determined within safe limits. Pharmacy provided the patient with some water and Gatorade. We had the patient remain in sitting position. Patient reported slowly feeling better over time. Repeated vitals check @11:10 am with no significant change in blood pressure, pulse, and respiration. Patient remained seated and when she was feeling better, attempted to call friends and family to come pick her up from the store. After approximately 1 hour after the event, patient was back to baseline. She was able to leave on her own without assistance. |
| 1198741 | 4/12/2021 | CA | 32 | F | 4/12/2021 | 4/12/2021 | Patient started to vomit, got pale, diaphoretic, and passed out for a few seconds. Epinephrine 0.3 mg IM was given and her blood pressure was low. 911 was called and she was transported to the nearest Emergency department. |

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| 1199084 | 4/12/2021 | GA | 60 | M | 4/9/2021 | 4/10/2021 | I was extremely tired on Saturday. My shoulder hurt. About 3 pm, while urinating, I felt very light-headed as if I was about to faint. I stopped urinating and went back to bed. That evening, about 8:30, I tried to eat dinner, but after three bites, I felt extremely tired. I leaned back in my chair, and I passed out. My wife woke me, but it took several minutes. She said my eyes rolled back in my head. She splashed water on my face. She said that I stopped breathing. I woke up, then pushed my plate away and put my head on the table. I could not hold it up. I was sweating profusely. After several minutes, I felt that I was about to have diarrhea. My daughter and wife tried to walk me to the bathroom, but I did not have the energy to get there. I collapsed in the hall and hit my head on the door jamb. After several minute of trying , they pulled me up, and I then got the strength to walk the rest of the way. I had diarrhea, not suddenly, but it was as if my GI system emptied. It was soft, not loose, and there was a lot. I went back to bed, and eventually slept. I felt queasy the next day (Sunday), and I felt lightheaded at times, so I just sat or laid down. But I was feeling better. Today (Monday) I feel much better. A little tired, but much better. I went to the Pharmacy this morning, and they referred me to this website. I did not see the doctor. |
| 1199077 | 4/12/2021 | CA | 19 | M | 4/12/2021 | 4/12/2021 | While patient was waiting out the 15 min, he states he felt weird and went to let his father know. Upon getting up and leaving waiting area, pt. fainted but was quickly alert and able to speak. Patients father did state the patient has a needle aversion and has experienced this situation in the past. |
| 1199073 | 4/12/2021 | NH | 23 | F | 4/12/2021 | 4/12/2021 | Patient has reported having an issue with fainting with vaccines in the past. Approximately 1 minute post vaccine, patient reported feeling dizziness and nausea. Patient was laid down on the floor with her feet elevated and given a cold compress for the back of her neck and her wrists. Patient did not lose consciousness but did report dizziness, nausea, and numbness in her hands and fingers. Patient was able to hold conversation and reported feeling better after about 5 minutes. Patient was allowed to move to a sitting position and was monitored for any changes. Patient reported feeling better. Patient was monitored for an additional 15 minutes and reported feeling normal before she left. |

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| 1199069 | 4/12/2021 | NJ | 89 | F | 4/8/2021 | 4/8/2021 | Approximately 4 hours after injection experienced dizziness. Approximately 5 hours after injection, subject fainted and fell to the floor. Subject remained unconscious for ~ 17 hours (fainted at ~3pm and woke the next morning ~8am). No treatment, no medical care - patient did not contact her primary care doctor. |
| 1199044 | 4/12/2021 | TX | 17 | M | 4/12/2021 | 4/12/2021 | pt experience syncope with normal blood pressure, but low pulse and loss of vision for short eperiod of time. EMS reported normal BP, heart check and pulse and oxygen. vision did return and pt felt better after about 20 minutes |
| 1199030 | 4/12/2021 | CA | 22 | F | 4/9/2021 | 4/9/2021 | High blood sugar: 216 Vasovagal syncope: heart rate dropped to 40, bp 70/30 |
| 1198990 | 4/12/2021 | MI | 37 | F | 4/12/2021 | 4/12/2021 | customer had syncope about 5 mins after the vaccine administration. The pharmacist immediately placed a cold compress on her forehead and arms. She was breathing and had a low pulse. She became responsive in 1-2 mins and started responding to our questions. We gave her glucose tablet and some water as she stated she had not had anything to eat for the past 2 hours. We monitored her for additional 30 mins and let her leave when she was normal. |
| 1198966 | 4/12/2021 | PA | 20 | F | 4/12/2021 | 4/12/2021 | After the vaccine the patient fainted in the vaccine waiting area roughly 5 minutes after the vaccine. The patient was unconcious for rougly 10 seconds then woke up. The patient had no other symptoms or concerns. When fainting the pharmacist on duty was beside the patient and helped them to the floor to put them in the recovery position and ensure their head did not hit the ground. After recovering the patient was attended to by EMTs who were suspecting a vasovagal reaction. |
| 1198962 | 4/12/2021 | PA | 39 | M | 4/12/2021 | 4/12/2021 | After i gave covid-19 Janssen shot to patient, he passed out (Syncope), out of anxiety and nervousness from the shot per patient and his wife. Incident happened around 3:40 pm. His senses soon come back. We called emergency (911) and they ran some test and took the patient to the emergency. Patient was in senses, responding and alive when he left . |

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| 1198937 | 4/12/2021 | | 26 | F | 4/12/2021 | 4/12/2021 | Patient is a 26 year old female who has completed a 15-minute observation period with the following signs and symptoms of an adverse reaction: other - initially have dizziness and anxiety right after vaccination, while in the observation area and while sitting down beside her boyfriend, suddenly fainted for 20 seconds. No head injury. No urinary or bowel incontinence. . Witnessed syncope. Pt has a hx of fainting spells after vaccination. Ate lunch at 11am. Vital sign and observation. given water. stable vital signs, physical exam unremarkable. stable to go home |
| 1198930 | 4/12/2021 | VA | 51 | F | 4/9/2021 | 4/9/2021 | patient had near syncope after administration of COVID-19 vaccine. patient was assess by EMS and transported to local hospital. HR 87; BP 150/102; Resp 12 GCS 15 |
| 1199086 | 4/12/2021 | CA | 42 | F | 4/8/2021 | 4/8/2021 | Patient began feeling anxious like her heart was working harder. She has a neurologic condition that causes her to have syncope with left arm parthesias. Patient felt overall off. |
| 1198924 | 4/12/2021 | MO | 21 | F | 4/12/2021 | 4/12/2021 | Patient fainted, became limp so we checked for pulse and held her head up, she began foaming saliva and choked on it, and began seizing for about 5 seconds then came to. Patient declined EMS |
| 1199094 | 4/12/2021 | TX | 20 | F | 4/12/2021 | 4/12/2021 | Patient fainted and had seizure like symptoms with eyes rolling back in head, clamminess, sweating, severe stomach cramps, blurred vision, and temporary loss of hearing |

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| 1198915 | 4/12/2021 | CA | 36 | M | 4/12/2021 | 4/12/2021 | After patient received his second dose of the COVID vaccine, patient was sitting in the hallway for the 15 minute period to monitor for any allergic reactions. Patient began to feel not well, was sweating and felt as if he was going to faint. Patient's wife alerted Walgreens staff and the immunizing pharmacist went to check on the patient. Patient was moved to the front of the pharmacy where there was more open space and cooler air. Patient felt dizzy and felt as if he was going to faint but did not actually faint. Patient was given water and Gatorade and had a fan pointed towards his direction to cool him down. Blood pressure was also taken. Paramedics were called and took his blood pressure and sugar levels. Patient was advised to go to the ER and patient and his wife agreed. Patient has history of fainting due to extreme heat but not previously after receiving a vaccine. |
| 1198911 | 4/12/2021 | NY | 27 | F | 4/12/2021 | 4/12/2021 | A few minutes after vaccination patient turned pale and eyes started closing. Patient seems to have fainted. Patient was then in and out of consciousness over the next 5 minutes. Patient was given water and was able to drink. 911 was called immediately, and a cop escorted her out of the pharmacy area and to an ambulance outside |
| 1198869 | 4/12/2021 | OK | 27 | F | 4/12/2021 | 4/12/2021 | Patient was given the Janssen vaccine and fainted just a few seconds after injection. She awoke shortly after after and was given some water and was monitored by pharmacy and store staff until she felt normal, about 30 minutes. Her boyfriend drove her home. |
| 1198867 | 4/12/2021 | PA | 57 | F | 4/12/2021 | 4/12/2021 | Fainting, sweating, light-headed |
| 1198863 | 4/12/2021 | SC | 53 | F | 4/7/2021 | 4/7/2021 | PATIENT WAS HOT AND DIZZY AND FAINTED. AFTER 10 MINUTES OF GETTING THE JANSSEN COVID VACCINE. WE ADMINISTERED AN EPI-PEN DOSE AND CALLED 911. SHE REGAINED CONSCIOUS APPROXIMATELY 30 SECONDS LATER. WE APPLIED COOL CLOTHS TO NECK .. PATIENT STATED SHE HAD NOT EATEN ANY BREAKFAST AND A LIGHT SUPPER. WE CALLED 911 AND THEY CAME AS WELL. |

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| 1198856 | 4/12/2021 | MI | 19 | M | 4/12/2021 | 4/12/2021 | A 19 y.o. male fainted about 15 seconds after being seated in the post IMZ waiting area. I had just walked away so didn't see it happen. I had him lie on the floor until he felt better. He was rubbing his head and thought he may have hit it on the floor. After 40 minutes he said that he felt ok and his head was not very sore. He declined to having us call for medical help. |
| 1198846 | 4/12/2021 | CO | 33 | M | 4/12/2021 | 4/12/2021 | Patient fainted 10 minutes after receiving his first dose of the Covid vaccine. He was sweating profusely and very clammy. We gave him an ice pack and monitored him for 30 minutes after. His blood pressure was 90/60 a few minutes after the episode but then it came up to 124/84 a few minutes later. His eyes were dilated and we were concerned about a possible concussion from the fall so EMS came and evaluated him. They cleared him to go home. |
| 1198843 | 4/12/2021 | CT | 25 | M | 4/12/2021 | 4/12/2021 | reported started to feel dizzy after receiving vaccine. Thought it was nerves, tried to walk to chair for monitoring. Observed by clinic staff fainted on way to chair. Medical Doctor who was vaccinating on premises responded to incident immediately and patient came too right away. Patient is reporting butt feels sore, head and shoulders are fine. Place where shot was given feels sore. |
| 1198835 | 4/12/2021 | WI | 25 | F | 4/8/2021 | 4/8/2021 | Pale skin, fast heart rate, almost fainted |
| 1198830 | 4/12/2021 | IL | 31 | F | 4/12/2021 | 4/12/2021 | Patient fainted and lost consciousness for about 30 seconds after receiving vaccine. When patient regained consciousness, she was alert and coherent. She was able to hold a conversation until the emergency personnel arrived. They took vitals and she was released to go home without further treatment. |
| 1198826 | 4/12/2021 | MI | 46 | M | 4/12/2021 | 4/12/2021 | patient given vaccine and fainted five minutes later |
| 1198779 | 4/12/2021 | NJ | 20 | F | 4/12/2021 | 4/12/2021 | Pt has a history of fainting. Pt felt faint. Pt fainted and was unconscious for 15-20 seconds. Pt is CAOx3. Pts vitals are stable. Pt didn't require transport to hospital. |

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| 1198744 | 4/12/2021 | AR | 27 | M | 4/12/2021 | 4/12/2021 | Patient fainted while walking to the waiting area in the pharmacy. He was very hot, dilated pupils. We gave him water, crackers and a cold napkin. After 30 minutes he was able to leave and go home. |
| 1198925 | 4/12/2021 | CA | 25 | M | 4/6/2021 | 4/6/2021 | Patient fainted. Medical Provider and RN immediately responded. Patient regained consciousness shortly after fainting. Patient stayed a few minutes longer to be observed by medical provider and was then cleared to go home. |
| 1199377 | 4/12/2021 | NV | 25 | F | 4/10/2021 | 4/10/2021 | Approximately ten minutes after the vaccination, she passed out for a few seconds and came back. She experienced lightheadedness, loss of vision, nausea, and vomiting. We called 911 and they took her vital. Ten minutes later, she was fine and drove home. |
| 1196646 | 4/12/2021 | OH | 39 | F | 4/11/2021 | 4/11/2021 | Pt. passed out, hit floor 5 minutes after vaccine. Vs 130/78, HR 68, OxSat. 98%. Pt on floor, legs elevated, water offered. Pt is now able to sit down in chair un assisted. |
| 1197682 | 4/12/2021 | WI | 49 | M | 4/12/2021 | 4/12/2021 | I counselled the patient prior to giving him the Pfizer Covid19 vaccine. He received the vaccine at 10:10am. During the 15 minute observation period, one of my technicians was standing next to him talking to another patient. She saw some papers slip out of patient's hand and noticed he was unresponsive when she tried to talk to him. She yelled out for help and I ran out and saw his head rolled back, eyes open, and he sounded like he was snoring. He never left the chair--just his head rolled back. We tried to rouse him awake and I had my other technician call 911. I also called for a store manager. The patient came to about 15-30 seconds later. I asked him his name, what day it was, and if he knew where he was. He answered all questions correctly. He told me that he's fainted before after vaccines, however he never disclosed this to me prior to the vaccine and had answered "no" under the question if you've ever had a serious reaction to the vaccine. We gave him some water and a cold paper towel. The paramedics came and evaluated him. He declined to go to the hospital and his wife came and picked him up. |
| 1199584 | 4/12/2021 | NJ | 33 | F | 4/12/2021 | 4/12/2021 | syncope, fainted, very low BP |

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| 1199550 | 4/12/2021 | CA | 32 | M | 4/12/2021 | 4/12/2021 | Patient received the Pfizer COVID vaccine at around 4:50pm and while under observation he began to feel dizzy. He eventually passed out and became unconscious (5:00pm). Unfortunately he hit the ground with his head after he became unconscious. He also appeared to begin shaking while unconscious. He regained consciousness after about 20 seconds and was immediately fully alert. He stated he had no history of losing consciousness in the past. He was then taken to a nearby hospital via ambulance for evaluation and required staples to address the cut. He was discharged from the hospital around 8:00pm. |
| 1199537 | 4/12/2021 | IL | 62 | F | 4/4/2021 | 4/4/2021 | Fever aches chills started after 12 hours, 24 hours after dizziness, weakness fatigue. Passed out at home after the 24 hour mark. After coming "to" was vomiting. Perhaps was a seizure. The paramedics were called and I was evaluated and all was ok- O2 was fine, sugar 138, BP 110/60. I was to drink pedialyte, rest . |
| 1199529 | 4/12/2021 | | 37 | F | 4/6/2021 | 4/6/2021 | My arm started hurting pretty much right away after I got the shot on Tuesday and hurt badly all day Wednesday. When I woke up Wednesday morning, I felt nauseated and light headed. My rectum and anus felt like they were on fire when I passed stool at 8:30 AM on Wednesday, then I almost fainted walking from the bathroom back to my bed. My skin hurt and I felt feverish all day, although I didn't actually have a fever. I was awake for fewer than 6 total hours on Wednesday, all of them lying in my bed. On Thursday I had some joint pain and muscle soreness, but was otherwise ok. By Friday morning I felt fine. |
| 1199523 | 4/12/2021 | CA | 28 | M | 4/12/2021 | 4/12/2021 | At 4:15 pm the Covid-Janssen vaccine was given to the left deltoid and the patient was told to sit down for 15 minutes. When the patient got up after 2-3 minutes, patient became disorientated, sat down, and shortly fainted thereafter. The patient was brought into a nearby room, away from a busy thoroughfare and laid down. The patient regained consciousness soon after. Symptoms included: sweaty, palpitations and low blood pressure. After resting for 15-30 minutes he was able to walk out. |

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| 1199521 | 4/12/2021 | TN | 19 | F | 4/9/2021 | 4/10/2021 | Patient passed out/syncopal episode with head injury approximately 16 hours after getting vaccine per patient. Patient states she had a headache, fever, body aches, chills approximately 7 hours the vaccine. Patient sustained a head injury/possible concussion with nausea, head pain, irritability after syncopal episode. |
| 1199512 | 4/12/2021 | GA | 29 | M | 4/12/2021 | 4/12/2021 | Patient was observed to have a syncope episode lasting less than a minute after receiving vaccination. Patient was placed from the chair is was sitting onto the floor and legs elevated. 911 was called patient was oriented X3 and did not want Ems to come. We had patient stayed in pharmacy for about 30 more mins. Patient left pharmacy and described he was feeling okay and had no further adverse reactions. Patient describes that he generally pass out after giving blood or dealing with needles. |
| 1199492 | 4/12/2021 | FL | 60 | F | 3/27/2021 | 3/27/2021 | Bleeding at injection site. Seven minutes after being seated for observation, I fainted and vomited while I was out for 5 minutes. An ambulance was called and took vitals for the 20 minutes after I awoke and vitals were all good, so I declined going to the hospital. |
| 1199491 | 4/12/2021 | VA | 28 | F | 4/10/2021 | 4/11/2021 | I received the vaccine at 1:30pm on April 10, 2021. The next morning at 10am, I fainted. |
| 1199409 | 4/12/2021 | MN | 56 | F | 4/9/2021 | 4/10/2021 | Vomiting, weakness, low temperatures, multiple incidents of vasovagal syncope, 1 resulting in a fall |
| 1199085 | 4/12/2021 | NC | 27 | F | 4/9/2021 | 4/9/2021 | Around 4/4:30pm I started to feel dizzy and by 5pm I grew worried I might faint (I've never previously fainted). Around approximately 8pm I was feeling very feverish, experiencing body aches, mental fog, intense shaking and chills, and within the next few hours threw up multiple times. I eventually fell asleep and sweated profusely, waking up multiple times (unusual for me). The next day I had low appetite, fatigue, and body aches, but other symptoms were reduced. |
| 1199394 | 4/12/2021 | MD | 28 | M | 4/12/2021 | 4/12/2021 | Pt received vaccine and counseled on side effects. Told to remain seated for 15 minutes. Pt got up after 15 minutes and said he was sok but got dizzy/passed out 30 feet away. Pt hit head on his way down and vomited when he sat up. Pt remained nausea and felt faint. Paramedics were called. |

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| 1199182 | 4/12/2021 | FL | 34 | M | 4/10/2021 | 4/10/2021 | 3 minutes after vaccination was given patient stood up and requested juice then fell down and fainted. About 15 seconds later the patient came to. EMS was contacted. Patient had his vitals checked, blood sugar taken. Patient reported to EMS that he was feeling anxious. Patient was asked by EMS questions in relation to time and place. Patient refused to have EMS take him in to the hospital for further tests. Patient was instructed to have a family member come in to take him home and advised him not to drive. Upon a follow up call 30 hours later patient reported he was bruised on his left shoulder, left hip and he had a puncture wound to his Jaw due to his fall. He reported he went to urgent care for follow up. they told him stitches would not be necessary for the puncture wound to his Jaw. |
| 1199375 | 4/12/2021 | FL | 34 | F | 4/12/2021 | 4/12/2021 | Patient fainted shortly after receiving vaccination. Patient came to about 30 seconds after fainting. Patient rested in chair for 30 minutes left on own accord. |
| 1199338 | 4/12/2021 | CT | 45 | F | 3/30/2021 | 3/31/2021 | Approximately 20 hours after receiving the vaccine, and after having no other side effects, I became very light headed and passed out I ended up passing out two times in a span of twenty minutes. |
| 1199307 | 4/12/2021 | CA | 40 | M | 4/12/2021 | 4/12/2021 | Pt fainted in observation room approximately 5 minutes after vaccination in left arm. Pt lost consciousness for approximately 30 seconds. Pt able to converse with medical personnel after that time, able to sit up approximately 10 minutes after episode and able to walk to his vehicle approximately 25 minutes after episode. Pt driven home by spouse. |
| 1199305 | 4/12/2021 | TN | 22 | F | 4/12/2021 | 4/12/2021 | Patient became light-headed, dizzy, and fainted. |
| 1199304 | 4/12/2021 | FL | 23 | F | 4/12/2021 | 4/12/2021 | Fainted for about 2 minutes. Called 911. Paramedics evaluated. |
| 1199272 | 4/12/2021 | NC | 24 | F | 4/6/2021 | 4/12/2021 | multiple bilateral PE with syncope |
| 1199266 | 4/12/2021 | MN | 59 | F | 4/1/2021 | 4/1/2021 | As soon as I received vaccine I left for a 2 1/2 car trip. As soon as I stood up to get out of the car I starting shivering violently. I fainted and fell onto my left foot which broke my foot. I have never fainted before. |

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| 1199253 | 4/12/2021 | TN | 34 | M | 4/12/2021 | 4/12/2021 | Pt fainted immediately after injection, regained consciousness after about 15 seconds. Reported feeling uneasy and weak for 20-30 minutes following injection. Provided supportive care with water. Pt was able to leave on his own after about 45 minutes. |
| 1199233 | 4/12/2021 | VT | 40 | F | 4/11/2021 | 4/11/2021 | Fainted/ sweats while walking to car. Recovered, but became very light headed in car and reclined seat to avoid losing consciousness (was not driver). |
| 1199217 | 4/12/2021 | NH | 32 | F | 4/12/2021 | 4/12/2021 | Shortly after receiving the COVID19 (Janssen) vaccine the patient reported being faint. While seated with her partner the patient briefly lost consciousness. She regained consciousness quickly and was provided with water, a snack, and a cool/damp towel. The patient was instructed to elevate her legs and maintain a clear airway. Patient remained seated. Patient affect normalized within 10 minutes and the patient reported feeling much better shortly thereafter. Patient and her partner remained waiting at the pharmacy for a total of 30 minutes to ensure that she was alright. Patient reported that she has experienced fainting episodes in high stress situations in the past (eg at concerts, events, etc) and maintained that she will be ok. |
| 1199179 | 4/12/2021 | IN | 41 | M | 4/12/2021 | 4/12/2021 | Patient was feeling warm and light-headed at 15 minute mark, so we kept for further observation and gave water to hydrate. At about the 17 minute mark patiently suddenly fainted in his chair for 15-30 seconds. He then began to vomit and woke up in the process. Once he fully came back to, he said he felt remarkably better and no longer felt light-headed or clammy. Following this episode he reported feeling back to normal and that he had just ate a large breakfast before coming in for the shot, but did not feel bad in any way anymore. We observed for another 30 minutes and patient showed no further sign of issues. He was released with his wife. |
| 1199117 | 4/12/2021 | CA | 63 | F | 4/10/2021 | 4/11/2021 | At 24 hours post-vaccination, I experienced Dizziness. Nausea. Increased Appetite. Muscle aches/pain. Then Fainted and was out for a few minutes. Then woke up on my own. Still experiencing fatigue and some nausea/dizziness and mild diarrhea. Did not get transported to hospital or recieve medical care. |

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| 1199112 | 4/12/2021 | NH | 27 | M | 4/12/2021 | 4/12/2021 | Patient has reported having an issue with fainting with vaccines in the past and patient requested to be given immunization while sitting on the floor. Patient was given a cold compress for his wrists before the vaccine was given. Approximately 1 minute post vaccine, patient reported feeling dizziness and feeling warm. Patient was given a cold compress for the back of the neck and the wrists. Patient did not lose consciousness but did report dizziness. Patient was able to hold conversation and reported feeling better after about 5 minutes. Patient was monitored for an additional 15 minutes and reported feeling normal before he left. |
| 1199396 | 4/12/2021 | NV | 40 | M | 4/10/2021 | 4/10/2021 | Ten minutes after the vaccination, pt passed out and came right back. He said he was fine except his hands were tingling. We called 911 and they took him for the vital. |
| 1197956 | 4/12/2021 | IL | 25 | F | 4/12/2021 | 4/12/2021 | Patient fainted while sitting in the waiting area about 5 minutes after receiving her first dose of the Pfizer COVID Vaccine. Patient was unconscious briefly, but woke up after less than a minute a little disoriented. She was sweating and felt very hot, except for her hands that were cold. We gave her water and an ice pack to cool her down and waited with her until paramedics came to treat her. She seemed alert and that the issue had mostly resolved as she left with paramedics approximately 15 minutes later, but it is unknown what happened after she left with them. |
| 1198218 | 4/12/2021 | MI | 25 | F | 4/12/2021 | 4/12/2021 | Patient received Janssen COVID vaccine at a clinic today at approximately 2:10pm. When seated in a chair in the waiting area, patient stated she started to feel light headed and sweaty and has fainted before (not from a vaccine), so she sat back in the chair and then awoke on the floor. She bumped her forehead on the floor and has an egg-sized raised bump on her forehead. We applied ice instantly and monitored her blood pressure until she felt well enough to sit up. She did not feel she needed an ambulance and refused going to urgent care. She is feeling fine other than the bump. A worker took a report and I discussed with her what to watch for to monitor for concussion. Her roommate is driving her home. Event will also be reported today. |

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| 1198217 | 4/12/2021 | FL | 76 | M | 4/10/2021 | 4/10/2021 | Chief complaint : syncope, vomiting, and weakness. Assessed by on site Medical and transported to Hospital. |
| 1198190 | 4/12/2021 | IL | 31 | M | 4/12/2021 | 4/12/2021 | pt c/o lightheadedness and vision turning white; pt able to ambulate with 2 guards at his side to private obs room; wife present; pt placed on exam table and HOB put flat and legs elevated; eyelids fluttering, pt warm and diaphoretic; remained responsive and answering questions; pt states that he has fainted in the past, also has "sensitivity" to certain anesthetics; initial VS at 1013:cuff not registering BP, HR 38/dinamap,RR 18,Sao2 100%. Switched to smaller BP cuff and Vs at 1015: BP 78/43,HR 40,RR 18, Sao2 100%. Pt c/o nausea. VS at 1020: 98/51, HR 58, RR 18, SaO2 100%. Pt states that he is feeling better except still nauseous. VS at 1025: BP 112/59, HR 68, RR 16, SaO2 100%. HOB raised to 45 degrees, no c/o. Pt given cold pak and drink of water. 1030:pt states less nauseous, still "cloudy". 10:45:HOB placed at 90 degrees, BP 114/67, HR 66, RR 16, SaO2 98%. 10:50:pt states that he is feeling much better, talkative, ambulated WNL in room. 1055: BP 112/72, HR 56, RR 16, Sao2 100%. Pt states that he feels a "little tired" but fine to leave. Wife will drive pt home. 1100 Pt leaves clinic; no c/o. |
| 1198132 | 4/12/2021 | TX | 28 | M | 4/11/2021 | 4/11/2021 | Patient received the vaccine and while waiting at the post vaccine observation lobby, fainted. He stated he was not diabetic, did not have breakfast that morning and was nervous about the vaccine. Fainting episode lasted less than 1 minute, and afterwards patient was alert to person time and place. He was taken by ambulance by paramedics for further evaluation because his fiance stated that she saw him have a small seizure. I did not witness the seizure. |

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| 1198130 | 4/12/2021 | CA | 36 | M | 4/12/2021 | 4/12/2021 | 10:30am: Pt was sitting in the vaccine site observation area after receiving vaccine for COVID-19 (Janssen). Pt had been sitting for approximately 15 min when RN noticed pt dropped paperwork and cell phone onto the floor. Pt's head went back, mouth open and eyes closed. Pt visibly pale. RN quickly approached pt while speaking loudly, pt did not respond. Audible "snoring" heard. RN placed pt's torso and head in her arms and moved patient to the floor into a supine position with legs raised onto his chair (pt did not fall to the ground). Once on the floor, pt opened eyes and asked RN, "Did I fall asleep?" RN reassure pt that he may have fainted while sitting in his chair. RN reassured pt and gave pt bottle water to drink. Color returning to patients face. 10:40: Pt reports "I'm feeling much better." Pt sitting upright on the floor. 10:45: Pt sitting up in chair. Alert to person, place, and time. Color WNL, peripheral pulses strong. Pt reports feeling well enough to leave. RN encourage pt to stay a few minutes longer to make sure able to stand/walk to his car. 10:50: Pt left observation area. |
| 1198125 | 4/12/2021 | | 27 | F | 4/12/2021 | 4/12/2021 | seeing spots, near syncope. Evaluated by EMS-Cleared |
| 1198122 | 4/12/2021 | OH | 24 | F | 4/2/2021 | 4/3/2021 | Severe back pain starting at 5pm on April 2, 2021. Frequent urination throughout the night, cold chills. April 3, 2021, 4:50am got up to use the bathroom and had extreme nausea and lightheadedness. Passed out and seized up. EMS arrived, BP 80's/50's and low grade fever. Put in chair to transport me downstairs and passed out and seized up again. Threw up. Transported to ER and still weak and severe back pain. Was given something for nausea. Two bags of fluid. EKG, blood work, and urine test. Left ER around 10 am |
| 1198111 | 4/12/2021 | | 21 | M | 4/12/2021 | 4/12/2021 | syncope. Evaluated by EMS-Refusal to transport. |
| 1198104 | 4/12/2021 | MN | 20 | M | 4/8/2021 | 4/8/2021 | Pt fainted and became diaphoretic. HR in the 60's, BP 140/80, SPO2 100%. Had pt lay down for 15 minutes, provided water and a granola bar, and had client sit another 15 minutes. HR remained in the 60s/70s, SPO2 remained stable, and BP was 125/70 after 30 minutes. Client reported feeling back to baseline and went home. |

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| 1198067 | 4/12/2021 | OR | 22 | M | 4/10/2021 | 4/10/2021 | syncope, HR 44, O2 90% RA. gave 50 mg IM Benadryl, 1 dose Epi-Pen, JR. B/P after meds- 143/72 and 122/68, HR improved to 76 |
| 1198064 | 4/12/2021 | TX | 45 | M | 4/1/2021 | 4/1/2021 | Became light headed, Fainted, Turned Pale, Sweated. EMTs were called who took BP, Blood Sugar, and ran EKG (I think). and was told all were normal. |
| 1198007 | 4/12/2021 | CA | 53 | F | 4/12/2021 | 4/12/2021 | After about 7 minutes of getting the Janssen Covid-19 vaccines, patient husband said patient is not feeling well. I attended to patient immediately. She said she is not feeling well, and her eye was rolling (as if when she tried to look up and couldn't get their eye to remain open) a for about few seconds and then she her eye was open back to normal. She was sweating on both hands and face were cold to the touch. I got the manager from the store to help me lie patient flat on the floor's surface gently to prevent her from falling off the chair. Based on this our adverse event protocol, patient exhibited similar symptoms to Syncope (paleness, sweating, coldness of extremities), so I patient is lying flat on the floor, feet elevated, and cold compression was apply on her arms and face. Unfortunately, patient conditions was not improving as it seem but she was alert and able to breath (fast pace) the whole entire time the incident occurred where she answer all questions when we myself, then the paramedics asked her questions. Paramedic arrived at scene within 10 minutes after individual got off the phone with 911. They took her away around 9 am and said patient probably experience anxiety attack. |
| 1198253 | 4/12/2021 | CA | 18 | M | 4/6/2021 | 4/6/2021 | About 10 minutes after the vaccine, the patient was standing in front of the pharmacy with his mom and fainted. He landed on his buttocks and did not appear to hit his head. He immediately appeared conscious but disoriented. He had a steady pulse and no itching or rash or trouble breathing, but he seemed pale. EMT was called and upon evaluation determined that he did not need further treatment. The patient went home with his mother. |

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| 1197977 | 4/12/2021 | MD | 51 | F | 3/5/2021 | 4/9/2021 | Left the parking lot felt warm down my arm to fingers started tingling & feeling warm, the fingers started to go numb. tried not to worry. Later fingers were getting tighter. Went to sleep hands were stiff 2 finger on right hand swollen. Sat.morning did not want to get out of bed was freezing and felt like I was going to vomit everywhere & headache.Tied to eat banana got water vitamin c pedialyte 2:530pm felt so bad.went home under covers 6blankets turned heat on 70 still ice cube,freezing wanted to vomit curled up in ball face bright red, passed out someone called I couldn't just said let me die, I am in so much pain, make it go away. I almost had them call 911, I do not have the money to pay. toughed it out cried . Body hurt so bad short of breathe. Sunday, still bad face not red woke up in puddle of sweat I was wet. Still feel like going to vomitstayed in bed drank , Sunday evening at 8:30pm I burped, Wow what a relief, still head pounding headache. Monday short of breathe whizzing. Took another hot shower, |
| 1197994 | 4/12/2021 | NY | 57 | M | 4/9/2021 | 4/9/2021 | Janssen COVID-19 Vaccine EUA Passed out while seated, 3-4 minutes after receiving vaccine. Fast onset of extreme nausea followed by blackout. Duration of blackout unknown. Woke up on floor not knowing how I got there. Sat up, nausea and lightheadedness returned, then dissipated with no further blackout. Felt rush of blood from head to toe and felt okay after that. Pharmacy staff took blood pressure, readings were close to normal (slightly elevated). Paramedics were called by pharmacy, and their BP readings were also close to normal. After all that, aside from some fatigue, no other appreciable side effects over the next 48 hours. No nausea, flu-like symptoms or fever, and very little soreness at injection site. |
| 1197949 | 4/12/2021 | TX | 18 | F | 4/8/2021 | 4/8/2021 | dizziness and fainted, shivers/chills, 4 x episodes of break through seizures |
| 1197878 | 4/12/2021 | NY | 26 | M | 4/12/2021 | 4/12/2021 | patient experienced low BP (68/39) and passed out, fell off the chair and onto the floor, woke up on the floor within 30 seconds. |
| 1197817 | 4/12/2021 | MA | 42 | M | 4/11/2021 | 4/11/2021 | Systemic: Confusion-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild |

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| 1197803 | 4/12/2021 | FL | 55 | M | 3/18/2021 | 3/18/2021 | I passed out and suffered a concussion. My wife found me on the floor when she heard me hit the ground. I was taken to the hospital and stayed for two nights while given numerous scans and tests. No indication of stroke or poor heart condition revealed by any of the tests. No other symptoms other than soreness (which could have been attributed to the fall). |
| 1197800 | 4/12/2021 | NH | 32 | F | 4/12/2021 | 4/12/2021 | After a few minutes receiving Janssen Vaccine at 12:45pm . Patient had syncope, patient fainted for about 10 seconds sitting on chair, regain conscious after. Decline additional treatment or call for emergency. Patient refused to stay for 30 minutes because of her anxiety. contacted patient at 1:55pm. Patient was back to home resting without any addition symptoms. Patient was instructed again to contact MD or emergency if any symptoms worsen ie skin rash , SOB, swelling or severe dizziness. |
| 1197789 | 4/12/2021 | HI | 28 | M | 4/7/2021 | 4/7/2021 | Syncope during observation time approximately 5min after receiving the injection. Unconsciousness for 10-15 seconds then returned to observation chair. until paramedics arrived. He was cleared to leave on his on recognizance. He remained seated for 1 to 2 hours then left the store. |
| 1197754 | 4/12/2021 | NY | 23 | M | 4/12/2021 | 4/12/2021 | Patient passed out at clinic - he has a history of anxiety and did not take meds before the shot because he was concerned about an interaction. The patient received his shot, sat down and fell out of the chair. He landed face first on the ground and hit his head on the corner of a post. He was rolled over and feet elevated. He came around quickly. He had a mark on his head. 911 was called on the scene to evaluate his head injury. Patient declined transport to the hospital and returned home. He was instructed to call 911 or report to hospital if he did not feel well tonight. |
| 1197745 | 4/12/2021 | | 18 | F | 4/12/2021 | 4/12/2021 | Fainted and lost consciousness, came back quickly (30 seconds) but did not remember anything. Was taken S/V, blood sugar test (DXT). All normal values |

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| 1197711 | 4/12/2021 | MS | 64 | F | 4/12/2021 | 4/12/2021 | Patient received J&J COVID Vaccine 4/12/21 around 12:05 pm. Patient waited in waiting area and complained to her husband about feeling dizzy and might faint. Pharmacists went to aid the patient and lay her down gently, monitored her blood pressure which was high at the time, once patient sat up her BP decreased, it fluctuated the whole time, EMT was called and once they arrived and monitored her, they said the cause of her fainting was due to her blood pressure. Patient was alert and responsive the whole time. Patient was unsure if she took her BP medicine this morning. |
| 1197691 | 4/12/2021 | KS | 88 | M | 3/10/2021 | 3/27/2021 | The weeks following vaccination, the patient felt lethargic, dizzy, unstable on his feet. Mental cognitive ability was unchanged, and he seemed to still be sharp. Up until the day of death, the patient was still active, able to drive, speak, make jokes, eat, and do everything normally. The morning of death, he had a bad fall, but couldn't recall what happened. It's assumed that a low blood pressure event, syncope, partial aneurysm, something of that nature causing temporary loss of consciousness occurred. We attended a funeral that afternoon, ate lunch, and dropped him off at his home. Sometime during that evening, he fell and died. The cause is unknown and still "undetermined" on the death certificate. (Heart attack or brain aneurysm is what I'm guessing) |
| 1198739 | 4/12/2021 | MD | 44 | F | 4/5/2021 | 4/5/2021 | patient had a syncope; was sweaty, then felt a little dizzy then fainted. This happen within about 5 minutes while waiting after the vaccination. Patient was laid on the floor before fainted for about few seconds (@5sec). Patient waited in the pharmacy for about 30 mins and felt better. After follow up with patient, she said she felt tired for couple more days then felt better |
| 1199230 | 4/12/2021 | MT | 33 | M | 4/12/2021 | 4/12/2021 | After the vaccination patient sat down in waiting room next to the pharmacy. He passed out in his chair and appeared to have a seizure. He was pale in color and had sweat dripping off is forehead. Blood pressure was 150/90 and pulse 80 bpm. He was given a cold compress and two bottles of water to drink. After 45 minutes patient felt fine and was able to leave on his own. |

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| 1197698 | 4/12/2021 | GA | 55 | F | 3/22/2021 | 3/22/2021 | Moderna EUA Patient reports after she left the site and drove about thirty minutes away, she had to pull into parking lot because she felt bad and confused. States she has passed out x2 that same day. Reported feeling lethargic and a strain on her heart. |
| 1197997 | 4/12/2021 | IL | 40 | M | 4/12/2021 | 4/12/2021 | Patient fainted and felt dizzy for ~15 minutes. no other symptoms. s/sx lasted ~15-20 minutes. pt refused medical treatment |
| 1198648 | 4/12/2021 | CA | 18 | F | 4/9/2021 | 4/9/2021 | At 2:00 pm, the patient had fainted 2-3 minutes after receiving the Janssen covid 19 vaccination. She regained consciousness about 1 minute later. The patient was sitting down, and collapsed over and hit her head on the table. The patient had answered "no" on the VARs consent form that she didn't have a history of dizziness or fainting after vaccinations. She also verbally answered "no" as well when she was asked if she had a history of dizziness/fainting. It was only AFTER the patient had received the vaccination and fainted that her mother mentioned that her daughter "often faints or gets lightheaded" after receiving vaccinations. |
| 1198423 | 4/12/2021 | AL | 30 | F | 4/2/2021 | 4/2/2021 | After injection pt was escorted by RN to observation area. In route, patient passed out. Color became dusky. Spo2 was 88-100 %. Dr ordered Epi Pen to be administered to left thigh at 1258. EMS was notified and patient taken to Hospital. Upon arrival to ED pt reports she became suddenly dizzy then woke up in the ED. She experienced chest tightness, sore throat, tongue swelling. Second epi was given in the ED. Developed muscle stiffness in the ED. |
| 1198432 | 4/12/2021 | IL | 58 | F | 4/8/2021 | 4/11/2021 | Sharp pain in left lower back. Moving down left leg and left foot. Numbness in leg and foot and slight swelling . Dizziness, fainting 1 time, with rapid heart beat after fainting. Symptoms started 2 1/2 days after shot. Taking Tylenol every 6 hours. Lower back improved leg and foot still swore |

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| 1198436 | 4/12/2021 | WI | 17 | F | 4/12/2021 | 4/12/2021 | Patient and Father were at desk to schedule follow-up vaccination when patient fell to the ground. Writer and additional clinic manager responded to event. Patient was rigid, eyes rolled back and not responding. Writer and manager attempted to arouse patient, with no response. Per father, patient has passed out in the past with blood draws. Feet were elevated and ice pack applied behind neck. Patient's fists were clenched, teeth clenched, back arched and appeared to have urinary incontinence. Episode lasted approximately 1-2 minutes. ED responded. Patient regained consciousness and was able to interact with writer appropriately. Bp 124/78, pulse 80 bpm, oxygen saturation 100%. Patient assisted to stretcher and transported to ED |
| 1198692 | 4/12/2021 | MT | 43 | F | 4/12/2021 | 4/12/2021 | Signs/Symptoms: Fainted |
| 1198484 | 4/12/2021 | IL | 30 | F | 4/12/2021 | 4/12/2021 | LIGHTHEADED AND DIZZY LEADING TO FAINTING. NEEDED ADDITIONAL OBSERVATION FOR 30 MINUTES AND NO FURHTER MEDICAL ATTENTION |
| 1198403 | 4/12/2021 | CA | 22 | M | 4/9/2021 | 4/9/2021 | Patient passed out. Mother stated he gets panic attacks every time he has a needle stick. Patient was fine shortly after. |
| 1198645 | 4/12/2021 | NY | 38 | M | 2/1/1983 | 4/12/2021 | Pt fainted 10 minutes after receiving J+J covid 19 vaccine |
| 1198458 | 4/12/2021 | NY | 29 | M | 4/9/2021 | 4/9/2021 | I received my first dose of the Moderna vaccine on Friday around 2:45pm. Felt zero symptoms beside soreness at the injection site, until about 10pm, when I became extremely overheated quite suddenly. I was trying to exit the building to get into cold air when I fainted twice. I was unconscious for 5 seconds or fewer each time. I did not hit my head or sustain any injury from the falls. Paramedics arrived about 10 minutes later, by which time I had regained consciousness and felt fine aside from weakness, dehydration, and some temperature fluctuation. They said my vitals were perfect and I went home from there. I was feeling completely fine and back to normal by 6pm the next day. |
| 1198654 | 4/12/2021 | IL | 27 | M | 4/12/2021 | 4/12/2021 | PT PASSED OUT AFTER 5 MINUTES OF GETTING VACCINE. BLACKED OUT FOR 30 SECONDS, CALL 911, PARAMEDICS TOOK TO HOSPITAL |

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| 1198269 | 4/12/2021 | NY | 23 | M | 4/10/2021 | 4/10/2021 | Patient experienced syncope about 1 minute after receiving the vaccine, falling from a seated position to the floor. Patient was evaluated by EMS on site and released from the clinic to care of his mother who came to drive him home. Follow-up with patient on 4/12/21, patient states he has not experienced any other negative reactions since the syncopal episode and is feeling fine. |
| 1197965 | 4/12/2021 | AL | 44 | F | 4/9/2021 | 4/9/2021 | PASSED OUT, WENT RIGID TEMPORARILY |
| 1198713 | 4/12/2021 | CA | 38 | M | 4/12/2021 | 4/12/2021 | After patient received Janssen vaccine patient felt dizzy, stated he had a needle phobia. Informed site lead of situation. Instructed patient to remain seated. Water was given to patient. Instructed patient to lie down on floor with legs elevated, applied cold pack to forehead. Patient stated he felt better, but advised patient to remain lying down for the full 15 minutes of observation. After 15 minutes, patient sat up slowly, then stood up and stated he felt fine and no longer dizzy. Patient walking normally, no signs or symptoms of dizziness or fainting. Patient left accompanied by his wife and child. |
| 1198721 | 4/12/2021 | WA | 46 | F | 4/12/2021 | 4/12/2021 | Bradycardia and near syncope |
| 1198736 | 4/12/2021 | OR | 32 | M | 4/10/2021 | 4/10/2021 | pt experienced- shakiness, syncope, clammy. B/P 133/81, O2 100%, HR 69. 50 mg IM Benadryl given. |
| 1198515 | 4/12/2021 | MO | 23 | M | 4/12/2021 | 4/12/2021 | patient was post pfizer covid vaccination about 5 minutes seated in chair. fainted and appeared to have a seizure of around 1 min. his mother and I were trying to revive/wake pt during this time. called 911. pt was disoriented upon awakening and vomited about 5 times. emt arrived in about 7 mins. pt left in ambulance. |
| 1198319 | 4/12/2021 | NC | 36 | F | 1/11/2021 | 1/11/2021 | Pain in back and bottom of head, Tachycardia, dizziness, syncope, sweating, weakness, elevated blood pressure, palpitations. |
| 1198282 | 4/12/2021 | FL | 39 | M | 4/11/2021 | 4/11/2021 | PATIENT RECEIVED THE VACCINE AND PASSED OUT, PATINET WAS SITTING IN THE CHAIR AND WAS DIRECTED TO STAY IN PLACE UNTIL RECOVERING. PATIENT RECIEVED A BOTTLE OF WATER. PATIENT RECOVERED AND WAS ESCORTED HOME WITH HIS PERSONAL NURSE. |

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| 1198298 | 4/12/2021 | PA | 20 | M | 4/10/2021 | 4/11/2021 | Janssen COVID-19 Vaccine EUA 4/11/2021 1-3:30 AM: Chills, muscle spasms 4/12/2021 10 AM: Fever 4/12/2021 11:30 AM: Lightheadedness, muffled/impaired hearing, fainted |
| 1198508 | 4/12/2021 | FL | 20 | F | 4/12/2021 | 4/12/2021 | Fainted, Recovered in 2 min |
| 1198288 | 4/12/2021 | CA | 62 | M | 3/24/2021 | 3/24/2021 | Warm feeling followed by fainting and slight convulsions. Nausea, gas, feeling faint, and usability to drive a vehicle for approximately 75 minutes. Slept for several hours, faint feelings subsided after 15 hours. |
| 1198314 | 4/12/2021 | IA | 64 | F | 4/1/2021 | 4/3/2021 | Friday morning 10 hours of temp, as high as 101.2. Went to bed and got up at 4:15 am woke up with nausea , got up one more time around 4:30 to go to the bathroom and woke up on the bathroom floor. Had passed out. Went to on Monday and was told that she had a concussion. |
| 1198299 | 4/12/2021 | CA | 51 | F | 4/12/2021 | 4/12/2021 | Patient is a 51 year old female who has not completed a 30-minute observation period due to the following signs and symptoms of an adverse reaction starting @ 1054: swelling of tongue and lips, body numbness, clammy skin, syncope, shortness of breath, hypertension, and tachycardia (see VS flowsheet for values). Pfizer-BioNTech COVID-19 vaccine # 1 in series administered @ 1035. Action(s) taken: @ 1056 Epinephrine administered and Transferred to higher level of care post RRT @ 1105. Allergy to COVID-19 vaccine documented in Allergies activity: Yes Patient and husband advised to discuss second dose considerations with a clinician and obtain refill for Albuterol and Epinephrine. |
| 1198321 | 4/12/2021 | IL | 66 | F | 4/11/2021 | 4/11/2021 | About 30 minutes after the vaccination (on the way home), I felt very faint and almost passed out. At the same time, my injection arm started burning. Also, I started experience a mild headache while on the way home which became VERY bad about an hour after the vaccination (at home). My head, neck and shoulders hurt so badly that I could not move and my vision was blurry; it was a searing type of pain. Then, I developed a fever which, at its highest temperature, was 101.6° along with overall achiness, malaise and severe fatigue, |

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| 1198352 | 4/12/2021 | MD | 18 | F | 4/12/2021 | 4/12/2021 | Patient fainted upon receiving the Janssen COVID-19 vaccine. They were in a chair in the waiting area and did not fall or injure themselves. We gave her no food or drink, took her blood pressure and stayed with her. She then fainted again at which point we called for a paramedic. They evaluated her and took her blood pressure again and her blood sugar. She then recovered and walked out of the store unassisted. She did not go to the ER but chose to go to an urgent care center I believe. |
| 1198364 | 4/12/2021 | IN | 35 | M | 4/8/2021 | 4/8/2021 | Nearly passed out. Lost color in face and felt hot |
| 1198371 | 4/12/2021 | VA | 23 | F | 4/10/2021 | 4/11/2021 | vasovagal syncope - Fainted 16 hours after receiving vaccination. Felt lightheaded when woke up. Received care from EMTs and was admitted into ER. |
| 1198383 | 4/12/2021 | OH | 32 | F | 4/11/2021 | 4/11/2021 | Immediately after injection at 10:20am, I felt hot and light headed. I have passed out from shots and IVs before so I brought my own smelling salts to my appointment, and I used them as soon as I felt faint, which kept me from passing out. I felt ok after waiting 30 minutes. Later that day around 5pm, I started getting chills and felt a little achy. At 6pm I checked my temperature and it was 99.9, at 7pm it was 101.9, at 7:30pm it was 104 so I took ibuprofen 400 since I had severe chills, headache fatigue and muscle and joint aches. At 8pm it was 102.7 so I took another 400mg of ibuprofen. At 9pm it was 101.7, and at 10pm it was 100.4 and then I went to sleep. On 4/12: it was 98.7 when I woke up at 9am, then 99 at 10:30 so I took ibuprofen 400, then 100.1 at 11:30 so I took ibuprofen 400 again. Since noon, the fever has subsided and the fatigue and aches and headaches have become mild so that I could work from home. |
| 1198385 | 4/12/2021 | KY | 20 | M | 4/12/2021 | 4/12/2021 | Vasovagal Syncope Patient was sitting in waiting area when his friend alerted pharmacy staff that he had passed out. Patient was sitting on a backless chair and fell off, but did not hit head or have any apparent abrasions. Pharmacy staff quickly responded and patient was conscious and stated he had a history of vasovagal responses to blood draws. |
| 1198312 | 4/12/2021 | | 47 | F | 4/12/2021 | 4/12/2021 | Syncope, blackout, with vomiting. 2 mins after injection. |

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| 1193786 | 4/11/2021 | TX | 24 | F | 4/11/2021 | 4/11/2021 | PATIENT EXPERIENCED SYNCOPE 15 TO 20 MINUTES AFTER SHOT WAS ADMINISTERED. HELD AND COMFORTED UNTIL CONSCIOUSNESS WAS REGAINED. OBSERVED FOR ADDITIONAL 30 MINUTES BEFORE PATIENT LEFT AT HER OWN WILL |
| 1193781 | 4/11/2021 | VA | 31 | M | 4/11/2021 | 4/11/2021 | syncope |
| 1193758 | 4/11/2021 | NY | 50 | F | 3/31/2021 | 4/1/2021 | 10 hours after my shot, I had a sudden wave of severe nausea, dizziness, and heat and fainted. I slammed my face on the bathroom floor and broke my nose (among other cuts and bruises). After I fainted, the symptoms were gone except for the injuries from fainting and a slight fever and minor queasiness the next 2 days. |
| 1193749 | 4/11/2021 | IL | 54 | M | 4/2/2021 | 4/2/2021 | Patient immediately complained of feeling light headed. Several minutes after receiving the vaccine, they fainted. Resuscitation several minutes after fainting. EMT was called and took blood pressure, temperature and EKG readings. All readings were normal and patient refused transport and hospitalization. Profuse sweating and dizziness after resuscitation and patient recovered enough to drive himself home 90 minutes later and left the store. After arriving home, patient experienced flu symptoms (nausea, aches, shivering, tiredness) for 24 hours after shot was administered. |
| 1193691 | 4/11/2021 | | 32 | M | 4/11/2021 | 4/11/2021 | fainting and patient fell on ground (hitting forehead), 911 was called; the patient came around in 10 seconds or so. Patient said they felt a little nauseous but then dizzy and things went dark. We kept them laying down on the floor with knees up, took their BP (127/72) and waited for medics to come. Medics arrived within 10 minutes to evaluate the patient, offered to take them to the hospital, patient declined and they released them to take it easy and call them/go to hospital if they felt faint again. |

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| 1193684 | 4/11/2021 | NY | 20 | F | 4/11/2021 | 4/11/2021 | Otherwise healthy 20 yo female presented to observation area after her first vaccine dose. Within first 5 mins while seated, talking on phone to Mom he then fainted, falling on floor. Fall witnessed, witnesses deny patient hitting head. Patient immediately regained consciousness, and appeared to be shaking. Placed in WC, while in med eval tent vitals: P 88, R16, BP 120/75, Glucose via fingerstick glucometer is 98. Patient alert, oriented. drinking apple juice. Patient admits to history of fainting after procedures such as injections. Advised her to inform healthcare personnel before vaccines or blood draws. Denies Chest pain, SOB, nausea, or pain anywhere. Denies visual changes. Patient felt well enough at 12:45, stood and walked without difficulty. Departed with friend without incident, who drove her back to dorm. |
| 1193790 | 4/11/2021 | VA | 19 | M | 4/7/2021 | 4/7/2021 | ~~Asyncope followed by apparent seizure activity. Palor, stiffness with jerking motion of muscles to extremities. Pt. lost conciousness multiple times (2 to 3). Patient was transported to hospital via EMS |
| 1193672 | 4/11/2021 | PA | 16 | F | 4/11/2021 | 4/11/2021 | After the patient got the vaccines she started to have the pre-verso symptoms related to cardioinhibitory syncope |
| 1193412 | 4/11/2021 | NJ | 40 | M | 4/11/2021 | 4/11/2021 | Arm pain, hot flash, then syncope |
| 1193654 | 4/11/2021 | PA | 27 | M | 4/11/2021 | 4/11/2021 | Patient has the vaccine and then got dizzy and started to put self on floor, passed out and hit face on the floor. Patient has a red bruise on his forehead and nose. Patient was advise that he should go to ER to get checked out because he passed out and hit his head. Patient refused and went home with girlfriend. They were advised as to what signs to look out for and then if the patient gets these symptoms to take him to the ER to get evaluated |

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| 1193448 | 4/11/2021 | CA | 38 | M | 4/10/2021 | 4/10/2021 | 38 y/o M with syncope 3-4 minutes after receiving Janssen vaccine at 12:54pm. Patient with loss of consciousness for 1-2 minutes with some rigidity to body. Patient placed in supine position with legs raised. RN administered smelling salts at 1:00 pm and patient regained consciousness slowly. 4 sets of vital signs taken between 1:07pm and 1:18pm. Emergency Medical Services called at 1:12pm. Patient denies prior history of allergies, denies current medication or medical conditions. Patient reports not eating or drinking prior to vaccine administration time. Last set of vital signs taken at 1:18pm showed blood pressure and heart rate within normal range. Paramedics took over assessment at 1:19pm, patient refused to go to hospital for further evaluation and left facility on his own. Patient with steady gait and ambulated on his own. Recommend follow up with Primary care physician. |
| 1193640 | 4/11/2021 | TX | 46 | F | 4/5/2021 | 4/6/2021 | FEVER; CHILLS; BODY ACHES; HA; SYNCOPE |
| 1193421 | 4/11/2021 | IL | 24 | M | 4/11/2021 | 4/11/2021 | The patient had a vasovagal response. He fainted briefly. He lost some color in his skin. The patient had not eaten so he was given some food (doughnut) and water. The paramedics came to evaluate him as well. The sequence of events occurred between 10:15 and 10:25 AM. |
| 1193820 | 4/11/2021 | | 57 | F | 4/10/2021 | 4/10/2021 | Patient experienced vasovagal syncope 5 minutes after receiving her vaccine. She woke up immediately after smelling alcohol and elevating her feet above chest level. 911 was called and was present within minutes and patient was taken to ER where she was monitored for 3 hours. She reported she had stable blood pressure, HR, and blood sugar. She was discharged after 3 hours of observation and is feeling well the next day. |
| 1193517 | 4/11/2021 | VA | 54 | M | 4/6/2021 | 4/6/2021 | Patient fell off chair within 15 minutes of vaccination. Patient fainted; BP dropped to 64/39. IV started and transported to ER by EMS. |

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| 1193665 | 4/11/2021 | IL | 39 | F | 3/9/2021 | 3/19/2021 | On March 10 (the day after my vaccine) I felt the normal body aches and had a pretty bad headache. That all went away in the evening on March 10. Since that day I have had off and on dizziness/lightheadedness. On March 19 I fainted in my kitchen. I hit my kitchen table and had a huge knot on my head and bruises all down my left side of my body. My left shoulder still hurts from the fall and I still have a small knot on my head (left side just above my left eye on my forehead). I went to my primary care doctor on March 24 and reported the event. I asked if it could be related to the COVID vaccine and she said she wasn't sure since the Jansen one was so new, but that she had seen these effects from the other two vaccines. At the doctor's office my blood pressure was on the lower end (110/60). My normal blood pressure runs about 118/70. They ran some blood work and that all came back normal. They did an EKG in the office, but my blood pressure stayed pretty close to the same as it was the first reading. They then sent me to get a CT scan on my head, which also came back normal. She did diagnose me with a concussion. I was out of work the entire week (March 22-March 26) due to this. She also ordered me to have an echo done. While at the office for the echo, my blood pressure ran 99/46 (this was on March 31). The results of the echo came back normal. I also got a monitor to wear for 72 hours on March 31. I took that to the doctor on April 5 and I am still waiting on results from that. Since the event on March 19, I have had headaches and body aches. I have also had slight lightheadedness off and on. |
| 1194208 | 4/11/2021 | PA | 54 | M | 4/11/2021 | 4/11/2021 | About 10 minutes after shot was taken I got a sharp pain in my stomach and felt like I had to throw up, about the same time I was sweating profusely and felt like fainting, they brought the wheel chair over to me and was going to move me, but the symptoms were improving and I started to feel better, I have never had symptoms appear that fast, very scary stuff for sure. |
| 1194317 | 4/11/2021 | FL | 37 | M | 4/11/2021 | 4/11/2021 | syncope, EMS called and patron transported by Fire Dept to unknown facility |

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| 1194306 | 4/11/2021 | CA | 51 | F | 4/8/2021 | 4/9/2021 | - Rapid Heart Beat along with Chills and Fever starting around 4/8/21 6:00 pm. -At 9:45 pm, Fever was 102.1. Took Tylenol (500 mg x2). - At 10:30 pm, Pulse rate was 145 bpm and fever was 101.9. - On 4/9/21 4:30 am, after urinating felt dizzy and fainted. Called 911 and went to the Emergency Room. Was treated there for syncope. |
| 1192868 | 4/11/2021 | MA | 57 | F | 4/10/2021 | 4/10/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: PATIENT WAS SITTING DOWN WHEN SHE FAINTED. SHE HIT HER HEAD LIGHTLY. SHE WAS UP IN A COUPLE OF SECONDS. WE CALLED 911 BUT AFTER CHECKING HER THEY LET HER STAY FOR A FEW MORE MINUTES AT THE STORE, SITTING DOWN. WE GAVE HER WATER AND AN ICE PACK FOR HER HEAD, AND WHEN SHE SAID SHE WAS FINE, WE LET HER GO HOME. |
| 1193399 | 4/11/2021 | NJ | 42 | F | 4/10/2021 | 4/11/2021 | Nausea followed by incoherence/fainting, rapid breathing, sweating, chills and and diarrhea. |
| 1194300 | 4/11/2021 | MN | 17 | F | 4/11/2021 | 4/11/2021 | PATIENT WAS SEATED AFTER VACCINATION FOR OBSERVATION PERIOD. PATIENT FAINTED IN HER CHAIR ABOUT 10 MINUTES AFTER VACCINE. SHE CAME TO AFTER ABOUT A MINUTE OR LESS. SHE LOOKED PALE, SHE WAS GIVEN ICE PACKS, WATER, AND ORANGE JUICE. 911 WAS CALLED, PATIENT WAS TAKEN AWAY VIA AMBULANCE ON A STRETCHER. |
| 1194291 | 4/11/2021 | PA | 46 | M | 4/10/2021 | 4/11/2021 | Pfizer-BioNTech COVID-19 vaccine EUA Patient passed out after waking up at 3 AM the day after the shot was administered. Symptoms included nausea and dizziness. Fever around 100°F begin the following day April 11, 2021 and persisted throughout the day. |
| 1194256 | 4/11/2021 | | 41 | M | 4/11/2021 | 4/11/2021 | Presyncope (lightheadedness, nausea, blurry vision). Normal vitals. Symptoms improved with supine rest and oral rehydration. |
| 1194221 | 4/11/2021 | NY | 20 | M | 4/11/2021 | 4/11/2021 | Syncope 5 min after injection |

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| 1194115 | 4/11/2021 | PA | | M | 3/23/2021 | 3/23/2021 | arm felt little bit achy; passed out; cold swats; felt the room was spinning; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (passed out) in a 54-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No reported medical history). On 23-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 23-Mar-2021, the patient experienced LOSS OF CONSCIOUSNESS (passed out) (seriousness criterion medically significant), COLD SWEAT (cold swats) and DIZZINESS (felt the room was spinning). On 24-Mar-2021, the patient experienced PAIN IN EXTREMITY (arm felt little bit achy). On 23-Mar-2021, LOSS OF CONSCIOUSNESS (passed out), COLD SWEAT (cold swats) and DIZZINESS (felt the room was spinning) had resolved. On 25-Mar-2021, PAIN IN EXTREMITY (arm felt little bit achy) had resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. There was no concomitant medications reported. Treatment included as Ibuprofen. Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded. Reporter did not allow further contact; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded. |
| 1194190 | 4/11/2021 | OH | 21 | F | 4/11/2021 | 4/11/2021 | Syncope following vaccine |
| 1194186 | 4/11/2021 | OH | 61 | M | 4/11/2021 | 4/11/2021 | fainting with loss of concious for about 30 seconds, sweating |

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| 1194182 | 4/11/2021 | MN | 56 | F | 4/9/2021 | 4/11/2021 | In the middle of the night of the 10th of April I started having what seemed like normal side effects---muscle aches, headache, fatigue.. and then all day on the 10th the same side effects. Then last night I slept 9 straight hours but woke up sweating a couple times in night and in morning woke up sweating but my aches and headache seemed better than the day before so I went downstairs to make tea. After pouring a glass of orange juice and having a couple sips I started to feel strange -- dizzy and oversome with a strange feeling that was not quite like the feeling before fainting -- my back had a weird pain and i was a little nauseous as well. ...it was more overwhelming -- more loss of control like a huge wave of dizziness and ringing. I made my way to a couch to try to regain balance -- but was still very dizzy-- something happened to make me try to get up and go upstairs so I remember walking 12 feet or so then told myself to sit down. Before that happened I must have blacked out. I faintly remember moving myself across the floor but then must have blacked out again. I woke up at the base of the stairwell and then was able to walk upstairs. I had collapsed the first time onto a hard floor as my orange juice glass had spilled all over and when I got upstairs my sweatshirt was covered in juice. I don't remember any of that. Once upstairs I drank water and have been fine since then. I had eaten dinner the night before but maybe it was the sweating in the night that dehydrated me and i cramped up and had a strange pain in my back---i don't know. I am a very healthy 56 yr old woman 5'3" 105 lbs so maybe the Johnson and JOhnson one dose was a lot for my body or maybe my body was just doing what it's supposed to do to react to vaccine.... i also may have had asymptomatic covid in the last year so my body was overreacting. This happened 7 hours ago and I seem fine aside from slight headache and continued weakness from vaccine but I thought I should report the incident in case there might be something more or in case others had similiar responses. |

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| 1194168 | 4/11/2021 | LA | 22 | F | 4/11/2021 | 4/11/2021 | Systemic: Confusion-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Weakness-Severe, Additional Details: This event happened approximately 30 sec after receiving the Janssen COVID-19 Vaccine. Patient was brought to the ER by firemen due to in and out consciousness. Patient was with boyfriend who caught her as she was falling. Patient did not hit her head. She did state that she has passed out in the pass once after receiving a vaccine, but not regularly. She states she does not have a fear of needles when asked by fireman. |
| 1194161 | 4/11/2021 | FL | 29 | F | 4/9/2021 | 4/9/2021 | Systemic: Confusion-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Nausea-Mild |

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| 1194143 | 4/11/2021 | WI | 60 | F | 3/31/2021 | 3/31/2021 | Nearly fainted twice on the bathroom floor; Postural hypotension; Left lower quadrant abdominal pain which continued for 24 hours; Dumping water from her rectum for approximately 24 hours; swelling of the lymph nodes on right side that increased to the size of a foot ball; Unable to move arm due to swelling in the lymph nodes; stabbing pains in chest that lasted from one to five minutes/pains on left lateral/Pain in chest wall and into heck on the lymph track; Throat was swelling with irregular heart beats; full compensatory pause when the patient was listening to heartbeat with her stethoscope; This spontaneous case was reported by a nurse (subsequently medically confirmed) and describes the occurrence of SYNCOPe (Nearly fainted twice on the bathroom floor) and ARRHYTHMIA (full compensatory pause when the patient was listening to heartbeat with her stethoscope) in a 60-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 040A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event. On 31-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 31-Mar-2021, the patient experienced ARRHYTHMIA (full compensatory pause when the patient was listening to heartbeat with her stethoscope) (seriousness criterion medically significant), CHEST PAIN (stabbing pains in chest that lasted from one to five minutes/pains on left lateral/Pain in chest wall and into heck on the lymph track) and PHARYNGEAL SWELLING (Throat was swelling with irregular heart beats). On 01-Apr-2021, the patient experienced LYMPHADENOPATHY (swelling of the lymph nodes on right side that increased to the size of a foot ball) and HYPOKINESIA (Unable to move arm due to swelling in the lymph nodes). On 04-Apr-2021, the patient experienced ORTHOSTATIC HYPOTENSION (Postural hypotension), ABDOMINAL PAIN (Left lower quadrant abdominal pain which continued for 24 hours) and DIARRHOEA (Dumping water from her rectum for approximately 24 hours). On 05-Apr-2021, the patient experienced SYNCOPe (Nearly fainted twice on the bathroom floor) (seriousness criterion medically significant). At the time of the report, SYNCOPe (Nearly fainted twice on the bathroom floor), ARRHYTHMIA (full |

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compensatory pause when the patient was listening to heartbeat with her stethoscope), ORTHOSTATIC HYPOTENSION (Postural hypotension), CHEST PAIN (stabbing pains in chest that lasted from one to five minutes/pains on left lateral/Pain in chest wall and into neck on the lymph track), PHARYNGEAL SWELLING (Throat was swelling with irregular heart beats), LYMPHADENOPATHY (swelling of the lymph nodes on right side that increased to the size of a foot ball), HYPOKINESIA (Unable to move arm due to swelling in the lymph nodes), ABDOMINAL PAIN (Left lower quadrant abdominal pain which continued for 24 hours) and DIARRHOEA (Dumping water from her rectum for approximately 24 hours) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Treatment was not reported/ unknown. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested.

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| 1194129 | 4/11/2021 | MI | 66 | F | 3/14/2021 | 3/25/2021 | <p>COVID-19; Passed out; Diarrhea; Dizziness; Weakness; Low blood pressure; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out) in a 66-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 044a21a) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No relevant medical history provided). On 14-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 25-Mar-2021, the patient experienced LOSS OF CONSCIOUSNESS (Passed out) (seriousness criterion medically significant), DIARRHOEA (Diarrhea), DIZZINESS (Dizziness), ASTHENIA (Weakness) and HYPOTENSION (Low blood pressure). On 26-Mar-2021, the patient experienced COVID-19 (COVID-19). At the time of the report, LOSS OF CONSCIOUSNESS (Passed out), DIARRHOEA (Diarrhea), DIZZINESS (Dizziness), ASTHENIA (Weakness), HYPOTENSION (Low blood pressure) and COVID-19 (COVID-19) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 26-Mar-2021, COVID-19 (positive-negative): positive (Positive) Positive. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Treatment was given intravenous bamlanivimab monoclonal antibodies therapy in the emergency room Based on the natural history of COVID-19, and the established information about the mRNA-1273 vaccine, a causal association between the event of Covid-19 and the product use is assessed as unlikely. The remaining events are assessed as a symptom of the disease and also assessed as unlikely related to mRNA-1273.; Sender's Comments: Based on the natural history of COVID-19, and the established information about the mRNA-1273 vaccine, a causal association between the event of Covid-19 and the product use is assessed as unlikely. The remaining events are assessed as a symptom of the disease and also assessed as unlikely related to mRNA-1273.</p> |

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| 1194288 | 4/11/2021 | TX | 34 | F | 4/11/2021 | 4/11/2021 | After the shot was administered the store had me wait in case there was a reaction. While I was sitting down, waiting for about 15 minutes I felt dizzy and fainted. My head hit the floor. The store called the paramedics. I woke up sweating and the paramedics arrived. The paramedics took my bloodpressure and reported it at 84 over 50. They waited while I felt ready to stand up. After a 3 to 4 minutes I felt I could stand up and they took me outside. Once outside they took my blood pressure again and it was at 110/80. I opted to go home instead of the hospital and I feel tired. |
| 1192883 | 4/11/2021 | PA | 46 | F | 4/5/2021 | 4/5/2021 | On Mon, April 5, had the vaccine, fainted at site 5 minutes after getting the vaccine. 9pm Apr 5, had fatigue, fever, slight headache, night sweats, clammy skin feeling. This continued until Wed Apr 7th Wed Apr 7 and Thursday Apr 8th were fine Friday, Apr 9th developed all of the above issues plus dizziness, nausea, upset stomach and dry heaving. This continued into Sat Apr 10th with added shortness of breath and heart palpitations. Went to the emergency room Sat Apr 10th Sunday, Apr 11th, severe nausea and stomach problems continuing along with continued night sweats. |
| 1192934 | 4/11/2021 | NY | 50 | F | 4/10/2021 | 4/10/2021 | Systemic: Dizziness / Light headiness-Medium, Additional Details: PThad a syncope evenet after vaccination with the J and J vaccine but after lying down recovered but was observed for 30 minutes. Pt has a history of sycope while receiving shots |
| 1192925 | 4/11/2021 | CA | 35 | M | 4/10/2021 | 4/10/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Exhaustion / Lethargy-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Hypotension-Medium, Systemic: Weakness-Medium |
| 1192914 | 4/11/2021 | | 29 | M | 4/10/2021 | 4/11/2021 | Passed out for approximately 10-15 sec, this has happened in the past with vaccine/blood draw. Stayed seated in chair, snack provided, feeling better. PB 84/50, PO2 95%, HR 77. |

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| 1192911 | 4/11/2021 | IN | 19 | M | 4/10/2021 | 4/10/2021 | Systemic: Fainting / Unresponsive-Severe, Systemic: Nausea-Medium, Systemic: Numbness (specify: facial area, extremities)-Medium, Systemic: Shakiness-Medium, Additional Details: Patient was feeling light headed when his girlfriend called me over. The patient explained that he was dizzy and may pass out. He lost conciousness for approximately 10 seconds. He came to and we laid him on the floor where the Pharmacist monitored him. He felt better and left here feeling fine. |
| 1192907 | 4/11/2021 | CA | 31 | F | 4/10/2021 | 4/10/2021 | Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Seizure-Mild, Additional Details: Pt felt lightheaded upon admin and fainted on immunizer after 10 sec. Asked others to help move pt to lying position. Upon moving pt, her body/arms seized up. Instructed others to call 911. Went to grab epipen. Within 5 secs of seizing, pt woke up, so epipen was no admin. Pt was alert, but did not know what occurred. After 30 min of resting, pt was ok and left pharmacy. |
| 1192904 | 4/11/2021 | CA | 31 | F | 4/10/2021 | 4/10/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Medium, Systemic: Seizure-Mild, Additional Details: Pt felt lightheaded after receiving vaccine. Instructed to sit for a few minutes before heading to the post vaccination area. Pt fainted within 10 secs onto the immunizer (me). Asked for help to move pt to a lying down position. Upon lifting pt up, her body/arms seized up. Asked someone to call 911 and I went to grab an epipen just incase. Within 5 secs, patient woke up, so did not admin epi. Pt was alert but did not know what happened. Pt refused ambulance, left after 30 min, was feeling ok. |
| 1192892 | 4/11/2021 | FL | 19 | M | 4/9/2021 | 4/9/2021 | Systemic: Dizziness / Lightheadness-Mild, Additional Details: Pt feeling dizzy and fainted after 3 mins of administration. Pt was sitting with his legs elevated on chair. BP 100/52 HR 54, Pt was pale in color and neasous. EMS was called but parents refused to leave pt w EMS. After 30 mins of resting, pt feel better and left with his parents. I called him to follow up, no one pick up left msg. |

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| 1192893 | 4/11/2021 | OK | 19 | M | 4/8/2021 | 4/8/2021 | Pt sts shortly after receiving the vaccine she became lightheaded. She passed out before she knew she was going to and as a result she fell out of her chair hitting her head. She has a minor abrasion approx 8mm in diameter to the L forehead. Swelling is minor as well, there does appear to be a light contusion as well. Pt sts she has not passed out with needles or injections before. VS: HR 110, BP 122/58, RR 14, Sats 98%. PMSx4, skin signs normal. Pt went to first aid area and allowed vitals. She does have tenderness to the site of her abrasion on her forehead. Her lightheadedness resolves and she denies all further complaints. She does not complain of headache and does not want further treatment. She declines further assessment, including a second set of vitals. Risks of refusal given. Pt notified that VAERS will be completed. Pt instructed to follow up with her doctor. |
| 1192969 | 4/11/2021 | MA | 21 | M | 4/10/2021 | 4/10/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Additional Details: Patient felt dizzy and passed out shortly after vaccine administration. Patient had not had anything to eat or drink all day and has passed out before after blood draws. Patient recieved gatorade and a granola bar in the store and recovered within 30 min and left store with a friend. |
| 1192855 | 4/11/2021 | NY | 19 | M | 4/10/2021 | 4/10/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient passed out about 2 minutes after vaccine administration. EMS was contacted and vitals were all normal as reported by EMS personnel. |
| 1192849 | 4/11/2021 | MA | 73 | F | 3/28/2021 | 3/28/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Additional Details: Patient called to inform us she had a reaction after her second moderna dose. She said she felt dizzy about 17 hours later and lost consciousness for a few minutes at home. She said she will followup with her doctor to get checked out. |

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| 1192699 | 4/11/2021 | MD | 26 | F | 4/7/2021 | 4/7/2021 | Nearly immediate after administration of vaccine- stood up to move to a waiting chair & experienced dizziness to the point of near syncope, heart pounding, nausea, sweating- pharmacy brought juice and watched me. Drank juice but was disoriented enough to spill a bit- sat for about 30 minutes until symptoms cleared up enough to walk around and got a ride home. |
| 1192676 | 4/11/2021 | HI | 43 | M | 4/8/2021 | 4/10/2021 | Approximately five minutes after the shot, I experienced vasovagal syncope. I was, reportedly, non-responsive for about three minutes. When aroused, my heart was reportedly beating about 40 beats per minute, my blood pressure was low, and it took me quite a while to regain my senses. |
| 1192656 | 4/11/2021 | WA | 24 | F | 4/9/2021 | 4/9/2021 | Five minutes after I received the vaccine, I fainted in my chair for 1-2 minutes. I awoke in a sweat, and the pharmacist called 911. The paramedics checked my vitals and cleared me to go. |
| 1194330 | 4/11/2021 | CO | 32 | M | 4/6/2021 | 4/6/2021 | Patient fainted after administration. |
| 1194435 | 4/11/2021 | PA | 20 | M | 4/9/2021 | 4/9/2021 | Chills difficulty breathing loss of consciousness altered mental status fainting fever fatigue gastrointestinal pain |
| 1192894 | 4/11/2021 | TX | 60 | F | 4/10/2021 | 4/10/2021 | Site: Pain at Injection Site-Mild, Systemic: Fainting / Unresponsive-Medium, Systemic: Seizure-Medium, Additional Details: Thirty minutes after shot, patient passed out and urinated on herself. Plus, had what she discribed as a seizure. |
| 1193129 | 4/11/2021 | VA | 38 | M | 4/1/2021 | 4/8/2021 | Fainting, pale hands, numbness on left arm, chest pain, clammy, hospitalization, elevated ALT, elevated AST, elevated Lipase, tachycardia, palpitations. |
| 1193295 | 4/11/2021 | MN | 50 | F | 2/23/2021 | 2/24/2021 | Increase in heart palpitations. Had significant rise in how many palpitations I have. Woke up at midnight night after vaccination with heart palpitations that I struggled to get to come done. The for next 3 days, I had 5-7 a day with one incidence that I almost passed out from. Slowly decreased from there. Also had fatigue and lack of energy for a few weeks. Just didn't feel like myself. |

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| 1193289 | 4/11/2021 | PA | 38 | M | 4/7/2021 | 4/7/2021 | Within approximately five minutes of injection, I experienced increased sweating, light headedness, and difficulty seeing until I passed out unconscious for a minute or two. When I awoke I was still sweating and cold for the next five to ten minutes. Paramedics checked my vital signs onsite afterwards (blood pressure, sugar levels, and pulse) and everything appeared to be normal. I was able to drive home 30 minutes later after making sure that all side effects subsided. I have not experienced any other side effects from the vaccine. |
| 1193278 | 4/11/2021 | FL | 41 | M | 4/10/2021 | 4/10/2021 | Patient received vaccine and was instructed to sit for 15 minutes as required for monitoring. About five minutes in, another patient who received the vaccine together with patient told us the patient had fainted. Patient was slumped over to the side when I came to check on patient. I called the patient a few times and patient started to come to. I asked the patient how he was feeling and if he had any difficulty breathing to assess for anaphylactic shock. Patient was breathing normal, but was sweating and a bit confused. Patient reported feeling dizzy. I explained to patient that he fainted for a few minutes and instructed to sit as I did not feel comfortable having patient lay down in the state he was in. Patient was given water and a fan to help cool him down and legs elevated (patient reported feeling much better with the fan blowing on him). Patient sat at the pharmacy for over 30 minutes before heading to the bathroom. At this point, patient were no longer dizzy and I instructed him to get up slowly and assessed that patient was no longer dizzy before letting him go to the bathroom. |
| 1193275 | 4/11/2021 | PA | 85 | M | 4/10/2021 | 4/10/2021 | developed stomach pain beginning minuets after the shot administered. Left site 15 minuets after the shot and returned home. Stomach pain increased and in a sitting position vision started to become blurred and I passed out for a very short period of time. After that proceeded to have uncontrolled diaherrea and developed blood in the stool and on the toilet paper. Mild spotting continues the day after the shot. No other adverse symptoms. |

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| 1193248 | 4/11/2021 | FL | 18 | M | 4/9/2021 | 4/9/2021 | Patient received the vaccine and was instructed to sit for 15 minutes as required before leaving. About five to ten minutes to, we were alerted that the patient had fainted. Upon coming to the patient, he was starting to come to but was out of it. I tried asking the patient how he was feeling, is he having a hard time breathing? Patient's entire arms and legs were bright red with possible rashes that lasted about 5 minutes and went away quick. Patient's face remained their normal shade. Patient reported he fell asleep and patient's father reported waking the patient up prior to coming to get his vaccine. Patient sat at the pharmacy to be monitored for an addition 30 minutes before leaving with father. Patient was given water and fan to help cool him down. Patient reported feeling ok after about 10 minutes with legs elevated but was instructed to sit for longer than that time. Patient was ok to leave with father after 30+ minutes of monitoring. |
| 1193209 | 4/11/2021 | WI | 30 | M | 4/10/2021 | 4/10/2021 | I developed extreme body aches and chills along with an extreme fever, and it progressed throughout the night until I was delirious. I fainted once trying to take medication (ibepofren) in the bathroom. I never measured the fever because I was delirious and could hardly move due to pain. I have never felt so sick in my life and I am a healthy 30 year old with no other health issues. I am feeling better this morning but have lingering symptoms of chills and aches. I am reporting this because the intensity of the reaction seemed overwhelmingly extreme and scary for someone of my health and age. |

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| 1193197 | 4/11/2021 | NY | 16 | M | 4/11/2021 | 4/11/2021 | 16 yo previously healthy male who presented with dad for his second vaccination today, after a couple of minutes later the patient without any prior hx of fainting, experienced a syncopal episode, patient had loss of consciousness for about 30 seconds, patient was held by the dad, never hit the floor, patient denies any prior episode, denies any use of ETOH, neither drugs, states that was hydrating over the last couple of days prior with gatorade for prevention of dehydration, denies any prior symptoms such as headaches. The patient was seen by EMS and Dr , he was assisted in the medical tent , vitals signs were consistent with HR; 56 BP: 112/48 O2 sats of 98% , patient was placed on a stretcher and legs we were elevated to 90 degrees with a chair, No head trauma, Patient was stable, AAOx3 , PERRLA, EOMI, Lungs CTA B/L and regular pulse was noted. hydration with water 16 oz was provided, father at side, patient was observed for 30 mins and another set of vitals was taken which revealed BP: 119/72 HR: 75 O2 sats: 99%. Patient was dispose to home, father was advised to take son for his regular check up, also to make any further medical provider that he had an episode of syncope after second dose of Pfizer vaccine. |
| 1192958 | 4/11/2021 | TX | 20 | M | 4/10/2021 | 4/10/2021 | Systemic: Fainting / Unresponsive-Mild |
| 1193164 | 4/11/2021 | NJ | 28 | F | 4/10/2021 | 4/10/2021 | patient exhibits symptoms of syncope and orthostatic hypotension after receiving first shot of moderna vaccine. patient experienced shortness of breath and tachycardic (HR: 134 bpm). Patient also complained of bilateral tingling/ numbness in upper arm, and nausea. To relieve symptoms patient was placed in supine position with legs elevated. Patient was transported to Hospital. |
| 1192963 | 4/11/2021 | WI | 47 | M | 4/10/2021 | 4/10/2021 | Systemic: Confusion-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Hyperventilation-Medium, Systemic: Seizure-Severe |

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| 1193112 | 4/11/2021 | MI | 34 | M | 3/29/2021 | 4/7/2021 | April 7, woke up with a headache, took ibuprofen. A few hours later, started feeling hazy, lightheaded and had trouble concentrating while working from home. Felt like I was going to pass out. Took a break from computer screen, symptoms appeared to subside. An hour later, same haziness feeling came back. Thought I was going to pass out again. Called 911. ER diagnosed me with near syncope. Told me to keep an eye on symptoms and come back if things worsen. I informed them I had received one dose of vaccine, they didn't seem to think it was related. Symptoms have slightly improved since, but still have bouts of dizziness four days later. |
| 1193064 | 4/11/2021 | | 53 | F | 3/1/2021 | 3/15/2021 | Extreme pain head to toe. Dizziness and I passed out 28 hours after my second shot. I passed out walking to the bathroom when I felt nausea. I have never passed out before. After the second shot in March, I have also experienced slight twitching in my legs and sometimes across my temples and other locations in my head. Not visual twitching but I can feel it. Now more than one month from second Moderna and I still feel it. Will this go away? |
| 1193060 | 4/11/2021 | NJ | 34 | F | 4/9/2021 | 4/10/2021 | I fainted around 6:35 am on 4/10/21. This was about 10 mins after I had taken Tylenol because my fever was at 101 and I had a bad headache. My heart was racing and I felt very weak. I was crawling on the floor to try to get my husband because I felt like I couldn't stand. I passed out in the hallway and came to probably 30 seconds later (I'm not sure how long it was, but I think it was only a little while) and was very disoriented. I then got my husband who told me to lay in bed but I felt so weak that I couldn't get off the floor for about a minute. Finally I was able to lay down in bed and I was very sweaty. I slept/laid there for a couple of hours and felt a little better after but had a bad headache until mid afternoon that day. |
| 1193046 | 4/11/2021 | NC | 71 | M | 2/15/2021 | 2/16/2021 | Chills,Body hurt all over, Passed out 3 times, left hand went numb, left arm numb,taken to an urgent care, transferred by ambulance to hospital, MRI, Cat Scan, ECG, neurological determined TIA, mini stroke, spent night in hospital. 4 days later rash on just both arms and both legs. Went to Urgent care directed by Dr put on Pregnazon for 10 days and follow up pack for 5 days. |

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| 1192979 | 4/11/2021 | FL | 24 | F | 4/10/2021 | 4/10/2021 | Systemic: Fainting / Unresponsive-Severe, Additional Details: PATIENT WAS SITTING WAITING HER 15 MINUTES AFTER GETTING INJECTION. HER MOM CALLED FOR HELP AND ANOTHER PERSON AND I RAN OVER AND ASSISTED HER AS HER DAUGHTER WAS UNRESPONSIVE. TOGETHER AS WE WENT TO PUT HER ON HER SIDE SHE CAME BACK AND ALL WAS OK. WHOLE EPISODE WAS ABOUT 10-15 SECONDS. |
| 1192974 | 4/11/2021 | WI | 23 | F | 4/10/2021 | 4/10/2021 | Systemic: Abdominal Pain-Mild, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Mild, Systemic: Hyperventilation-Mild, Systemic: Nausea-Severe, Systemic: Shakiness-Mild, Systemic: Vomiting-Medium, Systemic: Weakness-Mild, Additional Details: The first side effects of nausea and vomiting were reporting a few minutes after vaccination.The patient then reported some dizziness/lightheadness.Upon checking back,they changed their original report of dizziness/lightheadness to also include possible fainting.Blood pressure measurement was attempted 3 times with 2 different cuffs,but an error was displayed.It was successfully tested on a colleague.EMS noted BP 120/81.Patient was coherent and conscious,albeit nervous,while conversing. |
| 1193392 | 4/11/2021 | IL | 24 | M | 4/11/2021 | 4/11/2021 | Patient had a vasovagal response. He fainted. Once patient was aroused, he was sweating, lost some color in his skin. His temperature registered in the normal range. He was given water and food (doughnut). The patient had not eaten yet. The paramedics came to evaluate him. |
| 1193178 | 4/11/2021 | PA | 50 | F | 4/9/2021 | 4/9/2021 | Fainting |

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| 1194980 | 4/11/2021 | NC | 55 | F | 3/21/2021 | 3/21/2021 | Passed out got hives blood pressure went through the roof gave chewable benadryl started shaking could not control then ticket in thought next thing in ambulance and very hard to breath gave me shots ephedrine and steroids calmed a bit but came back at hospital gave albuterol HFA 108. Left 6 hours later with albuterol HFA 108 and 3 days of predniSONE 10 MG tablet. went my doctor next day put me on 10 of predniSONEcetirizine 10 MG tablet and clartoncetirizine 10 MG tablet at night and clarton in morning continue hydroCHLOROthiazide 25 MG |
| 1195080 | 4/11/2021 | NC | 44 | F | 4/7/2021 | 4/8/2021 | Fainted and got hurt on the forehead with the fall , Went for urgent care next day and was advised to go to emergency for further examination. Feeling better now |
| 1195069 | 4/11/2021 | MA | 43 | F | 4/6/2021 | 4/6/2021 | face and hand swelling, shortness of breath, increased heart rate to 120 BPM, dizziness and nearly fainted. Lasted 3-4 minutes. Was observed, blood pressure taken and was slightly elevated. Symptoms dissipated and was released to go home. Later had lasting headache and muscle pins for approx 18 hrs along with hot flashes. On 4/11/21 I then experienced the same episode lasting over an hour. |
| 1195047 | 4/11/2021 | TX | 22 | M | 4/5/2021 | 4/5/2021 | Pt was administered Pfizer dose #1. After administering to sister he passed out per mom. Mom got nurse's attention while returning to tent. When arrived to the car, pt was awake and alert and responding appropriately. He stated he feels light headed. EMS called to tent. Pt given bottle of cold water. Mother then drove pt over ti observation area and EMS continued to evaluate. EMS stated pt had vaso vagal response. Pt remained in observation until cleared by staff. |
| 1195022 | 4/11/2021 | MI | 21 | M | 4/11/2021 | 4/11/2021 | Patient became dizzy and fainted on the way to the observation chair. He did not lose conciousness, he said he just felt very dizzy. He said it felt good to lay on the ground, so I him lay for 5 minutes, then I helped him to a chair. I told him I wanted him to stay seated for 30 minutes so I can monitor him. He called his father, who came to pick him up after the 30 minutes were up. He slowly stood up and walked a few steps and then left the store with his father. |

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| 1195010 | 4/11/2021 | CA | 42 | F | 4/11/2021 | 4/11/2021 | 42 y/o female, hx of fainting ?when getting shots?. c/o SOB, stated ?I feel numb on my face from nose down to my mouth?. Also stated ?I feel like my throat is closing and having hard time swallowing?. Pt is hyperventilating, crying. Paramedics V/S taken HR 95, BP 149/88, O2 Sat 100%. Educated on calming and deep breathing techniques, given po fluids tolerating well. Pt now more calm and sent home without s/s acute distress. |
| 1195008 | 4/11/2021 | OK | 24 | F | 4/11/2021 | 4/11/2021 | pt become very dizzy, almost passed out (her companion had passed out just moments before), probably due to anxiety and stress in situation, also warm in the area. She was laid on ground and began to get color back in her face, dizziness went away after about 5 minutes, was assessed by EMT (since with companion who fainted), seemed to fine a few minutes later. |
| 1194809 | 4/11/2021 | PA | 19 | M | 4/11/2021 | 4/11/2021 | Near syncope. Trendelenburg position. Cold water bottle on neck. |
| 1194988 | 4/11/2021 | LA | 21 | M | 4/11/2021 | 4/11/2021 | Pt Fainted shortly after receiving vaccination. Pt came for a moderna covid vaccine with his friend, both first doses. Pt said he "fainted recently" from a shot where he fainted "for a couple minutes" according to his nurse, and he was sure it was psychologically induced by anxiety. He said he was more mentally prepared this time. After I gave the dose to him and his friend, he got lightheaded and slowly started losing consciousness in his seat after a few minutes. Pt was alert and responded to our questions. I quickly stepped out to give the pt a bottle of water, and upon coming back to the IMZ room, his friend said he urinated himself. He was less responsive, but still alert. I notified the technician. He started to turn pale and felt more cold. He pulse was weak. I encouraged the pt's friend to keep him alert while we call EMS. I reminded the pt to keep breathing. The technician called EMS, and I stayed with the patient to kept him calm, but alert until EMS arrived. Pt slowly felt better after a few minutes (color return, and temperature normalized). Pt said he was okay, and he was able to walk. EMS arrived and tested blood sugar; he was within normal range. Pt did not need EMS service, and went home with friend. |

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| 1195148 | 4/11/2021 | GA | 26 | F | 4/9/2021 | 4/9/2021 | Severe body aches and pain, chills and shakiness, dizziness, black out / fainting, nausea, stomach pain, vomiting stomach bile, profuse sweating, redness and swelling of injection site, sharp pain in shoulder on injection side, headache, brain fog, fatigue, cough, chest tightness. Timeline: Shot at 1:15pm. Headache at 6:30pm. Shoulder pain, redness, heat, and swelling on injection site at 8pm. Chills, shaking, body aches at 10pm. Cough, chills, body aches, chest tightness at 10:15pm. Same as above plus increased chest tightness, nausea, and stomach pain at 2am. Sweating, body aches, dizzy, brain fog, fatigue, weakness, stomach pain at 8:30am. Black out / fainting at 2:15pm. Nausea and subsequent vomiting at 2:30pm. Continued body pain, chills, and fatigue for the next 24 hours. All symptoms ended abruptly at 2-3pm next day (48 hours post-injection). |
| 1194970 | 4/11/2021 | WA | 26 | M | 4/11/2021 | 4/11/2021 | Patient was sitting for his 15 minutes. At about 5 minutes after his vaccine he passed out and fell off his chair to the floor. The Pharmacy intern noticed that the color of his skin was like a purple and he was passed out. When she started to approach him he started slowly moving his head and adjusting his eyes. He said he felt really dizzy and we had him lay down. He was very sweaty and was shaking a little bit. I took his blood pressure at 11:53 and it was approximately 124/93. He was responsive but feeling dizzy and warm and I stayed with him until the paramedics arrived at about 11:54 |
| 1194953 | 4/11/2021 | IL | 41 | M | 4/11/2021 | 4/11/2021 | About 10 minutes after shot I asked patient how he was feeling, he said he was hot. I walked out to talk to him and he said he felt dizzy. He turned pale and fell sideways off chair onto floor lowering himself with his knee. He did not bump his head, he was sweating profusely, but did not lose consciousness. I yelled to the tech to call 911. Patient was sitting on floor. He said he did not eat much all day. He was alert and talking. He said he fainted when his wife had their baby. We gave his some orange juice. The paramedics arrived 8 minutes later and checked his vitals. In the meantime we called his wife. Paramedics checked his BP, glucose and questioned patient. Patient refuse to go with paramedics. Wife came and paramedics released him to her. |

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| 1194920 | 4/11/2021 | NE | 26 | M | 4/1/2021 | 4/10/2021 | Patient passed out after sitting about 5 minutes after the vaccine. He went stiff and out for less than 30 to 45 seconds. He came to and was alert and talking. EMTs arrived and he passed out again and started vomiting. They did take him in the ambulance. |
| 1194860 | 4/11/2021 | FL | 35 | M | 4/9/2021 | 4/9/2021 | Patient fainted after receiving vaccine |
| 1194857 | 4/11/2021 | FL | 39 | F | 4/11/2021 | 4/11/2021 | Fainting, nausea, lightheaded |
| 1194856 | 4/11/2021 | NJ | 64 | F | 3/31/2021 | 4/11/2021 | 3 days after 1st pfizer shot, I almost fainted and I have been experiencing vertigo ever since, it is not getting any better almost 2 weeks later. |
| 1194996 | 4/11/2021 | OK | 23 | M | 4/11/2021 | 4/11/2021 | pt slumped in chair and fainted about 5 minutes after vaccine, was unconscious for about 10 seconds, came to suddenly, very disoriented. Very sweaty and continued to drift in and out of consciousness. No sign of andioedema or swelling of any kind. He was able to communicate mostly, just very drowsy and disoriented. EMT was called and was assessed. He refused going to hospital, remained at store for about 45 minutes after incident. Went home with family still somewhat dazed. |
| 1195310 | 4/11/2021 | CT | 43 | F | 4/9/2021 | 4/10/2021 | Dizziness, severe drop in blood pressure & weakness leading to Syncope. |

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| 1194417 | 4/11/2021 | FL | 57 | F | 4/11/2021 | 4/11/2021 | Patient received vaccine at 1153am in Left Deltoid, walked 20feet to observation area to wait 15 minutes in an armchair with arms under observation of staff. Was alert until 1156am when husband alerted staff that she was feeling very light-headed and nauseated. Pharmacist rushed over with hand-fan, but noticed Patient had started to become unresponsive. 911 Emergency response activated, ambulance on route. Pharmacist noted open eyes, glassy, there was no response to voice. She was sitting stable in chair husband and pharmacist at side. Pharmacist noted normal breathing and pulse. She was warm and sweaty to the touch. We kept talking to her, keeping the fan on her to keep her cool. Purse strap was removed from around her shoulders. Pulse and breathing still normal. She then came out of the syncope episode at 1159am. She was alert and oriented to time/place/person/self. Color returned to normal. Emergency services arrived approximately 3-4 minutes later. She was advised that it was a syncope episode that should be followed up at hospital/urgent care. She signed AMA with emergency ambulance services. She stayed in pharmacy under care of pharmacy support and store staff with water/fan staying seated whole time for additional 30 or so minutes until she and husband elected to leave the store. |
| 1194341 | 4/11/2021 | FL | 37 | F | 4/11/2021 | 4/11/2021 | syncope |
| 1195506 | 4/11/2021 | MN | 35 | F | 4/9/2021 | 4/10/2021 | About 15.5 hours after the injection, I had been experiencing some chills, headache, and slightly nauseous, but barely. I did not feel lightheaded or dizzy that I remember. I walked to my bathroom, at around 4:15 am I got up and used the bathroom, washed my hands. I fainted and lost consciousness. The next thing I remember I woke up and the light was off in the bathroom. It is not unusual for me to get up in the middle of the night, and do not believe I was dehydrated or ate less that evening. Luckily, I believe my butt took the brunt of the fall, as evidenced by the severe soreness there and lack of other areas of pain. |

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| 1195489 | 4/11/2021 | CA | 19 | F | 4/11/2021 | 4/11/2021 | While in observation area, patient started to feel dizzy/lightheaded, sweaty/numbness to hands/feet, "static" vision. BP after laying supine: 107/68, Pulse 58, repeat BP 10 minutes later after rest/hydration/snack: 120/83, Pulse 84. last meal/snack/drink: 2.5 hours prior to vaccine- fruit smoothie Prior history of syncope from tooth extraction/flu illness Patient gradually recovered after rest/hydration/food. |
| 1195432 | 4/11/2021 | MO | 29 | F | 4/9/2021 | | 3:00pm sudden chills, felt extremely cold and shivering, muscle ache and fatigue 3:30 pm lightheadedness/dizziness to the point of almost fainting 5:00PM continued symptoms with added naesua 9:00PM extremely hot , 101.8 degree fever Following day felt much better except for headache and fatigue. Continued to have some much aches and pains Currently on day 3 and have some aches and lains, arm tenderness still, but no lightheadedness or naseau since the first day Treated with Tylenol, rest, ibuprofen |
| 1195406 | 4/11/2021 | FL | 82 | F | 4/5/2021 | 4/5/2021 | Within 2 hours, hallucinations, fainting and falling down first two days. Total 4 times. Muscle weakness in legs, mild confusion then and continues. |
| 1195090 | 4/11/2021 | AZ | 22 | F | 4/11/2021 | 4/11/2021 | Patient received vaccination, fainted immediately following injection at 4:20pm. Safely positioned on the floor, vital signs assessed, BP was 77/59, pulse 55, pulse ox 99 on room air at 4:21pm; alert and oriented x4, responsive and vitals reassessed within normal limits at 4:25pm. cold compress and water provided. patient ambulated to observation area, monitored by EMT at 4:30pm. patient observed for 30 minutes, advised to download vSafe for follow guidance post discharge. |

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| 1195368 | 4/11/2021 | IN | 23 | M | 4/9/2021 | 4/9/2021 | Vasovagal syncope in the 15 minute waiting period. Response by staff was great: laid me down, brought a cot, regularly checked my heart rate, blood oxygen, and blood pressure until it returned to normal and waited to make sure the symptoms did not return. Later that night, I started experiencing some of the typical COVID vaccine side effects: sore arm, chills, nausea, and fever-like symptoms; in addition to the symptoms I was warned was possible, I also experienced periods of dizziness and an uncomfortable sense of balance. Three days later, the dizziness and other common symptoms have gone away, but my sense of balance still feels off, although I do not know if related to the vaccine. It's not so bad that I'm at risk of falling over, but I have a semi-regular feeling of unsteadiness which I cannot explain. |
| 1195146 | 4/11/2021 | VA | 25 | M | 4/9/2021 | 4/10/2021 | Fever, chills, and passed out when getting up middle of night after urinating. My family had to open the bathroom and pick me up off the floor before i regained consciousness |

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| 1195267 | 4/11/2021 | WA | 35 | M | 4/6/2021 | 4/6/2021 | DURING COVID VACCINATION CLINIC, DIVISION 1 EMPLOYEE ASSISTING WITH POST-VACCINE OBSERVATION REPORTED TO PHARMACIST THAT A PATIENT WAS FEELING LIGHTEADED. SHE IDENTIFIED PATIENT WHO WAS DISTRESSED AND APPEARED UNSTEADY. THE PATIENT REPORTED THAT THEY HAD TUNNEL VISION AND FELT VERY LIGHTEADED. PHARMACIST ASKED THE PATIENT TO REMAIN SEATED AND TRY TO TAKE SEVERAL DEEP BREATHS WHILE THE PHARMACIST HELD THE PATIENT'S LEFT SHOULDER TO ENSURE HE WOULD NOT FALL IF SYNCOPE OCCURRED. THE PATIENT HAD FLUTTERING EYELIDS AND APPEARED IAPHORETIC AT FIRST, BUT AFTER SEVERAL MINUTES RECOVERED SOMEWHAT. THE PATIENT REPORTED THAT HE HAD RARELY HAD SIMILAR EPISODES IN THE PAST DURING SOME MEDICAL PROCEDURES, BUT NEVER ASSOCIATED WITH A VACCINATION. PHARMACY TECHNICIAN HAD A D1 EMPLOYEE RADIO FOR A CODE WHITE AS SHE CONTACTED 911 ON HER CELLULAR PHONE. PARAMEDICS ARRIVED AND ASSESSED THE PATIENT'S HEART RATE, SEATED BLOOD PRESSURE. AND STANDING BLOOD PRESSURE. THE PATIENT REPORTED FEELING SLIGHTLY LIGHTEADED WHEN FIRST STANDING, BUT MUCH IMPROVED OVERALL. THE PARAMEDICS INDICATED THAT THERE DID NOT SEEM TO BE A MEDICAL EMERGENCY BY THIS POINT AND EXPRESSED CONCERN THAT THE PATIENT MAY BE DEHYDRATED BUT THE PATIENT REFUTED THIS POSSIBILITY. HE ALSO STATED THAT HE HAD NOT RECENTLY OVEREXERTED HIMSELF AND HAD EATEN LUNCH EARLIER THAT AFTERNOON. PHARMACIST PROVIDED THE PATIENT WITH GATORADE AND ICE TO IMPROVE BLOOD SUGAR, ELECTROLYTE, AND HYDRATION STATUS AND THE PARAMEDICS DEPARTED. THE PATIENT REMAINED FOR APPROXIMATELY 30 MINUTES UNTIL HE WAS FEELING CLOSE TO BASELINE AND FELT COMFORTABLE LEAVING. |

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| 1195248 | 4/11/2021 | NJ | 25 | F | 4/8/2021 | 4/8/2021 | Fainting 3 minutes after injection; around 5pm fever 102 degrees, chills, body aches, headache, nausea; treatment with Acetaminophen helped slightly |
| 1195232 | 4/11/2021 | NE | 20 | F | 4/10/2021 | 4/10/2021 | Headache, 7pm 4/10/2021, currently happening Severe Dizziness (nearly to fainting), 8:30am 4/11/2021, ended 12:00 pm 4/11/2021 Tiredness, 9pm 4/10/2021, currently happening Chills, 1pm 4/11/2021, currently happening |
| 1195229 | 4/11/2021 | IN | 56 | F | 4/6/2021 | 4/6/2021 | Night of and night after experienced body muscle aches; 3 days after had fainting spell and vomiting |
| 1195182 | 4/11/2021 | PA | 52 | F | 4/9/2021 | 4/9/2021 | Felt warm, with clammy skin, and then fainted |

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| 1195157 | 4/11/2021 | | 35 | M | 4/8/2021 | 4/9/2021 | Major symptoms, roughly 20 hours after vaccination, 10-15 minutes after waking, while walking and standing: - Extreme pain in right hip joint. Pain is sharp, stabbing, burning. Pain radiates down leg, and right foot numb and tingly - Overheating - Lightheadedness, blurred vision, confusion - Fainting or loss of consciousness, falling to ground Timeline of events: 2021-04-08 13:00 Injected with Johnson & Johnson 13:00 - 13:15 Very slight nausea 13:15 - 22:00 Very slight nausea and fatigue 22:30 Lymph nodes in neck feel swollen, ears feel slightly clogged (typical early cold symptoms) 23:30 Insomnia and chills 2021-04-09 00:00 - 07:30 Insomnia, poor sleep, and cycles of chills and overheating while trying to sleep or sleeping. Stronger nausea than before 07:30 Wake up, knees feel slightly weak when walking 07:35 - 07:40 While walking inside a market. Right hip joint begins to hurt with sharp, stabbing, hot pain. The pain radiates down right thigh. Right foot begins to feel numb and tingle. This pain increased over 5 minutes, to excruciating levels, with right leg feeling numb, and sharp stabbing tingles in right foot. Difficult to walk normally 07:40 - 07:45 Pain becomes unbearable, and market counter used for support. Begin to feel light headed. Begin to feel hot, and begin to overheat within ~2 minutes. Walk outside market (outside temperature 32 - 40F) to cool down. Lean on car hood for support, and become increasingly lightheaded. Vision becomes blurry. Stumble and fall onto face. Regain consciousness after unknown time, groggy and with blurred vision, lightheaded feeling. Attempt to stand and fall again onto face. Regain consciousness after unknown time. No longer feeling extremely hot. After roughly 1 minute, regain clear vision and lucidity. Pain in hip and leg completely subsided 07:45 - 09:00 Driven to hospital. Treated by hospital staff for laceration in forehead requiring 7 sutures. EKG reports normal. Concussion check negative. 09:00 - 00:00 Occasional nausea, fatigue, weakness (same as weak cold) 2021-04-10 11:00 While walking and standing in line. Right hip joint begins to hurt, with pain radiating down right thigh. Right foot begins to feel numb and tingle. Begin to feel warm. Hip Pain remains at manageable level, and walking normally is easy. Hip pain is roughly 1/3 of pain of 2021-04-09. 2021-04-11 07:30 - 11:00 Occasional slight pain in right hip and left hip joints. Hip pain is sharp and |

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| | | | | | | | burning, and roughly 1/10 of pain from 2021-04-09. |
| 1195262 | 4/11/2021 | CA | 50 | F | 4/5/2021 | 4/5/2021 | Within 10 seconds of receiving the shot, I was nauseous. Within 20 seconds very nauseous and dizzy. Passed out. Woke up on pharmacy floor. Do not know how long I was out. Continued to be nauseous and sweaty for 10 minutes. Had someone drive me home, nauseous and dizzy for 2 hours at home. Headache, body aches and sweaty all night. Nausea to a lesser degree with headache and body aches for another 24 hours. Feel still slightly off/slight nausea currently which is 6th day after vaccine. |
| 1195387 | 4/11/2021 | LA | 55 | F | 3/29/2021 | 4/2/2021 | Vertigo, Passed out during Physical Therapy |
| 1194407 | 4/11/2021 | DC | 37 | F | 4/11/2021 | 4/11/2021 | Patient fainted twice, EMS called |
| 1194554 | 4/11/2021 | OH | 35 | M | 4/9/2021 | 4/9/2021 | The patient became clammy, sweaty and pale. Patient almost passed out. Basic symptoms of syncope. Patient laid to floor with knees up and hands behind head. The patient came to rather quickly. The EMS squad was called and they took over with blood pressure and portable EKG machine. The patient had a gatorade and rested for about an hour and his wife drove him home. I called him 2 days later to check in on his status and he said he got a good nights sleep and felt much better with just a sore arm. |
| 1194503 | 4/11/2021 | OH | 31 | M | 4/11/2021 | 4/11/2021 | Patient passed out in sitting position 5 minutes after receiving vaccine, opened ammonia salts at 1:40pm, but patient became unresponsive by 1:48, administered EpiPen in right thigh. EMS contacted - HR of 54, BP too low to calculate. MD/hospital referral. |
| 1194502 | 4/11/2021 | MI | 21 | F | 4/9/2021 | 4/9/2021 | Fever of 101.3, bad headache, fatigue, mild cough. I passed out briefly the morning after due to the fever and fatigue. |
| 1194496 | 4/11/2021 | | 25 | F | 4/11/2021 | 4/11/2021 | syncope, chest tightness, seen by EMS, pt. refused transport |

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| 1194464 | 4/11/2021 | MN | 25 | M | 4/11/2021 | 4/11/2021 | Approximately 2 minutes after COVID-19 Moderna vaccination 0.5ml injected, patient fainted in the chair located in our 15 minute waiting area. RPH was called to respond. Patient was unresponsive upon arrival. Pulse present and strong, breathing appeared normal. Patient was aroused by touch and voice. Upon arousal patient was lethargic but could indicate name and DOB. Patient verbalized feeling warm, faint, and nauseated. Care was administered by visual monitor, cold compress to neck and forehead, water, and fan placed near patient. Patient's girlfriend was present and was a diabetic and took patient's BS reading with her own glucometer. BS was 98. Patient vomited x 1. Took approximately 50 minutes for patient to be fully awake and ready to try standing. Upon standing patient was steady on the feet. Patient was advised to discuss reaction with primary care provider and was assisted, when ready, to the door. |
| 1194457 | 4/11/2021 | NY | 19 | M | 4/11/2021 | 4/11/2021 | Patient experienced fainting spell. He complained of visual disturbance, blurry, twice within 5 minutes. His parents gave him a piece candy and drank some warm water. He was resting on a chair crouching over for about 5 minutes and feeling ok. I was going to call 911 for an ambulance and he refused. He was totally fine after 15 minutes of rest. |
| 1194557 | 4/11/2021 | PA | 59 | F | 4/11/2021 | 4/11/2021 | Within 2 minutes I had a horrific taste in my mouth followed by light headedness/dizziness. I almost passed out & had to be caught by a nurse & put into a wheelchair. They administered EpiPen, 50 mg of liquid benadryl & 2 puffs of a rescue inhaler. |
| 1194446 | 4/11/2021 | | 31 | F | 4/11/2021 | 4/11/2021 | 1-2 minutes after vaccine patient passed out for 30 seconds, pupils dilated |

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| 1194434 | 4/11/2021 | NY | 20 | F | 4/11/2021 | 4/11/2021 | Pt stated that she has vasovagal syncope when she has needles and stresses. Pt received vaccine lying down on recovery cot. Friend was at her side providing support. Ice to back of neck, feet elevated. status post receiving vaccine approx 30 sec while talking to pt she had syncope unable to recover with verbal nurse provide sternal rub pt came to alert and oriented smiling and laughing. She stated this happens and is normal for her to pass out due to vasovagal syncope condition that it happens all the time. refused to go to hospital. She has had all kinds of tests (cardiac, neurological, ENT per pt it has been dx as vit def, NA def, nutritional def) While talking to her she had a 2nd syncopal episode used ammonia salts to recover pt awakened immediately. VS 110/72, HR 84 reg strong, resps 12 reg nonlabored, SpO2 98%. Provided water for hydration. Friend stayed a side the whole time. after 20 min sat pt up, no LOC again, no SOB no N/V. Sat in recovery 30 minutes. Pt stated I feel fine . OK'd to exit |
| 1194401 | 4/11/2021 | MI | 22 | F | 4/11/2021 | 4/11/2021 | SYNCOPE & FAINT- GAVE WATER , ORANGE JUICE & FEEL FINE IN COUPLE OF MINUTES (Pt's mom with her also & told us that pt din't eat anything from the morning) |
| 1194399 | 4/11/2021 | ID | 27 | M | 4/11/2021 | 4/11/2021 | PATIENT WAS WAITING IN WAITING ROOM AFTER RECEIVING VACCINE. GIRLFRIEND KNOCKED ON HEALTH SCREENING ROOM WHILE ANOTHER PATIENT WAS GETTING READY FOR VACCINE. PATIENT HAD PASSED OUT IN CHAIR. PHARMACIST CAME INTO ROOM, TRIED TO ROUSE PATIENT AND DID STERNUM RUB. PATIENT SCARED AWAKE. TOOK A COUPLE MINUTES TO REGAIN COMPLETE CONSCIOUSNESS. PATIENT WAS SWEATING, SOON BECAME VERY COLD AND VERY SHAKY. EMS WAS CALLED AND ON SCENE WITH PATIENT. EMS WANTED PATIENT TRANSPLANTED TO HOSPITAL BUT PATIENT DENIED MEDICAL ATTENTION AND TRANSPORT. ACCORDING TO EMS, PATIENT DID HAVE LOW PULSE BUT BLOOD SUGAR WAS NORMAL. EMS HAD ME HAVE PATIENT SIT FOR ANOTHER HALF HOUR WHILE PATIENT ATE A PROTEIN BAR AND HAD A GATORADE. AFTER THE HALF HOUR PATIENT STATED THAT HE WAS FEELING FINE AND LEFT THE BUILDING. |

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| 1194381 | 4/11/2021 | NC | 22 | M | 4/7/2021 | 4/7/2021 | 12 hours after receiving vaccine I got sharp pains in back and legs. Burning sensation all over body. I was walking across my room and passed out waking up on the floor. Muscle cramps and tightness followed this. I could not move my muscles for roughly 12 hours. After 24 hours from receiving vaccine these extreme symptoms seemed to fade and I was left with fatigue, soreness and fever as expected. This lasted for the next 3 days |
| 1194807 | 4/11/2021 | | 53 | F | 4/11/2021 | 4/11/2021 | Pale, diaphoretic rigid, twitching, unconscious, syncope episode, EMS was called and patient was transported |
| 1195297 | 4/11/2021 | MD | 31 | M | 4/8/2021 | 4/9/2021 | 0800 - Experienced very mild common symptoms (tiredness, headache, muscle pains, and chills) while sitting at a desk. 0830 - Previous symptoms worsened. New symptom, nausea, appeared while still sitting at the same desk. 0840 - Fainted after standing up to use restroom. Consciousness and strength returned almost immediately after event. 0845 - Most symptoms dissipated except for lingering tiredness and slight headache (not due to fall). |
| 1194378 | 4/11/2021 | MA | 19 | F | 4/11/2021 | 4/11/2021 | Fainted. |
| 1194349 | 4/11/2021 | OH | 50 | F | 4/2/2021 | 4/5/2021 | I am a very healthy person but I had a rough time with a Covid shot. Severe rash and itching over the entire body 2 days after getting the vaccine. Took Benadryl for two days. The itching was getting worth. Went to see a doctor who prescribed IC Prednisone 10 mg tablet. On the 3rd of taking the IC Prednisone, I felt dizzy and fainted, lose consciousness. Ended up in ER. Multiple bruises, lost 4 front teeth. |

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| 1194456 | 4/11/2021 | MA | 39 | F | 4/9/2021 | 4/9/2021 | After the immunization was administered to the patient, she was asked to have a seat in the waiting area for observation. A few minutes after she sat, she told her husband who was seated with her she didn't feel well (he did not inform us). The technician observing her noticed she passed out and reported to the pharmacist (myself). I designated a team member to call 911 and ran out to the patient. She was extremely pale and her lips were blue. With the assistance of her husband I laid her on the floor, had him elevate her feet and checked for pulse and breathing. I couldn't immediately find her pulse but within 30 seconds she began to come to. She appeared to tremor a few times as she came to and her color began to return. She was extremely confused and did not know where she was upon awakening. EMS arrived on the scene approximately 10-15 minutes after the event. They did standard patient evaluation which was unremarkable and proceeded to bring her to the local ED, According to the patient, the ED visit yielded nothing and they said "she couldn't be more healthy". One note, that was revealed in conversation with the patient while waiting for EMS to arrive is that the patient had very little to eat or drink prior to being administered the vaccine. |
| 1194753 | 4/11/2021 | FL | 41 | M | 4/11/2021 | 4/11/2021 | Patient fainted 3 mins after IM injection |
| 1194772 | 4/11/2021 | HI | 73 | M | 4/9/2021 | 4/11/2021 | less than 2 days after second Pfizer vaccine near syncope, hypoxic aND DEVELOPED SUBMASSIVE PULMONARY EMBOLISM. NO OTHER KNOWN RISK FACTORS OR ACUTE EVENTS FOR CAUSE OF Pulmonary embolism and no prior dvt/pe |
| 1194782 | 4/11/2021 | CA | 66 | F | 4/7/2021 | 4/7/2021 | Pt was feeling hot and was on verge of fainting. Had pt lie down in supine position and applied ice pack to forehead and pt felt better |
| 1194771 | 4/11/2021 | | 51 | F | 4/11/2021 | 4/11/2021 | Patient had blood sugar readings in the excess of 400 mg/dL and was feeling ill, she fainted and was transported to the hospital. |
| 1194405 | 4/11/2021 | NJ | 25 | F | 4/10/2021 | 4/10/2021 | 5:20pm Post vaccination reports feeling dizzy w/ a brief episode of syncope w/ diaphoresis Medical monitoring w/vital assessment: BP 76/52 P65; rest, po hydration given w/symptom resolve; BP 102/ 71 P 75 Reports "feeling better", released from facility w/ sister |

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| 1194791 | 4/11/2021 | MI | 22 | M | 4/11/2021 | 4/11/2021 | patient fainted; light headed, dizzy, sweaty and nauseous for about 5 minutes watched patient closely, used ice pack, gave water .patient was fine after |
| 1194579 | 4/11/2021 | MA | 24 | M | 4/7/2021 | 4/7/2021 | Patient received the vaccine and was asked to wait in the observation area afterwards. He approached the counter a few minutes later to report he wasn't feeling well. As he was speaking with the technician he became very pale, reported lightheadedness and fainted with loss of consciousness. The technician reported that he witnessed convulsive type tonic movements concentrated in the neck and upper-arms more than the abdomen or legs. He also reported foaming at the mouth and following each event which repeated 3 times in less than 15 minutes, he woke with confusion and no memory of where he was. EMS arrived after 15 minutes and transported the patient to the ED for evaluation. Upon follow up with the patient the next day, he reported that the ED found nothing on his medical exam and he had worked a 10 hour shift prior to receiving the vaccine and had had nothing to eat or drink. |
| 1194769 | 4/11/2021 | LA | 32 | F | 4/1/2021 | 4/6/2021 | Constant vertigo to the point of almost fainting making it very difficult to partake in normal daily activities Also excessive drowsiness and sleeping. |
| 1194765 | 4/11/2021 | MI | 39 | F | 4/10/2021 | 4/10/2021 | Immediately dizzy, ringing in ears, excessively sweating and nauseous. Treated with cold compress and water. Better after 15 minutes. I have a history of fainting however it had been at least 5 years since that last occurred. |
| 1194749 | 4/11/2021 | AR | 22 | F | 4/9/2021 | 4/9/2021 | Light headed. Fainted. Shaking uncontrollably. Extreme fatigue and body aching. Extreme sweating. After 24 hours, all muscles very sore. |
| 1194695 | 4/11/2021 | VA | 33 | M | 4/10/2021 | 4/10/2021 | Client experienced syncope with in seconds of receiving vaccine. Assisted to wheelchair. Brought to EMS Observation area. Vitals monitored. Client recovered and left site in stable condition. |
| 1194599 | 4/11/2021 | OH | 45 | M | 4/11/2021 | 4/11/2021 | Patient passed out, opened ammonia salt within 2 minutes, pt lost responsiveness after 7 minutes, gave Epien, called EMS. Patient observed for additional 15 minutes, BP and HR stable per EMS review. |

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| 1194619 | 4/11/2021 | NY | 18 | F | 4/9/2021 | 4/9/2021 | I had horrible shaking/trembling in my arms, chest, and legs about six hours after the vaccine, and they continued for about four hours more, uncontrollably. I passed out briefly around 12 hours after the vaccine, and I'm not sure how long I remained unconscious. Through all of this, my left arm was difficult to move or use, I felt hot suddenly and then cold, and I was tired. The next day, the most serious side effects were gone, but I remained feverish, tired, and largely unable to move my left arm. Those side effects were gone on the third day and now I'm better. |
| 1194717 | 4/11/2021 | AL | 32 | M | 4/11/2021 | 4/11/2021 | Within 10 minutes of receiving the vaccine the patient became hot and sweating and passed out. He was given water, gatorade and crackers and remained seated for about 45 minutes before leaving the pharmacy. |
| 1194622 | 4/11/2021 | FL | 30 | M | 4/11/2021 | 4/11/2021 | PATIENT GOT LIGHT HEADED AND PASSED OUT |
| 1194677 | 4/11/2021 | VA | 21 | F | 4/11/2021 | 4/11/2021 | Patient fainted within a minute of getting the vaccine. She walked to her seat in the observation area. She was unaware she fainted. Her BP was 123/70. She said she felt fine she had scratched her face and hit her head when she fell on the floor. 911 was called immediately. They took her out to the ambulance because her HR was low and she eventually left on her own accord |
| 1194720 | 4/11/2021 | NC | 49 | M | 4/10/2021 | 4/10/2021 | Passed out in chair, vomitted, took a while to recover |
| 1194694 | 4/11/2021 | VA | 26 | F | 4/11/2021 | 4/11/2021 | Patient walked to her seat in the observation ear and sat down. Within 1 minute she jerked back and fell to her right side hitting her head and face on the glasses display and landing sprawled out on the floor. She had her eyes wide open. She was not aware she fainted and was completely conscious. Her blood pressure was 123/70. 911 was immediately called. The EMTs took her to the ambulance due to low heart rate when they arrived. She ended up leaving on her own accord |

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| 1191846 | 4/10/2021 | ID | 62 | F | 3/12/2021 | | <p>I thought that I had kidney stone; aches and pain/Pain in my right side was very severe/Body ache; Foggy brain; When I stood up and I had been standing for a minute or two and it wasn't that I got up too fast and then I got very dizzy; almost passed out; can't even focus; I was not feeling well; They did gave me Cyclobenzaprine, Prednisone and Hydrocodone and I took them for two days and then I just stopped because it was just making it worse and then I was foggy and couldn't event get up; This is a spontaneous report from a contactable consumer (patient). A 62-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), dose 1 via an unspecified route of administration on 12Mar2021 (Batch/Lot Number: EN6206) as SINGLE DOSE for COVID-19 immunisation; cyclobenzaprine, prednisone and hydrocodone; all via an unspecified route of administration from an unspecified date (Batch/Lot Number: Unknown) to an unspecified date, at unspecified dose for an unspecified indication. Medical history included COVID-19 from Dec2020 to an unknown date. The patient's concomitant medications were not reported. The patient stated, "First, I had COVID back in early December and then on 12Mar2021, I got my first vaccine and I have lot of aches and pain and very foggy brain. I was just with the 'chiropractor' and he was just with me and I stood up and we were talking and I just got super dizzy and almost passed out, I just don't know. I missed, I can't even focus." When clarified the concern, the patient stated, "When I stood up and I had been standing for a minute or two and it wasn't that I got up too fast and then I got very dizzy and almost passed out, luckily there was a chair to catch me. So, my concern is, do I get the second vaccine if I already had COVID, should I didn't had this first vaccine since I already tested positive? When I had COVID, I was very cloudy in the brain. I don't know if this is a part of side effect, I am trying to find out if I can get the second vaccine." The patient experienced kidney stone. The lab data is clear, upon checking, the blood and urine samples. CAT scan has been done and the report is clear. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.</p> |

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| 1191846 | 4/10/2021 | ID | 62 | F | 3/12/2021 | | <p>I thought that I had kidney stone; aches and pain/Pain in my right side was very severe/Body ache; Foggy brain; When I stood up and I had been standing for a minute or two and it wasn't that I got up too fast and then I got very dizzy; almost passed out; can't even focus; I was not feeling well; They did gave me Cyclobenzaprine, Prednisone and Hydrocodone and I took them for two days and then I just stopped because it was just making it worse and then I was foggy and couldn't event get up; This is a spontaneous report from a contactable consumer (patient). A 62-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), dose 1 via an unspecified route of administration on 12Mar2021 (Batch/Lot Number: EN6206) as SINGLE DOSE for COVID-19 immunisation; cyclobenzaprine, prednisone and hydrocodone; all via an unspecified route of administration from an unspecified date (Batch/Lot Number: Unknown) to an unspecified date, at unspecified dose for an unspecified indication. Medical history included COVID-19 from Dec2020 to an unknown date. The patient's concomitant medications were not reported. The patient stated, "First, I had COVID back in early December and then on 12Mar2021, I got my first vaccine and I have lot of aches and pain and very foggy brain. I was just with the 'chiropractor' and he was just with me and I stood up and we were talking and I just got super dizzy and almost passed out, I just don't know. I missed, I can't even focus." When clarified the concern, the patient stated, "When I stood up and I had been standing for a minute or two and it wasn't that I got up too fast and then I got very dizzy and almost passed out, luckily there was a chair to catch me. So, my concern is, do I get the second vaccine if I already had COVID, should I didn't had this first vaccine since I already tested positive? When I had COVID, I was very cloudy in the brain. I don't know if this is a part of side effect, I am trying to find out if I can get the second vaccine." The patient experienced kidney stone. The lab data is clear, upon checking, the blood and urine samples. CAT scan has been done and the report is clear. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.</p> |

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| 1191846 | 4/10/2021 | ID | 62 | F | 3/12/2021 | | <p>I thought that I had kidney stone; aches and pain/Pain in my right side was very severe/Body ache; Foggy brain; When I stood up and I had been standing for a minute or two and it wasn't that I got up too fast and then I got very dizzy; almost passed out; can't even focus; I was not feeling well; They did gave me Cyclobenzaprine, Prednisone and Hydrocodone and I took them for two days and then I just stopped because it was just making it worse and then I was foggy and couldn't event get up; This is a spontaneous report from a contactable consumer (patient). A 62-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), dose 1 via an unspecified route of administration on 12Mar2021 (Batch/Lot Number: EN6206) as SINGLE DOSE for COVID-19 immunisation; cyclobenzaprine, prednisone and hydrocodone; all via an unspecified route of administration from an unspecified date (Batch/Lot Number: Unknown) to an unspecified date, at unspecified dose for an unspecified indication. Medical history included COVID-19 from Dec2020 to an unknown date. The patient's concomitant medications were not reported. The patient stated, "First, I had COVID back in early December and then on 12Mar2021, I got my first vaccine and I have lot of aches and pain and very foggy brain. I was just with the 'chiropractor' and he was just with me and I stood up and we were talking and I just got super dizzy and almost passed out, I just don't know. I missed, I can't even focus." When clarified the concern, the patient stated, "When I stood up and I had been standing for a minute or two and it wasn't that I got up too fast and then I got very dizzy and almost passed out, luckily there was a chair to catch me. So, my concern is, do I get the second vaccine if I already had COVID, should I didn't had this first vaccine since I already tested positive? When I had COVID, I was very cloudy in the brain. I don't know if this is a part of side effect, I am trying to find out if I can get the second vaccine." The patient experienced kidney stone. The lab data is clear, upon checking, the blood and urine samples. CAT scan has been done and the report is clear. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.</p> |

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| 1190279 | 4/10/2021 | FL | 44 | M | 4/10/2021 | 4/10/2021 | patient got his 2nd covid vaccine and was waiting in the post vaccine waiting area and after about 5 minutes fainted. He regained consciousness in about 20 seconds. We had paramedics come out and checked all vitals and released him |
| 1190343 | 4/10/2021 | UT | 37 | F | 4/5/2021 | 4/6/2021 | The morning after getting the vaccine, I passed out while sitting. I had no warning, I just woke up on the floor. This has never happened to me before. |
| 1190380 | 4/10/2021 | | 34 | M | 4/10/2021 | 4/10/2021 | syncope |
| 1190357 | 4/10/2021 | | | U | | | During the observation period the patient lost consciousness for a short period. The patient was sitting in a chair and dropped her phone. She exhibited a mild fencing response and her hand trembled until she regained consciousness. Patient stated she has passed out from needles in the past. |
| 1190373 | 4/10/2021 | AL | 31 | M | 4/1/2021 | 4/1/2021 | Approximately 10 mins. after receiving vaccine, the patient started c/o feeling warm and cold at the same time, headache, dizziness, confusion and hands feeling heavy. Patient stated that he is allergic to Benadryl. Assessment: Person was alert and responsive to questioning. Patient denied of mouth and neck swelling. None noted. Patient denied of SOB or trouble breathing. Noted facial redness and perfused sweating. Nail-beds pink, resp. 24 with deep breathing off/on. Trembling noted while checking pulse 92. Manual fan blown in face. 911 notified. Ambulance arrived 10:45 am. B/P 142/90, P 104 and O2 Sat 99 %. Patient continue to c/o confusion and hands feeling heavy. Patient called wife on cell phone with a little difficulty in dialing cell phone. Wife spoke with patient and also EMT. Decision was made per patient and wife that he should go to the ER for evaluation. 11:20 am Patient was transported per stretcher to Hospital per ambulance for evaluation. 10:55 am Arrived at hospital per ambulance. Assessment started per CRNP with IV (NS bolus-1000 ml), Radiology (ECG Tracing/EKG) and Labs (BMP; CBC with Diff./Creatine Kinase/Troponin T). All procedures and labs within normal range. Discharged 04/01/2021 1:54 pm with diagnosis of Dizzy and Near Syncope. |

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| 1190419 | 4/10/2021 | CA | 32 | M | 4/10/2021 | 4/10/2021 | Approximately 2 minutes after the patient received the vaccine, the patient had other questions and while talking about the vaccine, the patient's eyes rolled back and he experienced a vasovagal reaction (syncope). Although he was sitting in a chair, his head fell to the left and his forehead bumped the table. The patient's legs were elevated and his upper body was laid back. Ammonia inhalant was crushed and immediately placed under the patient's nose. The patient came back to consciousness approximately 30 seconds after passing out. Patient was asked what symptoms he felt leading up to passing out. He said that he suddenly felt dizzy and does not remember much after. Patient states that he did not eat breakfast prior to receiving the vaccine and has a history of not doing well with needles or vaccines. He states that he now feels completely fine, however, the patient was advised to stay 30 minutes for monitoring, and once he felt comfortable standing up, a nurse walked with him to the observation area. Patient was provided an ice pack for his forehead. Observation nurse was notified of the adverse event and is now monitoring the patient. |
| 1190260 | 4/10/2021 | OH | 16 | M | 4/10/2021 | 4/10/2021 | Syncope after vaccine |
| 1190144 | 4/10/2021 | MD | 40 | F | 4/7/2021 | 4/7/2021 | Immediately following the vaccine administering I stood up and felt very sick and nauseated. I began to sit down again and was brought water. I tried to drink some water and my husband and I tried to walk to the tent for observation. I fell down and fainted. I was wheeled in a wheelchair to the ER and vital sign and blood sugar and EKG were performed. I declined being admitted to the hospital for further investigation. |
| 1190392 | 4/10/2021 | | 24 | M | 4/10/2021 | 4/10/2021 | Client recieved J&J vaccination and arrived at obseravtion area. Client stated he was feeling faint and dizzy, Prior to passing out. Nurses and EMT beside client. Client was assisted gradually to the floor with legs elevated. Client Vital signs 101/62 99% O2 HR 69. Dr educated patient to hydrate and to stay in observation area longer to be monitored. Client states he has a fear of needels and has experinced fainting after recieving a vaccine in the past. Client states he feels much better and no longer feeling faint. |

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| 1190384 | 4/10/2021 | | 24 | M | 4/10/2021 | 4/10/2021 | Client recieved J&J vaccination and arrived at obseravtion area. Client stated he was feeling faint and dizzy, Prior to passing out. Nurses and EMT beside client. Client was assisted gradually to the floor with legs elevated. Client Vital signs 101/62 99% O2 HR 69. Dr educated patient to hydrate and to stay in observation area longer to be monitored. Client states he has a fear of needels and has expernced fainting after recieving a vaccine in the past. Client states he feels much better and no longer feeling faint. |
| 1190348 | 4/10/2021 | IL | 49 | F | 3/31/2021 | 4/8/2021 | 8 Days after first injection almost fainted while driving. Heart raced and felt hot/clammy/dizzy/blurred vision. Lasted for 20 minutes. Continue to feel light headed, occasionally dizzy, and brain fog since then.. |
| 1190245 | 4/10/2021 | GA | 55 | F | 4/7/2021 | 4/7/2021 | Three waves of discomfort... felt like ice water was poured inside of my body. Extreme weaknesses of arms/legs. Visual issues. First wave within 60 seconds of shot (ended up on floor - embarrassing!). Second, and most severe, wave about 10 minutes later while sitting in chair. Apparently, I passed out with my eyes open. Hubby got nurse. They said I was unresponsive. Nurse checked blood pressure and heart rate after second wave - both normal. Third wave, much less severe, hit after 10 more minutes. Ice water/weakness feeling in arms and legs and not so much in chest area. Nurse speculated it could be low blood sugar (based on medications). Have never had low blood sugar event previously AND had eaten about an hour prior to vaccination. However, drank 4 ounces of orange juice, just in case. Went home about 20 minutes later... no other significant side effects. No swelling/redness at injection site. No other illnesses, etc. |
| 1190234 | 4/10/2021 | SC | 39 | M | 4/6/2021 | 4/6/2021 | Patient fainted about 3-4 minutes after receiving the vaccine. Patient was very pale and sweaty. We laid the patient down and gave him an ice pack and water. He quickly came back and felt better within 5-10 minutes. |
| 1190221 | 4/10/2021 | TX | 35 | F | 4/9/2021 | 4/10/2021 | This morning I was dizzy. I fainted. Witness said my head and hands were jerking and shaking. This was less than 10 seconds. I awoke disoriented. |

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| 1190199 | 4/10/2021 | WI | 40 | F | 4/6/2021 | 4/7/2021 | fast heart beat, hard time breathing, extreme dizziness, itching, near fainting spells, |
| 1190189 | 4/10/2021 | NY | 48 | F | 4/9/2021 | 4/9/2021 | Janssen COVID-19 Vaccine EUA 9:30am vaccine 9:45am Faint headache started 10:30am or so took one Tylenol 3pm started feeling blah 3pm or so.. heart started racing 6pm Headache - aches started 7:30pm. Dinner-pizza and salad 8-9pm. Stomach pains started 9pm. Dying. Worst headache Couldn't sleep entire day 11pm. Massive headache & aches. Went to bed & cried myself to sleep pretty much 3am Woke up massive headache took one more Tylenol Passed out til 8:15am. Woke up achey and slight headache. Passed back out til 10:30am. Still achey and no energy Drank 12 glasses water yesterday so was well hydrated. |
| 1190165 | 4/10/2021 | TX | 21 | F | 4/9/2021 | 4/10/2021 | I felt severe arm pain after the injection. About 12 hours later I had a fever of 100.1 and went to bed. At 1 am I went to the restroom and passed a good deal of blood as I am on my period. I got up and then fell to the floor. Then I went to my parents bedroom and fell again. I drank two bottles of water and took Tylenol at that point and after about two hours I felt better and went to sleep. I also twisted my ankle when I fell the first time. I have never fainted nor have I had such severe cramps or passed so much blood associated with a period. |
| 1190137 | 4/10/2021 | | 43 | M | 4/10/2021 | 4/10/2021 | syncope |
| 1190126 | 4/10/2021 | CA | 64 | F | 4/8/2021 | 4/9/2021 | Syncope |
| 1190115 | 4/10/2021 | IN | 19 | F | 4/9/2021 | 4/9/2021 | Patient fainted immediately after vaccination. |
| 1190469 | 4/10/2021 | NE | 17 | F | 4/10/2021 | 4/10/2021 | Patient fainted within 5 minutes of administration. She came to very quickly and felt nauseous. We monitored and had her drink water. Advised mother to call PCP on Monday |

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| 1190933 | 4/10/2021 | VA | 48 | F | 3/24/2021 | 3/25/2021 | passed out; severe dizziness with nausea feeling; severe dizziness with nausea feeling; huge knot on head that is swollen and bruised; cut on my left side of neck; This is a spontaneous report from a contactable consumer (Patient). A 48-year-old female patient (non-pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EP7533), via an unspecified route of administration in left arm on 24Mar2021 at the age of 48 years old at a single dose for COVID-19 immunisation. Medical history included asthma controller, anxiety. Patient had not received any other vaccines within 4 weeks prior to the COVID vaccine. The patient's concomitant medications were not reported. The patient previously took morphine and experienced allergy. Approximately 15hrs after receiving vaccine, On 25Mar2021 at 01:15, patient had severe dizziness with nausea feeling sat down and then passed out waking up after (unknown length of time) on the floor. Patient stated "i had struck my head and my left neck/shoulder on table and wall. Now I have huge knot on head that is swollen and bruised and a cut on my left side of neck." Prior to vaccination, patient was not diagnosed with COVID-19. Since the vaccination, patient had not been tested for COVID-19. The outcome of the events was not recovered. Follow-up Information has been requested. |
| 1190095 | 4/10/2021 | MD | 25 | F | 4/8/2021 | 4/8/2021 | Patient received vaccine. Approximately 10 minutes later, fainted. She fell out of her chair in the waiting area and hit her head on the ground. Ambulance was called and she was transported to hospital. |
| 1190081 | 4/10/2021 | NJ | 40 | F | 3/23/2021 | 3/23/2021 | Janssen COVID-19 Vaccine Body Chills and teeth chattering 3/23/2021 @ 6pm Body Hot/overheated 3/23/2021 @ 11pm Sweating and felt overheated Fainted 3/24/2021 @ 5:36am |
| 1190182 | 4/10/2021 | MI | 42 | M | 4/10/2021 | 4/10/2021 | Fainting. Patient fainted for about 30 seconds after immunization. Responsive and alert after fainting spell. Watched for additional time, gave water. |
| 1190656 | 4/10/2021 | NY | 19 | M | 4/10/2021 | 4/10/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient fainted about 2 minutes after administration. EMS was contacted and vitals were normal when checked by EMS personnel. |

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| 1189558 | 4/10/2021 | CA | 45 | F | 4/9/2021 | 4/9/2021 | Systemic: Allergic: Anaphylaxis-Mild, Systemic: Abdominal Pain-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Headache-Mild, Additional Details: Pt fainted 1 to 2 minutes after getting vaccinated and regained consciousness immediately. Her BP was normal - 108/80 and HR was 86. Pt's breathing was normal. She felt mild stomach pain and headache after gaining consciousness. |
| 1190069 | 4/10/2021 | NJ | 77 | M | 3/22/2021 | 4/6/2021 | Dizziness for days after shot leading up to 4/6/21 , on 4/6/21 passed out unconscious in the shower. 911 called takin by ambulance to ER. Admitted for 4 days, all testing was negative. |
| 1191018 | 4/10/2021 | FL | 34 | M | 4/10/2021 | 4/10/2021 | Patient passed out while in observation after receiving the vaccine. A passing customer noticed patient was in distress and asked for his welfare. Patient returned back to consciousness and asked to have someone check on him. 911 was contacted and firefighter department advised not to give him water. He was not taken to the hospital. |
| 1191001 | 4/10/2021 | CA | 20 | F | 4/6/2021 | 4/6/2021 | Client reported feeling "hot and light headed" approx 2 minutes after receiving vaccine. She was led by EMT to zero gravity chair. 12:31 V/S: HR 67, O2 99, BP 98/60. V/S @ 12:46 BP 118/80, HR 82, O2 99, AOx3 EMT observed client's to have pallor color. V/S @ 12:56 BP 92/58, HR 72, O2 100, RR 20 and client report of "feeling much better." Client reported having hx of syncope with nose piercing. At 1312, client left site unassisted and with a steady gait. |

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| 1190989 | 4/10/2021 | CA | 54 | M | 3/25/2021 | 3/26/2021 | Passed out; Blood pressure was low for him: 112/54; temp was also low: 96.6; thirsty; feel funny; This is a spontaneous report from a contactable consumer reported for self. This 54-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 25Mar2021 14:45 PM on Arm left at single dose (Lot # ER8732) for covid-19 immunisation. Medical history included Sleep apnea, breathing issues, IBS, Hypertension; Anxiety/Depressive disorder. No known allergies. No covid prior vaccination. Concomitant medications included other medications in two weeks. No other vaccine in four weeks. On 26Mar2021 08:00 AM, he went to the bathroom around 8 a.m. this morning and started to feel funny. He stood up and passed out onto the floor. Family members heard him and came to help. Blood pressure was low for him: 112/54. Temp was also low: 96.6. He was very thirsty. No treatments received. No covid tested post vaccination. Outcome of the events was recovering. |

| <u>VAERS_ID</u> | <u>RECVDATE</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1190962 | 4/10/2021 | NJ | 21 | F | 3/24/2021 | 3/24/2021 | Set off extreme fatigue that led to syncope and near-syncope episodes; Set off extreme fatigue that led to syncope and near-syncope episodes; Increased orthostatic intolerance; Increased orthostatic intolerance; Set off extreme fatigue that led to syncope and near-syncope episodes; This is a spontaneous report received from contactable consumer (patient). A 21-year-old non-pregnant female patient received the second dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Solution for injection and Lot Number: EB8727) via an unspecified route of administration in the right arm on 24Mar2021 11:30 AM (at the age of 21-year-old) as single dose for COVID-19 immunization in school or student health clinic. Medical history included ongoing POTS (Postural orthostatic tachycardia syndrome). Patient was not allergic to medications, food, or other products. Prior to the vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. Concomitant medications included corticosteroids, antihistamine and NSAID (all received within 2 weeks of vaccination). The patient previously received first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EN6205), via an unspecified route of administration in the left arm on 03Mar2021 10:00 AM for COVID-19 immunization. The patient did not receive any other vaccines within four weeks prior to the vaccination. On 24Mar2021 19:30 (reported as within 8hrs of vaccination), the patient experienced set off extreme fatigue that led to syncope and near-syncope episodes. Patient did not have an episode of POTS in months until receiving second dose, the patient experienced increased orthostatic intolerance. The patient did not receive any treatment for the events. The outcome of the events set off extreme fatigue that led to syncope and near-syncope episodes and increased orthostatic intolerance was recovering. No follow-up attempts are possible. No further information is expected. |

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| 1190957 | 4/10/2021 | NY | 58 | F | 3/4/2021 | 3/1/2021 | developed acute delirium; redness in arm; Right arm swelling; After that very wild, I was screaming. Very scary. My memory was gone; she passed out at home; she is very depressed has anxiety; she is very depressed has anxiety; panic attack; gained 16 pounds; vomited; loss of appetite; body ache/pain; This is a spontaneous report from a contactable Other HCP (patient). A 58-years-old female patient received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Solution for injection, Lot number: NN6206 and expiration date: Not available), via an unspecified route of administration in the right arm on 04Mar2021 12:00 as a single dose for COVID-19 immunisation. Medical history included removed brain tumor, she has sciatic nerve damage on left arm and left leg and is paralyzed, coma, chronic body aches, seizures, bad vision, high blood pressure and three brain surgery, short term memory. The patients historical vaccine included Flu vaccine injection in right arm deltoid muscle. The patient's concomitant medications included Oxycodone (5mg three times a day tablet) been taking for 3 years since she has brain tumor removed and for chronic body aches and Lyrica. On an unknown date, the patient gained 16 pounds. In Mar2021, the patient experienced she passed out at home and she was very depressed, anxiety, panic attack, body ache/pain, vomited and loss of appetite. On 04Mar2021, the patient experienced right arm swelling, screaming, scary, memory was gone. On an unknown date, she experienced developed acute delirium. On 06Mar2021, the patient had redness in arm. The patient was in the hospital for 4 days and was admitted on 14Mar2021. Her memory came back little by little and side effect of vaccine it says that if she had side effects from first one do not take second dose because it is worse and she is scared to be admitted to the hospital and does not want to experience that again. She was taking pain medication and did not tell her she cannot take Tylenol of course with body aches they did not tell her. It was not specific acute delirium it is a psychiatric disorder and she was wild and has never been like that before, she was tied up to the bed. The reporter states that she is disabled. She has bad vision and she is by herself at home. She is 5 1/2 already going down. She is not going to get the second one until get report results because it is ridiculous, and she is very nervous as she |

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was admitted at night to the hospital. Body ache happened 24 to 36 hours after vaccine not that severely unusual as it went away, and she has a chronic illness and is in a wheelchair from chronic pain. Reporter stated she could not swallow liquid or eat food and she was scheduled for a cat scan, but she could not go since she has been on the phone with Pfizer to get truth and fairness. Reporter stated yesterday this started getting better. Reporter stated was discharged from hospital last Tuesday but had pain at home. Developed acute delirium: stated when she woke up in the ER the next day in few hours she was admitted and in the ER she was crazy and tried running even though she cannot run because she is paralyzed and she did not remember nothing. Reporter stated no she did not get it that when she was discharged, it had been 48 hours. Pain started 48 hours after the vaccine. She has chronic pain the pain is not that excruciating, and it has stopped. She could not remember what happened but just knew it was redness and hurt a lot. Her memory and everything came back. States she had MMR (as provided by Reporter) done, because of pain in her whole body and everything came back negative. She had terrible pain, she asked to be given pain medication, and was given pain medication. Reporter stated it disappeared about one week now it disappeared and has recovered completely. Reporter stated black and blue inflammation and it does not hurt and the pain it went away. She was discharged from the hospital and discharge paper said second vaccine on 26Mar2021. She has been taking Oxycodone pain medication, reporter thinks she even got a higher dose since the pain was excruciating. The patient did not take any vaccines with 4 weeks. No Relevant Tests were performed. While providing an AE for the COVID vaccine she took Tylenol and Motrin as treatment, on top of it, but the pain didn't go away. She has been taking Oxycodone pain medication, reporter thinks she even got a higher dose since the pain was excruciating. The clinical outcome of events gained 16 pounds, passed out at home, depressed, anxiety, panic attack, body ache/pain, vomited and loss of appetite, right arm swelling, screaming, scary, developed acute delirium, redness in arm was unknown whereas of memory gone it was recovering/resolving.; Sender's Comments: Based on known drug safety profile, there is reasonable possibility

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| 1190945 | 4/10/2021 | MD | 44 | F | 3/24/2021 | 3/25/2021 | <p>of causal association between the events peripheral swelling, amnesia, delirium, loss of consciousness, depression, anxiety, panic attack, and erythema and the suspect drug. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.</p> <p>I fainted; I was disoriented and the room was spinning.; I was disoriented and the room was spinning.; extremely nauseated; This is a spontaneous report from a contactable consumer (patient herself). A 44-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection) via unknown route of administration on 24Mar2021 at single dose in left arm for COVID-19 immunization. Medical history included Cancer. No known allergies. No covid prior vaccination. Patient was not pregnant at time of vaccination. Concomitant medication in two weeks included letrozole. No other vaccine in four weeks. The patient previously took first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) for COVID-19 immunization. It was reported that when patient woke up in the middle of the night. Patient was disoriented and the room was spinning. patient fainted and then was extremely nauseated all on 25Mar2021 02:00 AM. No treatment for adverse events. No covid tested post vaccination. The outcome of events was recovering. Information about lot/batch number has been requested.</p> |

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| 1190934 | 4/10/2021 | NC | 27 | M | 3/24/2021 | 3/24/2021 | About 5 minutes after receiving vaccine, patient passed out unconscious and woke up about a minute later.; This is a spontaneous report received from a contactable consumer (patient). A 27-years-old male patient received first dose of BNT162B2 (Solution for injection, PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: UNKNOWN), via an unspecified route of administration in the left arm on 24Mar2021 at 11:55 (at the age of 27-year-old) as a single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient did not have any allergies to medications, food, or other products. Prior to the vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. On 24Mar2021, the patient about 5 minutes after receiving vaccine, passed out unconscious and woke up about a minute later. Treatment received for the event was unknown. Event resulted in Doctor or other healthcare professional office/clinic visit. The outcome of the event was recovered. Information about lot/batch number has been requested |

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| 1190912 | 4/10/2021 | NJ | 34 | F | 3/24/2021 | 3/25/2021 | Fainted while sitting; Too much pain in hand; chills; Weakness; This is a spontaneous report from a contactable consumer (patient). A 34-year-old female patient received first dose of BNT162B2(Batch/Lot Number: Unknown), via an unspecified route of administration on 24Mar2021 18:15 at single dose in the left arm for COVID-19 immunization. Medical history included Known allergies: NSAID on an unknown date. The patient's concomitant medications were not reported. The patient previously took ibuprofen and experienced allergy. On 25Mar2021 03:00, the patient experienced fainted while sitting, too much pain in hand, chills and weakness. Therapeutic measures were taken as a result of all the events which included Tylenol. The adverse event result in doctor or other healthcare professional office/clinic visit. The patient was not pregnant at the time of vaccination. The patient did not receive any other vaccines within four weeks prior to the vaccination and did not receive any other medications within four weeks prior to the vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The outcome of the events was not recovered. The following information on the lot/batch number has been requested. |
| 1190675 | 4/10/2021 | MI | 39 | M | 4/10/2021 | 4/10/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild |
| 1190669 | 4/10/2021 | MD | 16 | M | 4/10/2021 | 4/10/2021 | Patient fainted during post vaccination time. He was conscious. Pharmacist raised his Feet for few minutes, Patient's symptoms started improving in 15 minutes. |
| 1190497 | 4/10/2021 | VA | 57 | F | 3/20/2021 | 3/20/2021 | 17 minutes after injection, I experienced Nausea, Sweats, Dizziness, Lightheadness, and Fainting occurred. BP dropped to 80/39 per EMT arriving at Pharmacy site. Did EKG, Sugar Level, and administered fluids. EMTs took me to the hospital for treatment. ER staff noted vitals and bloodwork were alright and could not determine if Anaphylaxis reaction. ER Doctor ruled it a Vaso Vagal Syncope suspected response to vaccine as body saw it as foreign substance that rejected and severe reaction response occurred after 15 minutes. |

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| 1190645 | 4/10/2021 | IL | 16 | F | 4/9/2021 | 4/9/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: passed out for less than 1 minute immediately after shot given-Mild, Additional Details: passed out immediately after shot given for less than 1 minute, after coming to, had her lay on floor with legs up, blood pressue and pulse normal 111/88 , 70bp, was okay. had her stay over 30 minutes for obervation, her dad with her |
| 1190644 | 4/10/2021 | NC | 24 | F | 4/7/2021 | 4/8/2021 | 7 AM (about 21 hours after I received the second dose) I woke up having the most intense nausea I have ever experienced. I went to my kitchen to get water and passed out, dropping the glass I was in the process of getting from the cabinet, and I crashed. I felt so horrible I just tried to get back to my bed at that point without getting water. I passed out again trying to get back to my bed, bruising my right knee and my ribs. One the most horrible feelings I have experienced. I stayed on the floor for a bit recovering the second spell. My sister heard the commotion and quickly brought me water and Tylenol. My head felt full of pressure that I couldn?t get rid of by holding my nose and blowing. Eventually that went away. I stayed in bed for the rest of the day drinking water and Gatorade. I felt like I had an intense flu for the remainder of the day with chills and fever. The following day I needed more sleep but felt better. Now today, Saturday I feel better, but I still feel shocked at how intense my body?s reaction was to the second dose. |
| 1190620 | 4/10/2021 | ME | 37 | M | 4/10/2021 | 4/10/2021 | Patient was administered the COVID vaccine and felt fine. He relocated to our pharmacy waiting area for observation. Once there he started to read the provided material (EUA, V-Safe) and started to feel anxious. He said the next thing he knew he was sweating and had tunnel vision. He wasn't 100% sure he passed out. A fellow associate helped him to the ground and elevated his feet. We got ice for behind his neck, and a cold cloth for his forehead. We took his blood pressure and it started to come back up. He waited for about 30 minutes before leaving. His color had returned and he stated he felt fine. |

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| 1190612 | 4/10/2021 | IN | 19 | F | 4/7/2021 | 4/7/2021 | Upon resting later the day of my vaccine at home, my left arm became extremely painful and sore. Which I found to be normal and expected. However, I became very exhausted suddenly and ended up falling asleep 2-3 hours before my normal bedtime. I woke up 12 hours later unable to motivate myself to get out of bed. Finally, I did and went to go take a shower. I had chills as soon as I got out of bed and had to sit down in the shower for 10 minutes out of exhaustion and had the water running extremely hot but I was still cold. My arm was still in extreme pain. Finally, I arose from the shower floor and began showering when I started to feel as if I was going to puke right away. I laid down in the shower quickly becoming dizzy, and tried to puke. I dry heaved once to no avail. Immediately after dry heaving, my ears went numb and the shower noise was barely audible. My hands went completely numb. Home alone, I knew I needed to get out of the shower before I passed out. I managed to step out of the shower before immediately falling and possibly blacking out for some seconds and fell to the floor and laid there for a minute. Finally, I was somehow able to grab a towel and struggle to my bedroom and laid there numb for about 10 minutes. This episode ended at about noon but for the rest of the day, I had to sleep on and off, it exhausted me to try and eat, I had hot flashes, more dizziness, arm pain, and nausea. I called the doctor and they said there was nothing they could do and my symptoms were normal since I had COVID-19 in December. |
| 1190586 | 4/10/2021 | NY | 36 | F | 4/8/2021 | 4/10/2021 | syncope |
| 1190567 | 4/10/2021 | FL | 37 | M | 4/8/2021 | 4/8/2021 | Pt passed out after vaccine was given, pt states that "I don't like shots and this always happens when I get shots". Episode was not related to the vaccine. |
| 1190521 | 4/10/2021 | | 26 | F | 4/10/2021 | | Syncope |
| 1190520 | 4/10/2021 | NJ | 35 | F | 4/7/2021 | 4/8/2021 | The morning after (8 April) the vaccine I had sever muscle aches that started from the arms, shoulders, back and legs. It seemed to be getting better but today (10 April) I felt dizzy and had symptoms of almost fainting. I did go running this morning, had breakfast, and then around 12:00, I had the dizzy spell. |

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| 1190515 | 4/10/2021 | | 23 | F | 4/10/2021 | 4/10/2021 | post vaccine syncope, upper arm tingling, pt recovered and sent home |
| 1190510 | 4/10/2021 | MI | 36 | M | 4/10/2021 | 4/10/2021 | About a minute after the injection patient rolled his eyes up and fainted, woke him up after 30 seconds and stayed with him until emergency crew came and took him to hospital. according to emergency crew his Blood Pressure was very low. |
| 1190508 | 4/10/2021 | KY | 32 | F | 3/29/2021 | 3/29/2021 | Flushing, immediately Dizziness, fainting, fever of 104F, confusion, nausea, fatigue; began 10-12 hours after vaccine, lasted 48 hrs Injection site pain- immediately, lasted 48 hrs Injection site bruising- started 24 hrs after vaccine, still bruised 2 weeks after |
| 1190674 | 4/10/2021 | FL | 34 | M | 4/10/2021 | 4/10/2021 | 5-10 minutes after receiving the Janssen COVID-19 vaccine the patient fainted. |
| 1189518 | 4/10/2021 | FL | 44 | M | 4/7/2021 | 4/7/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Hypotension-Mild |
| 1189602 | 4/10/2021 | FL | 25 | F | 4/9/2021 | 4/9/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: fainting but responsive-Medium, Systemic: Weakness-Medium |
| 1188455 | 4/10/2021 | AK | 55 | F | 4/2/2021 | 4/2/2021 | Severe headache onset one minute after vaccine administered-reported to nurse. Lasted 8 hours, by 1 week daily but less severe. Nausea and dizziness began 15 minutes after dosage and has lasted seven days so far. Passed out and needed help standing twice during week. Low blood pressures 88/62, HR 42. Symptoms continue presently. |

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| 1189598 | 4/10/2021 | OK | 47 | F | 4/7/2021 | 4/7/2021 | Around five hours after shot I felt what I would describe as brain fog and light headache, by the evening I was aching, chilling and had 101 fever. Aches in my muscles and joints as if I had Rocky mountain spotted fever again. That is what the side effects reminded me of. This went on for over 48 hours. I have never been so sick. Very nauseous by next day. Also fell to the floor from nearly passing out the following morning. Took a minute for the light headed To pass. Arm pain still today. It was very scary and seemed to be a very serious reaction. Friday after noon finally started feeling better. The other strange part of this is that my daughter and best friend and I received the shot together in the same lot number and every one of us was deathly ill with the same symptoms. I am the only one with the fainting spells. Still feel fatigued today. And shoulders and left arm injection site still sore and achy. |
| 1192205 | 4/10/2021 | AK | 33 | F | 4/10/2021 | 4/10/2021 | Pt received her Covid vaccine and within the first 5 minutes of observation period she fainted. We immediately activated 911. She was pale and clammy to the touch. Her pulse was normal and her breathing was steady during the initial observation. She slowly regained consciousness within the next 5 minutes and told us her chest hurt, her right hand hurt and she couldn't move her right arm or hand. The fingers on her right hand were white. EMT arrived shortly after and immediately took over. |

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| 1189597 | 4/10/2021 | MA | 34 | M | 3/29/2021 | 3/29/2021 | felt like he was about to pass out; felt dizzy; felt like his heart was racing; felt like he had a cold; felt like he wanted to sleep; felt nauseous; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PRESYNCOPE (felt like he was about to pass out) in a 34-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 018B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No medical history reported). On 29-Mar-2021 at 8:45 AM, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 29-Mar-2021, the patient experienced PRESYNCOPE (felt like he was about to pass out) (seriousness criterion medically significant), DIZZINESS (felt dizzy), PALPITATIONS (felt like his heart was racing), NASOPHARYNGITIS (felt like he had a cold), SOMNOLENCE (felt like he wanted to sleep) and NAUSEA (felt nauseous). On 29-Mar-2021, PRESYNCOPE (felt like he was about to pass out), DIZZINESS (felt dizzy), PALPITATIONS (felt like his heart was racing), NASOPHARYNGITIS (felt like he had a cold), SOMNOLENCE (felt like he wanted to sleep) and NAUSEA (felt nauseous) had resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant drugs were reported. On 29 Mar 2021, the patient went to emergency room and was monitored for a couple hours, not medical treatment was provided for side effect relief.; Sender's Comments: This case concerns a 34-year-old male with a serious unexpected event of presyncope, palpitations, and nonserious unexpected dizziness, somnolence, palpitations, nasopharyngitis and expected nausea. Event onset Day1 after first dose. Events resolved. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. |

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| 1189596 | 4/10/2021 | CA | 16 | M | 4/8/2021 | 4/8/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: pt fainted but regained his consciousness shortly after, he was observed for 1 hour after the incident, I called the parent on 4/9/21 and father said that he is doing well and back to normal |
| 1189572 | 4/10/2021 | MI | 57 | F | 4/9/2021 | 4/10/2021 | passed out. felt funny before passing out. tongue felt weird prior to passing out |
| 1189561 | 4/10/2021 | CA | 41 | M | 4/9/2021 | 4/9/2021 | Site: Redness at Injection Site-Mild, Systemic: Chills-Mild, Systemic: Dizziness / Lightheadness-Medium, Systemic: Flushed / Sweating-Mild, Systemic: Shakiness-Medium, Systemic: Tingling (specify: facial area, extremities)-Mild, Additional Details: patient reported not having eaten since previous day in the afternoon, briefly experienced syncope and fell out of chair that he was seated in while waiting 15 min after given first dose of covid shot, patient waited full amount of time and felt fine after 15 min |
| 1189554 | 4/10/2021 | VA | 23 | F | 4/9/2021 | 4/9/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe |
| 1189551 | 4/10/2021 | NJ | 18 | F | 4/9/2021 | 4/9/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Additional Details: Patient fainted face down after receiving the covid vaccine. Patient indicated that she blacked out. She regained consciousness after a few seconds and became aware of her surrounding. Patient was rehydrated with water and orange juice. |

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| 1189563 | 4/10/2021 | NJ | 66 | F | 3/6/2021 | 3/16/2021 | <p>Arm kept getting more red and more swollen so she was told to go to the emergency clinic; Arm started turning red and swelling; Very sick; Bad headache; Nausea; Fever; Passed out; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out), ERYTHEMA (Arm kept getting more red and more swollen so she was told to go to the emergency clinic) and PERIPHERAL SWELLING (Arm started turning red and swelling) in a 66-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 010A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Chemotherapy. On 06-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 16-Mar-2021, the patient experienced LOSS OF CONSCIOUSNESS (Passed out) (seriousness criterion medically significant), ERYTHEMA (Arm kept getting more red and more swollen so she was told to go to the emergency clinic) (seriousness criterion hospitalization), PERIPHERAL SWELLING (Arm started turning red and swelling) (seriousness criterion hospitalization), ILLNESS (Very sick), HEADACHE (Bad headache), NAUSEA (Nausea) and PYREXIA (Fever). At the time of the report, LOSS OF CONSCIOUSNESS (Passed out), ERYTHEMA (Arm kept getting more red and more swollen so she was told to go to the emergency clinic), PERIPHERAL SWELLING (Arm started turning red and swelling), ILLNESS (Very sick), HEADACHE (Bad headache), NAUSEA (Nausea) and PYREXIA (Fever) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 17-Mar-2021, SARS-CoV-2 test: negative (Negative) Negative. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Products known to have been used by the patient, within two weeks prior to the event, included chemotherapy. Treatment for the event included ice, cortisone, 4x iv antibiotics and oral antibiotics. Based on the current available information and temporal association between the use of the product and the start date of the event,s a causal relationship cannot be excluded. This case was linked to MODERNATX, INC.-MOD-2021-062175, MODERNATX, INC.-MOD-2021-062175 (E2B Linked</p> |

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| 1189529 | 4/10/2021 | MI | 24 | M | 4/9/2021 | 4/9/2021 | Report).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event,s a causal relationship cannot be excluded. MODERNATX, INC.-MOD-2021-062175:Crosslinked case MODERNATX, INC.-MOD-2021-062175:Crosslinked case |
| 1189620 | 4/10/2021 | | | F | 3/31/2021 | 3/31/2021 | Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Additional Details: Patient was being monitored after their immunization when started to feel dizzy. Patient fainted and fell out of chair to the floor where we responded to him and called EMS. Patient was still breathing and became coherent as he was rolled onto his back. EMS confirmed he was ok to not go to the hospital so patient opted out. |
| | | | | | | | Passed out and convulsed; Passed out and convulsed; Vertigo; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out and convulsed) and SEIZURE (Passed out and convulsed) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No reported medical history.). On 31-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 31-Mar-2021, the patient experienced LOSS OF CONSCIOUSNESS (Passed out and convulsed) (seriousness criterion medically significant), SEIZURE (Passed out and convulsed) (seriousness criterion medically significant) and VERTIGO (Vertigo). At the time of the report, LOSS OF CONSCIOUSNESS (Passed out and convulsed), SEIZURE (Passed out and convulsed) and VERTIGO (Vertigo) outcome was unknown. She received 2nd dose of Moderna vaccine 31 MAR 2021 and while she was at the pharmacy she passed out and convulsed, and later that night while at home she passed out and convulsed again. Treatment information was not provided.; Sender's Comments: Very limited information regarding these events has been provided at this time. Further information has been requested. |

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| 1189346 | 4/10/2021 | CO | 22 | M | 4/9/2021 | 4/9/2021 | Systemic: Allergic: Difficulty Breathing-Medium, Systemic: Confusion-Severe, Systemic: Dizziness / Lightheadedness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Hypotension-Severe, Systemic: Weakness-Severe. |
| 1189337 | 4/10/2021 | MA | 21 | M | 4/8/2021 | 4/8/2021 | Fainted a couple minutes after receiving the shot |
| 1188855 | 4/10/2021 | TX | 21 | M | 4/2/2021 | 4/2/2021 | tunnel vision for a bit which then went away; felt like fainting; tingling in his toes and left arm and fingers.; This spontaneous case was reported by a consumer and describes the occurrence of TUNNEL VISION (tunnel vision for a bit which then went away) in a 21-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 031A217) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No reported medical history). On 02-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 02-Apr-2021, the patient experienced TUNNEL VISION (tunnel vision for a bit which then went away) (seriousness criterion medically significant), PRESYNCOPE (felt like fainting) and PARAESTHESIA (tingling in his toes and left arm and fingers.). At the time of the report, TUNNEL VISION (tunnel vision for a bit which then went away), PRESYNCOPE (felt like fainting) and PARAESTHESIA (tingling in his toes and left arm and fingers.) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No concomitant medications were provided. Treatment information were not reported.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded. |
| 1188835 | 4/10/2021 | MS | 24 | F | 3/1/2021 | 4/7/2021 | currently in hospital (ICU). Fainting, lightheadedness, extreme fatigue, petechiae, extremely low platelet count, possibly kidney damage, nose bleed, weakness, |

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| 1188823 | 4/10/2021 | MD | 61 | F | 3/26/2021 | 3/29/2021 | <p>Passed out; Arm is still sore; 102°F fever; This spontaneous case was reported by a health care professional and describes the occurrence of LOSS OF CONSCIOUSNESS (Passed out) in a 61-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 018B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included COVID-19 (COVID-19 in November.) in November 2020. On 26-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 29-Mar-2021, the patient experienced LOSS OF CONSCIOUSNESS (Passed out) (seriousness criterion medically significant), PAIN IN EXTREMITY (Arm is still sore) and PYREXIA (102°F fever). At the time of the report, LOSS OF CONSCIOUSNESS (Passed out), PAIN IN EXTREMITY (Arm is still sore) and PYREXIA (102°F fever) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No treatment information was provided. Concomitant medications was not provided.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p> |

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| 1188821 | 4/10/2021 | NV | | M | 3/23/2021 | 3/23/2021 | An episode of seizure; Syncope; Unconscious; Dizziness; Fever; Nausea; Muscle aches; This spontaneous case was reported by a consumer and describes the occurrence of SEIZURE (An episode of seizure), SYNCOPE (Syncope) and LOSS OF CONSCIOUSNESS (Unconscious) in a 43-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 046A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 23-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 23-Mar-2021, the patient experienced SEIZURE (An episode of seizure) (seriousness criterion medically significant), SYNCOPE (Syncope) (seriousness criterion medically significant), LOSS OF CONSCIOUSNESS (Unconscious) (seriousness criterion medically significant), DIZZINESS (Dizziness), PYREXIA (Fever), NAUSEA (Nausea) and MYALGIA (Muscle aches). On 23-Mar-2021, SEIZURE (An episode of seizure) and LOSS OF CONSCIOUSNESS (Unconscious) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 23-Mar-2021, Chest X-ray: normal (normal) normal. On 23-Mar-2021, Computerised tomogram head: normal (normal) normal. On 23-Mar-2021, Electrocardiogram: normal (normal) normal. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown Route) was unknown. Patient was taken to the emergency room (ER). Treatment included intravenous fluids.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded. |

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| 1188733 | 4/10/2021 | TX | | U | | 3/30/2021 | <p>ARM FEELS LIKE HIT BY BASEBALL BAT; JUST ABOUT PASSED OUT; FELT FEELING HOT; DEVELOPED LACE TYPE RASH; PHYSICALLY EXHAUSTED, TIRED, FATIGUE; FEVER; FELT FREEZING COLD; SEIZURE LIKE TREMORS UNCONTROLLED; PAIN AT INJECTION SITE; This spontaneous report received from a patient concerned a patient of unspecified age and sex. The patient's height, and weight were not reported. The patient's concurrent conditions included genetic liver mutation, and other pre-existing medical conditions included the patient had sensitivity to blood thinner product. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, administered on 30-MAR-2021 16:00 on Right Arm for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On 22-MAR-2021, Laboratory data included: Blood test (NR: not provided) negative. On 30-MAR-2021, the subject experienced pain at injection site. On 31-MAR-2021, the subject experienced seizure like tremors uncontrolled. On 31-MAR-2021, the subject experienced felt freezing cold. On 31-MAR-2021, the subject experienced fever. Laboratory data included: Body temperature (NR: not provided) 100.2. On 01-APR-2021, the subject experienced felt feeling hot. On 01-APR-2021, the subject experienced developed lace type rash. On 01-APR-2021, the subject experienced physically exhausted, tired, fatigue. Laboratory data included: Body temperature (NR: not provided) 97.1. On 01-APR-2021 12:18, the subject experienced just about passed out. On 02-APR-2021, the subject experienced arm feels like hit by baseball bat. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from seizure like tremors uncontrolled, and fever on 2021, and developed lace type rash on APR-2021, had not recovered from pain at injection site, and physically exhausted, tired, fatigue, and the outcome of just about passed out, felt freezing cold, felt feeling hot and arm feels like hit by baseball bat was not reported. This report was non-serious.; Sender's Comments: V0: Medical assessment comment is not required as per standard procedure as case assessed as non-serious.</p> |

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| 1188630 | 4/10/2021 | NC | | U | | 3/1/2021 | CHILLS; FEVER; PATIENT FAINTED IN BATHROOM; FAINTING RESULTED IN BLACK EYE; This spontaneous report received from a patient via a company representative concerned a patient of unknown sex. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin, and batch number were not reported) dose was not reported, administered on 05-MAR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On the night of vaccination, 05-MAR-2021, the patient had chills and fever. The following day, the patient fainted in the bathroom which resulted in a black eye. At the time of this report, there were no reports of the previously mentioned adverse events. The patient would get a head x-ray to make sure everything was okay. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from patient fainted in bathroom, chills, and fever on MAR-2021, and the outcome of fainting resulted in black eye was not reported. The reporter causality between covid-19 vaccine ad26.cov2.s and chills, fever, patient fainted in bathroom was related. The reporter causality between covid-19 vaccine ad26.cov2.s and fainting resulted in black eye was possible. Company causality between covid-19 vaccine ad26.cov2.s and chills, fever, patient fainted in bathroom, fainting resulted in black eye was possible. This report was serious (Other Medically Important Condition).; Sender's Comments: V0 20210318094-covid-19 vaccine ad26.cov2-fainting. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event. |
| 1188460 | 4/10/2021 | CA | 57 | M | 4/5/2021 | 4/5/2021 | Chills, muscle and joint pain, headache, dizziness/fainted, headache, light nausea |
| 1191033 | 4/10/2021 | FL | 21 | M | 4/10/2021 | 4/10/2021 | passed out |
| 1189530 | 4/10/2021 | GA | 20 | M | 4/9/2021 | 4/9/2021 | Systemic: Fainting / Unresponsive-Severe |

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| 1189742 | 4/10/2021 | FL | 42 | M | 4/9/2021 | 4/9/2021 | syncope loss of vision and dizzy |
| 1190040 | 4/10/2021 | FL | 38 | F | 4/8/2021 | 4/9/2021 | Lightheadedness, nausea, severe headache, lethargy, body aches, nearly fainted a time or two. |
| 1190011 | 4/10/2021 | FL | 37 | M | 4/8/2021 | 4/8/2021 | Patient fainted about 1 and 1/2 hours after receiving the vaccine @ a grocery store. After waking up, he drank water and was able to feel better. |
| 1189984 | 4/10/2021 | NY | 37 | F | 4/3/2021 | 4/5/2021 | Headache, dizziness, tinnitus, arm tingling, hot and cold flashes (pre-syncope sx's) |
| 1189948 | 4/10/2021 | UT | 60 | F | 4/7/2021 | 4/8/2021 | I couldn't sleep because of the pain in my right arm. I sat on the side of the bed and felt dizzy. The next thing I know, I'm waking up on the floor with my husband standing over me. I passed out twice. I was very woozy the rest of the day and stayed in bed. Took extra strength Tylenol (that did nothing to relieve the pain) All over body aches and fever over 100 degrees all day. |
| 1189906 | 4/10/2021 | GA | 38 | F | 4/7/2021 | 4/8/2021 | Very dizzy immediately, first day was very dizzy and almost fainted, very tired second day I had a rash on my arms and was still very exhausted and had high fever, also tight chest and coughing third day I was still exhausted and had a mental health episode of severe depression and suicidal thoughts, which I do have depression sometimes, but not LIKE THIS. It was very scary. Day 4 I am more myself currently, but unsure of how things will go from here. |
| 1189901 | 4/10/2021 | TX | 23 | M | 4/8/2021 | 4/8/2021 | About 5 minutes after receiving the vaccine, patient felt dizzy and fainted but quickly regained consciousness. We had him lay flat on the floor and continued to monitor and have conversations with him. His vitals were confirmed to be normal by the EMS and patient declined to be transported to the hospital. He remained in the premises for about an hour for observation after which he had a friend drive him home. |
| 1189870 | 4/10/2021 | | 40 | F | 4/10/2021 | 4/10/2021 | syncope |

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| 1189822 | 4/10/2021 | MI | 21 | F | 4/9/2021 | 4/9/2021 | It was around 5:00-6:00 PM when I started to feel very lightheaded all the time and had bad muscle aches. It got to the point where if I did anything but lay down, I would feel lightheaded and off balance. The worst happened at 3:00 AM on 4/10/2021 (the day after) when I got up to use the bathroom. I was washing my hands afterwards and nearly passed out. I couldn't hear, I couldn't see, and it was a bit difficult to breath. Luckily I knew what all of this meant and I sat down and took deep breaths until I felt fine again. |
| 1189802 | 4/10/2021 | VA | 36 | F | 4/9/2021 | 4/9/2021 | patient stated was very anxious and gets light headed when given vaccines or shots. WE keep her in the wellness room to observe. it was about 15 minutes after injection and patient fainted. She said she felt warm before fainting. She responded to her name laid on the floor for awhile and felt much better A relative of hers came in later for a shot and stated she was doing well |
| 1189796 | 4/10/2021 | | 36 | F | 4/10/2021 | 4/10/2021 | Patient developed lightheadedness/presyncope. Given water. Vital signs taken. Patient monitored for additional 15 minutes. |
| 1189604 | 4/10/2021 | NY | 29 | M | 4/9/2021 | 4/9/2021 | Systemic: Fainting / Unresponsive-Severe |
| 1189761 | 4/10/2021 | CA | 29 | M | 4/8/2021 | 4/8/2021 | Systemic: Fainting / Unresponsive-Mild |

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| 1189617 | 4/10/2021 | TX | 21 | F | 3/3/2021 | 4/1/2021 | fainted; HR - 46-48 beats per minute; cold sweats; chest pains localized in the apex of her heart; inflammation in the left upper arm extending to the back; hard time breathing; weak; This spontaneous case was reported by a nurse and describes the occurrence of SYNCOPE (fainted) and HEART RATE DECREASED (HR - 46-48 beats per minute) in a 21-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 017B21A and 074M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No medical history reported). On 03-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 31-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 01-Apr-2021, the patient experienced SYNCOPE (fainted) (seriousness criterion medically significant), HEART RATE DECREASED (HR - 46-48 beats per minute) (seriousness criterion medically significant), COLD SWEAT (cold sweats), CHEST PAIN (chest pains localized in the apex of her heart), VACCINATION SITE INFLAMMATION (inflammation in the left upper arm extending to the back), DYSPNOEA (hard time breathing) and ASTHENIA (weak). On 01-Apr-2021, SYNCOPE (fainted), HEART RATE DECREASED (HR - 46-48 beats per minute), COLD SWEAT (cold sweats), CHEST PAIN (chest pains localized in the apex of her heart) and DYSPNOEA (hard time breathing) had resolved. At the time of the report, VACCINATION SITE INFLAMMATION (inflammation in the left upper arm extending to the back) and ASTHENIA (weak) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |

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| 1189735 | 4/10/2021 | FL | 23 | M | 4/9/2021 | 4/9/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Severe, Additional Details: Patient fainted minutes after receiving the dose. He was sweating and disorientated after passing out. Recovered with iced tea and some crackers. Took about 30 minutes before he was comfortable standing again. He has never previously reacted to a vaccine before |
| 1189719 | 4/10/2021 | FL | 27 | M | 4/9/2021 | 4/9/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Additional Details: Shortly after vaccine was administered, patient lost consciousness |
| 1189715 | 4/10/2021 | WI | 30 | M | 4/9/2021 | 4/9/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: patient was given J and J \r\nCOVID vaccine. patient was seated when patient fainted. patient came to right away and was instructed to lay flat and elevate feet. patient started fo feel better. bp 100/80. Pt was monitored for 30min. Further BP was also 100/80. Pt was instructed to take it easy tonight and leave early from target shift and to seek medical care if any further fainting or symptoms. |
| 1189708 | 4/10/2021 | WI | 33 | F | 4/7/2021 | 4/7/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Shakiness-Medium, Systemic: Weakness-Medium |
| 1189705 | 4/10/2021 | DE | 44 | M | 4/5/2021 | 4/6/2021 | - Arm Sore at injection site from 4-6-21 to 4-9-21 - Passed out at 1:00am 4-6-21, and fell to floor with disorientation. - Severe Chills, uncontrollable shaking of body/teeth, 4-6-21 to 4-7-21 - Feverish 04-6-21 to 4-8-21 - Heart Arrhythmia, causing abnormal breathing and inability to breath and sleep 04-6-21 to 4-7-21 - Dizziness 04-06-21 to 04-09-21 - Food/Water/mouth tastes of metal 04-7-21 to 4-8-21 - Loss of Appetite 04-06-21 to present - Bloating, feeling full when haven't eaten 04-06-21 to present - Brain fog, not able to concentrate - 04-06-21 to 04-09-21 - Excessive sweating 04-06 to 04-08-21 - Tired 04-06 to 4-10-21 - Irritability, 04-09-21 to 04-10-21 - Emotional, crying for no reason sporadically 04-06 to 04-9-21 |

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| 1189704 | 4/10/2021 | FL | 51 | M | 4/9/2021 | 4/9/2021 | Systemic: Confusion-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Exhaustion / Lethargy-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium |
| 1189687 | 4/10/2021 | MI | 23 | M | 4/9/2021 | 4/9/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Additional Details: PATIENT FAINTED FOR A MOMENT. AFTER EXAMING PATIENT. MOTHER EXPLAINED DEVELOPED SAME CONDITIONS BEFORE BECAUSE FEAR OF NEEDLES. PATIENT WAS OFFERED GATORADE AND A BAG OF CHIPS. AT THE SAME MOMENT WE CALLED 911. THE PATIENT WAS RESPONSIVE AND WAS FEELING FINE AFTER A COUPLE OF MINUTES. AMBULANCE ARRIVED AFTER AND PROVIDED EXTRA CARE FOR HIM. PHARMACIST IN CHARGE WENT TO AMBULANCE TO SEE PATIENT OFF. |

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1189637 | 4/10/2021 | AZ | 70 | M | 3/15/2021 | 3/15/2021 | <p>patient collapsed and taken to emergency department; low blood pressure; becoming depressed; difficulty sleeping due to rash; felt itchy on the inside of the body; rash that covered his arms, upper torso, shoulders and went down the back/rash developing on face and neck; nausea; dizziness; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of SYNCOPÉ (patient collapsed and taken to emergency department) in a 70-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 031A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (no medical history provided.). On 15-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 15-Mar-2021, the patient experienced DIZZINESS (dizziness) and NAUSEA (nausea). On 31-Mar-2021, the patient experienced DEPRESSION (becoming depressed), INSOMNIA (difficulty sleeping due to rash), PRURITUS (felt itchy on the inside of the body) and RASH (rash that covered his arms, upper torso, shoulders and went down the back/rash developing on face and neck). On 01-Apr-2021, the patient experienced SYNCOPÉ (patient collapsed and taken to emergency department) (seriousness criterion medically significant) and HYPOTENSION (low blood pressure). At the time of the report, SYNCOPÉ (patient collapsed and taken to emergency department), HYPOTENSION (low blood pressure), DEPRESSION (becoming depressed), DIZZINESS (dizziness), INSOMNIA (difficulty sleeping due to rash), PRURITUS (felt itchy on the inside of the body), RASH (rash that covered his arms, upper torso, shoulders and went down the back/rash developing on face and neck) and NAUSEA (nausea) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown Route), the reporter did not provide any causality assessments. A pharmacist suggested the patient take Children's Benadryl followed by Zyrtec to help with the itching. These medicines have not helped alleviate his intense itching. On 1Apr2021, the patient collapsed and was taken to the emergency department. The patient was treated at the emergency department after he collapsed from low blood pressure. He was</p> |

VAERS_ID RECVDATE STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

prescribed Hydroxyzine HCl 10mg for the itching by the emergency room physician, but the medicine has done nothing to alleviate the patient's symptoms. Based on the current available information which includes a temporal association between the use of the product and onset of the reported events of vaccination site reaction, a causal relationship cannot be excluded. Ras and nausea are consistent with the known safety profile of the vaccine.; Sender's Comments: Based on the current available information which includes a temporal association between the use of the product and onset of the reported events of vaccination site reaction, a causal relationship cannot be excluded. Ras and nausea are consistent with the known safety profile of the vaccine.

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1189627 | 4/10/2021 | NY | 65 | F | 4/1/2021 | 4/1/2021 | <p>passed out; not feeling well; dizziness; could not get up; slept all day on and off; bruised knees; washed in cold sweat; nausea; fatigue; vomiting; bad headache; tender arm; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (passed out) in a 65-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 045A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event. Concomitant products included METOPROLOL for Blood pressure. On 01-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 01-Apr-2021, the patient experienced VACCINATION SITE PAIN (tender arm). On 02-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (passed out) (seriousness criterion medically significant), MALAISE (not feeling well), DIZZINESS (dizziness), ASTHENIA (could not get up), SOMNOLENCE (slept all day on and off), CONTUSION (bruised knees), COLD SWEAT (washed in cold sweat), NAUSEA (nausea), FATIGUE (fatigue), VOMITING (vomiting) and HEADACHE (bad headache). At the time of the report, LOSS OF CONSCIOUSNESS (passed out), MALAISE (not feeling well), DIZZINESS (dizziness), ASTHENIA (could not get up), SOMNOLENCE (slept all day on and off), CONTUSION (bruised knees), COLD SWEAT (washed in cold sweat), NAUSEA (nausea), FATIGUE (fatigue), VOMITING (vomiting), VACCINATION SITE PAIN (tender arm) and HEADACHE (bad headache) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Patient did not receive any treatment for the events. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p> |

| <u>VAERS_ID</u> | <u>RECVDATE</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1189623 | 4/10/2021 | SC | 60 | F | 4/1/2021 | 4/1/2021 | Patient blacked out on the way home after receiving the vaccine and was driving on the opposite side of traffic/ patient blacked out again; feels faint each time she stands; chills; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (Patient blacked out on the way home after receiving the vaccine and was driving on the opposite side of traffic/ patient blacked out again) in a 60-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 025B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event. On 01-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 01-Apr-2021, the patient experienced LOSS OF CONSCIOUSNESS (Patient blacked out on the way home after receiving the vaccine and was driving on the opposite side of traffic/ patient blacked out again) (seriousness criterion medically significant), PRESYNCOPE (feels faint each time she stands) and CHILLS (chills). On 01-Apr-2021, LOSS OF CONSCIOUSNESS (Patient blacked out on the way home after receiving the vaccine and was driving on the opposite side of traffic/ patient blacked out again) had resolved. At the time of the report, PRESYNCOPE (feels faint each time she stands) and CHILLS (chills) outcome was unknown. No concomitant medications reported by patient. Treatment of these events included Zyrtec and Tylenol.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded. |
| 1190055 | 4/10/2021 | FL | 41 | F | 4/8/2021 | 4/8/2021 | Passed out, had a seizure. Required hospital transport. |

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| 1189765 | 4/10/2021 | SC | 39 | F | 4/9/2021 | 4/9/2021 | Site: Pain at Injection Site-Mild, Systemic: Fainting / Unresponsive-Mild, Additional Details: about 5-10 minutes after shot pt was already seated, then fainted. i laid her on the floor with her feet elevated on the chair then she came back and was alert and oriented to person place and time. i checked her BP systolic was approximately 140/80 with a 62 pulse. EMS was called and patient was checked out by them. She was offered transport but declined |
| 1191952 | 4/10/2021 | WA | 29 | F | 4/10/2021 | 4/10/2021 | Heart racing/nervous/fainted. Feeling better now |

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| 1191778 | 4/10/2021 | MA | 70 | F | 3/23/2021 | 3/23/2021 | <p>Very difficult to fall asleep that evening; Passed out in bed; nausea/queasy; simultaneously had diarrhea and vomiting (several times in a row).; simultaneously had diarrhea and vomiting (several times in a row).; headache; Slept all day; sore arm; chills; very tired; Fever about 100.5/temp now almost 101; This is a spontaneous report received from a contactable consumer (patient) reported for herself. A 70-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: ER2613) via unspecified route of administration in left arm on 23Mar2021 09:30 AM at single dose for COVID-19 immunization. Medical history included prone to bronchitis with bad cold. Known allergies included strong reactions to oxycodone hydrochloride;paracetamol (PERCOCET), zolpidem tartrate (AMBIEN) and some anesthetics. Patient did not have COVID prior vaccination, did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Patient was not pregnant at the time of vaccination. Concomitant medications included rosuvastatin, loratadine, ergocalciferol (VIT D) and multi-vitamin. The patient previously received first dose of BNT162B2 (lot number: EN6205) in left arm on 01Mar2021 09:30 AM for COVID-19 immunization. Evening of the shot on 23Mar2021 07:30 PM, patient experienced sore arm, chills, later and very tired. Fever about 100.5. Middle of night, about 16-17 hrs after shot (24Mar2021) awoke with nausea. Rose to go to bathroom and simultaneously had diarrhea and vomiting (several times in a row). Extreme tiredness and nausea. About 4:30 took 2 paracetamol (TYLENOL) and anti-nausea med. Passed out in bed on 24Mar2021. Woke about 11:30 AM. temp now almost 101, headache, paracetamol and more anti-nausea med. Slept all day until 10:45 PM 24Mar2021 fever normal, nausea gone, quite tired still. On 25Mar2021, patient was able to get up, still tired but so much better, stomach still queasy. Ate bit of toast, later, rice and applesauce. Bit of headache took paracetamol. Very difficult to fall asleep that evening (25Mar2021), awoke 26Mar2021 and fell so much better although stomach still a bit queasy. Treatment was received for all events. Patient had not tested COVID post vaccination. The outcome of events was recovering.</p> |

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| 1192096 | 4/10/2021 | NY | 23 | M | 4/8/2021 | 4/8/2021 | Pt is 23 YOM at vaccination site, status post Johnson and Johnson vaccination, pt states he has a hx of fear of needles where he has ?passed out in past? from other medical procedures, pt states he returned to chair after receiving vaccine and began to feel light headed and dizzy, where he then fell to ground off chair, pt believes he may have syncopized however is unsure because he ?woke up right away?. Pt skin initially pale and clammy, but quickly had color return to face and extremities. Pt can recall events in entirety, is alert and oriented x4 and states negative head/neck/back pain, negative blurred vision, negative vomiting but + nausea/dizziness, which resolved after approx 3 minutes, initial systolic BP in 90?s but improved to 130 once seated, pt states eating full breakfast, with BGL of 106 mg/dL, pt initially denied transport to hospital but after brief period of time began to feel dizzy again and agreed to transport, due to reoccurrence of SBP in 90?s, IV placed in RAC 1:1 with NSL given KVO, pt 3 lead sinus rhythm without ectopy, upon arrival of ambulance full report given to EMT who assumed care of patient |
| 1192092 | 4/10/2021 | CA | 20 | F | 4/10/2021 | 4/10/2021 | Patient fainted 1 minute post vaccination. Patient said experienced arm pain and felt off immediately after vaccine. Patient came to within one minute of fainting. Blood pressure was checked and was in range at 119/90. Patient was slowly given water and started feeling better. Patient was also given orange juice and crackers. Blood pressure was taken again at 122/82. Patient experienced feeling cold and some yellowing of hands as well. Patient has a history of fainting when giving blood and is afraid of needles. After 50 minutes patient felt much better and left pharmacy. Followed up with patient after 2 hours and patient stated felt fine. |
| 1192090 | 4/10/2021 | WI | 31 | M | 4/10/2021 | 4/10/2021 | patient fainted right after he was give his vaccine, he seemed very stiff. It took 2 minutes for hi to regain conscious. he mentioned that he sometimes faints when he gets injected by a needle. he was observed for 30 minutes offered water, and left the pharmacy in good shape |

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| 1192082 | 4/10/2021 | AL | 22 | F | 4/8/2021 | 4/8/2021 | A few minutes after receiving the vaccine, patient (was sitting), felt dizzy, we put her on the floor, legs raised, took her bp 93/60. She felt nauseated. We monitored her, took bp again, then 93/57. She did not want an ambulance. She had a male with her. She stayed approximately an hour. We took her final bp and it was 117/73, she felt better and left on her own (walking unassisted). She made the statement that she does not like needles, and that every time she has given blood, she had passed out, or almost passed out. |
| 1192064 | 4/10/2021 | WI | 24 | F | 4/10/2021 | 4/10/2021 | Syncope 5 minutes post vaccination while standing |
| 1192026 | 4/10/2021 | WI | 50 | F | 4/10/2021 | 4/10/2021 | Client received vaccine and became dizzy and was "seeing stars". Sat for about 20 seconds right after being vaccinated and then passed out for 10 seconds. BP was unreadable, pulse 72, O2 saturation 98%. Was transported to hospital |
| 1192024 | 4/10/2021 | IN | 29 | F | 4/10/2021 | 4/10/2021 | shortly after receiving vaccine patient felt very faint and almost passed out, then vomited. Felt very weak and after about 1/2 hour said she was having difficulty forming words in her head. Her mother did want an ambulance called when I asked her, and they came out and took her vitals, which were normal. They felt anxiety was the reason she was having trouble thinking of the words she wanted to use, and felt that she was not having an anaphylactic reaction since there was no rash at injection site or anywhere else forming, and patient had stated that she had passed when she had blood drawn in the past. They asked if she wanted to go to the hospital and she said no and that she felt she could go home with her parents. She was still feeling weak, but the paramedic felt she was ok to go home also. |
| 1192019 | 4/10/2021 | CA | 35 | M | 4/9/2021 | 4/9/2021 | I passed out in my vehicle right after the vaccine was administered. A nurse found me unconscious at the vehicle and called 911 |
| 1192018 | 4/10/2021 | WI | 21 | F | 4/10/2021 | 4/10/2021 | At 7 hours after getting the vaccine, I nearly passed out. I got extremely dizzy and lost my hearing for a bit. |

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| 1192129 | 4/10/2021 | IL | 24 | M | 4/7/2021 | 4/7/2021 | Patient felt lightheaded, and his brother laid him on the ground and then he passed out for a few seconds. Pt was responsive after but felt drowsy. Pt was given water felt better. Per discussion with patient, he has a history of getting faint from seeing needles and getting blood drawn. |
| 1191986 | 4/10/2021 | NY | 17 | F | 4/10/2021 | 4/10/2021 | patient stated feeling dizzy and seeing darks spots. patient passed out for about 30 seconds. |
| 1192154 | 4/10/2021 | NM | 25 | M | 4/10/2021 | 4/10/2021 | Patient had trouble breathing (and is Asthmatic), and turned white and almost fainted, their brother went to the care to get their inhaler, and we provided orange juice and cold water for the patient. |
| 1191944 | 4/10/2021 | TX | 42 | M | 4/10/2021 | 4/10/2021 | About 10 minutes after receiving the shot, patient felt dizzy. He continued walking and fainted. He was caught by his wife and was let down to the floor. After resting, he regained consciousness. After resting longer, he felt better and was able to leave on his own. After about 2 hours, he said he felt fine and had no lingering effects. |
| 1191939 | 4/10/2021 | MI | 73 | F | 3/31/2021 | 3/31/2021 | On the day of my 2nd vaccination, I developed chills and felt slightly queasy. I woke the next morning with the same symptoms plus a headache. After being up several minutes, I suddenly had a syncopal episode and fell against an antique trunk I use for a coffee table, hitting my face. There was no explanation for the fainting other than the Moderna shot. I have had no symptoms since then other than the injuries I sustained from the fall. I saw a dentist the same day and have an appointment with my PA on Monday, April 12. I was encouraged to report this incident by family members since it was more than mild flu- like symptoms. |
| 1191938 | 4/10/2021 | MI | 22 | F | 4/10/2021 | 4/10/2021 | COVID vaccine given at 10:58 AM. Patient had syncope (fainted) at 11:00AM. Patient did not fall but was brought down to lay on floor and became conscious in 30-60 seconds. 911 was called with EMT's responding. Patient felt fine, no further faintness, dizziness, was able to ambulate on her own. Desired no further treatment. Patient left Pharmacy at 11:30 AM with no further adverse events. |

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| 1191937 | 4/10/2021 | UT | 22 | M | 4/9/2021 | 4/10/2021 | Severe chills and fever. Fainted once about 18 hours after injection. Nausea. |
| 1191883 | 4/10/2021 | IN | 55 | F | 3/25/2021 | 3/26/2021 | must have fainted; severe nausea; This is a spontaneous report from a contactable consumer. A 55-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered on right arm on 25Mar2021 14:00 (Batch/Lot Number: EW6204) at single dose (at the age of 55 years old) for COVID-19 immunisation. The patient medical history was not reported. Concomitant medications included estradiol, progesterone, esomeprazole sodium (NEXIUM [ESOMEPRAZOLE SODIUM]) and spironolactone, all taken for an unspecified indication, start and stop date were not reported. The patient previously took BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1, on 04Mar2021 (Lot number: EN6198), 02:00 PM on the right arm. The patient stated on 26Mar2021, "woke up with severe nausea, went to restroom, must have fainted, because I came to with my face on the register vent". The outcome of the events was unknown. No follow-up attempts are possible. No further information is expected. |

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| 1191846 | 4/10/2021 | ID | 62 | F | 3/12/2021 | | <p>I thought that I had kidney stone; aches and pain/Pain in my right side was very severe/Body ache; Foggy brain; When I stood up and I had been standing for a minute or two and it wasn't that I got up too fast and then I got very dizzy; almost passed out; can't even focus; I was not feeling well; They did gave me Cyclobenzaprine, Prednisone and Hydrocodone and I took them for two days and then I just stopped because it was just making it worse and then I was foggy and couldn't event get up; This is a spontaneous report from a contactable consumer (patient). A 62-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), dose 1 via an unspecified route of administration on 12Mar2021 (Batch/Lot Number: EN6206) as SINGLE DOSE for COVID-19 immunisation; cyclobenzaprine, prednisone and hydrocodone; all via an unspecified route of administration from an unspecified date (Batch/Lot Number: Unknown) to an unspecified date, at unspecified dose for an unspecified indication. Medical history included COVID-19 from Dec2020 to an unknown date. The patient's concomitant medications were not reported. The patient stated, "First, I had COVID back in early December and then on 12Mar2021, I got my first vaccine and I have lot of aches and pain and very foggy brain. I was just with the 'chiropractor' and he was just with me and I stood up and we were talking and I just got super dizzy and almost passed out, I just don't know. I missed, I can't even focus." When clarified the concern, the patient stated, "When I stood up and I had been standing for a minute or two and it wasn't that I got up too fast and then I got very dizzy and almost passed out, luckily there was a chair to catch me. So, my concern is, do I get the second vaccine if I already had COVID, should I didn't had this first vaccine since I already tested positive? When I had COVID, I was very cloudy in the brain. I don't know if this is a part of side effect, I am trying to find out if I can get the second vaccine." The patient experienced kidney stone. The lab data is clear, upon checking, the blood and urine samples. CAT scan has been done and the report is clear. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.</p> |

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| 1191822 | 4/10/2021 | IL | 42 | F | 3/25/2021 | 3/26/2021 | fainting; nauseous; I hit my head and chin on the dresser; I hit my head and chin on the dresser; I hit my head and chin on the dresser/seven stitches in my chin; This is a spontaneous report from a contactable consumer (patient). A 42-year-old female patient received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot ER8727) via an unspecified route of administration, administered in left arm on 25Mar2021 09:00 as single dose for COVID-19 immunization. The patient had no medical history. The patient was not pregnant and no known allergies to medications, food, or other products. The patient was not diagnosed with COVID-19 prior to vaccination and since the vaccination, the patient had not been tested for COVID-19. Concomitant medications included hair vitamins, and tru metabolism in which the patient received within 2 weeks of vaccination. The patient received first dose of bnt162b2 for Covid-19 immunization on 04Mar2021, 09:30. On 26Mar2021, the patient reported that she went to use the restroom around 0300 am as she was feeling nauseous. The next thing she remembered was being woken up on the floor of her bedroom by her husband. As a result of fainting, she hit my head and chin on the dresser. This resulted in needing seven stitches in her chin. The events resulted in emergency room/department or urgent care and therapy included stitches, x-rays, EKG and urine test on an unspecified date with unknown results. Outcome of events was recovering. |

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| 1191803 | 4/10/2021 | NY | 23 | F | 3/23/2021 | 3/24/2021 | I fainted and my heart rate was 144 which is extremely high; I fainted and my heart rate was 144 which is extremely high; I had woken up in a sweat, had 103.6 fever.; I had woken up in a sweat, had 103.6 fever.; After fainting I threw up and continue to not feel good; After fainting I threw up and continue to not feel good; I also had a bad headache; This is a spontaneous report from a contactable consumer (patient). A 23-years-old female patient received bnt162b2 (BNT162B2), dose 1 via an unspecified route of administration on 23Mar2021 (Batch/Lot number was not reported) as single dose for COVID-19 immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient stated that, "The 24th, the day after my shot. I had woken up in a sweat, had 103.6 fever. I fainted and my heart rate was 144 which is extremely high. After fainting I threw up and continue to not feel good. I also had a bad headache and continue to have one." The adverse event result in Doctor or other healthcare professional office/clinic visit. No allergies to medications, food, or other products. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The outcome of the events was not resolved. No follow-up attempts are needed. No further information is expected; information about lot/batch number cannot be obtained. |

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1191799 | 4/10/2021 | | 35 | F | 3/18/2021 | 3/1/2021 | pressure in her ears; right ear was burning; almost passed out; dizzy; hot; couldn't hear everything sounded really far away; had impaired thinking, couldn't think straight; no concentration for two days straight; had buzzing in her ears and heightened sounds; pins and needles sensation in her feet that went up to her legs/on day 9 the pins and needles sensation seems to be in her hands and arms as well; This is a spontaneous report received from a contactable consumer (patient). A 35-year-old female patient received 1st dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, LOT/Batch number and expiration date unknown) via an unspecified route of administration on 18Mar2021 at age of 35-year-old at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. Patient stated she received the first dose of the Pfizer COVID vaccine on 18MAR 2021. She stated ten minutes after the vaccine on 18Mar2021 she became dizzy, hot, almost passed out, couldn't hear everything sounded really far away. Patient stated this lasted for 20 minutes. Patient stated she also had impaired thinking, couldn't think straight and no concentration for two days straight. She stated she also had buzzing in her ears and heightened sounds for three days. She stated she had pins and needles sensation in her feet that went up to her legs. She stated on day 9 the pins and needles sensation seems to be in her hands and arms as well. Patient stated yesterday (26Mar2021) her right ear was burning and today (27Mar2021) she has pressure in her ears in addition to the pins and needles sensation. Events were reported as non-serious. Patient would like to know if her symptoms have been reported or are normal. She would like to know how long will her symptoms last and if they are permanent. She would like to know if she should receive the second dose of the vaccine. She would like to know what treatment she should have for her symptoms. She would like to know if there were any reports of autoimmune diseases being diagnosed after receiving the vaccine. She would like for someone to notify her if any information or data becomes available regarding the side effects she has mentioned that were not mentioned in the FactSheet. No information in PI regarding impaired thinking, loss of hearing, heightened hearing, pins and needles in extremities, and burning and pressure in ears. |

VAERS_ID RECVD STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

There were no other notable patterns or numerical imbalances between treatment groups for specific categories of non-serious adverse events (including other neurologic or neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine. Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination. No information in PI regarding autoimmune disorders being diagnosed after receiving Pfizer COVID vaccine. Outcome of dizzy, hot, almost passed out, couldn't hear everything sounded really far away was recovered on 18Mar2021, of had impaired thinking, couldn't think straight, no concentration for two days straight, buzzing in her ears and heightened sounds for three days was recovered in Mar2021, of the other events was unknown. Information on the lot/batch number has been requested.

1191781 4/10/2021 FL

58 M

3/26/2021

3/26/2021

passed out/unconscious; feel weak; dizzy; not normal; This is a spontaneous report from a contactable consumer (patient). A 58-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration in arm left on 26Mar2021 09:45AM (Lot Number: ER8730) as single dose for COVID-19 immunisation. The patient had COVID prior vaccination. The patient had no other medical history or known allergies. The patient's concomitant medications were reported as none. The patient did not have COVID test post vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. After taking the vaccine the patient waited for 15 minutes prior to departing the facility in order to make sure there was no adverse reactions. At approximately 10:15 10:30 AM the patient drove back home. After driving for about five minutes while stopped at a traffic light the patient completely passed out at 10:45, he was unconscious for approximately 2 to 3 minutes, almost crashed his car and EMT support had to be called. The patient regained his conscience but it took him over a half hour to feel 50% better. Until 8:30 PM 26Mar2021, the patient still felt weak and dizzy and not normal. No treatment was received for events. The outcome of events was recovering.

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| 1192004 | 4/10/2021 | NY | 31 | M | 4/10/2021 | 4/10/2021 | syncope w / prodrome during post-vaccine obs period, while sitting in chair |
| 1192327 | 4/10/2021 | CA | 27 | F | 4/10/2021 | 4/10/2021 | Client was sitting in a 15 minute observation after receiving a first dose Pfizer vaccination. She alerted the EMT that she felt lightheaded and then fainted. The EMT was able to catch her and assist her to the floor. Paramedic did a sternal rub and client regained consciousness within 10 seconds. She was then awake, alert and oriented to time , situation, person and place. She was assisted to a wheel chair and zero gravity chair, given water. Vital signs were monitored and within normal limits, client denied any other symptoms and stated she has a history of vasovagal syncope episodes with other injections. Client ambulated with a steady gait after a total 45 minute observation and resolution of dizziness. She stated she would walk to her home which was close by. |
| 1192173 | 4/10/2021 | IA | 24 | F | 4/10/2021 | 4/10/2021 | Requested by PH administrator to look in on Down's Syndrome client post covid vaccination as thought her behaviors indicated she was having a reaction. Upon first assessment, saw patient with eyes open but then her head would bob like she passed out or fell asleep. Her father accompanied her to clinic and reported that this is normal for her as she is being worked up for sleep apnea but does not have the machine as yet. He wanted to show me how she walked but seemed unsteady upon first standing and encouraged dad to place her back in the wheelchair that she came in. Her father also stated that her gait is circular normally. She is limited in hearing and signs. VSS at 1050: BP: 102/70, 71 pulse, 97% ox reading. pulse ox reading, skin pink. Developmentally stunted . Assisted into the truck and no falls, abnormal gait noted getting from wheelchair to the truck. Contact information given to father in case something happens at home or on the way home. Offered water but father refused due to autism and obsessive compulsive behaviors and that he did not have a straw. |
| 1191034 | 4/10/2021 | FL | 33 | F | 4/5/2020 | 4/5/2021 | near syncope and weakness |
| 1192591 | 4/10/2021 | OR | 49 | M | 4/8/2021 | 4/8/2021 | Nausea, dizziness, syncope |

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| 1192581 | 4/10/2021 | CA | 27 | F | 4/10/2021 | 4/10/2021 | Nausea, vomiting, diarrhea, headache, fainting |
| 1192541 | 4/10/2021 | WA | 24 | F | 4/9/2021 | 4/9/2021 | Fainting and dizziness about four hours later |
| 1192506 | 4/10/2021 | | 61 | M | 4/9/2021 | 4/9/2021 | Sore arm, prolonged fever lasting 32 hours so far, the fever has not subsided yet. Extreme tiredness, I have slept for almost 30 hours. Aches and a side ribs are sore. I also fainted and fell several times during the night. |
| 1192429 | 4/10/2021 | | 21 | M | 4/9/2021 | 4/9/2021 | Approximately 1 minute after administering the vaccine the patient fainted. Within 15 seconds the patient was awake and oriented. His last memory before fainting was experiencing pain in his arm after the injection. The patient was monitored for at least 20 minutes and given some water and a protein bar. When questioned whether he often faints, he said the only other time he had fainted was in the past when he was experiencing stomach pain. He appeared to be doing very well when he left the pharmacy with a friend. |
| 1192420 | 4/10/2021 | FL | 18 | M | 4/7/2021 | 4/8/2021 | Rapid heartbeat, dizziness, weakness, shaking (not chills), fainting, confusion |
| 1192362 | 4/10/2021 | VA | 20 | F | 4/1/2021 | 4/1/2021 | While the vaccine was going in my arm it was stinging and burning. I fainted about 30 seconds after the injection. I waited at my vaccination site for about 30 minutes after that. My vision was blurring and turning black and white and my hearing went out. I felt lightheaded and fainted for a few seconds. Afterwards, I was lightheaded for quite some time and my blood pressure was a bit low. |
| 1192351 | 4/10/2021 | CA | 54 | F | 4/10/2021 | 4/10/2021 | patient fainted less than a minute after injection. She regained consciousness and were taking care by fire department crews. Other wise doing fine. |

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| 1192128 | 4/10/2021 | NC | 37 | F | 4/10/2021 | 4/10/2021 | Upon administering Janssen COVID19 vaccine, patient experienced vasovagal syncope approximately 5 seconds after administration. This occurred at approximately 11:15 am on 4/10/21. After approximately 5 to 10 seconds, patient opened eyes, became alert and was assisted to a sitting position where she was observed for approximately 30 minutes. Patient left pharmacy and was contacted at 1:10 pm to check up on condition. Patient said she was feeling fine and was thankful for pharmacy's concern. Patient instructed to contact pharmacy with any questions or change in status. |
| 1192346 | 4/10/2021 | | 64 | M | 4/9/2021 | 4/9/2021 | Patient had syncope from a sitting position, history of vasovagal syncope, occurred 10 minutes after receiving vaccine. Patient recovered in the recovery area, advised to follow up with MD |
| 1192221 | 4/10/2021 | CA | 26 | M | 4/10/2021 | 4/10/2021 | patient occasionally faints after shots. layed down on mat for 20-25 minutes after short fainting spell. BP 102/70 |
| 1192309 | 4/10/2021 | IL | 35 | F | 4/5/2021 | 4/5/2021 | Cold flash, lightheaded, heavy chest and throat while driving home from receiving vaccine. Pulled over and called 911 because I thought I was going to pass out and couldn't breath normally. I was by myself. Lasted about 3-5 minutes. I started to feel better while on the phone with 911 dispatcher. I was able to walk to the ambulance. Still felt a little woozy, but could breath fine. My chest got a little heavy while in back of ambulance, but not as severe. Was transported to ER. Discharged same day Diagnosis- vaccine reaction; syncope near-vasovagal reaction |
| 1192277 | 4/10/2021 | CO | | M | 4/10/2021 | 4/10/2021 | Patient fainted about 5 minutes after getting vaccine. He gained consciousness right away. He complained of heart palpitations, sweating, hand tingling, and nausea. |
| 1192255 | 4/10/2021 | CA | 70 | F | 3/11/2021 | 3/28/2021 | Syncope while working in garden 3/28/21, ED visit, no imaging, EKG NSR, treated with IVF attributed to dehydration Severe neck pain radiating to chest started 4/2/21, CT showed large pericardial effusion, admitted to hospital for acute pericarditis with pericardial effusion |

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| 1192252 | 4/10/2021 | IL | 69 | F | 2/28/2021 | 3/5/2021 | Patient developed nausea, chills, lightheadedness/near-syncope, decreased appetite, weight loss, hoarse voice, a "nasty taste and smell", and worsened insomnia, anxiety, and fatigue after the 1st Moderna shot. Continues to have symptoms as of 4/5/2021. |

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| 1192239 | 4/10/2021 | IL | 26 | F | 4/8/2021 | 4/8/2021 | 26-year-old female with past medical history of asthma and anxiety, and syncopal episode after her first Covid vaccination, presents to the emergency department after syncopal episode after her second Covid vaccination. Patient states she received her shot, and about 45 seconds later started feeling similar to the way she felt during the first syncopal episode. She started having tunnel vision, and her mom who is with her this time, notes that she was getting more pale. Mom notes that patient was talking about what she was feeling and was slowing down, until she passed out for about 30 seconds. During her LOC, she was shrugging her shoulders repeatedly, and after she awoke, she returned to her baseline mental status after about a minute or 2. As she was returning to her baseline mental status, she was talking about how she was feeling and it was appropriate. No urinary incontinence or tongue biting. Denies any recent chest pain, shortness of breath, other episodes of lightheadedness or syncope. She is not had syncopal episodes after shots before. After her last injection, she had a syncopal episode and fell flat on her face, thus had a CT head. At the time her CT head is negative, she had a D-dimer that was also negative. Her labs at the time were notable for hypokalemia 3.3, and in preparation for that she states she has been eating a lot of bananas this week. At this time she does not want any lab work, and feels as if this was a similar vasovagal episode similar to last time. syncopal episode right after a COVID vax. Same thing happened with the first dose. Prior to passing out felt sweaty, lightheaded, body tingling then passed out. Didn't fall this time as she was expecting it. Never had fear of needles before. No abd pain, back pain, chest pain. No h/o PE, DVT, OCPs, calf pain, SOB. No cough, SOB, palpit, diaph, chest pain/pressure, headache. No abd pain, no back pain, no vomit, no diar. No urinary complaints. No rash. No numb/weakness. No URI Sx. Mom noted a few shoulder twitches but not GTC type symptoms. rapid response called, pt went to emergency department |
| 1192213 | 4/10/2021 | OR | 82 | F | 4/7/2021 | 4/8/2021 | Fainted and fell to ground, dry heaving for 30 min and chills, |

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| 1192212 | 4/10/2021 | CA | 19 | F | 4/9/2021 | 4/9/2021 | Patient received 2nd Moderna vaccine. Patient felt lightheaded and fainted 5 minutes after getting the vaccine. Firefighters and patient's mother brought her outside the observation room for more privacy and sat patient down on a chair with her head tilted down, and patient regained consciousness within 1 to 2 minutes. Patient's blood pressure and pulse were both low and patient stated she couldn't hear out of her left ear. Firefighters decided to call the ambulance and send the patient to the nearest emergency room. I followed up with the patient the next day on 4/10/2021. Patient stated she had a vasovagal response to the injection and received IV fluids at the emergency room. Patient stated it was very unexpected and she had ate before coming to the clinic. She has not felt lightheaded or faint since the incident and is experiencing flu-like symptoms from the vaccine and has been taking Tylenol for it. |
| 1192202 | 4/10/2021 | MO | 77 | F | 3/22/2021 | 3/23/2021 | Following the vaccine, my day progressed normally. Started feeling a bit tired and dizzy in the evening. Next morning, upon rising became very dizzy. Sat in my chair and promptly passed out. Eyes rolled to back of head. Husband could not rouse me for several minutes. Following that experience, became very tired. Returned to bed. Was dizzy, fever of 100.2, headache for a few days. Minor arm pain. |
| 1192168 | 4/10/2021 | TX | 29 | M | 4/10/2021 | 4/10/2021 | IMMEDIATELY AFTER RECEIVING THE SHOT, THE PATIENT SLUMPED. THE PATIENT REVIVED A FEW MOMENTS UPON CALLING HIS NAME. HE IDENTIFIED HIMSELF BY ANSWERING WHEN HE WAS CALLED BY NAME AND VERIFIED HIS ADDRESS AND DATE OF BIRTH. HE INSISTED HE WAS FINE AND PASSED OUT BECAUSE HE WAS ANXIOUS AND WAS HUNGRY AS HE HAD NOT EATEN. THE PARAMEDICS WERE CALLED TO THE SCENE. |
| 1192165 | 4/10/2021 | FL | 27 | F | 4/10/2021 | 4/10/2021 | FIVE MINUTES AFTER RECEIVING VACCINATION, PATIENT FELT DIZZY AND PASSED OUT FOR APPROXIMATELY 30 SECONDS. NO NAUSEA OR VOMITING. PATIENT WAS MONITORED FOR 30 MINUTES AFTER INCIDENT BEFORE SHE LEFT THE PHARMACY. |

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| 1192350 | 4/10/2021 | CA | 28 | F | 4/10/2021 | 4/10/2021 | HPI: PT 28 y/o F feeling light headed after J&J vaccination. PT with her mother, became light-headed and dizzy while walking from vaccination site back to vehicle for 15 minute wait. PT became unresponsive with mother and fainted. Parking staff alerted rapid response team, PT regained responsiveness and was given chair to sit on, water to drink. Rapid response team arrived to a responsive, A&Ox4, pale female who was still feeling weak and light-headed. PT was transferred to a cot (in the shade) where she was placed in supine position with legs elevated on a chair. PT was given water and hard candy to suck on while vitals were taken,, Airway, breathing and circulation were all WNL. PT states she presently has a strep infection (throat area) and has been afebrile, and is to begin oral antibiotics once she picks RX up from pharmacy. PT began feeling significantly better over 10-15 minutes of laying down in the shade. EMS LAFD was called and transfer of care to EMS Station 93 for further work-up was instituted. PT felt much better and was able to stand and ambulate from cot to EMS vehicle without issue. PT chose to go home with her mother instead of being transported by EMS to medical facility. Exam (update as needed): GEN: Alert and oriented x 4, relaxed in appearance. HEAD: WNL EYES: PERRL, EOMI ENT: Ears normal, Nose normal, OP normal, no evidence of angioedema, no cyanosis NECK: Supple, without LAD. CV: RRR, no m/r/g |
| 1191175 | 4/10/2021 | MA | 19 | F | 4/10/2021 | 4/10/2021 | Fainted. Did not need transport. |
| 1191363 | 4/10/2021 | MO | 36 | F | 4/8/2021 | 4/8/2021 | 10 hours post-vaccination, lightheadedness and one episode of syncope (fainting). Then approximately one hour of shivering and chills. |
| 1191359 | 4/10/2021 | | 19 | F | 4/10/2021 | 4/10/2021 | After vaccine, patient fainted and registered nurse and CNA assisted to floor with no incidents. EMT and Doctor at side. Vitals 123/75, HR 86, 97%. Food and water was given. Dr. cleared patient to sit at the thirty minutes tent for closer observation. |

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| 1191351 | 4/10/2021 | IN | 45 | F | 4/5/2021 | 4/9/2021 | I reported previously that the day of the shot (that evening at close to midnight) I fainted. I woke up on my bathroom floor. I walked down my hall and saw black dots and felt dizzy with nausea. The next thing I knew I was on the bathroom floor and didn't remember how I had gotten there. It is Friday and I now am experiencing shooting pains in the side of my head. I also have been experiencing pains in my calf muscles and some chest pains. I am still extremely tired and having abdominal pain. I have contacted my doctor's office about the fainting but I am going to call Monday to get an appointment to get checked out. I am concerned about possible blood clots. |
| 1191343 | 4/10/2021 | FL | 53 | F | 4/7/2021 | 4/7/2021 | Dizziness, tingling, heart rate increased, blood pressure increased-stayed longer in the tent with paramedics but then another person fainted nearby and I signed off to leave so they could assist the other person. After getting home, nausea, chills, high fever of 102.9, severe headache, sore muscles, My skin turned red on my chest soon after the shot and I took Benadryl. Took ibuprofen for the high fever. The next day still had a severe headache, muscle aches, fatigue and still feel that way today. |
| 1191324 | 4/10/2021 | TX | 26 | F | 4/10/2021 | 4/10/2021 | Client received first dose of Vaccine, complained of dizziness and experienced a Syncope episode. |
| 1191316 | 4/10/2021 | SC | 23 | F | 4/8/2021 | 4/8/2021 | Patient fainted shortly after getting the Janssen vaccine. She felt faint and let us know so we laid her down elevated her legs, and she fell out for a few seconds she continued to have a strong pulse. We gave her an ice pack and water after she came back and had her lay down for 10 more minutes. I checked with her a few days later she said she had fever and chills 8 hours after the vaccine but felt better. |
| 1191308 | 4/10/2021 | FL | 34 | M | 4/10/2021 | 4/10/2021 | VISIBLE FULL BODY SWEATS, CHILLS, LIGHT HEADEDNESS, ALMOST PASSED OUT. GAVE PATIENT WATER, COOL DAMP CLOTHS, AND KEPT THEM SEATED FOR OBSERVATION FOR 30 ADDITIONAL MINUTES. PATIENT FELT FINE AND RETURNED TO NORMAL AFTER ABOUT 5 TO 10 MINUTES AFTER ONSET OF SYMPTOMS. |

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| 1191277 | 4/10/2021 | NY | 33 | F | 4/10/2021 | 4/10/2021 | Patient had a moderately severe syncope reaction. Patient had trouble communicating, reported loss of vision and hearing, light headedness, dizziness, semi consciousness. Patient was seated when the episode began. By the time staff were notified, patient was barely conscious, and could not be safely told to put their head between their legs for fear of falling. Patient came out of the episode within 10 minutes before emergency services could arrive. |
| 1191265 | 4/10/2021 | | 26 | M | 4/10/2021 | 4/10/2021 | Patient fainted from sitting position and hit forehead. Had symptoms of nausea, HA, and laid down for 15 minutes. Drank OJ, ate chips upon sitting and laid back down due to dizziness. Patient sat up, vomited, and continued symptoms of headache. Stayed in observation for an hour and felt better enough to go home with friend. Recommended patient visit medical provider if no improvement or worsening of symptoms. |
| 1191247 | 4/10/2021 | KS | 62 | M | 4/10/2021 | 4/10/2021 | client was injected at 1:36p.m. and passed out at 1:39 p.m. client was in and out of consciousness until 1:40p.m. This happens every time client gets a shot |
| 1191365 | 4/10/2021 | MI | 29 | M | 4/9/2021 | 4/9/2021 | Patient received their vaccine at 4:25pm, and fainted at 4:30pm, and at 4:35pm the patient was back to baseline. He drank a bottle of water and felt normal. He initially was sweaty, had a dry mouth immediately fainted. He stated he only had a pretzel before the vaccine, and had an issue with needles in the past. |
| 1191200 | 4/10/2021 | | 29 | M | 4/10/2021 | 4/10/2021 | Patient fainted from sitting on chair, felt nauseous, dizzy, and lightheaded 5 minutes after receiving vaccine. Felt dizzy for an additional 15 minutes and laid supine. Patient drank juice, ate a salty snack, and sat up. Continued to feel lightheaded, laid down for additional 15 minutes. Patient vomited, complains of headache and nausea. Symptoms continued for an additional 45 minutes before patient felt comfortable to leave with friend. |
| 1191217 | 4/10/2021 | MO | 36 | F | 4/10/2021 | 4/10/2021 | Pt passed out after shot - paramedics came and checked her out - pt recovered after a few minutes and was released |

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| 1191140 | 4/10/2021 | MO | 84 | F | 4/10/2021 | 4/10/2021 | Pt experienced vasovagal syncope after 2nd dose of moderna vaccine today. After administration, pt was able to walk and sit in chair in waiting area to begin 15 min waiting period. After 1 minute I overhear pt tell husband she is getting dizzy. I go over and talk to pt and she states she is getting very dizzy, but states no issues breathing. Pt closes eyes and begins to mutter responses. I lay her down on the floor and have someone call 911 and code white at the store. I raise the patients legs while pt lays flat on the floor, pt begins to be responsive and regains full consciousness. She sits up and begins sipping on a bottle of water. Paramedics show up and evaluate her vitals. Her daughter is called and pt is able to leave with daughter and husband to return home. |
| 1191111 | 4/10/2021 | UT | 55 | F | 3/21/2021 | 3/23/2021 | I had the expected symptoms of chills and low grade fever. The unexpected symptoms were really acidic stomach and I passed out. |
| 1191089 | 4/10/2021 | NC | 34 | F | 4/9/2021 | 4/9/2021 | Around 5.5 hours after I got the shot my blood sugar bottomed out. I had a hot flash, started sweating and my vision went blurry. I couldn't walk 3 feet without having to sit with my head between my knees. I passed out in a 5 foot walk but luckily I sat down on my couch as it was happening. I'm not diabetic, haven't ever been hypoglycemic. Ibuprofen and food after about 2 or 3 hours is a must. |
| 1191074 | 4/10/2021 | KY | 44 | F | 4/8/2021 | 4/9/2021 | 6 weeks 2 days pregnant for second shot - due date Nov30, 2021 mild morning sickness until vaccine reaction day, then severe nausea and vomiting the day of vaccine reaction day - return to low morning sickness symptoms day after vaccine reaction day. Other vaccine reaction day symptoms: nearly fainted (panic attack?) 35 minutes after receiving shot, next day I had low fever, chills and muscle/joint aches for 12 hours. Note: After 1st shot I also nearly fainted (panic attack?) about 35 minutes after shot; had pain at injection site and neck ache that lasted 30 hours. |

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| 1191066 | 4/10/2021 | CO | 59 | F | 4/6/2021 | 4/6/2021 | Immediate pain /ache at injection site Approximately 6 hours later experienced headache and body aches. About 12 hours after vaccine I had chills, fever, vomiting diarrhea, and almost passed out. The vomiting and diarrhea went away after one episode. The headache/body aches continued throughout the next day. The chills/fever were gone by morning on April 7. I developed a red rash around the injection site 2 days after receiving the vaccine and as of today, April10, I still have some redness and soreness. |
| 1191057 | 4/10/2021 | MI | 23 | F | 4/10/2021 | 4/10/2021 | Dizzy, Left ear buzzing which lead to syncope upper arms tingling for 2-3 seconds |
| 1191042 | 4/10/2021 | UT | 23 | M | 4/9/2021 | 4/10/2021 | Approximately 12 hours after vaccination, awoke with severe trembling and nausea. Fainted twice. Fever of 100F. Nausea lasted approximately 30 minutes, trembling lasted about 45 minutes. Important to note that I previously had COVID-19 60-70 days prior to vaccination. The symptoms from the vaccine were significantly worse; however, they appear to have lasted for a much shorter period. |
| 1191037 | 4/10/2021 | NC | 32 | F | 4/10/2021 | 4/10/2021 | Patient arrived at pharmacy to receive her vaccine. Patient seemed nervous. Pharmacist asked if she has any questions and whether she's eaten or drank anything today. Patient states that she's had a little something. Pharmacist engaged patient in conversation during vaccination. Patient was able to raise her arm and walk to waiting area after vaccination to wait her required 15 minutes waiting time. After around 5 minutes, pharmacist went to check on patients at the waiting area, and patient got up and mentioned that she's not feeling too well. In the next second, she had fainted on the floor. Associates in the store called 911 while pharmacist and pharmacy tech stayed beside the patient to monitor breathing and heart rate. Pulse was faint but breathing was steady. Patient was completely unconscious for a good 3-5 minutes, but she started opening her eyes when EMS arrived. After EMS took over, patient was able to sit up with assistance, talk, and respond. Patient was taken out of the store on a stretcher. EMS recorded that patient's BP was 132/82. |

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| 1191759 | 4/10/2021 | FL | 25 | U | 4/10/2021 | 4/10/2021 | Patient passed out couple minutes after shot but became conscious in couple minutes. Patient legs were elevated and wet towels were placed on him and was given something to drink. Emergency response team cleared patient after checking all vitals. |
| 1192248 | 4/10/2021 | TX | 57 | F | 4/10/2021 | 4/10/2021 | patient fainted about a minute after IMZ was administered |
| 1191235 | 4/10/2021 | CA | 25 | F | 4/9/2021 | 4/9/2021 | After vaccination for couple minutes, patient felt dizziness and fainted and fell. 911 was called and ambulance dispatched to the pharmacy. Before ambulance arrived, breathing is heavy and blood pressure was measured with readings of 92/51. Patient complaint of dizziness and hot. |
| 1191620 | 4/10/2021 | NC | 37 | F | 4/10/2021 | 4/10/2021 | As the vaccine was being administered into my left deltoid, the vaccine hurt at the injection site and I immediately felt very strange and felt a rushing sensation to my head and throughout my body, with a concentration in my upper body. It felt like an out of body experience: I fainted, hitting my head on the adjacent wall and fell to the ground, where the impact caused a bruise to my shoulder and back. It was reported to me that I lost consciousness for about 10 seconds. I felt disoriented, but lucid when I came to. I was not exactly sure what happened, but I could feel that I hit my head on the right side and asked if I fainted since I was disoriented and on the floor. With assistance, I was able to sit back on the bench, but felt extremely dizzy, light headed, fuzzy/strange type of blurry vision, and intense sweating. I did not feel well and knew I would have an unsteady gait if I attempted to stand. After about 15 minutes, I felt well enough to return home. |
| 1191749 | 4/10/2021 | | 32 | M | 4/10/2021 | 4/10/2021 | Syncope. |

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| 1191729 | 4/10/2021 | IN | 22 | M | 4/3/2021 | 4/4/2021 | At around 7PM the day of the J&J vaccine, I began to feel very fatigued and could tell that I was going to come down with a fever. I went to bed early that day around 10PM. Woke up around 1:30AM on the 4th. Felt terrible and took my temperature. It read 101.5. Got up to use restroom and when washing hands, everything started to go blurry, I thought i had just become lightheaded and that it would pass so i stood there leaning against the bathroom door.I ended up fainting and hitting my head on the cabinets. I was completely soaked in sweat. An hour later we drove to the ER to make sure everything as okay. IV was started, some test performed, and fever was gone by 5AM. Felt completely fine after going home and resting for a few hours. |
| 1191192 | 4/10/2021 | AZ | 20 | F | 4/10/2021 | 4/10/2021 | Patient fainted a few minutes after vaccination. The patient told her father she was feeling lightheaded and then her legs became weak. Her father grabbed her to make sure she didn't fall and hit her head. We had the patient sit on the ground. Pulse and color for patient was good. We gave the patient water and had her sit for about 30 more minutes before releasing her. We checked in with her every few minutes and patient had noi issues. |
| 1191402 | 4/10/2021 | | 27 | F | 4/10/2021 | 4/10/2021 | syncope. Evaluated by EMS-Cleared |
| 1191725 | 4/10/2021 | MO | 21 | F | 4/9/2021 | 4/10/2021 | Vaccinated at 2:10 pm April 9th. Began feeling chills and body aches around 8pm same day. Had 101 degree fever at around midnight. Stood up to get water and fainted at approximately 2am April 10th. Was treated at hospital emergency room around 2:30 am. Was given 1 round of IV fluids and 1000mg Tylenol. Was discharged at about 8am April 10th. |
| 1191715 | 4/10/2021 | | 19 | M | 4/7/2021 | 4/7/2021 | Patient experienced syncope, flushing/sweating, and dizziness, likely vasovagal response. Patient fell, fall braced by healthcare provider, did not hit head. BP 96/46, HR 49, R16. Given water and crackers, stabilized within 30 minutes, BP 124/49 P52, stable and released from vaccination site |
| 1191662 | 4/10/2021 | CA | 32 | M | 4/10/2021 | 4/10/2021 | Pt states "Chills, diaphoresis, nausea and almost passed out." Pt states he has not eaten yet today. P: 111/57, HR 61, O2 100% RA |

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| 1191654 | 4/10/2021 | | 37 | M | 4/8/2021 | 4/8/2021 | Patient had syncope, dizziness, ringing of ears, chills. BP 144/92 P73 RR17. Given water and recovered, discharged home in stable condition |
| 1191639 | 4/10/2021 | OH | 18 | F | 4/10/2021 | 4/10/2021 | fainting, followed by seizure like involuntary movement for 15 secs. patient regained consciousness and left with family to healthcare providers. |
| 1191610 | 4/10/2021 | PA | 27 | M | 4/9/2021 | 4/9/2021 | Side effects started at 630pm same day of vaccine Started with muscle aches, then severe chills and fever of 101°F. At 5am the following day a fainting spell occurred after awakening in severe hot flash with fever of 100°F. Lost consciousness for about a minute. Continued with chills and fever for about another 3 hours. Awoke next day with headache for about 2 hours then felt better and continued on normal. Treated with tylenol |
| 1191591 | 4/10/2021 | MI | 32 | M | 4/10/2021 | 4/10/2021 | Patient was waiting in chair about 2 minutes after he received his covid shot, said he felt dizzy. Tried to assist him but he had fainted and hit his head. |
| 1191590 | 4/10/2021 | WI | 20 | F | 4/10/2021 | 4/10/2021 | Fainted but responded when I talked to her. Had her lie on floor. Gave cold compress and cold water to drink. She stayed awake from then on. We sat her up and had her wait until she felt better. Waited here 30 minutes after vaccine and felt ok when she left. |
| 1191581 | 4/10/2021 | CA | 30 | F | 4/8/2021 | 4/8/2021 | I sat in waiting area for 5 minutes after shot and felt fine. I got up to use restroom and felt very lightheaded and dizzy. I turned around because I didn't think I would make it to bathroom and told site worker I felt dizzy. He tried walking me back to car but my sight for super blurry and I passed out. I came back into it pretty quickly after passing out. I was super sweaty after shot. |

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| 1191495 | 4/10/2021 | FL | 19 | F | 4/10/2021 | 4/10/2021 | After receiving her vaccine, patient moved into our waiting/observation area at my request to wait for 15 minutes of observation. Within a few minutes I heard the patient's mom calling out for help. I quickly ran over to help. I observed the patient who was now sitting on the floor. Her eyes were wide and she looked shocked. I helped her mother to calm patient and asked her to remain seated. I asked her mom what happened and she stated patient twitched a couple of times and began to fall off of her chair at which point mom caught her. Mom had blood on her arm and I noticed it had come from patient's ear where a couple of earrings were pulled as she fell. I asked if she wanted water and quickly provided her a bottle of water. Mom stated that patient had fainted from vaccine(s) in the past, but mom stated that this appeared to look like a seizure. Mom went to get a chocolate bar since patient had had nothing to eat and they were worried about low blood sugar. After patient looked like she was back to normal I left to administer another vaccine but asked mom to remain until she felt necessary. Mom and patient advised my tech that they were ok and they left the store. |
| 1191542 | 4/10/2021 | | 37 | F | 4/10/2021 | 4/10/2021 | fainting, loss of vision |
| 1191445 | 4/10/2021 | NC | 49 | F | 4/9/2021 | 4/10/2021 | From 1:30 am to 7:30 am 4/10/2021 Tachycardia Tightness in chest Possible Difficulty breathing ?? Fingers and tongue tingling or numb Dizzy and fainting if attempt to get up or sit up (needed ambulance but could not unlock door or call) Severe pain everywhere Feet cold and numb(no fever) After 7:30 am 4/10/2021 just very mild pain,fever,fatigue. |

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| 1191533 | 4/10/2021 | TX | 52 | F | 4/8/2021 | 4/9/2021 | 0900, 8 Apr: Vaccine administered. 2100, 8 Apr: Muscle aches and pains. "Pinprick" sensations on body. 2230, 8 Apr: Went to bed. Exceptionally poor night's sleep, with constant wakefulness (confirmed by FitBit). 0816, 9 Apr: Got out of bed. Went downstairs. Began washing dishes and making breakfast. 0820, 9 Apr: Felt light-headed. Sat down in a chair. 0825, 9 Apr: Husband reports finding me with muscles constricted, eyes wide open, and pupils fully dilated. I did not respond to his touches or yells to get my attention. 0916, 9 Apr: Ambulance arrives at Hospital Emergency Room. Attending physician examines me and blood samples are taken. 1207, 9 Apr: Discharged with diagnosis of vasovagal syncope. Instructed to follow up with primary care manager and cardiologist on 12 Apr for further evaluation. |
| 1191506 | 4/10/2021 | FL | 35 | M | 4/10/2021 | 4/10/2021 | After giving the vaccine, I was talking with the patient and he said he felt dizzy. He passed out and while he was out/when he was regaining consciousness, he started having seizure like movement. EMS was called and were here within 5 minutes. The paramedics took his vitals which were all WNL. Approximately 15 minutes later, the patient had a repeat episode. The paramedics and I suggested that the patient go to the emergency room via ambulance. He declined and left with his wife. They both reported that he would seek care at the emergency room. |
| 1191646 | 4/10/2021 | OH | 60 | F | 4/7/2021 | 4/8/2021 | Patient reports experiencing chills starting 12 hours later and continuing all night, back pain, body aches and fainted next day at 3pm after experiencing dizziness. Said she was unconscious for about 15 seconds. Feeling better now at time of reporting 4/10/21. Patient did not seek medical treatment for the incident. |

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| 1191425 | 4/10/2021 | NC | 39 | M | 4/10/2021 | 4/10/2021 | PATIENT WAS LETHARGIC AND SLUMPED IN HIS CHAIR. HE WAS SWEATING PROFUSELY AND COMPLAINING OF NAUSEA AND DIZZINESS. PATIENT'S BREATHING WAS LABORED. PHARMACIST SPOKE WITH PATIENT AND DETERMINED THAT HE HAD SYMPTOMS OF SYNCOPE. BLOOD PRESSURE WAS ASSESSED TO BE 110/69 MMHG. WE APPLIED COLD COMPRESSES TO THE PATIENT'S HEAD, NECK AND WRISTS. EMS RESPONDED AND CONFIRMED DIAGNOSIS. PATIENT REMAINED SITTING AND BEGAN TO RECOVER FROM SYMPTOMS AFTER 20 MINUTES OR SO. |
| 1191457 | 4/10/2021 | WI | 61 | F | 4/10/2021 | 4/10/2021 | syncopal episode, client had history of syncope with vaccination that was not reported until after the fact. |
| 1191568 | 4/10/2021 | | 22 | M | 4/10/2021 | 4/10/2021 | Pre-syncope |
| 1191439 | 4/10/2021 | FL | 35 | F | 4/9/2021 | 4/9/2021 | Blood pressure plummeted and I fainted within 4 minutes of receiving the vaccine. |
| 1191474 | 4/10/2021 | | 40 | F | 4/10/2021 | 4/10/2021 | fainted, "feels like BP low". Evaluated by EMS-Refusal to transport. |
| 1191463 | 4/10/2021 | FL | 32 | F | 4/9/2021 | 4/9/2021 | I was told I could leave the observation site before the 15 minutes and a couple minutes later I fainted while driving and wrecked my car. |
| 1185399 | 4/9/2021 | GA | 33 | F | 4/7/2021 | 4/7/2021 | High fever and body aches over 48 hours. Oscillating tylenol and ibuprofen every 4 hours, lots of fluids, and ice packs on major arteries along with tepid baths. Fainted walking up stairs. Fever up to 104 at 48 hour mark. Still ongoing currently |
| 1185380 | 4/9/2021 | MA | 28 | F | 4/9/2021 | 4/9/2021 | Patient had an episode of vasovagal syncope about 2 minutes after vaccine administration followed by about 10 seconds of seizure. |
| 1185375 | 4/9/2021 | AZ | 52 | M | 4/9/2021 | 4/9/2021 | Syncope, Diaphoretic, Flush, arrhythmia |

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| 1185367 | 4/9/2021 | MI | 29 | F | 3/26/2021 | 4/8/2021 | On April 8, I fainted shortly after getting out of bed around 8:30 AM EST. Despite increasing my hydration and ensuring I was eating adequately, I've felt dizzy and off-balance since then to now (April 9 2:00 PM EST). I also had "moderna" arm a week after the shot where I had a rash/splotch at the site of the injection. I could feel a bump on Friday, April 9 and then the splotch grew over April 3-5. It then started to fade and is almost gone. |
| 1185326 | 4/9/2021 | MN | 39 | F | 3/25/2021 | 3/25/2021 | 2:00pm - headache and body aces started 5:30pm- headache, body aches, low grade fever and chills 5:45pm- was driving with my children and felt a wave of heat, followed by extreme nausea, was able to pull over my vehicle and then fainted. After passing out, I started to seize. Rapid breathing, lost feeling of my arms and legs. Ambulance was called. I was transported to the hospital. |
| 1185310 | 4/9/2021 | | 58 | F | 4/9/2021 | 4/9/2021 | Near syncope that resolved without intervention |
| 1185385 | 4/9/2021 | FL | 48 | M | 4/8/2021 | 4/8/2021 | 5 minutes after receiving the vaccine, the client fainted. Attending nurse performed a sternum rub and administered an ammonia inhalant. The client woke up pale and diaphoretic. Fire Rescue responded. Client presented hypotension, Client's vitals recovered to normal limits. Client was released to home at 4:45pm. No further evaluation needed as per Fire Rescue. |
| 1185425 | 4/9/2021 | OH | 26 | M | 4/6/2021 | 4/6/2021 | Pt experienced vasovagal syncope within 15 minutes after vaccination. Supportive care provided and pt recovered without incidence. |
| 1185489 | 4/9/2021 | NY | 32 | F | 4/9/2021 | 4/9/2021 | patient became pale and stated she was not feeling well and fainted immediately after receiving the vaccine. Patient regained consciousness immediately and was alert and oriented x 3. Recovered and was well enough to leave the clinic on her own. |
| 1185535 | 4/9/2021 | OH | 19 | F | 4/6/2021 | 4/6/2021 | Pt experienced vasovagal syncope within 15 minutes of vaccination. Supportive care provided and pt recovered without incidence. |
| 1185306 | 4/9/2021 | TN | 21 | M | 4/9/2021 | 4/9/2021 | Immediate brief episode of syncope without hitting head or injury. Monitored for 30 minutes with full recovery. |

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| 1185505 | 4/9/2021 | MI | 40 | M | 4/8/2021 | 4/8/2021 | Approximately 5 minutes after the patient received his vaccination, he rested his head on the wall behind him in the chair he was being observed in and passed out and turned white. His wife began slapping his face and screaming his name and the observer called for me. I arrived within seconds and assisted his wife in moving him from the floor to the chair. Within seconds of getting his head to the ground safely, he came back to and was very sweaty, red in the face. He stayed on the ground laying down, and then sitting for approximately 25 minutes. During that time, he told us that he had previously passed out during 3 procedures done at doctors offices. We got him an ice pack and a orange pop as he was complaining of being hot and having only eaten a granola bar all day. He was able to get up to a chair and sat there for an additional 5 minutes, before he was able to walk out on his own accord. I have spoken with the patient twice since, once last evening and once today and he reports he feels great now besides the expected body aches from the vaccination. |
| 1185207 | 4/9/2021 | WA | 30 | M | 4/9/2021 | 4/9/2021 | syncope |
| 1185494 | 4/9/2021 | FL | 26 | M | 4/8/2021 | 4/8/2021 | Site: Pain at Injection Site-Mild, Systemic: Chills-Mild, Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Flushed / Sweating-Mild, Systemic: Hypotension-Medium, Additional Details: Patient experience Syncope |
| 1185502 | 4/9/2021 | NE | 34 | M | 4/9/2021 | 4/9/2021 | -Pt fainted ~ 10 minutes after receiving vaccine while sitting in designated post vaccine waiting area -He became alert almost immediately and laid on his back for ~ 15 minutes -A cold pack was placed on this head and a pillow was supplied -He drank apple juice per his request and started feeling better -He stated he faints when he gives blood occasionally -He felt fine after ~ 30 minutes and got a ride home with a friend |
| 1185485 | 4/9/2021 | WA | 20 | M | 4/9/2021 | 4/9/2021 | dizzy, light-headed, near syncope |
| 1185258 | 4/9/2021 | CA | 24 | M | 4/9/2021 | 4/9/2021 | Patient was fainted for 15 seconds after 5 minutes of vaccine |

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| 1185182 | 4/9/2021 | FL | 77 | F | 4/7/2021 | 4/7/2021 | She got the vaccine, did not have any reaction or that she was even given a vaccine. Then around 7:00 PM her arm started to get a little sore but kept moving it and massaging it. She then could not move anything by 10:00 PM, and had gone straight to bed as she felt so bad. She was dizzy, light headed, and these symptoms continued all night and all day Thursday. She dozed to sleep off and on all day Thursday and was in so much pain, didn't have to move to have pain. She is still having some pain today, but feeling much better. She still is a little bit dizzy. Feels as if she laid down she could sleep for a long time. She has pain in her back area, her arms, her hips. She did not take anything for her reaction as was told not to take aspirin and does not use other medications. She feels exhausted and if she moves her arm too much and also her legs then they start to hurt. Getting in and out of bed is easier today, but she could not get them over the bed to get in or out on Wednesday. Her neck also hurt to turn. She had similar symptoms to when she had the COVID virus in November/December. She had been hospitalized for it twice, was informed that she had a stroke after she had passed out. |
| 1185189 | 4/9/2021 | GA | 44 | M | 4/9/2021 | 4/9/2021 | pt fainted, the pt was sitting in the chair and fell off. the pt immediately woke up after falling. the pt said he was ok. he said he just wanted to lie down. he did so for about 10 minutes and then sat back up in the chair. we said he was feeling ok. he said he fainted because he was nervous. he did not think that it was because of the covid shot. |
| 1186173 | 4/9/2021 | CO | 47 | F | 4/5/2021 | 4/6/2021 | Fainted, blacked out, for maybe a few seconds - I was alone. Whooshing in my ears, dizziness lasted appx. 15-20 minutes. I didn't think it was a big deal, but it was unusual for me to faint. I haven't fainted since I moved in 1985 because of altitude. I also had moderate body aches different from my fibromyalgia or RA symptoms. This all happened about 25 hours after I received the Johnson Johnson vaccine. I didn't think to report it until I read the news. I am fine now and don't need any help. |

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| 1185539 | 4/9/2021 | IA | 35 | M | 4/9/2021 | 4/9/2021 | patient stated he felt light headed about 5 minutes after the injection, then collapsed gently to the floor and rested there. after a few minutes he asked to sit up. with 2 peoples help he sat up. after a few more minutes he was helped to a wheel chair where he passed out for approximately 5 seconds. He had some water after that and was feeling better. He went home with a family member. |
| 1185190 | 4/9/2021 | NH | 36 | F | 4/9/2021 | 4/9/2021 | Right after receiving the Janssen vaccine, patient got dizzy then she fainted for a few seconds. Patients was in the vaccination room with a technician and a pharmacist, reported she was getting better. She was fine and fully recovered after 30 minutes plus. She also stated that the reaction is just similar to what she got when she had other vaccines (she couldnot remember what it was) |
| 1185248 | 4/9/2021 | FL | 26 | F | 4/8/2021 | 4/8/2021 | Nurse administered vaccination 1 min. later or less, client had face in steering wheel, passed out and urinating on herself. Client stated she thinks this happened because of the anxiety of getting vaccine. Client given ammonia inhaler and stabilized awaiting EMS arrival. |
| 1185257 | 4/9/2021 | | 58 | F | 4/9/2021 | 4/9/2021 | High blood pressure. Near syncope |
| 1185303 | 4/9/2021 | | 22 | M | 4/9/2021 | 4/9/2021 | Near syncope |
| 1185263 | 4/9/2021 | CA | 34 | M | 4/8/2021 | 4/8/2021 | Patient given COVID J&J vaccine and within a minute complained of being dizzy/faint. While seated, patient fainted, eyes rolled, arms and hands clonic/tonic activity which caused him to fall from chair. Doctor was able to hold on to upper back of patient as both fell to the floor. Patient hit head on carpet with not traumatic injury. 911 was called and by time of paramedic arrival the patient was alert and oriented. Patient was assited to wheelchair and taken to ED for evaluation. |

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| 1185269 | 4/9/2021 | CO | 36 | F | 4/7/2021 | 4/7/2021 | I experience Vasovagal syncope within 2 min of the J&J Jansen injection. The nurses were very nice and explain to me what it was. I got hot and sweaty and horrible tunnel vision, I almost fainted. I laid down on one of their medical beds to recover while the sweet nurse fanned me. I was observed over 30 min before leaving. I woke up yesterday and felt weird along with bodyaches, chills, joint pains, random stinging sensations throughout my body (almost like a pen prick), sporadic short headaches and muscle cramps. I left work yesterday and didn't even go in today. |
| 1185276 | 4/9/2021 | MO | 22 | M | 4/9/2021 | 4/9/2021 | Passed Out |
| 1185278 | 4/9/2021 | | 54 | F | 4/9/2021 | 4/9/2021 | syncope |
| 1185293 | 4/9/2021 | | 58 | F | 4/9/2021 | 4/9/2021 | Near syncope resolved without intervention. |
| 1185295 | 4/9/2021 | CA | 30 | M | 4/8/2021 | 4/8/2021 | Just after receiving vaccine, subject fainted for approximately 30-40 seconds. Describes feeling light headed with tunnel vision. Eye open entire time, rolled back. |
| 1185214 | 4/9/2021 | | 30 | M | 4/9/2021 | 4/9/2021 | Syncope |

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| 1186175 | 4/9/2021 | NC | 56 | F | 4/8/2021 | 4/8/2021 | U/A found EMS with 56 yo F seated in stationary vehicle, CAO x 4, c/o N/V and dizziness approx 10 mins after receiving her Covid vaccine (Johnson & Johnson). Paramedic advised that pt had initial BP of 90 mmHG systolic, 12 lead showed sinus rhythm w/o ectopy, and that he attempted ODT zofran w/o success due to pt's vomiting, all prior to EMS arrival. Pt. denied CP, abd pain, diarrhea, fever, cough, HA, syncope, neck or back pain. Pt. stated she felt SOB immediately after vomiting. All assessments/interventions as noted in rest of ePCR. GCS= 15, skin pink, warm, diaphoretic. No obvious signs of trauma. Pt. assisted from vehicle to stretcher, secured w/ straps. VS taken, WNL. Abd. soft, non-tender to palpation. Cardiac monitor showed sinus rhythm, rate of 60 bpm. Pt. actively vomited x 3 while IV access attempted and established. Pt. given 4 mg zofran IV w/ improvement in N/V. Pt requested transport for further evaluation. During transport, pt's VS remained WNL, and pt stated she was feeling better, that dizziness and nausea had stopped. Noted occasional unifocal PVC on 4 lead as well as increase of HR to 124 bpm for approx. 3 seconds during transport, then returning to baseline of sinus rhythm or sinus brady. Pt. stated she normally had a low HR and BP, and had felt palpitations in the past, but no episodes of palpitations today, including during transport. Pt. transported COLD traffic to where pt care, 12 lead, and report were transferred to RN in triage w/o incident. |
| 1186081 | 4/9/2021 | NC | 59 | M | 4/2/2021 | 4/3/2021 | FULL BODY RASH STARTING 36 HOURS AFTER VACCINATION. ONE EPISODE OF SYNCOPE AT 42 HOURS POST VACCINATION |
| 1186083 | 4/9/2021 | OH | 47 | M | 4/2/2021 | 4/2/2021 | Pt experienced vasovagal syncope within 15 minutes of vaccination. Supportive care provided and pt recovered without incidence. |
| 1186125 | 4/9/2021 | PA | 18 | F | 4/9/2021 | 4/9/2021 | Pt started to "not feel well" about 5 minutes after her first dose. She laid down on the ground before she fainted was never lost consciousness. She began feeling back to normal after 5 minutes of laying down. |

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| 1186128 | 4/9/2021 | NC | 63 | F | 4/8/2021 | 4/8/2021 | Patient is found with secondary provider reporting the patient had an episode of syncope and hypotension. Patient reports that she is hot, diaphoretic and dizzy after receiving J&J Vaccine. A 12 lead ECG is completed as noted in chart. Patient's vitals are taken as noted in chart. Patient reports that she is beginning to feel better, patient continues to be monitored by EMS. Patient is found A&O x4, flushed warm and diaphoretic. Patient has no noted neurological deficits, pupils are PERRL. No trauma is noted to patient's face. Airway is patent, respirations are as noted. No JVD is noted, trachea is midline. Patient has equal chest rise/fall, lung sounds are equal bi-laterally. Patient denies chest pain, shortness of breath. Abdomen is soft/non tender. Patient denies abdominal pain, no GI/GU Symptoms are noted. Patient has no deficits noted to extremities, pulses are strong. Patient denies covid 19 concerns, other injuries or illness. 12 lead ECG is taken showing sinus rhythm as noted in chart |
| 1186139 | 4/9/2021 | OH | 31 | F | 4/2/2021 | 4/2/2021 | Pt experienced vasovagal syncope within 15 minutes of vaccination. Supportive care provided and pt recovered without incidence. |
| 1186166 | 4/9/2021 | OH | 63 | F | 4/2/2021 | 4/2/2021 | Pt experienced vasovagal syncope within 15 minutes of vaccination. Supportive care provided and pt recovered without incidence. |
| 1186169 | 4/9/2021 | MA | 68 | M | 3/13/2021 | 4/5/2021 | Admitted to Hospital after episode of Syncope. |
| 1186020 | 4/9/2021 | FL | 21 | F | 4/9/2021 | 4/9/2021 | While waiting the 15 minutes after vaccination patient attempted to get up to go to the restroom fainted, and fell. Patient get up and seat again looking pale, sweating and skin was cold. While seated she started to heve some involuntary movements in her left arm and leg (possible seizure) for a few seconds. |
| 1186186 | 4/9/2021 | OH | 36 | M | 4/2/2021 | 4/2/2021 | Pt experienced vasovagal syncope within 15 minutes of vaccination. Supportive care provided and pt recovered without incidence. |
| 1186192 | 4/9/2021 | CA | 28 | F | 4/9/2021 | 4/9/2021 | FAINTING REACTION SYNCOPE - PATEINT REPORTS OF PREVIOUS HISTORY OF FAINTING REACTION TO NEEDLE PRICKS IN THE PAST. PATIENT WAS STABLE ABD MONITORED FOR MORE THAN 30 MINUTS |

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| 1186203 | 4/9/2021 | MI | 61 | F | 4/7/2021 | 4/8/2021 | Woke up at 5am, walked to kitchen, started sweating and then fainted. Other symptoms include swollen red arm up to her neck, swollen glands, and hard to turn neck. |
| 1186210 | 4/9/2021 | ME | 29 | F | 4/9/2021 | 4/9/2021 | Patient was sitting down and started to feel dizzy and her vision was starting to become blurry. She got up to let us know that she was having a reaction and fainted. She was awake immediately after she fell and said that she was experiencing the blurred vision still, extremely sweaty/hot flashes, and ringing in her ears. She drank some water and sat down for a little bit and started to feel better. |
| 1185179 | 4/9/2021 | PA | 68 | M | 4/9/2021 | 4/9/2021 | pt has severe syncope, during vaccine pt experienced syncopal episode doesnt remember receiving vaccine, in between receiving vaccine and transport to med obs pts wife states pt had 4 more syncopal episodes, pt transported to med obs via wheelchair, at 1100 pt sitting in wheelchair experienced another syncopal episode x20-30 seconds given ammonia inhalant and pt became arousable with ammonia inhalant alert and oriented. pt transferred with little assistance to stretcher vs taken, pt found to be hypertensive, pt instructed to lie down and further bps were taken as noted,. pt denies further symptoms no further syncopal episodes noted EMS called due to bp. 1125 EMS arrival report given to EMS personnel 1131 EMS departed VS: 1103 BP 211/127 HR 73 RR 20 O2 98 automatic Bp sitting up in bed, 1105 BP 231/146 HR 71 RR18 O2 96 lying in bed, 1110 BP 183/108 HR 69 RR 18 O2 98 1115 BP 177/101 HR 73 RR 20 O2 95 1125 BP 176/107 HR 74 RR 18 O296 |
| 1184068 | 4/9/2021 | MA | 17 | F | 4/8/2021 | 4/8/2021 | Systemic: Abdominal Pain-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Nausea-Mild, Additional Details: Patient lost of consciousness for a few second after received the vaccine. She was feeling better with taking rest and hydrating with water. Patient's father reports this has happened with vaccination in the past. Vitals signs@12:30pm: BP 110/60; HR 72; O2 Sat 99%. One tablet of 25mg Benadryl was given to patient. |

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| 1186147 | 4/9/2021 | NV | 47 | F | 3/24/2021 | 3/25/2021 | 03/25 - day after shot, developed calf tightness, weakness, chills, shortness of breath, and headache. discomfort continued for several days. 04/05 - SOB continues to increase, patient experienced lightheadedness and passed out without losing consciousness. 04/06 - continues to have increasing SOB, fainted and lost consciousness. 04/08 - ultrasound done to leg, found DVT, sent to ER |
| 1185946 | 4/9/2021 | OH | 42 | F | 4/2/2021 | 4/2/2021 | Pt experienced vasovagal syncope within 15 minutes of vaccination. Supportive care provided and pt recovered without incidence. |
| 1185889 | 4/9/2021 | OH | 19 | F | 4/2/2021 | 4/2/2021 | Pt experienced vasovagal syncope within 15 minutes of vaccination. Supportive care provided and pt recovered without incidence. |
| 1185894 | 4/9/2021 | WA | 48 | M | 4/8/2021 | 4/8/2021 | About 20 seconds after shot patient became dizzy, sweaty and labored breathing. He then told pharmacist that he had Covid in may of 2020. He then fainted and lost bladder control. The EMT's were called and about 45 minutes later his vital signs were normal and patient left under his own power. |
| 1185899 | 4/9/2021 | MA | 19 | M | 4/9/2021 | 4/9/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Medium |
| 1185909 | 4/9/2021 | | 39 | F | 4/9/2021 | 4/9/2021 | PATIENT FAINTED AND HAD A 20SEC SEIZURE SEVERAL MINUTES AFTER RECIEVING VACCINE. PATIENT HAD EXTREME ANXIETY ABOUT BEING VACCINATED BEFORE HAND AS WELL AS HAD NOT EATEN DAY OF. PATIENT SYMPTOMS SUBSIDED AND HSOPITLIZATION WAS NOT REQUIRED. |
| 1185913 | 4/9/2021 | OH | 35 | F | 4/8/2021 | 4/8/2021 | Systemic: Confusion-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Additional Details: The patient fainted within 5 minutes of getting the vaccination. When she regained consciousness, she stated that she tends to pass out after contact with needles and it has happened several times previously. |
| 1185918 | 4/9/2021 | OH | 33 | F | 4/2/2021 | 4/2/2021 | Pt experienced vasovagal syncope within 15 minutes of vaccination. Supportive care provided and pt recovered without incidence. |

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| 1186067 | 4/9/2021 | OH | 47 | M | 4/2/2021 | 4/2/2021 | Pt experienced vasovagal syncope within 15 minutes of vaccination. Supportive care provided and pt recovered without incidence. |
| 1185937 | 4/9/2021 | | 48 | F | 4/9/2021 | 4/9/2021 | post vaccine syncope. no history of syncope with vaccines or blood draws. pt reports lightheadedness within minutes of vaccine and they passed out when transferred to chair. Given juice. Quickly felt better. |
| 1186060 | 4/9/2021 | IL | 21 | F | 4/8/2021 | 4/8/2021 | Received vaccine and ambulated over to the observation area where she started feeling dizziness and nausea and then felt faint prior to fainting. Treated with ondansetron and IV fluids. Was discharged once symptom free and able to tolerate fluids without vomiting. |
| 1185947 | 4/9/2021 | FL | 45 | F | 4/7/2021 | 4/8/2021 | Headache, nausea, weakness, and fainted the next evening |
| 1185952 | 4/9/2021 | CA | 33 | F | 4/9/2021 | 4/9/2021 | Near syncope, low blood pressure |
| 1185954 | 4/9/2021 | FL | 54 | F | 4/7/2021 | 4/7/2021 | Around 10pm on 4/7 I felt a sudden onset of body aches. I had similar symptoms after the first vaccine so I knew this was an expected side effect and decided to take two Tylenol 500mg and go to bed. I had a restless night with pain on the injection site, chills, and severe body aches. At 8:30am on 4/8, I got out of bed and still feeling sick, thought of taking Tylenol again. I didn't want to take medication on an empty stomach so I took two sips of milk and coffee and two bites of a cookie, when I started feeling severe nausea. It was a very strong nauseous sensation. I started sweating. I stood up from the table to take the cup to the sink and my vision turned partially black. I thought I had stood up too quickly, so I sat down again. I walked back to the table and sat down. I felt I was losing control of my body. I stood up again with the intention of going back to bed, and started walking towards my bedroom. I told my husband that I was seeing all black. I don't recall what happened next. My husband says that he was asking me if I was alright but didn't answer. He walked towards me and I fainted against the pantry door and he was able to hold me. I lost consciousness for a few seconds. Paramedics came and took me to emergency room. I was released 2 hours later. Had a fever of 100.4C in the afternoon with chills and body aches. |

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| 1185959 | 4/9/2021 | NC | 25 | F | 4/7/2021 | 4/7/2021 | BEFORE VACCINE ADMINISTRATION, PATIENT STATED THAT HE HAS A PHOBIA TOWARDS RECEIVING SHOTS. ALMOST IMMEDIATELY AFTER VACCINE, PATIENT REPORTING FEELING LIGHT-HEADED. HE SAT DOWN IN A CHAIR FOR 5 MORE MINUTES. ONE PATIENT TRIED TO GATHER HIMSELF AND WALK TO THE PHARMACY EXIT, HE PASSED OUT AND FELL FORWARD INTO THE ARMS OF THE PHARMACIST MANAGER AND VACCINATOR. HE WAS AGAIN PROVIDED WITH A CHAIR, SOME WATER, AND A COLD TOWEL. HE RECOVERED ABOUT 15 MINUTES LATER. |
| 1186013 | 4/9/2021 | OH | 21 | M | 4/2/2021 | 4/2/2021 | Pt experienced vasovagal syncope within 15 minutes of vaccination. Supportive care provided and pt recovered without incidence. |
| 1185558 | 4/9/2021 | | 56 | M | 4/9/2021 | 4/9/2021 | Vasovagal Syncope that resolved |
| 1185928 | 4/9/2021 | NY | 35 | F | 4/9/2021 | 4/9/2021 | Systemic: Fainting / Unresponsive-Severe, Systemic: Seizure-Severe |
| 1184212 | 4/9/2021 | CA | 32 | M | 4/8/2021 | 4/8/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Shakiness-Medium, Additional Details: Patient sat down after vaccine and became dizzy. He laid down and fainted but regained consciousness. He was sweating profusely and could not speak well. This lasted about 10 minutes. BP was measured at 150/71 with a pulse of 71. He drank some gatorade and was monitored for 30 minutes and was able to leave. |
| 1184114 | 4/9/2021 | NY | 28 | M | 4/8/2021 | 4/8/2021 | Site: Pain at Injection Site-Mild, Systemic: Fainting / Unresponsive-Medium, Systemic: Fainted due to fear of needles-Medium, Additional Details: Patient has fear of needles and passed out after administration- EMS called to assess him and he was cleared to go home. No pain at injection site, no adverse effects from vaccine |
| 1184129 | 4/9/2021 | | 26 | M | 4/9/2021 | 4/9/2021 | near syncope / vaso vagal |
| 1184171 | 4/9/2021 | NJ | 40 | F | 4/1/2021 | 4/1/2021 | Immediate feeling of fainting 5 minutes after administration. Later in the day the following symptoms: nausea, fatigue, fever, severe chills, stomach pains. |

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| 1184178 | 4/9/2021 | CA | 25 | M | 4/8/2021 | 4/8/2021 | Systemic: Chills-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Mild, Systemic: Hypotension-Severe, Systemic: Shakiness-Severe, Systemic: Weakness-Medium, Additional Details: Within 15 minutes of receiving the vaccine, pt BP dropped to 97/47 and 37 BPM. Pt was put to lay down on their back with their feet elevated, and their BP and BPM returned to normal levels. Within 15 min from then, pt complained of feeling chills and was strongly shaking. 911 was called w/ pt and relative consent. Pt later left home, returning to normal. Seemed like vasovega response |
| 1184187 | 4/9/2021 | FL | 22 | F | 4/8/2021 | 4/8/2021 | Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Severe, Systemic: Weakness-Severe, Additional Details: Patient was give vaccine and fainted a couple minutes after sitting |
| 1184284 | 4/9/2021 | LA | 31 | M | 4/8/2021 | 4/8/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Additional Details: about 1-3 mins after patient received vaccine said he felt dizzy and lightheaded then he passed out and hit his head on table and floor. patient came back conscious quickly and i helped him get to his feet and back to a seated position. an ambulance was called immediately. they checked him out and he refused ride to hospital. |
| 1184205 | 4/9/2021 | | 38 | M | 4/8/2021 | 4/8/2021 | Complaints of spotty vision and tingling in hands. Approximately 5 mins after receiving Janssen vaccine. Suddenly patient became pale but did not have loss of consciousness, During evaluation tingling sensation included abdomen and chest area. Denied facial swelling, throat/lip swelling, difficulty breathing, shortness of breath or difficulty swallowing. Able to take water at 4:38 pm. Tingling in abdomen or chest resolved at 4:45 pm. Tingling in hands resolved at 4:50 pm 1630: BP 131/78, Pulse 108, RR 12 O2 Sat 98% 1650: BP 134/86, Pulse 108, RR 12, O2 Sat 97% Medical history of anxiety/depression, has fainted with needles in the past |
| 1184081 | 4/9/2021 | IL | 18 | M | 4/8/2021 | 4/8/2021 | dizziness/light headed, cold, clammy and sweating in face, fainted, then vomited. Occurred 4 hours after shot was given. |
| 1184223 | 4/9/2021 | | 51 | F | 4/9/2021 | 4/9/2021 | syncope |

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| 1184235 | 4/9/2021 | NC | 38 | M | 4/8/2021 | 4/8/2021 | fainted |
| 1184248 | 4/9/2021 | CA | 34 | M | 3/31/2021 | 3/31/2021 | Systemic: Fainting / Unresponsive-Mild |
| 1184254 | 4/9/2021 | MD | 26 | M | 4/8/2021 | 4/8/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Nausea-Mild, Systemic: Vomiting-Mild, Additional Details: After administration of vaccine, patient was still seated in the waiting area. I went back and checked on him after 5mins of waiting, then came back to the pharmacy. But heard a big bang shortly after. Some how, he had fallen out of his chair and bumped his head and neck on an end camp. He seemed a little confused, when I ran over, but was awake, a little sweaty and nauseated. EMS was called. They transported him to ER to have his head checked, since he bumped it. |
| 1184261 | 4/9/2021 | GA | 29 | F | 4/8/2021 | 4/8/2021 | Systemic: Chills-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Medium, Systemic: Fever-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Hypotension-Medium, Systemic: Shakiness-Medium, Systemic: Weakness-Medium, Additional Details: Shortly after administration of the vaccine (~3 min) pt started shaking, sweating, looking flushed, feeling clammy, dizziness, lightheaded and briefly fainted. Pt was put on the floor and legs were elevated, given water and a snack and started feeling better. 911 was called and an evaluation was done. |
| 1184091 | 4/9/2021 | MI | 29 | M | 4/8/2021 | 4/8/2021 | Systemic: Fainting / Unresponsive-Severe |
| 1184202 | 4/9/2021 | CA | 56 | M | 4/8/2021 | 4/8/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: pt w/ needle-phobia and hx of vasovagal response following injections, blood draws in past. fainted 1 min following vax (1st dose). was still in immunizing chair, and was unresponsive x 10 sec. pt then awoke and was able to move to observation area x 15 min w/o issue. provided water, and pt's daughter was present w/ him the entire time. pt was educated and to alert future immunizers of potential for reaction. |

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| 1183999 | 4/9/2021 | NC | 80 | F | 2/14/2021 | 3/1/2021 | No memory; Passed out; Hallucination; lost feeling in her legs; incontinent of urine and feces; Had a terrible fall; Never able to walk, she crawled; Bruises all over body; urinary tract infection; Severely dehydrated; Legs felt weak; emotionally distraught; A Spontaneous report received from a physician concerning a 80-year-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced weakness in legs/muscular weakness , legs felt weak / hypoaesthesia , fall , never able to walk so she scrawled /gait inability , hallucination ,passed out / loss of consciousness , bruising / contusion ,urinary tract infection , dehydration , emotionally distraught/emotional distress, memory loss /amnesia. The patient's medical history was not provided. concomitant product used not provided by reporter. On 14-feb-2021, the patient received their first of two planned doses of mRNA-1273 (batch no: 031L21A) via unknown route for prophylaxis of COVID-19 infection. On 01-mar-2021, the patient experienced muscular weakness (legs felt weak). On 03-mar-2021, the patient experienced fall (had a terrible fall), gait inability (never able to walk, she crawled) and contusion (bruises all over body). On 05-mar-2021, the patient experienced loss of consciousness (passed out) (seriousness criteria hospitalization and medically significant) and hallucination (hallucination) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced urinary tract infection (urinary tract infection), dehydration (severely dehydrated), amnesia (no memory) and hypoaesthesia (lost feeling in her legs). The patient was hospitalized on 05-Mar-2021 due to hallucination and loss of consciousness. No treatment information was provided. The outcome for the events, loss of consciousness (passed out), hallucination (hallucination), fall (had a terrible fall), gait inability (never able to walk, she crawled), contusion (bruises all over body), urinary tract infection (urinary tract infection), dehydration (severely dehydrated), emotionally distraught/emotional distress, amnesia (no memory) and hypoaesthesia (lost feeling in her legs) was not reported. The action taken with mRNA-1273 in response to the event was not reported.; Sender's Comments: Very limited information regarding these events has been provided at this time. The events are probably related to the patient's comorbidities |

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| 1183529 | 4/9/2021 | | 32 | F | 4/8/2021 | 4/8/2021 | Fainted, regained ambulation in 25 minutes |
| 1183539 | 4/9/2021 | MD | 42 | F | 4/6/2021 | 4/6/2021 | Immediately after injection, there was a feeling of being warm and lightheaded within a minute after sitting in the waiting area. As I have had a history of low blood pressure and feeling lightheaded and occasionally fainting after injections during adolescence, I monitored my symptoms to see if they were progressing. However, those symptoms seemed to dissipate after 5 minutes. Then arm soreness started within 10 minutes after injection and worsened over the course of the day. As pain began, arm was rotated and moved around which seemed beneficial in improving the discomfort. As the level of arm soreness seemed moderate and tolerable, there was no additional treatment besides moving and stretching the arm. The arm soreness was However, when trying to go to sleep more than 12 hours after injection, the arm pain was problematic enough to prevent sleep. I then shifted my weight onto the arm that received the injection which seemed to alleviate the soreness and was then able to fall asleep. The arm soreness was still there the next day but less noticeable and more tolerable. |
| 1183560 | 4/9/2021 | PA | 20 | F | 3/21/2021 | 3/21/2021 | On 3/21, 10 hours after shot 101 fever. 11 hours after shot fainted Fever for 24 hours 36 hours after shot developed swollen lymph nodes in neck that lasted 4 days |

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| 1183596 | 4/9/2021 | CO | 50 | F | 3/26/2021 | 3/26/2021 | At 12 hours through 16 hours after administration of the vaccine I experienced rigorous shivers, feeling freezing cold to the bone for hours and couldn't get warm (even with piles of blankets), periodic heart pain and some chest pressure, periodic knife like stabbing pain in my right knee, mild nausea, dizziness, lightheadedness, severe weakness, sometimes a cough. At 16 hours I got up to get water and had to hold onto things to keep my balance. After drinking a couple of cups of water, I turned away from the bathroom sink and lost consciousness, fainting and falling onto my bathroom floor. The jolt of the fall woke me up and it took a lot of strength to get up. The symptoms were vicious. When I fainted, the brunt of my weight must of been on my upper left rib cage. My ribs were so sore for a week. It was difficult to walk, breath, blow my nose, or cough. My health provider recommended a Tylenol regime for pain control so that I could take deep breaths and prevent pneumonia. I had a low grade fever of 99 degrees F for one to two days following the vaccine. During the week that followed I felt periodically very ill, had a constant headache for a day or two, and had extremely foggy thinking and sometimes confusion. I was very fatigued all week long. I lost my appetite and have still not gained my typical appetite back. Day 8 to 9 is when I was finally feeling closer to normal. Today I feel I may be back to 100%, but my rib cage is still healing, either from a contusion, fracture, or break (likely a contusion). |

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| 1183800 | 4/9/2021 | NY | 59 | F | 2/13/2021 | 3/15/2021 | Sodium levels dropped dangerously low; Passed out; Dizzy; Hit my head; Headachy; This spontaneous case was reported by a consumer and describes the occurrence of blood sodium decreased (Sodium levels dropped dangerously low) and loss of consciousness (Passed out) in a 59-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 015M20A and 038A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event. Concomitant products included FEXOFENADINE HYDROCHLORIDE (ALLEGRA) and CALCIUM CARBONATE, COLECALCIFEROL (VITAMIN D 2000) for an unknown indication. On 13-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 15-Mar-2021, the patient experienced (Sodium levels dropped dangerously low (seriousness criterion hospitalization), Passed out (seriousness criterion medically significant), dizzy, Hit my head and Headache. The patient was hospitalized from 24-Mar-2021 to 26-Mar-2021 due to BLOOD SODIUM DECREASED. At the time of the report, BLOOD SODIUM DECREASED (Sodium levels dropped dangerously low) was resolving and LOSS OF CONSCIOUSNESS (Passed out), DIZZINESS (Dizzy), HEAD INJURY (Hit my head) and HEADACHE (Headachy) outcome was unknown. Treatment medication included intravenous sodium.. She was being monitored through blood samples and she was fine on 29 Mar 2021, she will have to do it one more time in a week.; Sender's Comments: Based on the current available information and temporal association between the use of the product and onset of the events of blood sodium decreased, loss of consciousness, dizziness, and headache, a causal relationship with the events cannot be excluded. Head injury was due to dizziness. Headache is consistent with the product safety profile. |

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| 1183807 | 4/9/2021 | CA | 45 | F | 3/3/2021 | 3/31/2021 | Fainted twice; Soreness of right arm; Sweating; Feeling chills; This spontaneous case was reported by a consumer and describes the occurrence of SYNCOPE (Fainted twice) in a 45-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 030B21A and 029A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No medical history was reported.). Concomitant products included THYROID for an unknown indication. On 03-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 31-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 31-Mar-2021, the patient experienced SYNCOPE (Fainted twice) (seriousness criterion medically significant), PAIN IN EXTREMITY (Soreness of right arm), HYPERHIDROSIS (Sweating) and CHILLS (Feeling chills). At the time of the report, SYNCOPE (Fainted twice), PAIN IN EXTREMITY (Soreness of right arm), HYPERHIDROSIS (Sweating) and CHILLS (Feeling chills) outcome was unknown. Treatment for the event included acetaminophen. Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded. |

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| 1184111 | 4/9/2021 | NM | 46 | M | 4/5/2021 | 4/5/2021 | Site: Pain at Injection Site-Medium, Systemic: Cardiac Disorder (diagnosed by MD)-Severe, Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Headache-Medium, Systemic: Tachycardia-Medium, Additional Details: PT HAD FLUSHING AT 9 PM HEADACHE AND PASSED OUT FRACTURING HIS MANDIBLE IN PROCESS. PT HAD ATRIAL FIBRILLATION PT IS IN STABLE CONDITION ON DILTIAZEM HAD NO HX OF HEART DISORDERS PRIOR TO VACCINE |

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| 1183919 | 4/9/2021 | MS | 55 | M | 3/23/2021 | 3/23/2021 | passed out; busted head; bruised/broke elbow/dont know if it chipped elbow or just bruised; about 1 hr after shot my stomach started feeling upset; had diarrheas' and gas; had diarrheas' and gas; This is a spontaneous report from a contactable consumer (Patient). A 55-year-old male patient received bnt162b2 (Solution for injection, PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in right arm on 23Mar2021, 12:30 (Lot Number: EP7534) as single dose for Covid-19 immunisation (age at vaccination was 55 years). Medical history included high blood pressure (controlled with RX). There were no known allergies. No other vaccine was received in four weeks. Patient received other medications in two weeks. Historical vaccine included bnt162b2 (Solution for injection, PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in right arm on 02Mar2021, (Lot Number: e19266) as single dose for Covid-19 immunisation (age at vaccination was 55 years). On 23Mar2021, the patient about 1 hour after shot her stomach started feeling upset and she stopped at a rest area, had diarrhea and gas. This continued some through the evening. On 24Mar2021 (The next day), while outside with her friend, she passed out, ended up with a busted head and bruised/broke elbow/don't know if it chipped elbow or just bruised. She could feel it was coming on but then it started to pass, and the next thing was that she woke up in her driveway. No treatment received for events. No covid prior vaccination and no covid tested post vaccination was reported. The outcome for all the event(s) was recovering. No follow-up attempts are possible. No further information is expected. |
| 1186237 | 4/9/2021 | AL | 45 | U | 4/9/2021 | 4/9/2021 | Lightheaded sensation, nausea, sweating, normal HR, O2, BP, no fainting/vasovagal concerns; drank water and used a cool washcloth on her neck, rested and felt better. Was observed x 30 minutes. No SOB/HIVES/STRIDOR/SWELLING. |
| 1184029 | 4/9/2021 | CA | 21 | M | 4/8/2021 | 4/8/2021 | Systemic: Fainting / Unresponsive-Severe, Systemic: Shakiness-Medium, Systemic: Tachycardia-Severe, Systemic: Tingling (specify: facial area, extremities)-Severe, Additional Details: Pt said he was feeling tingling in arms and legs |

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| 1184031 | 4/9/2021 | GA | 30 | M | 4/8/2021 | 4/8/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: Seizure-Medium, Additional Details: THE PATIENT FELL FROM A CHAIR IN THE POST-VACCINATION AREA AND WAS FACE-DOWN, NOT RESPONSIVE. THE PATIENT WAS TURNED ON HIS BACK WHEN HE BEGAN TO SEIZE, SO HE WAS PLACED ON HIS SIDE. HE RECOVERED AND OPENED HIS EYES SHORTLY THEREAFTER. HIS BP WAS 120/59 MMHG, AND HE WAS PROVIDED CRACKERS AND WATER. THIS PATIENT DENIED ANY EPISODES LIKE THIS IN THE PAST BUT ALSO DENIED HAVING BREAKFAST THIS MORNING. THE PHARMACIST RECOMMEND FOLLOWING UP WITH HIS PCP, AND A RELATIVE PICKED HIM UP FROM THE CLINIC. |
| 1184055 | 4/9/2021 | TX | 29 | F | 4/8/2021 | 4/8/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient was in observation area and fainted while seated in chair. Patient recovered and stated that she forgot to inform us that sh faints after injections or drawing blood.. Patient stated she was afraid of needles. EMSwas called Patient left with husband before EMS arrived. |
| 1184058 | 4/9/2021 | NY | 45 | M | 4/8/2021 | 4/9/2021 | Fainted at 445 am |
| 1186243 | 4/9/2021 | NJ | 20 | M | 4/9/2021 | 4/9/2021 | In 15 minute observation area, Passed out, fell off chair, had some shaking, difficult to rouse, hit head on floor and got a small cut, was taken on stretcher to private area, vitals taken every 10 minutes, released in 30 minutes. He still feels off, several hours later. Incident wasn?t documented at site. |
| 1184298 | 4/9/2021 | MA | 19 | F | 4/8/2021 | 4/8/2021 | Systemic: Fainting / Unresponsive-Medium |

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| 1183893 | 4/9/2021 | CA | 27 | M | 3/30/2021 | 3/30/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Hypotension-Mild, Systemic: Visual Changes/Disturbances-Mild, Additional Details: pt fainted while sitting down 10 mintues after vaccine and hit his head. RN assessed-weak pulse, blurred vision. BP was stabalized at 110/797, hr 72, o2 sat 98%. 911 was notified because he hit his head. Pt was suggested for CT for head injury but signed himself AMA from the paramedics. Pt's said friend would take him to ER. Followed up next day- CT scan clear. Pt is fine. |
| 1184873 | 4/9/2021 | WI | 35 | M | 4/9/2021 | 4/9/2021 | Patient received first Moderna vaccine this morning. Immediately after walking to the waiting room, patient fainted, fell backwards to the floor and hit his head on the corner of a desk and trash can. Patient came to, and shortly after loss consciousness again. When patient came to, this RN kept him talking and moving his feet. Patient reported he has fainted from giving blood before. Patient taken back to private room with code team. He was then taken to a higher level of care. |
| 1184719 | 4/9/2021 | AZ | 43 | F | 3/26/2021 | 3/26/2021 | IMMEDIATE METALLIC TASTE IN MOUTH RIGHT AFTER VACCINE. THE FOLLOWING DAY WOKE UP STILL WITH TASTE BUT HAD A FAINTING SPELL AROUND 9AM THEN ANOTHER AROUND 530PM. THE METALLIC TASTE LAST LIKE 5 DAYS BUT THE FAINTING SPELLS HAVE CONTINUED SINCE. HAVE DECIDED TO SET UP APPOINTMENT WITH A FAMILY DOCTOR DONT KNOW IF ITS NORMAL FOR THIS TO BE ONGOING. |
| 1184751 | 4/9/2021 | NJ | 41 | F | 4/9/2021 | 4/9/2021 | Patient received her first dose of the Pfizer/BioNTech today at 0850. She reports intense dizziness and syncope soon after (5 minutes after) at the location where she received it. She was bought to the ER by EMS and received some continuous NS via IV by medics which she reports helped her feel normal again. |

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| 1184753 | 4/9/2021 | IL | 23 | F | 4/9/2021 | 4/9/2021 | Patient had a vasovagal response to the needle after being vaccinated with the Pfizer -Biontech vaccine dose #1.. EMS personnel were at the site, she was given the appropriate care. Patient's vitals were Pulse ox read 99% in room air, heart rate 72,blood pressure 128/86. Patient was awake and alert. after few seconds of the syncope spell. . No signs of head trauma ,denies, head and neck pain. Small abrasion noted on nasal bridge no bleeding noted. Patient was observed for an hour. Patient went home in stable condition. |
| 1184767 | 4/9/2021 | NH | 38 | M | 4/9/2021 | 4/9/2021 | Patient passed out within a couple minutes of injection, had seizure like activity, was sweating. He was alert shortly after. Ambulance came and took the patient |
| 1184818 | 4/9/2021 | WI | 34 | F | 3/31/2021 | 3/31/2021 | within 10 minutes of the injection, my vision blurred and felt like I was going to faint. the next day, I had severe anxiety attacks due to the overwhelming sensation of fainting. I never lost consciousness or fainted, but I feel that I was very close to it. |
| 1184279 | 4/9/2021 | CA | 25 | M | 4/8/2021 | 4/8/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Hypertension-Mild, Additional Details: 12:20pm\r\n24/Male fainted after administration of Janssen vaccine. No other symptoms noted. Had patient sit on the floor and elevate legs. Assessed for anaphylaxis, epinephrine was not indicated.\r\n12:24pm BP 140/75 (unsure of patients baseline, no diagnosis of hypertension). Ambulance was called. When ambulance arrived patient felt better. May have just been nervous due to needle itself, not COVID vaccine. followed up with patient 4:20pm and he states he feels perfectly normal now. |
| 1184868 | 4/9/2021 | IL | 18 | F | 4/9/2021 | 4/9/2021 | Patient fainted within minutes after receiving vaccine. Fell out of chair and blacked out. She woke up immediately but felt very confused and shakey. 911 was called and vitals were taken by EMTs. Patient was picked up by her parents. |
| 1184611 | 4/9/2021 | | 35 | F | 4/9/2021 | 4/9/2021 | Near syncope |

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| 1184953 | 4/9/2021 | TX | 39 | F | 4/1/2021 | 4/2/2021 | I was sick for 6 day straight, flue like symptoms. fever for 3 days diarrhea for 5 days on my 3rd day nausea to the point of fainting and didn't know if i was going to throw up or more diarrhea. My body wouldn't allow me to do either for hours until the evening when I got fever and diarrhea again. Body aches and headaches for 5 days. chills like i was freezing in the evenings. it was absolutely horrible! |
| 1184954 | 4/9/2021 | OR | 48 | F | 3/25/2021 | 3/26/2021 | I had the usual flu symptoms and then about 12 hours after the second shot I was up in the night to find an Advil and two minutes later I fainted. This was not a result of getting up too fast. In the subsequent two weeks, I have had two episodes of feeling weak at the knees, like it is happening again. I had never fainted before this. |
| 1184998 | 4/9/2021 | GA | 20 | F | 4/9/2021 | 4/9/2021 | Gave patient the vaccine approximately 9:50am. Shortly after giving the vaccine, patient fainted in her chair. Patient said she was fine, however, she fainted afterward again. We did get the patient to lie down on the floor while we call 911. EMS responders arrived and assessed her, patient did refuse to go to the hospital. We did monitor her for 45 minutes before she left our facility with her friend. |
| 1185091 | 4/9/2021 | FL | 18 | F | 4/8/2021 | 4/8/2021 | The Pfizer shot was given at 1:30. We shopped at the store for 15 minutes (they didn't have a waiting area to sit down). We left the store. As I (her mother) was driving home she passed out and her head almost hit the dashboard. I grabbed her head and pulled into a parking spot. She was white as a ghost. I called 911. The ambulance arrived 6-8 minutes later. She was speaking incoherently to the paramedics and her blood pressure was extremely low. They transported her to the Medical Center. Her blood pressure was monitored and she was given a bag of fluids. We were there over 2 hours before she was released. They said it was Vasovagal Syncope and the paramedic said he had a few similar calls shortly after the Covid-19 shot had been administered (I hope they are all reporting it). A friend of ours called us and told us his daughter passed out after the Pfizer shot just last week. She was at (college in out of state) and got her shot there. They didn't report it or anything. I think this needs to be looked into. Especially in regards to younger people. |

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| 1185124 | 4/9/2021 | TN | 34 | M | 4/8/2021 | 4/8/2021 | Patient passed out shortly after vaccination, patient fell to floor and hit his head, he was immediately attended to, patient had legs elevated and was monitored and evaluated for 45 minutes. |
| 1185148 | 4/9/2021 | WA | 61 | M | 4/9/2021 | 4/9/2021 | Soon after shot felt sweaty - dizzy - that is all he remembers. States he was very nervous on arrival and does not like needles. Patient observers states they noticed patient coughing and then he passed out. |
| 1184820 | 4/9/2021 | IA | 33 | M | 4/8/2021 | 4/8/2021 | After vaccine he reported being nauseous and dizzy. He got very pale and about 5 minutes after the vaccine he passed out. He came back after about a minute. EMT was called to check patient. Vitals were stable. |
| 1184514 | 4/9/2021 | MD | 52 | F | 4/5/2021 | 4/5/2021 | Once vaccinated, walked to seating area and fainted while sitting down. Then 5 minutes later started vomiting which continued for 5 hours. Than normal side effects for 2 days (headache, nausea) |
| 1184311 | 4/9/2021 | TX | 34 | M | 4/8/2021 | 4/8/2021 | Systemic: Fainting / Unresponsive-Mild |
| 1184352 | 4/9/2021 | IA | 53 | F | 4/8/2021 | 4/8/2021 | Syncope patient had her first Covid vaccination today waited 15 minutes stood up to leave and had a syncopal event she really did not have any prodrome with this she was not aware of feeling nauseated and awoke on the floor. She did not strike her head. On awakening she had chest pain that is typical of her known coronary artery disease and she presents here by ambulance for further evaluation. Patient does have periodic angina although this is been worse pain and longer duration than is typical for her. Patient had her last stenting done in late 2020. Transported to hospital for evaluation. Troponin and EKG negative. Discharged to follow up with cardiologist. |
| 1184353 | 4/9/2021 | GA | 44 | F | 4/7/2021 | 4/7/2021 | After vaccination, patient passed out in observation area. Patient diaphoretic, pale, hypotensive and bradycardic. Heart rate in the 40s and EMS called by nurse. Patient evaluated by EMS, but patient decided against transport. |

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| 1184385 | 4/9/2021 | CA | 36 | M | 4/8/2021 | 4/8/2021 | Site: Pain at Injection Site-Mild, Systemic: Allergic: Rash Generalized-Medium, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Shakiness-Mild, Systemic: Weakness-Mild, Additional Details: Pt fainted after a couple minutes after vaccine administration. We were able to assist him down to the floor. Pt regained consciousness within a minute. Shortly after, we noticed a rash. Gave pt 50mg benadryl. Paramedics called. They checked pt's blood pressure and pulse. All were normal. |
| 1184438 | 4/9/2021 | NY | 34 | F | 4/7/2021 | 4/7/2021 | PATIENT FAINTED ABOUT 1 MINUTE AFTER RECEIVING THE VACCINE. SITTING IN CHAIR, SLUMPED FORWARD AND HIT FACE ON THE FLOOR. PATIENT REGAINED CONSCIOUSNESS SHORTLY THEREAFTER AND WAS MONITORED FOR 45 MINUTES BEFORE LEAVING WITH HER BOYFRIEND WHO SAID SHE WAS OK. I CONTACTED PATIENT LATER IN THE DAY, AND SAID SHE IS OK BUY MAY HAVE TO BE CHECKED FOR A BROKEN NOSE |
| 1184455 | 4/9/2021 | WA | 29 | M | 4/8/2021 | 4/9/2021 | Fainting, fever, headache, body aches |
| 1184686 | 4/9/2021 | UT | 22 | F | 4/8/2021 | 4/8/2021 | fainted. she faints with most shots however. about 5 minutes after shot |
| 1184486 | 4/9/2021 | | 30 | F | 4/9/2021 | 4/9/2021 | Seven minutes after receiving the vaccine client began to convulse followed by syncope. EMS was called. Client was caught before she fell. and stabilized shortly after. She states "this is something that happens to her regularly bc she has a fear of needles." Vitals taken are as follows BP 176/123, SPO2 99%, pulse 74. |

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| 1184672 | 4/9/2021 | NC | 47 | M | 4/8/2021 | 4/8/2021 | PATIENT LOOKED AT WIFE AND SAID I DON'T FEEL RIGHT, AS I WAS CALLED BACK TO THE CAR HIS HEAD BEGAN TO ROLE FORWARDS, THEN IN A CIRCULAR MOTION. HIS EYES ROLLED BACK IN HIS HEAD AND HE MADE A GASP FOR BREATH THEN PASSED OUT. EPI PEN WAS IMMEDIATELY ADMINISTERED. PATIENT BECAME MORE RESPONSIVE, LAID SEAT BACK IN CAR. PATIENT SWEATING , COULD NOW SPEAK TO ME BUT STILL SOMEWHAT DISORIENTED. VERY FAINT PULSE. 911 WAS CALLED AND COOL WET PAPER TOWEL PLACED ON HIS NECK AND OBSERVED UNTIL 911 ARRIVED WITHIN 5-10 MINUTES. PATIENT TRANSPORTED TO ER DUE TO VERY LOW PULSE EVEN AFTER EPI ADMINISTRATION. PATIENT REMAINED AT ER UNTIL 1:30 PM FOR MONITORING. THEY TRULY FELT IS WAS A VASOVAGUL REACTION. PATIENT WAS OUTSIDE WORKING IN YARD AT 6:30PM WHEN I CALLED TO CHECK ON HIM, HAS NO RECOLLECTION OF RECEIVING SHOT OR EPI PEN, JUST SAID HE REMEMBERS MEDICINE FEELING "HOT" GOING DOWN HIS ARM. |
| 1184537 | 4/9/2021 | WA | 35 | F | 4/8/2021 | 4/8/2021 | 20 weeks pregnant (due Aug 23) Within five minutes strong vasovagal response, blood pressure significantly dropped, dizziness, nausea, extreme sweating, threw up, nearly passed out. Recovered enough to go thirty minutes later. Around 12:30am that night woke with chills, body aches, which eventually turned to fever and body aches which lasted until tylenol administration. |
| 1184559 | 4/9/2021 | PA | 22 | F | 4/7/2021 | 4/8/2021 | I felt fine immediately following my shot, as well as the rest of the day. Overnight I started developing a fever which I knew was normal. However at 3 am I got up to use the restroom. I was sitting on the toilet and then next thing I remember I was on the floor with my face down. I passed out, and I am unsure how long I was out for, before I realized what happened. I have never passed out before, and do not have a history of doing so, so it is unclear why I passed out randomly. |

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| 1184580 | 4/9/2021 | FL | 26 | F | 4/8/2021 | 4/8/2021 | Pt. stated, "I felt fatigue, like fainting, 5 minutes after getting vaccinated." Vital signs taken, BP 108/67, HR 81, O2Sat 100%, R 18. At 3:30pm, pt. reported feeling better, fatigue is almost gone. At 3:55pm pt. stated, "I feel better, I think I'm good to go home." At 3:37pm pt. went home with family member. |
| 1184586 | 4/9/2021 | UT | 29 | M | 4/3/2021 | 4/3/2021 | Fainted/fell unconscious in chair immediately after injection. Out for 20 seconds or so. Reportedly stiff as a board and twitchy. No significant history of fainting. |
| 1184602 | 4/9/2021 | NJ | 28 | F | 4/6/2021 | 4/6/2021 | Patient received Pfizer vaccine on 4/6 at the Clinic Site out of allocated doses from 1582. She received vaccination, waited 15 minutes in one of the waiting room chairs, and while departing the facility fainted and fell into her significant other's arms. They were on the sidewalk and he brought her so that she was laying down. I called 911 and rushed over to her. It took her about 30 seconds to come to and she became coherent while I was on the phone with 911. Police were dispatched first, followed by EMS about 10 minutes later. Patient stated she has a history of fainting spells. This occurred about 4:27 pm on 4/6 and patient stated she last ate about 12:30 pm on 4/6. Patient was seen by EMS and cleared. |
| 1185160 | 4/9/2021 | IN | 22 | F | 4/7/2021 | 4/7/2021 | At 15 min mark after receiving vaccine: sudden loss of hearing (extremely muffled, underwater sounding), profuse sweating, and then lost vision and passed out entirely when attempted to stand up for help. After laying down, quickly regained consciousness and felt better. After effects and soreness have been minimal. Have not fainted during/after vaccine before. |
| 1184473 | 4/9/2021 | MO | 31 | M | 4/9/2021 | | light headed and passed out |

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| 1187903 | 4/9/2021 | IN | 32 | F | 4/9/2021 | 4/9/2021 | About one minute after the woman sat down from getting her COVID shot she told our cashier she was feeling ill and was going to the bathroom. I went in the bathroom and found her sitting on the floor with her head between her legs. She said she started feeling ill and hot and sweaty. Her palms were sweaty as well. She was dizzy and she was starting to black out and then got tunnel vision. I tried twice to take her blood pressure and could not get a reading from the machine. We got her a glass of water that she wanted. She said she did not eat that morning. During our conversation she started feeling worse and laid down. She felt that 911 did not need to be called. After a few minutes she started feeling better and was able to stand. She said she has previously passed out after getting a shot. She answered no on the questionnaire and to the direct question of have you ever fainted afer getting a vaccine before the shot. She went back out to sit in the waiting room for 15 more minutes. Before she left she came to me and said she felt better. We went to the HIGI machine to get her BP. It was 116/79 |
| 1187779 | 4/9/2021 | NY | 18 | F | 4/5/2021 | 4/5/2021 | Patient was reported to have fainted in an aisle about 10 minutes after administration of the vaccine. Upon arriving the patient was conscious but appeared to be disoriented, sitting in a chair. 911 was called and a police officer responded; patient was evaluated and EMT services were called in afterwards. |
| 1187797 | 4/9/2021 | LA | 18 | F | 4/9/2021 | 4/9/2021 | Patient felt dizzy after injection, head hit the plexiglass divider at pharmacy counter. Pharmacist was able to go out and grab her before she fainted. |
| 1187809 | 4/9/2021 | WI | 26 | F | 4/9/2021 | 4/9/2021 | Patient immediately had a syncope episode after injection. Patient tensed up and made grunting sounds. Episode lasted 10-15 seconds. EMS was called and assessed patient. Patient refused further medical services. |
| 1187821 | 4/9/2021 | WI | 61 | F | 3/25/2021 | 3/26/2021 | Fainted the next morning and split my chin open- went to clinic and then to ER- needed 10 stitches in my chin and split my lip and needed 2 stitches in my lip |

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| 1187823 | 4/9/2021 | CA | 22 | M | 4/3/2021 | 4/3/2021 | Chills for 2-3 hours of duration following 5 hours after vaccination, nausea, The following morning: 10/10 non-radiating chest pain of pleuritic feeling, tingling in limbs, syncope, SOB Tachycardia(108 bpm) |
| 1187993 | 4/9/2021 | NJ | 20 | F | 4/5/2021 | 4/5/2021 | Patient stated that she has a previous history of fainting when receiving vaccination, and was nervous to be vaccinated. Patient was seated but became pale, sweaty, and fainted for approximately 5 seconds after receiving the vaccination. Conversation was maintained with the patient through out the entire transaction. Pt was evaluated by emergency personnel, refused treatment, and went home to rest. |
| 1187901 | 4/9/2021 | SC | 18 | M | 4/9/2021 | 4/9/2021 | Patient received the COVID-19 vaccine (first dose Pfizer). He reported no previous adverse reactions to vaccines. During the 15 minute monitoring period, the patient fainted. He appeared pale and sweaty, and he reported dizziness, lightheadness, and blacking out. He laid down for several minutes and sat up in the chair with assistance when he was no longer lightheaded. His blood pressure was 108/71 with heart rate 76. EMS checked the patient and cleared him approximately 20-25 minutes after receiving the vaccine. |
| 1187754 | 4/9/2021 | KS | 32 | F | 4/9/2021 | 4/9/2021 | INJECTION GIVEN AT 1:47PM AND CLIENT REPORTED FEELING LIGHT HEADED AT 1:52. CLIENT ASKED TO SIT BACK IN CHAIR AND BREATH NORMALLY. REMOVED SWEATER AND REQUESTED WATER. OBSERVED IN CHAIR AND FAINTED IN CHAIR AROUND 1:55 P.M. FOR 1 OR 2 MINUTES. IN PROCESS OF CALLING 911, CLIENT REGAINED CONCIUSNESS, AND CLIENT SAID FEELING OK, SO 911 CALL WAS CANCELLED. AT 1:57, SPO2 92, PULSE WAS 62. BP WAS TAKEN AT 1:58 AND 115/71. |

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| 1187931 | 4/9/2021 | NY | 27 | F | 4/9/2021 | 4/9/2021 | The patient was seemed OK after I gave her the shot. She came in with her mother who was in the vaccination room with her while I gave the shot. I told them to stay in the store at least 15 to 30 minutes after receiving the first dose. They walked out the vaccination room and I returned to the dispensing area. The mother immediately came up to the pharmacy dispensing window to ask for an ice pack because her daughter passed out on the floor and hit her head. I got the ice pack and went to the patient to see if she was OK. She was lying down on her back. The mother took the ice pack and rested it under the patients head. I checked her pupils and checked her pulse. Those vitals were normal. I asked the patient if she could tell me her name and what day of the week this was. She answered correctly. I took her temperature on her forehead and it was elevated to 100.4 - I re-checked her temperature again in 3 minutes and it was 99. The patient was able to get up to a chair a few minutes later, and then they left after 15 minutes and the patient seemed OK. |
| 1187933 | 4/9/2021 | VA | 60 | F | 3/25/2021 | 3/25/2021 | Felt hot within a few minutes after the vaccine, then passed out. The NP on site said she was unable to find a pulse so did 10 chest compressions before I woke up. Called the rescue squad who did an EKG on route to Hospital and once I was in the ER another EKG was performed along with blood work and chest X-ray. Entry was noted as allergic reaction but diagnosis was noted as Vasovagal Syncope, Adult. EKG?s performed along with labs were normal. I have pulled muscles, tendons and ligaments from the chest compressions which were questionable but since that day have experienced tingling in upper body and arms and have felt bad. Went back to my Primary Care Doctor for follow up on March 29 for another EKG. Have had panic attacks from the situation and per Doctor will take 2 months for my chest, muscles, tendons and ligaments to heal. Hard to determine if the way I have felt is from the vaccine or what transacted when I fainted. Today which is April 9, I still feel weak, normally I am very energetic. Just wanted to report as when I saw the news that others had some situations thought best to let you know. |
| 1187942 | 4/9/2021 | CT | 33 | F | 4/7/2021 | 4/8/2021 | Multiple syncope episodes, fever for 24 hours, low blood pressure, chills, sweating |

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| 1187946 | 4/9/2021 | CA | 31 | F | 4/9/2021 | 4/9/2021 | We are a Pharmacy. Today, April 9, 2021, we had a patient. She was scheduled for her first dose of the Pfizer vaccine at 9:30 am. The pharmacy manager gave her the vaccine inside the store at around 9:30 am. She was accompanied by her husband. After the shot, she sat down in one of the chairs in front of the pharmacy to wait for the mandatory 15 minutes wait for any reactions. At 9:43 am, we noticed that she was looking a bit dizzy. As we were approaching her, she slid down the chair and became unconscious. Luckily her husband was right beside her and caught her before she fell. Pharmacy manager then helped her husband to quickly lay her down flat on her back. The husband asked to call 911. The pharmacy technician was there to assist and she called 911. The patient regained consciousness roughly around 30 seconds after she fainted. She was alert and breathing normally. We asked again if they wanted us to continue calling 911. They said yes. Roughly 5 mins later, the paramedics came and assisted the patient. The sugar was good, blood pressure was good, temperature was good. They asked her if she wanted to go to the hospital. The patient denied. The paramedics left and the patient stayed for more time at the pharmacy and eventually left. |
| 1187952 | 4/9/2021 | AZ | 63 | F | 4/7/2021 | 4/7/2021 | Started with Chills, headache, aches and pains in joints and muscles. Body feeling heavy. Got up to use the restroom around 2:45am and got nauseous and very hot and passed out for about 15 seconds. Woke on the floor which cooled me down, drank some water and went back to bed. Next morning I got woozy and had trouble standing. Slept most of april 8. April 9th felt better. |
| 1187359 | 4/9/2021 | CA | 35 | M | 4/9/2021 | 4/9/2021 | Syncope (Vasovagal Response) |
| 1187852 | 4/9/2021 | TX | 48 | F | 4/9/2021 | 4/9/2021 | PATIENT PASSED OUT AND WAS SHAKY. HER EYES ROLLED BACK FOR 2 SECONDS THEN UNRESPONSIVE FOR 10 SECONDS WHILE RUBBING CHEST COMPLAINED OF LEFT SIDE NUMBNESS AND TINGLING. PUT COLD WHATER ON PATIENTS HEAD AND HAD HER DRINK COLD WATER. TRANSPORTED TO ER. |
| 1187494 | 4/9/2021 | KY | 32 | F | 4/7/2021 | 4/8/2021 | Fever of 101.5, fatigue, body aches, passed out, light headed |

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| 1187382 | 4/9/2021 | AL | 31 | F | 4/9/2021 | 4/9/2021 | PATIENT FELT LIGHTEADED AND REALLY HOT. SHE FAINTED WITHIN ONE MINUTE OF INFORMING ME. HER HUSBAND HELPED ME MOVE HER FROM THE CHAIR TO THE FLOOR. WE CALLED 911 BUT LATER CANCELLED SINCE SHE REGAINED CONSCIOUSNESS IMMEDIATELY. WE PLACED COLD COMPRESS ON HER FOREHEAD AND BACK OF NECK. CHECKED HER BLOOD PRESSURE AND IT WAS A LITTLE LOW SO I HAD HER SIT AT THE PHARMACY TO OBSERVE HER A LITTLE LONGER. |
| 1187385 | 4/9/2021 | NY | 57 | M | 4/9/2021 | 4/9/2021 | PATIENT FAINTED AT APPROXIMATELY 3:25 PM. ASKED PATEINT HIS NAME, DATE OF BIRTH, AND IF HE IS FEELING WELL? PATIENT STATES HE FEELS MUCH BETTER AND STAES HE WOULD LIKE TO SIT FOR 30 MINUTES. PATIENT WAS OFFERED TO CALL THE AMBULANCE HE DENIED. AT 3:45 PM PATIENT STARTED FEELING NAUSEOUS AND TURNED PALE WITH SWEAT, EMERGENCY SERVICES WAS CALLED EMERGENCY SERVICES CAME IN 5 MINUTES - PATIENT WAS CHECKED AND REMAINED AT PHARMACY. PT'S SISTER PICKED HIM UP AT 5PM, PATIENT WAS FULLY ALERT AND ORIENTED TO TIME AND PERSON. |
| 1187386 | 4/9/2021 | WA | 85 | M | 4/8/2021 | 4/8/2021 | Pt fainted 10 min after receiving vaccine.He was talking to his friend who brought him in to the clinic when event happened.Pt fell from the chair, did not remember what happened.Initial BP is elevated,HR elevated,pt was pale and clammy and diaphoretic,O2 100%.Pt monitored for 30 min BP and HR stabilized. Pt was comfortable going home. |
| 1187397 | 4/9/2021 | MN | 36 | F | 4/8/2021 | 4/8/2021 | Fainted, peed myself, was brought to ER by ambulance |
| 1187422 | 4/9/2021 | OH | 41 | M | 4/9/2021 | 4/9/2021 | PATIENT WAS SEATED AND GIVEN VACCINE AND PASSED OUT IMMEDIATELY. PATIENT REGAINED CONSCIOUSNESS A FEW MOMENTS LATER. PATIENT WAS MOVED TO THE FLOOR IN SUPINE POSITION WITH LEGS ELEVATED. PATIENT STAYED CONCIOUS AND RECOVERED IN 20-25 MINUTES. BLOOD PRESSURE WAS 122/78, PATIENT REMAINED AWAKE AND ALERT. PATIENT LEFT STORE UNDER HIS OWN POWER WITH HIS SPOUSE. |

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| 1187423 | 4/9/2021 | WI | 20 | F | 4/8/2021 | 4/8/2021 | I began feeling a migraine at 3pm. I took a nap and woke up at 6pm feeling extremely ill. My temperature was 101.5F and my entire body was in pain. I took two Tylenol as suggested. Over the course of the entire evening, I was vomiting profusely; I vomited approximately 10 times. By around 10pm my extremities became numb and I could not walk without assistance. I could not think or speak straight. I nearly fainted every time I tried to sit up. I tried to take ondansetron for vomiting but proceeded to vomit the medication as well. I wanted to go in to the ER because I felt like I was dying, but I do not feel financially comfortable doing so. All symptoms remained consistent until about 3am when I was able to sleep until 7am. I woke up with several bouts of diarrhea, intense nausea, and head to toe muscle and joint pains, as well as numbness and tingling in my arms and legs still. It is now 5pm the next day and I still can't eat or stand for too long without feeling faint. I still have diarrhea and strong migraine. |
| 1187767 | 4/9/2021 | PA | 59 | F | 4/9/2021 | 4/9/2021 | Near syncope, nausea, hypertension |
| 1187489 | 4/9/2021 | | 48 | M | 4/9/2021 | 4/9/2021 | Dose was administered at 0805, patient passed out at 0810. Patient reported that he had worked all night and hadn't eaten for a while. He also said he has passed out from blood draws before. |
| 1187755 | 4/9/2021 | CO | 29 | M | 4/9/2021 | 4/9/2021 | Nausea, Lightheadedness and Syncope 5 minutes after receiving Janssen Covid Vaccine. Given epinephrine at the facility, transported to ER by ambulance. Pt discharged in stable condition after 3 hours of monitoring. |
| 1187499 | 4/9/2021 | NC | 63 | M | 4/9/2021 | 4/9/2021 | PATIENT SAID HE WAS FEELING DIZZY ABOUT 10 MINUTES AFTER RECEIVING HIS VACCINE. RPH WAS IN THE PROCESS OF CHECKING HIS BP, WHEN HE FAINTED. 911 WAS CALLED . HE SHORTLEY GAINED BACK CONSCIOUSNESS AFTER EPI PEN WAS ADMINISTERED |

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| 1187520 | 4/9/2021 | MO | 19 | F | 4/9/2021 | 4/9/2021 | Patient received the vaccine and approximately 5 minutes later, patient passed out and fell out of her chair onto the floor. 911 was called. Patient was unresponsive for approximately 30 seconds. She came to and was very disoriented and her pupils were extremely dilated. The paramedics came and did blood pressure checks and several other evaluations. They advised her to go with them by ambulance to the ER to be evaluated due to falling directly on her face/head. Patient went outside and was evaluated further in the ambulance but was not willing to go to the ER. |
| 1187526 | 4/9/2021 | AL | 42 | F | 4/9/2021 | 4/9/2021 | PATIENT'S HUSBAND SAID SHE WAS FEELING REALLY SLEEPY. I ASKED IF SHE WAS NERVOUS BECAUSE SHE JUST SAW ANOTHER PATIENT FAINT AND SHE SAID YES. SHE FAINTED JUST AFTER THAT AND HER HUSBAND HELPED ME MOVE HER TO THE FLOOR. SHE WAS STILL BREATHING BUT SHE WAS IN AND OUT OF CONSCIOUSNESS SO WE CALLED 911. PATIENT WAS RESPONDING TO CONVERSATION BUT WOULD SLUR SOMETIMES AND EYES WOULD ROLL BACK AS SHE LOST CONSCIOUSNESS AGAIN. PLACED COLD COMPRESS ON FOREHEAD AND BACK OF NECK. PATIENT'S HEART RATE WFLUCTUATED THE WHOLE TIME. PARAMEDICS CAME TO ASSESS HER, BLOOD PRESSURE WAS HIGH 180 SYSTOLIC (DIASTOLIC WOULDN'T READ), AND SUGAR WAS 401. PATIENT DECIDED TO GO TO ER VIA AMBULANCE AFTER SHE ALMOST FAINTED AFTER STANDING. |
| 1187529 | 4/9/2021 | CA | 33 | M | 4/9/2021 | 4/9/2021 | Fainting |
| 1187747 | 4/9/2021 | MA | 39 | F | 3/22/2021 | 3/22/2021 | Immediate nausea, Fainting 10 minutes after, vomiting and chest pain after awakening, sore arm radiating from injection area. the next day, worsening headaches and felt weak. The next night fever 100.6, chills , muscle aches and swollen joints, fatigue. |

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| 1188009 | 4/9/2021 | VA | 36 | F | 2/24/2021 | 2/25/2021 | Vasovagal syncope - Once I started feeling sick the morning after the second dose, I was unable to sit up or stand without feeling like I was going to faint. This persisted throughout the day. The fainting feeling was accompanied by dizziness, nausea, drop in BP, and needing to lay down to catch my breath. I had a fever that day and took NyQuil which allowed me do sleep and broke my fever. But the fainting feeling persisted throughout the day until 8 pm when I was able to sit up and eat. |
| 1187459 | 4/9/2021 | CO | 43 | F | 4/9/2021 | 4/9/2021 | Syncope/Nausea/Light-headed, Diaphoretic |
| 1188339 | 4/9/2021 | CA | 34 | F | 4/7/2021 | 4/8/2021 | Woke up 1am with extreme headache crown of head. Chills, nausea. Weak limbs. Barely made it to bathroom, had dhiarrhea. Fainted on bathroom floor. After about an hour was able to get back into bed. Shivering with 100 fever for 3 hours. Loud ringing in ears. Was blacking out. Still sick but the fainting and extreme episode at 1am seemed worth reporting and extreme |
| 1188205 | 4/9/2021 | WI | 34 | U | 4/9/2021 | 4/9/2021 | After 90 seconds felt warm and dizziness come on, then I fainted, the EMT that administratored the shot said I had a seizure. I have never had one before this vax and never had issues with the navy and vaccinations then. |
| 1188208 | 4/9/2021 | NY | 18 | M | 4/9/2021 | 4/9/2021 | Patient received vaccine in left arm and during waiting/observation period a few minutes later (while sitting), he told the person near him he felt dizzy, and he fainted. He soon regained consciousness (within about a minute) and was observed/attended to. 911 was called immediately as a precaution, and paramedics monitored his vital signs slowly helped him into a chair. He drank some water and a little electrolyte drink. He did not want to seek hospital treatment, and paramedics left. He stated he was experiencing nausea while sitting in the chair, and said he started to feel like he was going to faint again. Again 911 was called and paramedics attended to him, but he did not faint again. After resting in a chair and drinking some more water and some electrolyte drink, as well as cold compresses on his forehead and the back of the neck, he was eventually escorted by two store employees on a motorized scooter cart to his parent's car and went with his parent home (he did not want to seek hospital treatment). |

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| 1188215 | 4/9/2021 | CA | 57 | F | 4/8/2021 | 4/9/2021 | Fainted when getting up in the middle of the night. Came to, then fainted again. Called nurse, then video call with doctor on 4/9/21, then visit to urgent care on 4/9/21. |
| 1188230 | 4/9/2021 | NJ | 23 | M | 4/9/2021 | 4/9/2021 | Patient fainted 5 minutes after receiving vaccine. He regained consciousness immediately and paramedics were called. Patient reported having breakfast at 5am and did not have lunch yet. The paramedics said he was ok to go home. I followed up with a phone call to the patient a few hours later and he said he felt better after having lunch and resting. |
| 1188251 | 4/9/2021 | FL | 44 | M | 4/9/2021 | 4/9/2021 | pt became weak and sweating, passed out. came to, and was sweating and weak and confused. |
| 1187958 | 4/9/2021 | CA | 31 | F | 4/9/2021 | 4/9/2021 | Patient was given the vaccine at 12:26 pm and was advised to wait for observation. While waiting, patient started to complain of some anxiety and lightheadedness. We advised patient to wait a little longer for further observation. A few minutes later, at 12:36 pm patient said the lightheadness was getting worse and then passed out for a few seconds while waiting sitting in our observation area. The pharmacy technician was in the area to hold up the patient and keep her calm while patients mother requested that EMS/911 be called. EMS came minutes later and patient was coherent and talking to the technician and her mother. EMS asked patient if she wanted to be taken to the hospital and patient agreed. Patient called a few hours later to follow up with pharmacy staff and informed us that she was discharged and feeling better. |

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| 1188329 | 4/9/2021 | CO | 37 | M | 4/9/2021 | 4/9/2021 | Patient was waiting in designated waiting area following vaccine administration. About 5 minutes after vaccine I heard wife calling for help. When I went out to assess patient I found him laying back in chair with his head back, shaking, eyes open, and making fists with his hands. I asked him if he wanted me to call 911. He was able to respnd through clenched teeth that he felt very strange and to call 911. He remained conscious and knew his name. We contacted 911 and I supported pt from opposite side of wife. After a few minutes he calmed down and asked for water, he appeared to be sweating around head area. He took a few sips of water until operator on phone asked us to withhold further liquid until EMTS arrived. He was completely back to normal status within 5 minutes, EMTS came and assessed pt and allowed him to leave of his own accord. After the incident her relayed that similar reactions including full fainting spells have occurred to him in the past when receiving vaccines. this was not indicated on his intake form |
| 1188184 | 4/9/2021 | CA | 40 | M | 4/9/2021 | 4/9/2021 | Vagal - passed out while driving to observation. Was assessed on site and refused medical treatment. Left against medical advice |
| 1188340 | 4/9/2021 | AK | 18 | F | 4/9/2021 | 4/9/2021 | RIGHT AFTER THE SHOT, THE PATIENT SAID THAT SHE FELT LIGHT HEADED AND TIRED. SHE STARTED TO SHAKE AND SLUMPED OVER AGAINST HER FATHER THAT WAS NEXT TO HER. SHE STARTED TO SNORE, WOKE UP AND THEN PASSED OUT AGAIN. HER FATHER SAID THAT SHE REACTS TO SHOTS THIS WAY. SHE DID NOT RECEIVE ANY TREATMENT. SHE WAS IN THE PHARMACY FOR A TOTAL OF 25 MINUTES. |

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| 1188342 | 4/9/2021 | MI | 33 | M | 4/8/2021 | 4/8/2021 | It was a drive thru shot facility. They gave me a shot in my left arm and asked me to pull around to park. I parked my vehicle and didn't feel well so I switched seats with my girl friend. As soon as I got into the passenger seat I was out. She said My eyes rolled back in my head and I started shaking and eyes at this point she said where going up down and side to side . She ran for help and after about 1-2 minutes I woke up. I thought I passed out so I instantly put my feet on the dash of my car and the pharmacist gave me water and chocolate milk. He then checked my heart rate it seemed good and after 20 minutes he let us go home. |
| 1188343 | 4/9/2021 | CA | 19 | F | 4/9/2021 | 4/9/2021 | patient was sitting in waiting area and felt dizzy and fainted. was on ground for 30-40 seconds and had nurses and paramedics attend to her. blood pressure was high at first and then she felt fine after 30 minutes and denied ambulance and went home |
| 1188377 | 4/9/2021 | CA | 18 | M | 4/8/2021 | 4/8/2021 | Perfectly healthy, fit, thin 18 year old young man with no allergies and no previous reactions to vaccines or medications... immediately upon receiving J&J injection his eyes rolled back into his head and he was unconscious for two to three minutes, then in and out of consciousness for another eight to ten minutes. He convulsed for around ten seconds after about two minutes of being unconscious. Four to five healthcare workers attended to him, asking him to "stay with us." They called an ambulance, and the medics monitored him for awhile. Heart rate dropped to 34 bpm, clothing drenched with perspiration. Blood sugar was slightly low, although he had eaten a late brunch of two fried eggs, sourdough toast and fruit salad. The last thing he remembers is a cold sensation shooting down his arm and into his left hand. He tried to talk to say he wasn't feeling well, but he couldn't form the words, so he raised his arm and then fainted. He felt generally unwell the rest of the day, and today he is still not fully recovered. |
| 1188392 | 4/9/2021 | CA | 31 | M | 4/7/2021 | 4/7/2021 | Near syncope, diaphoretic, nausea, BP 60/30 |
| 1188412 | 4/9/2021 | WA | 48 | M | 4/3/2021 | 4/5/2021 | Flu-like symptoms for two day (I don't consider this an adverse reaction) followed by intermittent drops in blood pressure and fainting on days 2 and 4 |

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| 1188322 | 4/9/2021 | CA | 31 | F | 4/9/2021 | 4/9/2021 | Patient fainted post vaccination. |
| 1188132 | 4/9/2021 | CO | 23 | M | 4/9/2021 | 4/9/2021 | Patient had syncope symptoms and gave ice pack and asked him to put his head between his legs to help with the dizziness, took BP and was normal and found out he was pre-diabetic so I gave a coke in case it was low sugar, he felt better 30-45 mins post-vaccine and returned to work, he came back after 5 minutes feeling cold and spinning, so we called EMS and asked him to lay down with feet elevated and covered him to try to keep him warm. EMS arrived and conversed with patient, took vitals, and recommended him to go home and rest as he was finally feeling better; overall, it took roughly 3 hours for symptoms to completely fade. |
| 1188013 | 4/9/2021 | ME | 18 | F | 4/9/2021 | 4/9/2021 | The patient fainted a few minutes after receiving the vaccine. She came to shortly thereafter and checked out thoroughly by paramedics. All vitals were normal and she was picked up by another party. |
| 1188014 | 4/9/2021 | FL | 27 | F | 4/9/2021 | 4/9/2021 | Patient was sitting in chair for 15 minutes and started to feel dizzy and tried to get up from chair and passed out for 5 to 10 seconds, hitting her head on the aisle as she went down. Myself the Pharmacist ran down the aisle to her where I instructed her to remain laying down on her side as we called 911 for help! She was alert and oriented with no rash or breathing difficulties! I sat with her until paramedics arrived and evaluated her and recommended that she get checked out by someone at a hospital or her own doctor. She was released without future assistance from us! She did complain of a headache and was told by paramedics that it maybe the vaccine or the head injury and needs to seek medical attention. |
| 1188034 | 4/9/2021 | ME | 31 | M | 4/9/2021 | 4/9/2021 | Patient received the vaccine and fainted shortly thereafter. He became very sweaty and came to in a couple of minutes. Paramedics attended to him and deemed it necessary to take him to Medical Center for further evaluation due to irregular heart rate. |

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| 1188042 | 4/9/2021 | CA | 20 | F | 4/8/2021 | 4/8/2021 | Patient was sitting down for about 10 minutes after receiving 1st dose of COVID vaccine. She stood up to ask for some water and a few seconds later she fainted. She was on the floor for a few seconds unconscious but then quickly regained consciousness. We called 911 to get an ambulance to arrive. EMT's tended to her and checked her vitals upon arriving. Patient was able to leave on her own power and have a friend take her home. |
| 1188078 | 4/9/2021 | IL | 22 | M | 4/9/2021 | 4/9/2021 | after administering the johnson and johnson covid vaccine patient fainted a few minutes later. He fell to the floor . he also cut his jaw in the process once we saw what was happening we rushed to help patient but he got back up almost immediately and refused calling 911 or going to convenient care of emergency room from for further care. he reported that he had fainted in the past with a different vaccine and believes he will be fine. we had patient sit in the pharmacy for an additional 30 minutes and confirmed that he wasn't experiencing any more symptoms before letting him go. |
| 1188103 | 4/9/2021 | CA | 53 | M | 4/8/2021 | 4/8/2021 | Patient was scheduled for an appointment for a Johnson &Johnson covid-19 vaccine through a drive thru Thursday April 8, 2021 @12:45pm. We arrived early and he received the vaccine at 12:15pm, waited 30 minutes for reaction and he was feeling fine. Later that same evening, the patient was driving to work on the freeway when he felt a dry throat so he coughed hard, at that cough he felt a massive pain in his head, like his "head was going to explode." He immediately had tunnel vision closing in on him, so he pulled over and later woke up in our parked car with flashing emergency lights on, parked on the shoulder of the freeway. Disoriented and confused why he was there, he looked at his watch and saw he lost 15 minutes when he had passed out. MY HUSBAND COULD HAVE BEEN SERIOUSLY INJURED OR KILLED IF HE HAD NOT PULLED HIMSELF OVER WHEN PASSING OUT. Today we reported this to our doctors office and to you! |
| 1186223 | 4/9/2021 | OH | 28 | M | 4/2/2021 | 4/2/2021 | Pt experienced vasovagal syncope within 15 minutes of vaccination. Supportive care provided and pt recovered without incidence. |

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| 1188128 | 4/9/2021 | VA | 36 | M | 4/9/2021 | 4/9/2021 | PATIENT FAINTED WITHIN 2 MINUTES OF RECEIVING THE VACCINE, SWEATING. EMS ARRIVED BY THAT TIME PATIENT WAS CONSCIOUS. DURING THEIR ASSESSMENT, PATIENT FAINTED AGAIN |
| 1188190 | 4/9/2021 | PA | 58 | F | 3/29/2021 | 3/30/2021 | Severe joint pain for 24 hours. Passed out in the morning after the vaccine. |
| 1188135 | 4/9/2021 | MA | 17 | F | 4/8/2021 | 4/8/2021 | Patient felt weak and fainted, came to without Epipen and was had nausea and vomiting and was very thirsty. Pale, EMT's called. Blood pressure was normal. She went home with mother. Mom said she has done this before with medical procedures, very anxious. |
| 1188136 | 4/9/2021 | OK | 23 | F | 4/9/2021 | 4/9/2021 | Patient received vaccine and stated she might pass out as she has with past vaccines. She then immediately fainted with a temporary loss of consciousness. She stirred several times and seemed to wake but then would faint again. She finally regained consciousness and stated she felt okay. I put cold compress on the back of her neck and on her forehead. We had someone move a fan to blow cooler air into the area. Also removed her mask to make sure she was breathing and airway was open. We had her stay an extra 30 minutes for observation. I later called to patient and she stated she felt fine with the exception of a sore arm from the injection. |
| 1188141 | 4/9/2021 | FL | 21 | M | 4/9/2021 | 4/9/2021 | Dizzy, sweating, chest tightness, impaired vision/hearing, SOB, pale, Syncope |

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| 1188151 | 4/9/2021 | MA | 49 | M | 4/2/2021 | 4/2/2021 | I went with my wife, whom we were more concerned about possible reactions to the vaccine given her history of anaphylaxis reactions to bee and wasp stings, has had to carry a Epi-pen always, so we stayed an additional 15 minutes for 30 minutes total before we left. She was completely fine throughout, I however as we were walking out I began to feel a little "Off?", not necessarily nauseous or dizzy, just a bit Off. Told my wife that and that I wasn't sure I should drive us home (I drove us there), so she drove. About 15-20 minutes into the drive, it got worse and I passed out. My wife says my eyes rolled in the back of my head with my eyes open but no responsive. She says she kept hitting my chest but I didn't respond. I came to about 2 minutes after passing out. She asked me if I felt like I needed to goto the hospital, I told her I needed to eat, that I felt like what I needed was food, then we go from there. I did eat breakfast, an English muffin at about 8am that morning, it was almost 12:30 by that point. When I finally got food in me I felt much better and have had no adverse reactions since. |
| 1188173 | 4/9/2021 | NJ | 24 | M | 6/13/1996 | 4/9/2021 | after administering patient fainted and got light head in pharmacy hit his head |

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| 1188186 | 4/9/2021 | IL | 18 | M | 4/7/2021 | 4/7/2021 | We gave patient the vaccine and advised him to wait for the CDC recommended 15 minutes observation time. He decided to leave after just a few minutes, despite his dad (who was with him) questioning the decision and suggesting he stay 15 minutes. I was then told by a member of management through our walkie-talkie system that they needed me at the front register immediately because someone passed out after getting a vaccine. I was there within the minute with my vaccine emergency bag. Upon arriving, the patient was already awake, talking, and sitting in a chair. He also was profusely sweating. He stated he's never experienced anything like this before. He said he normally has low blood pressure. He starting drinking some water. When I checked his blood pressure it was so low the machine gave an error message. Throughout this time, the patient progressively was feeling better and eventually wound up laughing and smiling. Him and his father said that he would be ok and that he was feeling himself. I told him to sit for a bit more before leaving and stay as long as he wants. I called him later that evening to check on him and had to leave a voicemail. His father called back 2 days later and said he's been fine. |
| 1188119 | 4/9/2021 | | 21 | F | 4/5/2021 | 4/6/2021 | Dizziness and passed out twice in a matter of 15 minutes. Fatigue day after. |
| 1186567 | 4/9/2021 | FL | 65 | F | 4/8/2021 | 4/8/2021 | 1158: Vaccination given 1215: c/o dizziness, transferred to recliner. Passed out in recliner, airway protected. RR 12 1220: able to arouse; feels dizzy 1222: BP: 127/58. HR 62. SpO2% 97. Itchy, can barely speak, difficult to arouse. Epinephrine 0.3 mg IM in Right quad. 1225: BP: 126/58. HR 60. SpO2 100 %. no signs of angioedema: breathing without difficulty; speech more clear; follows commands. Drank water without signs or symptoms of dysphagia. States normal HR 80-100. 1235: BP: 123/83. HR 59. SpO2 100%. awake and alert; will continue to observe. DC at 1300 if stable. Advised to notify PCP of reaction to determine if 2nd dose advised. 1256: BP 117/64. HR 61. SpO2 98%. Awake and alert. Ready to leave in care of husband. 1743: Called and checked on patient. Patient doing well. |

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| 1186682 | 4/9/2021 | TX | 23 | F | 4/8/2021 | 4/8/2021 | PT FAINTED AND APPEARED TO BE HAVING SEIZURES FOR ABOUT 3 MINUTES, SHE STATED THAT IT HAPPENED TO HER BEFORE! 911 WAS CALLED, HER VITALS WERE CHECKED SHE WAS STABLE AND COHERENT. SHE WAS ADVISED TO SEE HER PCP AND REPORT WHAT HAPPENED TO HER PREVIOUSLY AND AFTER SHE RECEIVED THE VACCINE. |
| 1186454 | 4/9/2021 | NY | 48 | M | 2/24/2021 | 2/25/2021 | After second dose, tired, very fatigued, whole body was sore, chest rash, injection site pain, this was the day after the shot and last for about 4 days. Felt bad for weeks after 2nd dose. On 3/23/21, Syncope and collapse, 3 days in hospital. Dr's could not find the cause of syncope and collapse, they ran many tests. On 3/23/21, woke up with severe chest pains and collapsed, large gash on my head, taken to hospital by ambulance. Dr's did not think it was from 2nd dose, but they could not find another reason for Syncope and collapse. |
| 1186459 | 4/9/2021 | MN | 16 | F | 4/9/2021 | 4/9/2021 | Pt was vaccinated. She said she felt fine. Pt walked 15 feet then fainted. Her mom was able to catch her. We moved her to a cot. She slowly regained consciousness. She had no signs of anaphylaxis. She was breathing fine. Her mother states she has fainted during blood draws in the past and her daughter hadn't eaten this morning. We monitored pt for 30 minutes. Her color and smile came back. Pt was able to walk out on her own. Her mother will monitor her today. |
| 1186516 | 4/9/2021 | IL | 49 | F | 4/8/2021 | 4/8/2021 | Immunization clinic note: Patient reported feeling dizzy after about 20 minutes post-vaccination. Patient had a blood pressure of 140/100, had pulse and was breathing well. She was in and out of consciousness and non-responsive. EMT arrived about 10 minutes later and she was transported to ER. ED note: Pt observed while in the ED - ambulating about dept, maintains stable vitals, no recurrence of syncope. Remains symptoms free. Discussed with pt that syncope - likely vasovagal in light of covid vaccine administration. We discussed possibility of allergic reaction - at this time, no signs for airway compromise and pt remains comfortable on RA. We will dc home with rx for benadryl and 4 additional days of prednisone. |

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| 1186519 | 4/9/2021 | CA | 21 | M | 4/9/2021 | 4/9/2021 | Patient passed out roughly 5-10 minutes following vaccine while seated on a planter; witnessed by store employee. Hit his head causing a small laceration above the right eyebrow which was cleaned with alcohol and bandaged prior to EMS arrival. The patient experienced dizziness and numbness/tingling in both hands/arms. He was able to tell RPh his name, the year, and knew where he was. Paramedics were called to assess his condition. Per patient and mother, only underlying condition is anxiety and only medication is zoloft. |
| 1186400 | 4/9/2021 | TX | 27 | F | 4/7/2021 | 4/7/2021 | Almost fainting, dizziness, dilated pupils, black vision, could not speak, unable to move which occurred minutes after receiving the J&J vaccine. Side effects dissipated within five minutes after onset. Normal BP recorded |
| 1186546 | 4/9/2021 | MO | 30 | F | 4/9/2021 | 4/9/2021 | Patient fainted/ seized about 10 minutes after receiving vaccination. Patient admitted to not eating anything prior to coming in for vaccine. Patient was sat up on the floor and given crackers and water and a cold rag. |
| 1186356 | 4/9/2021 | TX | 22 | M | 4/9/2021 | 4/9/2021 | Patient was given the Janssen covid vaccine and after he had sat down in the waiting area he fainted. time was 12:39 pm Friday, 4/9/21. We called EMS and code white at that time. Patient was unresponsive for a few seconds but woke up quickly. When we asked about any reactions to previous vaccine patient stated he had no reactions. After talking to him once he was feeling better, he did mention that this has happened in the past when his blood sugar was low. We gave cool compress and patient refused services from EMS. We also offered water and store management offered orange juice. We also advised him to stay for an additional 30 minutes for observation. |
| 1186581 | 4/9/2021 | NC | 71 | F | 3/26/2021 | 3/27/2021 | Received Moderna vaccine from Medical Group on 03/26/2021-2nd dose. Reports that about 5:30am on 03/27/2021 she began to have chills, weakness. States she eventually passed out, falling on the floor in which she does not remember, breaking her ankle. Ankle repair required surgical interventions. She is now back home wearing a cast to affected foot. |
| 1186615 | 4/9/2021 | AL | 47 | M | 4/9/2021 | 4/9/2021 | Started to feel light headed and passed out within 5 minutes. |

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| 1186645 | 4/9/2021 | TX | 42 | M | 4/9/2021 | 4/9/2021 | He got cold and clammy and passed out in the chair with head slumped. His wife rubbed his chest and spoke to him and I, waved ammonia inhalants under his nose. He immediately came to. We got him a bottle of water and a snack (he had not eaten yet today). I also checked his blood pressure and it was normal. We had him sit a little longer until he felt better. We initially called an ambulance, but called it off at his request. |
| 1186652 | 4/9/2021 | MI | 32 | M | 4/9/2021 | 4/9/2021 | Patient started fainting a few minutes after the Janssen vaccine was injected. Patient started fainting in while he was seated. He wasn't very responsive but his eyes were open. Patient stated that he has a panic attack to the injection of the needle and has had similar reactions in the past from other injections. |
| 1186670 | 4/9/2021 | | 45 | M | 4/9/2021 | 4/9/2021 | Transient hypotension/near syncope. |
| 1186674 | 4/9/2021 | NY | 19 | F | 4/9/2021 | 4/9/2021 | passed out 2 minutes after moving from vaccine seat to observation area 20 ft away, very brief mild, seizure less than 30 seconds. regained complete alert and consciousness |
| 1186545 | 4/9/2021 | CO | 39 | M | 4/8/2021 | 4/8/2021 | Patient lost consciousness about 10-15 seconds after vaccination administered. Concerned initially that patient may have been having a seizure due to twitching motion of head lasting 2-3 seconds. Then patient appeared to be sleeping. He was breathing, but audibly snoring and it seemed somewhat irregular. I moved patient from chair to floor and had staff call 911. Patient was still breathing but remained unconscious for about 1.5-2 minutes. He then woke abruptly and was immediately lucid. He was awake when EMS arrived. He stated he has passed out on previous occasions of abrupt pain/use of needles. EMS monitored patient for around 20-30 minutes, and he also had a bottle of orange juice and a granola bar and appeared to feel better. Patient declined transport to hospital by emergency personnel. |
| 1186288 | 4/9/2021 | OH | 29 | M | 4/2/2021 | 4/2/2021 | Pt experienced vasovagal syncope within 15 minutes of vaccination. Supportive care provided and pt recovered without incidence. |

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| 1188198 | 4/9/2021 | NJ | 51 | M | 4/7/2021 | 4/8/2021 | I received the vaccine at 12:15 PM. I was a little tired but generally fine the rest of the day. I woke up at 2:30 and didn't feel well. I got up to go to the bathroom. I started getting the chills and feeling dizzy. I passed out. My wife found me passed out on the ground and bleeding. I needed six stitches in my head and have a black eye as well as other facial lacerations. I have no recollection of anything until my wife woke me. I have never passed out in my life prior to this. |
| 1187314 | 4/9/2021 | CT | 24 | F | 4/7/2021 | 4/7/2021 | Syncope a few minutes after injection, nausea dizziness sweating blurred vision |
| 1186244 | 4/9/2021 | OH | 19 | F | 4/2/2021 | 4/2/2021 | Pt experienced vasovagal syncope within 15 minutes of vaccination. Supportive care provided and pt recovered without incidence. |
| 1186255 | 4/9/2021 | OH | 18 | M | 4/2/2021 | 4/2/2021 | Pt experienced vasovagal syncope within 15 minutes of vaccination. Supportive care provided and pt recovered without incidence. |
| 1186263 | 4/9/2021 | MI | | F | 4/9/2021 | 4/9/2021 | Patient was given the vaccine and was sitting in the observation area. After around 5 minutes patient passed out while sitting on the chair. The two pharmacists ran out to the observation area with an epi pen and had the tech call 911. Patient had a pulse and before administering the epi pen the patient woke up. |
| 1186419 | 4/9/2021 | NC | 33 | F | 4/8/2021 | 4/8/2021 | Pt alert, oriented. Pt rcv'd J&J vaccine and approx 6 minutes later felt tingling in both of her hands. Pt reports hx of sesame seed allergic reaction (anaphylaxis), and she was concerned that this may progress to that point so she just wanted to be checked. Pt declines chest pain, diff breathing, dizziness, syncope, N/V, diaphoresis. Speaking in full sentences. V/S as shown. Pt remained in monitoring area until parking area was released.. Pt stated she felt better and left. |
| 1186272 | 4/9/2021 | OH | 28 | F | 4/2/2021 | 4/2/2021 | Pt experienced vasovagal syncope within 15 minutes of vaccination. Supportive care provided and pt recovered without incidence. |

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| 1186296 | 4/9/2021 | MN | 52 | M | 4/7/2021 | 4/7/2021 | <p>Patient did say before vaccine that he has fainted in the past from previous vaccines. I had a Representative administer vaccine while i stood next to patient and talked with him as a distraction from the shot. After Representative gave the vaccine patient asked "did you give vaccine?", he then immediately started to sweat very hard and said he was light headed (he was sitting down), then his eyes rolled back and he slouched down in chair, at which point I held him so he did not fall on floor. He started to jerk and twitch, perhaps was having a seizure, and was sweating very hard. I held him in chair so he would not hit his head or get hurt. After about 30 seconds he regained consciousness and asked how long he was out. His T-shirt was soaked in sweat and he said he felt very dizzy. The Representative got him an ice pack and placed at base of neck, which he said helped alot. I sat with him for 10-15 minutes until he said he felt fine. I asked if he needed medical care and he said he did not, just needed to sit for awhile, and said this has happened before. I gave him a chair to sit in after he was fully alert and he sat for close to half an hour, at which point he said he was back to himself and felt fine. I did offer he could stay as long as needed and I could call anyone if he needed me too, he insisted he was fine and after about 45 minutes he left. I did call him the next day to check on him and he said he was fine.</p> |

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| 1186297 | 4/9/2021 | NC | 34 | F | 4/7/2021 | 4/7/2021 | 34yr old female with shellfish allergy (reaction: anaphylaxis), exercise induced asthma, previous issues with injections/blood draws (reaction: dizziness) and other comorbidities presented for COVID-19 J&J vaccine on 4/7/21. CMA administered the JANSSEN COVID19 VACC (LOT # 043A21A, exp 6/21/21) IM in patient's left deltoid at 1318. Within 2 minutes of administration, patient became lightheaded and shortly after passed out. Patient had one convulsion (arching back, tense limbs) lasting 5-6 seconds. Once relaxed, patient was arousable. Patient denied hives, shortness of breath, throat swelling, or chest pain. At 1325, BP 48/31, MAP 76, HR 79. Patient assisted to Trendelenburg position and remained lying for 20m. Patient developed chills and tremors during this time stating she was cold. At unknown time later, patient endorsed feeling better and was lifted to sitting position and allowed to sit for another 10minutes. At 1346, final BP 105/58, HR 73. Patient endorsed feeling back at baseline. Provider released patient and patient discharged. Of note, provider notes patient with vasovagal syncope and convulsions after receiving J&J COVID vaccine. Patient has history of vasovagal reactions. |
| 1186302 | 4/9/2021 | PA | 24 | M | 4/9/2021 | 4/9/2021 | Syncope |
| 1186307 | 4/9/2021 | OH | 25 | M | 4/2/2021 | 4/2/2021 | Pt experienced vasovagal syncope within 15 minutes of vaccination. Supportive care provided and pt recovered without incidence. |
| 1186318 | 4/9/2021 | TN | 22 | M | 4/9/2021 | 4/9/2021 | Immediate brief episode of syncope without hitting head or injury. Full recovery after 30 minutes of observation |
| 1186321 | 4/9/2021 | OH | 22 | M | 4/2/2021 | 4/2/2021 | Pt experienced vasovagal syncope within 15 minutes of vaccination. Supportive care provided and pt recovered without incidence. |

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| 1186349 | 4/9/2021 | NY | 39 | F | 4/9/2021 | 4/9/2021 | within a minute of patient leaving the consultation room after receiving the vaccine - patient sat down and passed out. When I looked over, I saw patient experiences minor convulsions. She was still in her chair. Episode lasted not even 10 seconds. Patient awoke and said she blacked out. She was coherent and responsive. We called 911. Patient said she has no history of seizures or low blood sugar. She said she tends to faint when giving blood or during vaccines due to the needle. Paramedic checked patient out and cleared the patient. No ambulance was taken. Will call patient tomorrow to follow up. |

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| 1186264 | 4/9/2021 | NY | 33 | M | 4/9/2021 | 4/9/2021 | <p>Patient presented for his first vaccine dose. He later stated he felt a sensation of something moving through his arm after vaccine administered, then states he felt some increased anxiety, followed by cold sweats, and then lost consciousness. He was noted to be unresponsive, initially with brief period of apnea, and was unresponsive to sternal rub by vaccine administration staff. He was placed into a reclined position in the driver seat of his vehicle. He regained consciousness within a minute, and was normally responsive but with pale color noted to face and chest, diaphoresis, and thready pulse with bradycardia, HR 43. Difficult to auscultate HR and breath sounds clear but shallow. EMS responded promptly and assisted with evaluation, with initial BP 80/50, SpO2 97%. Patient became less responsive and started to lose consciousness again, but responded to questioning, then lost consciousness again. His feet were placed on the dashboard to elevate them, and he quickly regained consciousness, pulse improved to HR 86, and repeat BP after a few minutes was 140/76. Oxygen saturations briefly dipped to 90% then rebounded to 100%. He improved quickly, was normally responsive and able to drink orange juice. He had pale clammy skin on the face, neck and hands, and some facial flushing. Patient was monitored for several minutes, had improvement in symptoms, and refused transport by stretcher to the ambulance. He was able to walk to the passenger side of his vehicle and was driven out of the vaccination facility and further monitored. Blood glucose noted to be 96, EKG normal with sinus rhythm, no acute ST or T wave changes or other acute abnormality. Patient was offered transport to the hospital for further evaluation, but he declined. Symptoms resolved completely, he was monitored for resolution of symptoms. He reported prior similar symptoms after a hand laceration at work and after a dental visit. Risks discussed, prevention measures for second dose discussed. Encouraged follow up with PCP given recurrent vasovagal syncope. No signs of allergy noted.</p> |
| 1187271 | 4/9/2021 | | 38 | M | 4/9/2021 | 4/9/2021 | <p>syncope, diaphoresis, bradycardia. Evaluated by EMS-Cleared</p> |

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| 1186942 | 4/9/2021 | GA | 40 | F | 4/9/2021 | 4/9/2021 | patient has mitral insufficiency and vasovagal syncope. hit a vein and sight of blood and needle almost caused her to pass out. she was sitting on floor, very nauseous, blacking out, cold sweats, and palpitations. |
| 1186980 | 4/9/2021 | TX | 25 | M | 4/9/2021 | 4/9/2021 | Patient received injection and the pharmacist stayed for a few minutes to talk to him and make sure he was ok before leaving patient in the waiting area. About 5 minutes later pharmacist was notified that the patient was feeling dizzy. As the pharmacist approached the waiting area, the patient and fainted and fell out of his chair. The pharmacist helped the patient sit up and he immediately regained his consciousness. The patient was assisted by being given a pillow and ice pack. He was monitored for over 30 minutes before leaving the clinic after recovering. Patient claims to have fear of needles and had not eaten lunch prior to receiving vaccine but had never passed out before, but was states that they were very anxious. |
| 1186985 | 4/9/2021 | RI | 20 | U | 4/9/2021 | 4/9/2021 | Near syncope, elevated heart rate |
| 1187033 | 4/9/2021 | | 20 | M | 4/9/2021 | 4/9/2021 | Vasovagal syncope |
| 1187039 | 4/9/2021 | CA | 20 | F | 4/8/2021 | 4/8/2021 | pt stated that 4 hours after vaccine on 4/8/21 she fainted while at home and hit her arm. She stated that she believes she did not eat enough. She said that after eating and drinking electrolytes she felt better. AS of 4/9/21 she states she has a headache and feels icky. pt stated she did not receive any medical attention |
| 1186901 | 4/9/2021 | CT | 26 | F | 4/9/2021 | 4/9/2021 | Patient received first dose Pfizer covid without incident. Upon sitting in waiting area post vaccination, patient experienced syncope and fell off chair to floor. Patient regained consciousness within moments and was verbally conversing with staff. EMS was called and responded. Patient was given blood pressure check. patient declined any other medical treatment. Patient left without further incident. |
| 1187075 | 4/9/2021 | CA | 66 | F | 4/9/2021 | 4/9/2021 | First dose. Pt fainted, father states pt fainted two times on the drive to clinic. Pt recently admitted to assisted living for syncope..pt remains awake after episode oriented to person place and time paramedics here to evaluate. |

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| 1187087 | 4/9/2021 | OH | 19 | F | 4/9/2021 | 4/9/2021 | Syncope immediately following vaccine Rapid recovery |
| 1187284 | 4/9/2021 | KS | 23 | M | 4/9/2021 | 4/9/2021 | pt started feeling nauseous/hot/sweaty in the after in waiting area and signaled, bench pharmacist made it to chair and guided him to floor, pt was alert and did not hit head. may have lost consciousness for a few seconds while on the floor. elevated his feet with chair. pt opened eyes and we chatted and did breathing exercises. pt states history of fainting w/ IVs and IMZs in the past. declined offer to call someone for him, stated his people were too far away. called emergency medical and they responded, and checked him over. did not check back in with pharmacy, but emergency medical released him and walked out with him. |
| 1187287 | 4/9/2021 | IA | 32 | F | 4/6/2021 | 4/6/2021 | within 5 minutes of immunization: syncope, nausea later that day: feeling winded, lessened syncope and nausea overnight: fever 103 F, chills, body aches, headache continuing through today: occasional, mild lightheadedness, nausea and feeling winded |
| 1186683 | 4/9/2021 | WI | 44 | M | 4/8/2021 | 4/9/2021 | Patient fainted when standing for count. Fell to the floor, lost consciousness, and hit his head against the wall. Reported overnight he experienced chills and lightheadedness |
| 1186282 | 4/9/2021 | | 83 | M | 3/18/2021 | 3/18/2021 | PATIENTS WIFE STATED PATIENT FAINTED WHILE WALKING THE DOG AROUND 5:30 PM ON THE SAME DAY 03/18/2021 |
| 1187288 | 4/9/2021 | CA | 59 | F | 4/9/2021 | 4/9/2021 | Pt had a syncopal episode @1152 while being observed in waiting area. The pt slipped off chair onto the ground, did not sustain any injuries. Physician onsite indicated that it may have been a Vagal response. The pt has history of fainting related to anxiety. |

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| 1187306 | 4/9/2021 | NJ | 19 | M | 4/8/2021 | 4/8/2021 | Patient, while waiting for for the 15 minutes post-vaccination, fainted. The mom, accompanying the patient, started helping him off the floor and as I was helping her, the patient immediately woke up and regained consciousness, but was a little pale. I brought water for the patient, took his blood pressure which was about 100/50. His mom brought him orange juice and as I was sitting with the patient, he stated that he usually faints when getting blood drawn and such. I sat with the patient for about 10-15 minutes, and he was improving, regaining color and more talkative. I then had the patient slowly get up and had his blood pressure measured again and it was 105/75 which according to himself and his mom was his normal. They then decided to leave and the patient was doing well by then. |

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| 1187061 | 4/9/2021 | CA | 35 | M | 4/9/2021 | 4/9/2021 | <p>HPI: Patient is a 35 year old male who presents following administration of a single dose of J&J COVID19 vaccine in the left deltoid. Patient started to feel light headed and nauseous while walking to his car. About 20 minutes following vaccination, a vaccinator had walked passed his vehicle and noted that he was unconscious. Patient was still unconscious upon medical response team arrival and unresponsive to stimuli. Once the patient awoke about 30 seconds later, he continued to state that he was nauseated and ?did not feel good.? Patient was unaware that he had lost consciousness. He further disclosed that he had been working in the sun planting trees all day and had not consumed any food or beverage. He denied allergies to medication, food, and other vaccines. He relayed that he had passed out from vaccinations in the past as a child. He affirms lightheadedness and nausea. He denies chest pain, difficulty breathing, swelling of the face/lips/tongue/throat, skin rash/itching, cramping abdominal pain, and vomiting. Exam (update as needed): GEN: Upon arrival, patient unconscious and not responsive to stimuli HEAD: NCAT EYES: pupils unreactive and mydriatic ENT: Ears normal, Nose normal, OP normal, no evidence of angioedema NECK: Supple, without LAD. CV: RRR, no m/r/g, palpable strong radial pulse PULM: Clear to auscultation bilaterally, no accessory muscle use ABD: Soft, no tenderness. SKIN: Skin pale, cool, and clammy. No rashes. No erythema or edema of the injection site. MSK: FROM, MS 5/5 NEURO: Patient unconscious upon arrival. CN 2-12 grossly intact, no ataxia, gait steady Clinical Impression/Field Tx: Vasovagal syncope. EMS called immediately to respond to the site for further evaluation. Patient placed into a reclined position. Patient not displaying active signs or symptoms of anaphylaxis. Upon regaining consciousness, patient was alert and oriented x4. Once the patient demonstrated ability to control airway, he was given candy and water. EMS arrived and an EKG and BGL were performed, both of which were normal. Vital signs were stable. Instructed patient to consult their PCP regarding the post-vaccination reaction. Patient instructed to go to emergency department should they develop chest pain, difficulty breathing, swelling of the face/lips/mouth/tongue/throat, or cramping abdominal pain with nausea/vomiting, as these are signs of possible</p> |

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| | | | | | | | anaphylaxis that requires immediate intervention. Medications administered: None Disposition: FD EMS called to the scene for further evaluation. Patient elected to go home after evaluation by EMS. |
| 1186802 | 4/9/2021 | FL | 19 | M | 4/9/2021 | 4/9/2021 | PATIENT BECAME DIZZY AND FAINTED BRIEFLY(SECONDS). PATIENT DID NOT LIKE SHOTS. HELD HIM AT PHARMACY FOR 30 MINUTES UNDER SUPERVISION. GAVE WATER. CONFIRMED HE HAD A RIDE HOME AND FELT 100% |
| 1186753 | 4/9/2021 | MA | 42 | M | 4/8/2021 | 4/8/2021 | Almost fainted from extreme dizziness. Laying down and having a drink prevented fainting and improved symptoms. |
| 1187273 | 4/9/2021 | CA | 29 | F | 4/8/2021 | 4/8/2021 | DURING THE OBSERVATION PERIOD AFTER PATIENT HAD RECIVED THE VACCINE, THE PATIENT FAINTED. |
| 1186879 | 4/9/2021 | FL | | U | | | PATIENT FAINTED FOR 30-40 SECONDS..CALLED AMBULANCE..HE WAS AWAKE AT THE TIME OF AMBULANCE ARRIVAL.CHECKED EKG..HE WAS OK..WAS NOT TAKEN TO HOSPITAL |
| 1186736 | 4/9/2021 | NY | 60 | F | 4/6/2021 | 4/6/2021 | patient fainted 40 seconds, regained complete alertness |
| 1186759 | 4/9/2021 | SC | 21 | M | 4/6/2021 | 4/6/2021 | 1. Vasovagal syncope almost immediately after vaccination, little to no warning of oncoming syncope 2. Extremely fast acting fever (temperature went from 98.6 to 100.5 in roughly 30 minutes) followed by nausea, pounding headache, and body aches/chills. Remedied by alternating very high doses of ibuprofen (800mg) and acetaminophen (1000mg or 1g) every two to three hours. This did not ever bring down the fever below 100 degrees. 3. Blurred vision around 29 hours after vaccine - advised to go to ER by triage nurse. ER doctor determined not to worry about, likely due to headache but not 100% sure. |

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| 1186751 | 4/9/2021 | WI | 49 | M | 4/9/2021 | 4/9/2021 | Patient fainted post vaccination. Patient was sitting in observation chair when he fainted. Staff immediately attended to patient, and he regained consciousness rapidly. He was given water/snacks and monitored for an additional 15 minutes and then left and he stated he was feeling fine. Patient was called later for follow-up and said he was still feeling fine/no issues. |
| 1186711 | 4/9/2021 | RI | 37 | F | 4/7/2021 | 4/8/2021 | Passed out on 4/8 @ 8am Was at home. On going headache for remainder of 4/8 |
| 1186804 | 4/9/2021 | MI | 40 | F | 3/31/2021 | 3/31/2021 | Pain in arm immediately upon injection. Extreme dizziness, light-headedness, and a warm flush came over me within 2-3 minutes. Sat down on a chair, put my head between my knees. Wasn't helping so I sat down on the floor cross-legged and put my head to the ground to try to keep myself from fainting. A medic noticed I wasn't doing well and took me to a tent on the other side of the large room to lie down. She asked if I wanted a wheelchair and I declined. I barely made it to the tent to lie down before I would have fainted. Lying down was significantly better than sitting down. After staying prone for about 20 minutes, I was doing better so I left. Immediately after walking outside and feeling cool fresh air I was much much better. Dull headache approximately 19hrs after shot that lasted half a day. 48hrs post shot had tingling and numbness in injection arm that lasted about a day. Injection arm soreness for 3 days total. |
| 1186854 | 4/9/2021 | SC | 40 | M | 4/9/2021 | 4/9/2021 | Patient passed out during waiting period after vaccination. |
| 1186812 | 4/9/2021 | MS | 44 | F | 2/5/2021 | 2/5/2021 | Dizziness Vision loss Fainting Came to, drank water, ate banana, cold rags on face |
| 1186839 | 4/9/2021 | NV | 23 | M | 4/9/2021 | 4/9/2021 | Syncope |

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| 1186848 | 4/9/2021 | OR | 60 | F | 4/9/2021 | 4/9/2021 | Pt arrived to vaccination clinic stating she had multiple allergies and after her shingles vaccination she had an allergic reaction. 3 RN's present in room during this time. Vaccination given and patient ambulated to observation location. Within 30 seconds patient started complaining of feeling dizzy, SOB, and passed out. Patient assisted to floor by 2 RN's while 3rd RN called RRT. Patient not responded to verbal commands. Pt with pulse and respiratory effort. Patient began shaking in seizure like activity. Oxygen applied at 4 L NC. Unable to get B/P or SPO2 due to shaking. Epi 0.3 mg administered SQ by RN. Patient began to mumble words and laughed at husband. RRT present and patient accompanied to stretcher and transferred to ER for evaluation. Report given to ED RN by Primary RN. |
| 1186849 | 4/9/2021 | NC | 28 | M | 4/9/2021 | 4/9/2021 | lightheaded, sweating, and fainted twice |
| 1186876 | 4/9/2021 | MA | 41 | M | 4/9/2021 | 4/9/2021 | I got the vaccine at about 12:55pm. About ten minutes after getting the vaccine, while sitting in a chair, I began to get tunnel vision and felt extremely tired. I broke out in a cold sweat all over my body. I began to lose my vision like I was fainting and I momentarily blacked out or dozed off, then came back awake. I started to get tunnel vision again for a minute, then it faded away. Then I continued sweating for a minute and then it faded away. After a couple minutes I felt fine again. I sat for another several minutes then left at 1:15 feeling ok with just a sore shoulder. |
| 1186786 | 4/9/2021 | TN | 31 | F | 4/9/2021 | 4/9/2021 | Patient stated that she passes out from all vaccines or pain like bee stings. 30 seconds after vaccinating patient she passed out. She passed out 5 times over the next 10 minutes. We gave her some chocolate candy and a water, then she started feeling better after that. |

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| 1186863 | 4/9/2021 | CO | 36 | F | 4/7/2021 | 4/7/2021 | Beginning approximately 2 minutes after receiving shot, experienced the following in sequential order: - Mild but Sharp pain (2-3 on pain scale) in my right elbow (same side as injection) - Slight lightheadedness - Sweating Profusely - Extremely blurred vision - Muffled hearing/Deafness I recovered within 10-15 minutes and was sent on my way by the paramedics. Was not particularly nervous about getting the shot, and I don't have any history of fainting. Felt perfectly fine the rest of the evening. |
| 1180580 | 4/8/2021 | | 24 | U | 4/7/2021 | 4/7/2021 | post vaccine fainting episode, recovered and sent home |
| 1180702 | 4/8/2021 | | 25 | M | 4/8/2021 | 4/8/2021 | Syncope occurred within 5 minutes of vaccine. LOC lasted about 60 seconds with return to baseline after 5 minutes. Vital signs remained within expected range for 40 minutes with 5 separate checks. Discharged home. |
| 1180596 | 4/8/2021 | MA | 63 | F | 3/24/2021 | 3/24/2021 | Immediately after receiving the 1st dose I had a bad reaction, I started getting dizzy and weak, sweating, shaking, blurred vision and low blood pressure, and I fainted. I never had that before and it took me an hour before I could get up and walk. |

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| 1180614 | 4/8/2021 | IN | 18 | F | 4/6/2021 | 4/6/2021 | Initially she passed out following the vaccine - within 90 seconds- she has a history of passing out with injections and blood draws. Around noon she had a seizure. She describes a feeling of darkness and dread closing in on her and she was unable to speak or move. She was on the stairs at the time. I witnessed her stiffen, then go limp and fall between the electric stair hair and the wall. She hit the hardwood floor face first then she began to shake/twitch. She was unconscious. She awoke screaming, incoherent speech, and flailing limbs. It took about 5 minutes to calm her and be able to understand her speech. She only remembers the darkness and waking up scared and feeling awful. She was put supine on the floor with feet elevated, blood pressure monitored, given juice to drink, and vitals checked routinely. After about an hour supine and conscious, she felt good enough to sit up. She sat up for 15 minutes before she was able to stand with assistance. Family physician was notified immediately and we are still waiting for a response. She has a goose egg sized knot on her forehead, a bruise on the side of her face and a black eye from hitting the floor. She has a huge bruise on her outer thigh and lower leg where she hit the stair chair and then seized and it it repeatedly on the metal. She has underarm pain from where her armpit hit the edge of the stairs when she fell and seized. She has no history of any types of seizures. |

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| 1181655 | 4/8/2021 | CA | 23 | F | 4/8/2021 | 4/8/2021 | The patient was sitting for their 15 minute observation time and about 5 minutes after the patient's vaccination the patient was holding her head and tilting forward. I came over to ask if the patient was ok. The patient said they felt unwell and needed to vomit. The patient proceeded to vomit several times in a garbage can. The patient and their mother were sent to the back of the store near the bathroom to be observed for further symptoms. Patient and mother stated no need to call 911. After about 20 minutes the patient felt well enough to try to home. I escorted the patient and their mother out of the store when the patient felt ok. The Vaccine Administration Record(VAR) form filled out by the patient did not state that they had felt dizziness or fainting from any vaccine previously. Upon questioning the patient after vomiting the patient stated she had dizziness/fainted and vomited before after blood draws. However, the patient has not gotten any recent vaccinations and no such adverse reactions took place before. |
| 1178955 | 4/8/2021 | ID | 19 | M | 4/7/2021 | 4/7/2021 | The patient experienced syncope, diaphoresis, nausea and vomiting. The patient was able to recover within 45 minutes and leave under his own power. The patient was coherent and not in any noted distress. |
| 1180677 | 4/8/2021 | AZ | 16 | M | 3/31/2021 | 3/31/2021 | Approximately 5 minutes after receiving his first shot he passed out and seized for approximately 15 seconds. Fire and EMT called and stabilized him then taken to hospital for tests. |
| 1180402 | 4/8/2021 | | 38 | F | 4/7/2021 | 4/7/2021 | Started with chills, then dizziness, nausea and passed out until was found by another person. Had ringing in ears either right before passing out or when coming to consciousness. Vomited after waking up. Chills returned, fever of 100.3, blue lips. Headache came later |
| 1180653 | 4/8/2021 | WA | 19 | M | 4/8/2021 | 4/8/2021 | vasovagal response. - sudden flushing - faint feeling x30 seconds - passed out while seated (x3 seconds) - resolved unconsciousness after laying prone - nausea and dry heaving once conscious x1 minute return to normal after 5 minutes (and given 500mg tylenol & 25mg benedryl) |

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| 1180670 | 4/8/2021 | FL | 49 | M | 4/8/2021 | 4/8/2021 | Patient passed out fell to ground and started with jerking motions. Patient was taken by ambulance to the emergency room. Patient's blood pressure and pulse were low when checked by paramedics. |
| 1180628 | 4/8/2021 | WA | 30 | F | 4/1/2021 | 4/1/2021 | fainting vasovagal syncope |
| 1180567 | 4/8/2021 | CA | 33 | M | 4/8/2021 | 4/8/2021 | patient fainted in the observation room after vaccine was given, brought to EMS room via Wheelchair. States this happens every time he gets a shot. Allowed to rest and given water discharged in stable condition @ 930am |
| 1180559 | 4/8/2021 | PA | 31 | F | 4/7/2021 | 4/7/2021 | Patient was given the Janssen Covid 19 vaccine on 4/7/21 around 11:55am in her left deltoid. She was accompanied by her husband at the clinic. After the immunization she was seated in the waiting area to be observed for 30 minutes after her vaccine. Approx. 5 mins after the vaccine was given, the patient passed out in the chair and I (the pharmacist) was alerted. The patient came back to when I arrived at her seat and was able to talk and asked for water. Her husband stayed by her side while I went to obtain water and I heard her husband say she passed out again and then regained consciousness. He layed her on the floor while I called 911. An ambulance came and took the patient to the hospital. |
| 1180447 | 4/8/2021 | MN | 28 | F | 4/8/2021 | 4/8/2021 | Nearly fainted after vaccine. Moved to cot and recovered. |
| 1180446 | 4/8/2021 | | 18 | U | 4/7/2021 | 4/7/2021 | post vaccine syncope. lowered to floor, consciousness returned. transferred to observation tent, recovered, sent home |
| 1180409 | 4/8/2021 | | 16 | F | 4/7/2021 | 4/7/2021 | post vaccine syncope. did not fall. brought to observation tent. monitored for 25 minutes and sent home. |
| 1180395 | 4/8/2021 | | 29 | U | 4/7/2021 | 4/7/2021 | episode of syncope. recovered immediately. pt evaluated and vitals were stable. |
| 1180355 | 4/8/2021 | IL | 26 | M | 4/8/2021 | 4/8/2021 | patient reported feeling dizzy and faint 5 minutes after vaccine while sitting down. water was offered. 3 minutes later, patient was still feeling dizzy and requested to lie down. upon helping patient to a place to lie down, they fainted in the store. paramedics were called and personnel stayed with patient until paramedics arrived |

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| 1180352 | 4/8/2021 | | 23 | M | 4/8/2021 | 4/8/2021 | patient reports he "passed out" and slowly rolled his car into the car in front of him at drive thru vaccine event. Vasovagal event resolved within minutes and pt improved |
| 1180708 | 4/8/2021 | MT | 29 | F | 4/7/2021 | 4/7/2021 | Within five minutes after receiving vaccination, the patient became pale and fainted. She became responsive again in less than one minute, and her color was restored within two minutes. A cold compress was placed on her forehead and the back of her neck, and she was given orange juice. Around ten minutes later, the patient gagged a bit and she spit up saliva. Patient reported she has fainted before while giving blood and that she was experiencing high anxiety over the thought of a vaccination. |
| 1181465 | 4/8/2021 | PA | 44 | F | 4/8/2021 | 4/8/2021 | Pt stated she felt dizzy and passed out. Called EMTs |
| 1180298 | 4/8/2021 | FL | 44 | M | 4/7/2021 | 4/7/2021 | Rapid onset of nausea and dizzy / lightheaded feeling shortly after standing up from chair within 2 minutes after vaccination. Immediately sat back down to place my head between my knees, and completely blacked out, fallout out of the chair and hitting my head and knee on the floor and nearby fixtures. Regained consciousness on floor about 30 seconds after fainting and immediately felt much better. Pharmacy staff were on hand and promptly called 911, instructed me not to move and took my pulse and monitored me until EMS arrived within 5-10 minutes. Vital signs normal including BP 120/90, 100% o2 levels, normal blood sugar and EKG. EMS assisted in getting me back to seated position and monitored for another 10-15 minutes. Declined transport and had family member drive me home where I rested for a few hours and woke up feeling fine. Very minor bruising / bump on head with no lasting sign of concussion or other trauma. 24+ hours post vaccine no other notable vaccine reactions aside from sore arm / muscles on injection site. |

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| 1180266 | 4/8/2021 | | 43 | M | 4/8/2021 | 4/8/2021 | Patient has a history of fainting after vaccination. Had patient sit for awhile before releasing him to the recovery room. He informed the vaccinator he was fine and was released to the recovery room. Just about to sit down, fell over off chair to the left. Had patient lay on his back and elevated his feet. Checked BP several times 130/70 then 170/100 then 142/100 and finally 150/100. Pulse ox readings were 97 then 99 SpO2. Pulse was 90 and fell to 82. Patient was stable and had a friend give him a ride home. |
| 1180252 | 4/8/2021 | NC | 32 | M | 4/7/2021 | 4/7/2021 | 32yroid patient with PMH including anxiety presented on 4/7/21 at office for J&J COVID 19 vaccine. Administered JANSSEN COVID19 VACC (LOT # 043A21A, exp 6/21/21) IM in patient's left deltoid at 1350. After receiving vaccine, patient felt lightheaded and sweaty. At 1358, BP 81/49, HR 37, 93% RA. Patient endorsed previous reactions during immunizations previously. Other symptoms denied and no history of anaphylaxis. Patient placed in Trendelenburg position with resolution of symptoms. BP while in Trendelenburg position, 1010/58, HR 66, 98% RA. Minutes later while in sitting position, VS remained stable and BP 125/89, HR 87. Provider assessed patient and noted vasovagal reaction following vaccination. No syncope. All symptoms resolved. Patient discharged home in stable condition. |
| 1180427 | 4/8/2021 | | 20 | M | 4/7/2021 | 4/7/2021 | post vaccine syncope. monitored in med tent. Recovered, sent home. |
| 1181388 | 4/8/2021 | NC | 24 | M | 4/8/2021 | 4/8/2021 | The patient fainted 10 minutes after his shot and fell from the chair he was sitting in. He had a brief seizure while on the ground and someone called for help. I ran over and yelled for someone to call 911. He stopped seizing and stood up when he came to. I supported him and asked him to have a seat. He sat down and I asked how he felt and if he would like food or water. He said he felt okay but accepted the food and water. At that time, firefighters that had been shopping in the store arrived and started interviewing the patient. They took his pulse and blood sugar levels. Medics arrived and he continued to be monitored. After several minutes, he refused the ambulance and said he was feeling good enough to leave. |

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| 1181654 | 4/8/2021 | IL | 34 | F | 4/6/2021 | 4/6/2021 | Patient received her vaccination at 5:15. Patient did state she has a history of fainting after vaccination when sitting up. Ems on site able to lie down to receive vaccination. Patient continued to lie down until 15 min after then transferred her walking to monitoring station. EMS on hand monitoring. B/p/112/70 100 Pulse ox, 88P. While patient sitting in monitoring station began to feel faint was able to lie down with help of EMS and started feeling better. Patient was able to drink juice and stated she started to feel better. Declined further treatment from EMS. Patient left after 15 more min of monitoring. Gait stable talking with no difficulty. |
| 1179404 | 4/8/2021 | CA | 18 | F | 4/7/2021 | 4/7/2021 | Site: Redness at Injection Site-Mild, Systemic: Chills-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Shakiness-Mild, Additional Details: Patient fainted twice, possibly due to low sugar because she did not ingest any food in the morning. Family member stated that patient has fainted multiple times after vaccination. Patient did not develop any swelling/inflammation. Nurse offer to call 911, family declined. |
| 1180219 | 4/8/2021 | | 50 | F | 3/23/2021 | 3/23/2021 | Shortly after being vaccinated, patient began to experience lightheadedness and pre-syncope. Vital signs showing tachycardia. Improved on own |
| 1181605 | 4/8/2021 | ID | 24 | F | 4/8/2021 | 4/8/2021 | Patient fainted right after receiving her shot. She woke up immediately after, though very pale and shaky. Patient stayed laying down for 15 minutes until she felt better and left under her own power with no problems. |
| 1181596 | 4/8/2021 | FL | 28 | U | 4/8/2021 | | Syncope, vasovagal |
| 1181559 | 4/8/2021 | DC | 38 | M | 4/8/2021 | 4/8/2021 | Patient was being observed after vaccine and passed out. While laying on the floor, he seized x 2 for about 45 seconds. No memory of seizure/seizure-like activity. |
| 1181536 | 4/8/2021 | PA | 44 | F | 4/8/2021 | 4/8/2021 | Patient stated she felt dizzy and passed out. Called for EMT |
| 1181526 | 4/8/2021 | CT | 19 | M | 4/8/2021 | 4/8/2021 | Shortly after receiving vaccination patient fainted while sitting on bench. Paramedics were called and patient was transported to hospital for evaluation. |
| 1181525 | 4/8/2021 | | 54 | M | 4/8/2021 | 4/8/2021 | Syncope, low Heart rate, passed out |

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| 1181485 | 4/8/2021 | CO | 27 | M | 4/8/2021 | 4/8/2021 | Patient received immunization and felt fine after sitting in chair for a few seconds. Pt got up and went to waiting area and was sitting down in chair during the 15 minute observation window. Pt passed out and slumped/fell out of chair on patients left side. I was called out by the person monitoring the waiting area to see pt in fetal position on their left side seizing. The seizing lasted for about 15 seconds and then stopped. PT was motionless for a few more seconds and then came around and said "I'm back". The pt was given a bottle of water because he said he was thirsty. In the meantime the paramedics were called and arrived. They checked his BP and Blood Glucose. After several minutes they took the pt out on a gurney for further evaluation, there was a question as to whether or not pt hit his head. |
| 1181399 | 4/8/2021 | FL | 43 | M | 4/1/2021 | 4/1/2021 | Within 15-minutes of vaccination, the patient experienced a syncopal event. EMS evaluated the patient on-site. The patient was hypotensive (54/31) and bradycardic (42bpm). EMS transferred the patient to Medical Center Emergency Department. In the ED, the patient reported a syncopal event that lasted 1-minute. Th patient was resting comfortably in no acute distress and reported feeling improved. Physician administered 1L IV normal saline. After noted improvement, the physician discharged the patient with diagnoses of Vaccine reaction and secondary Near syncope. |
| 1181409 | 4/8/2021 | TN | 36 | M | 4/6/2021 | | The patient received his Janssen Covid 19 vaccine, and sat down in the waiting room for about 2 minutes. He started feeling sick and got up to go to the restroom. On his way to the restroom, he passed out and fell in the hallway. We then got him to a seat and gave him some water and orange juice. The patient was adamant that we not call an ambulance for him, so we made the patient stay seating under our direct supervision. He sat in the waiting room for about an hour until someone could come to pick him up. By the time someone arrived to take him home, he seemed to be doing much better. |

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| 1180734 | 4/8/2021 | MO | 18 | F | 4/8/2021 | 4/8/2021 | Patient vomited immediately after vaccination. She sat for approximately 7 minutes with an ice pack before asking to walk somewhere to lay down. About 100 feet in to the walk, she fainted. She was being supported on both sides by pharmacist and her boyfriend, so she went to the ground gently. |
| 1181308 | 4/8/2021 | OH | 39 | F | 4/8/2021 | 4/8/2021 | About 10 minutes after receiving the vaccine the patient was showing signs of becoming light headed and pale and passed out momentarily. She slide out of her chair tot he floor but quickly regained consciousness. She said she felt light headed and was having trouble breathing. We called 911 and kept her comfortable until they arrived. No medication was given. Patient left with the squad. |
| 1181293 | 4/8/2021 | MA | 26 | F | 4/8/2021 | 4/8/2021 | Pt recieved covid19 vaccine. While sitting in observation. PT began experiencing dizziness. PT fainted and struck the floor causing an abrasion on her top right forehead and chipped her tooth cap. PT was evaluated with EMS on scene. PT was transported by fire rescue shortly after. |
| 1181283 | 4/8/2021 | NJ | 48 | M | 4/8/2021 | 4/8/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Pt seemed to be fainting after administering the Janssen COVID vaccine - felt better and was normal after administering EpiPen. 911 was called after administering EpiPen - they came and cleared the pt to go. Pt sat for another 15 minutes afterwards and left after assuring us that he was feeling normal - he was accompanied with his wife the entire time. |
| 1181275 | 4/8/2021 | MI | 64 | F | 4/8/2021 | 4/8/2021 | Patient was feeling light headed, shaky and started to sweat. She then fainted and was caught by myself. We immediately called 911 , her blood pressure was taken and it was within normal limits. She did not have any difficulty breathing, swelling of the tongue or other side effects that were showing signs of anaphylaxis. Patient received water and started to feel cooler and less shaky. Once the paramedics arrived, she was assessed and was monitored for at least 25 minutes by myself and the paramedics. Patient was not disoriented and was given the OK to go home by the paramedics. Patients husband was contacted to come and drive her home. |

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| 1181259 | 4/8/2021 | PR | 54 | F | 3/27/2021 | 3/27/2021 | Patient previous receiving the vaccine shot he alerted the medical staff and nurses since he almost every time he undergoes an injection he develops vasovagal syncope. Medical staff was prepared to deliver attention. Approximately two minutes after having the vaccine, patient developed lightheaded and faint. He had self-limited systemic hypotension , which promptly resolved as well patient mentation and alertness once he regain consciousness. Afterwards patient only complained of mild nauseas that as well resolved previous leaving the observation area of the clinic. Patient previous leaving the vaccination clinic recover himself completely denied any constitutional symptom including chest pain, headaches, nauseas or vomiting. Blood pressures returned to normal limits. No medication nor further test were needed, only vital signs monitoring. |
| 1181256 | 4/8/2021 | FL | 43 | F | 4/8/2021 | 4/8/2021 | Syncope, loss of consciousness, nausea fell off chair |
| 1180887 | 4/8/2021 | FL | 46 | M | 4/1/2021 | 4/1/2021 | Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Hyperventilation-Medium, Systemic: Hypotension-Medium |
| 1180879 | 4/8/2021 | FL | 46 | M | 4/1/2021 | 4/1/2021 | Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Hypotension-Medium |
| 1180876 | 4/8/2021 | MO | 28 | M | 4/8/2021 | 4/8/2021 | Patient has a known needle anxiety and faints with any vaccine or blood draw. His doctor recommended pre-medicating with diazepam 5mg to reduce anxiety and hopefully prevent syncope. He initially did well for a minute or two, then fainted for a few seconds, woke up, felt nauseous, vomited, then fainted again for a few seconds. Once he woke up, he felt much better. He waited a few extra minutes and went home. |

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| 1180867 | 4/8/2021 | TX | 57 | F | 3/31/2021 | 4/5/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: pt reported hurting ankle while getting up-Medium, Additional Details: On 03/31/2021 pt was given covid vaccine by Technician at 12:11 pm, pt was seated in chair, fainted and rolled out of chair, pt reported twisting ankle when attempting to get up. Technician tended to pt until pt was well enough to leave the pharmacy on her own accord. After pt left Technician reported to Pharmacist, was told pt fainted but felt fine enough to leave. On 04/05 pt called store manager to report that she suffered from a broken wrist ankle and rib. |
| 1180819 | 4/8/2021 | TX | 54 | M | 4/8/2021 | 4/8/2021 | Vaccine was given at 11:30AM. Approx. 5 minutes after dose given, patient was lightheaded, broke out into a sweat, pale, cold, and fainted twice in the course of 15 minutes. 911 was called and arrived at 11:45AM. |
| 1181476 | 4/8/2021 | IL | 62 | F | 4/7/2021 | 4/8/2021 | Low blood pressure, fainted once while sitting on stool. Patient has similar response when actually having COVID back in October. Possible interaction with blood pressure medicine |
| 1179346 | 4/8/2021 | CO | 21 | F | 4/7/2021 | 4/7/2021 | Systemic: Chills-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Nausea-Medium, Systemic: Shakiness-Medium |
| 1179457 | 4/8/2021 | FL | 30 | M | 4/7/2021 | 4/7/2021 | Site: Pain at Injection Site-Mild, Systemic: Fainting / Unresponsive-Medium, Systemic: Hypotension-Medium, Systemic: Nausea-Medium, Systemic: Shakiness-Medium, Systemic: Tingling (specify: facial area, extremities)-Medium |
| 1179437 | 4/8/2021 | SC | 32 | F | 4/7/2021 | 4/7/2021 | Systemic: Fainting / Unresponsive-Severe, Systemic: Seizure-Severe, Systemic: Weakness-Severe, Additional Details: Patient reported a history of "passing out" with injections. Pt experienced diaphoresis and dizziness immediately following injection. Two to three minutes later she said she was feeling better. Five minutes after dose, she began to present with seizure symptoms; blank stare, arms and hands contracting. First seizure lasted 30 seconds. One minute later, her second seizure began(45 seconds) with the same symptoms, plus convulsions. We transferred her to the floor and on her side. VSS. EMS called |

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| 1179433 | 4/8/2021 | FL | 27 | M | 4/7/2021 | 4/7/2021 | Site: Pain at Injection Site-Mild, Systemic: Fainting / Unresponsive-Mild |
| 1179429 | 4/8/2021 | AL | 28 | M | 4/7/2021 | 4/7/2021 | Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Joint Pain-Mild, Additional Details: Patient passed out hit his head while dropping to the ground. Paramedic was called and came. He was fine after, but called a ride to get him to be on the safe side. |
| 1179413 | 4/8/2021 | CA | 24 | M | 4/7/2021 | 4/7/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Shakiness-Mild, Additional Details: patient has no medical condition and is not on medication. he had anxiety attack in the past. He passed out after covid administration and recovered a minute after. He did not have any other symptoms (i.e., shortness of breath, vomiting, swelling, vision changes, or so.) We gave him a 25 mg benadryl. We called 911 and his vital signs were normal when 911 checked. They admitted him to the hospital for monitoring the symptoms. |
| 1179400 | 4/8/2021 | MA | 25 | F | 4/7/2021 | 4/7/2021 | I walked up the stairs to go to bed at 10:45pm and started feeling very dizzy, lightheaded, and nauseous. At the top of the stairs I passed out and fell backwards. Not sure exactly how long I was out, but no more than a few minutes. When I woke up I was disoriented and nauseous but didn't have the strength to get up. I rolled into my side and vomited 3 times. My fiance helped me get up slowly. He took my temp but I did NOT have a fever. The nausea, dizziness, and lightheadedness subsided after about 10 minutes, so I decided to NOT seek medical attention. This morning I have a headache and body aches in my lower back and left arm. |

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| 1179394 | 4/8/2021 | CT | 33 | M | 4/6/2021 | 4/6/2021 | Systemic: Seizure-Mild, Additional Details: Patient sitting after vac. was administered. Patient was about to stand up but fainted while on floor he had a seizure for about 3 secs. After the event he was alert & oriented, but did not remember the episode. BP #1 was 98/70 . Client was provided water and stayed in lying position for 40min with the supervision of the nurse. He wanted to drive himself to work but was told he should have someone pick him up however client refused stating his job was only "5 min away".BP before leaving 110/70. |
| 1179384 | 4/8/2021 | CO | 18 | F | 4/7/2021 | 4/7/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: Vomiting-Medium, Additional Details: Patient was administered vaccine per protocol. Prior to injection patient was complaining of being nervous, and permission was sought to proceed with the shot. Patient fainted about 10 seconds after the completion of the injection and was stabilized in the chair. When the patient came to she was complaining of nausea and proceeded to vomit several times. Mother of the patient was present at the time and said that she had a crippling fear of needles. |
| 1179377 | 4/8/2021 | IN | 31 | M | 4/7/2021 | 4/7/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: patient fainted after only about 2 minutes in chair. he came to immediately, was surprised, he sat in observation area for 25min as he recovered. |
| 1179361 | 4/8/2021 | GA | 21 | M | 4/7/2021 | 4/7/2021 | Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Mild, Systemic: Dizziness / Lightheadness-Medium, Systemic: Exhaustion / Lethargy-Medium, Systemic: Fainting / Unresponsive-Medium, Additional Details: Syncope, light head, blurry vision. |
| 1179419 | 4/8/2021 | NY | 26 | M | 4/7/2021 | 4/7/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Nausea-Mild, Systemic: Tingling (specify: facial area, extremities)-Mild, Systemic: Visual Changes/Disturbances-Mild, Additional Details: Patient felt lighthead and almost passed out. Sweating was profuse but no fever. |
| 1179348 | 4/8/2021 | CO | 20 | M | 4/7/2021 | 4/7/2021 | Systemic: Body Aches Generalized-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Exhaustion / Lethargy-Medium, Systemic: Fainting / Unresponsive-Severe. |

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| 1179483 | 4/8/2021 | MI | 40 | F | 4/6/2021 | 4/6/2021 | My vaccine was administered at 12:30pm. I waited until 12:55 at CVS after the vaccine to make sure there were no reactions. I also move my arm around a lot after the injection to keep it from hurting. I drove home, at lunch and about 2:45 was hit with a very noticeable headache. I never get headaches and eat healthy and consume about a gallon of water a day. I knew it wasn't from dehydration or being hungry. Headache was in the temple area and made my eyes hurt in the same way they would if you had cried for an extended period of time or were overtired. At 3pm a wave of exhaustion hit me. I was sitting working trying to combat the headache and felt almost wiped out. I got through the rest of my work day (4:30) and went to lay down immediately. I passed out almost instantly until 7 pm. I work up and showered, ate dinner and started to feel a little warm. It should be noted it was an unseasonably warm day and got up to 77, so it was a tiny bit warm in my home. I put on loose fitting clothes and slayed on the couch still with the bad headache and the injection site started to throb so I placed and ice pack on for 20 minutes. I could only stay awake until 8:45 and got in bed. I could not get comfortable for several hours feeling very warm. I tried a fan on high and drinking more water but i felt very warm like how you feel with the flu. I took my temp at 1130pm it was normal. I continued to toss and turn and feel very warm and slightly dizzy, in the sense that I hadn't been able to sleep and with the headache my body was just exhausted. Around 2 am i woke up for more water and got in the shower because I had sweated so much my sheets were wet and my clothes. I got out of the shower around 10 minutes later, changed and got new sheets and got back in bed. Around 330 I felt very hot again and opened the windows and got another ice pack for my arm which was throbbing again. I finally fell asleep after 3:45am. I got up for work at 6am. I felt slightly foggy, and very hot. But no fever. My temp is normally around 97.4-97.9 and it was 98.4. Still normal but I was running warmer than usual. It took a long time to get ready and despite hot water in the shower I was freezing. i got dress and debated going to work. Got in the car at 6:45 and my drive to work is 30 minutes. 1/2 way into my drive I got very sweaty again and went home to change my clothes because they were too warm. Got to work around 7:20 and still felt warm but they take our temps at the door and |

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| 1179342 | 4/8/2021 | FL | 31 | M | 4/7/2021 | 4/7/2021 | min was still okay, no fever. I drank a lot of water and ate, and at 8:30 am all of a sudden the exhaustion was gone and I felt normal. I got home from work at 5:30p and took a 3 hour nap and felt normal again. |
| 1179272 | 4/8/2021 | CT | 73 | F | 2/20/2021 | 2/21/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Additional Details: Patient fainted after getting his pfizer shot. he was sweating. |
| | | | | | | | body aches; headache; coughing; fever; This is a spontaneous report from a contactable consumer. A 73-year-old female non-pregnant patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: UNKNOWN) via unspecified route of administration on 20Feb2021, at 08:00 (at the age of 73-year-old) as a single dose for COVID-19 immunisation. The patient medical history included COPD, hypertension, hyperlipidemia, Osteoporosis, Spinal Stenosis, Syncope, tobacco use, neuropathy. Prior to the vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient concomitant medication included clopidogrel at a dose of 75 mg, irbesartan at a dose of 300mg, metoprolol at a dose of 50mg, pregabalin (LYRICA) at a dose of 100mg thrice a day, hydrochlorothiazide at a dose of 25mg, tramadol at a dose of 50mg, ibuprofen at a dose of 800mg as needed, duloxetine at a dose of 60mg, trazodone at a dose of 50mg, tiotropium at dose of 18ug, and albuterol [salbutamol sulfate] at a dose of (.5 - 2.5mg/3ml) (as reported). The patient previously took Tylenol, Wellbutrin, Steroids (high dose) and experienced allergy. The patient previously took historical vaccine, first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: UNKNOWN) via unspecified route of administration on 30Jan2021 at 07:30 (at the age of 73-year-old) for COVID-19 immunisation. On 21Feb2021, at 04:00 the patient experienced body aches, headache, coughing and fever. The patient received ibuprofen 800mg as treatment medication to all the events. The outcome of the events was not recovered. Information about lot/batch number has been requested. |

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| 1179224 | 4/8/2021 | TN | 85 | F | 2/10/2021 | 2/10/2021 | swollen lymph nodes after vaccination; If she accidentally picks up something or tries to pull on something with right arm she has excruciating pain; Right arm bicep muscle is so sore and is a hard knot; the muscles if you were going to make a muscle is very sore and hard/If I try to lift something too heavy, its excruciating pain; the day I got the shot, my hand became a little weak; This is a spontaneous report from a contactable consumer. A 85-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), dose 1 via an unspecified route of administration, administered in Arm Right on 10Feb2021 (Batch/Lot Number: EL9264) as SINGLE DOSE for covid-19 immunisation. Medical history included covid-19 from 21Dec2020, Stomach problem, Acid reflux, fatigue felt tired , little fever , historical allergies, Neuropathy , High blood pressure. Concomitant medications included atorvastatin; gabapentin for neuropathy peripheral,; cyanocobalamin (VITAMIN B12 [CYANOCOBALAMIN]) taken for an unspecified indication. The patient previously took codeine and experienced she almost passed out, demerol and experienced she almost passed out. It was reported arm that received the injection, "the muscles if you were going to make a muscle is very sore and hard". Caller says this is not the same area/muscle that the injection was given. the day I got the shot, my hand became a little weak. It went away. "Caller also says she had covid infection in Dec2020, This consumer was administered her first dose of Pfizer COVID-19 Vaccine 10Feb2021 at (Facility name). She had no problem whatsoever until 16Feb2021. Starting 16Feb2021 her right arm bicep muscle is so sore and is a hard knot; If she accidentally picks up something or tries to pull on something with right arm she has excruciating pain. She has no fever. She cannot get ahold of her doctor because their office is closed today due to the weather. She called to ask about these events; if she should put ice or heat on the affected area; how many Tylenol she should take for this. She initially reported that the affected area is the area of the muscle that you make, not in the backside muscle where the Pfizer COVID-19 Vaccine injection was administered; affected area is the front muscle, bicep that tightens when you flatten your hand forward and curl upward with the lower arm. If she raises her right arm up so far it's |

VAERS_ID RECVDATE STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

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| 1179193 | 4/8/2021 | FL | 20 | M | 3/5/2021 | 3/5/2021 | <p>very painful, but not so painful that she cannot stand it. She also developed swollen lymph nodes after vaccination. Therapeutic measures were taken as a result of right arm bicep muscle is so sore and is a hard knot (muscle swelling), the muscles if you were going to make a muscle is very sore and hard/if i try to lift something too heavy, its excruciating pain (myalgia), the day i got the shot, my hand became a little weak (muscular weakness), if she accidentally picks up something or tries to pull on something with right arm she has excruciating pain (pain in The outcome of the event Swollen lymph nodes; Muscle pain; was unknown; Pain in arm; Muscle swelling was not recovered; Hands weakness of was recovered;</p> <p>he fainted for 1-2 seconds; palpitation; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of SYNCOPE (he fainted for 1-2 seconds) in a 20-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 024M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Neutropenia. On 05-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 05-Mar-2021, the patient experienced SYNCOPE (he fainted for 1-2 seconds) (seriousness criterion medically significant) and PALPITATIONS (palpitation). On 05-Mar-2021, SYNCOPE (he fainted for 1-2 seconds) and PALPITATIONS (palpitation) had resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No concomitant medications reported. No treatment information reported. Based on the current available information and temporal association between the use of the product and the onset date of the reported events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the onset date of the reported events, a causal relationship cannot be excluded.</p> |

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| 1179192 | 4/8/2021 | OH | | F | 3/25/2021 | 3/25/2021 | <p>very weak; very tired; heart was pounding; vomit; headaches; passed out 3 times; seizure; lost control of her bowels; very low blood pressure; migraine; very low temperature; chills; fever; This spontaneous case was reported by a consumer and describes the occurrence of SYNCOPE (passed out 3 times), SEIZURE (seizure), ANAL INCONTINENCE (lost control of her bowels) and HYPOTENSION (very low blood pressure) in a 67-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 006B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Thyroid disorder. Concomitant products included DILTIAZEM for Arrhythmia, LEVOTHYROXINE SODIUM (SYNTHROID) for Thyroid disorder. On 25-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 25-Mar-2021, the patient experienced PYREXIA (fever) and CHILLS (chills). On 26-Mar-2021, the patient experienced SYNCOPE (passed out 3 times) (seriousness criterion medically significant), SEIZURE (seizure) (seriousness criterion medically significant), ANAL INCONTINENCE (lost control of her bowels) (seriousness criterion medically significant), HYPOTENSION (very low blood pressure) (seriousness criterion medically significant), MIGRAINE (migraine), BODY TEMPERATURE DECREASED (very low temperature), VOMITING (vomit) and CLUSTER HEADACHE (headaches). On 28-Mar-2021, the patient experienced PALPITATIONS (heart was pounding). On 29-Mar-2021, the patient experienced ASTHENIA (very weak) and FATIGUE (very tired). On 26-Mar-2021, SYNCOPE (passed out 3 times), SEIZURE (seizure), ANAL INCONTINENCE (lost control of her bowels), HYPOTENSION (very low blood pressure), BODY TEMPERATURE DECREASED (very low temperature), PYREXIA (fever), VOMITING (vomit), CLUSTER HEADACHE (headaches) and CHILLS (chills) had resolved. On 28-Mar-2021, PALPITATIONS (heart was pounding) had resolved. At the time of the report, MIGRAINE (migraine) had resolved and ASTHENIA (very weak) and FATIGUE (very tired) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. This case was linked to MOD21-</p> |

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| | | | | | | | 064116 (Patient Link).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Further information has been requested. |
| 1179042 | 4/8/2021 | CO | 37 | M | 4/7/2021 | 4/7/2021 | within in minutes of the vaccine and while driving to the rest area almost fainted, started to black out, dizziness an hollow hearing/tinitus. Lasted for 10 mins and gradually subsided over 20 minutes |
| 1179041 | 4/8/2021 | CA | 32 | F | 4/5/2021 | 4/6/2021 | I had my vaccine Monday. On Tuesday morning I was nauseous and had diarrhea. I had a brief time where I felt very hot, sweaty, nauseous, my arms felt like pins and needles, and my hearing started sounding muffled or far away. I drank water, cooled down my arms and face as soon as I could, and laid down. I felt nauseous the rest of the day and today. I feel ok now. I've never fainted before I'm not sure if that was happening but it was completely unexpected and not listed on vaccine side effects. |
| 1178965 | 4/8/2021 | | 36 | F | 4/7/2021 | 4/7/2021 | Symptoms: Light headed, nausea, shaky and pain at injection site, history anxiety. History of nausea an syncope episode when getting any vaccine, asthmatic and didn't have any albuterol and baclofen today and didn't have it with her on site. Pain started at the injection site (left arm) and over 5-7 minutes the pain increase and radiated to the left clavicle. We pulled EMT from already on site to further evaluated cardiac concerns. EKG was normal that was performed by EMT on site. EMT administered: 4mg Zofran, 100 micro sublimaze for pain 1st VS: 158/110, RR 22-24, Oxygen 98%, pulse 88 15 minutes later 2nd VS: 150/110, RR 22-24, Oxygen 98%, pulse 88 Transported by EMT to hospital Will follow up with phone call tomorrow |
| 1178956 | 4/8/2021 | WA | 47 | F | 4/7/2021 | 4/7/2021 | SYNCOPE - PATIENT LOST CONSCIOUSNESS AFTER ADMINISTERING THE SHOT. PATIENT REGAINED CONSCIOUSNESS QUICKLY. NO FALL OR INJURY INVOLVED. |

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| 1180648 | 4/8/2021 | MA | 49 | F | 4/8/2021 | 4/8/2021 | Patient reported that she felt light headed immediately following administration (2 to 5 minutes) and asked if we could get her some apple juice. She then bent over in her chair to get bloodflow back into her head, and reported that she felt as though she passed out during that time and requested to lay down on the floor. Once on the floor she said that she was beginning to feel better, but vomited a little when she was sitting back upright. Because she lives over an hour away, I stated I wanted to call EMS to get her checked out. EMS reported to the scene and evaluated her. She said she was feeling better, declined to go to the hospital, and walked around the store before leaving. |
| 1179352 | 4/8/2021 | CA | 17 | M | 4/7/2021 | 4/7/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: light headed, fainted after 5-10mins received vaccine-Mild, Additional Details: After received vaccine 5-10mins, he started feeling light headed, fainted. RN notified him to floor leftside, cold water to back of neck and forehead. BP: 91/66 -90/70, HR 91-85 when left side lying, BP 123/87, Hr 100 when sitting on floor. BP 122/85- 117/83, HR 99-95 when sitting in chair. He went home accompanied by his mother when feeling better. He has fainted in past with shots and blood draws |
| 1179720 | 4/8/2021 | IA | 54 | F | 4/7/2021 | 4/7/2021 | Janssen COVID-19 Vaccine EUA 5 minutes after receiving the shot, I was sitting in my car waiting for the 15 minute monitoring period, and I passed out. Help responded and I came out of it, and proceeded to vomit 4-5 times. Felt weak, dizzy, nauseous. My mom came to drive me home. Slept the rest of the morning and had some feeling of tightness in my chest in the late afternoon and evening. Thursday morning when I woke up, my arm was sore but I felt mostly better (still a bit of tightness in the chest). Did not seek medical attention at this time - just monitoring symptoms as of Thursday, 4/8/21. |
| 1180091 | 4/8/2021 | NY | 27 | M | 4/6/2021 | 4/6/2021 | Patient fainted immediately after getting vaccine. Pt reports that he has a history of fainting with vaccinations. He was reported to be unconscious for approximately 40 seconds. He was not injured and denied any other symptoms. He was released at 1:30 pm. |

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| 1180046 | 4/8/2021 | CT | 29 | F | 4/7/2021 | 4/7/2021 | Recipient fainted after receiving the vaccine. Stated she always faints with needles, however, did not inform us before-hand. She quickly regained consciousness and laid on the cot for an hour until someone came to pick her up. Refused 911 or going to the ED as this happens all the time. |
| 1180018 | 4/8/2021 | SC | 57 | F | 4/8/2021 | 4/8/2021 | patient shortly passed out |
| 1180016 | 4/8/2021 | OH | 23 | M | 4/2/2021 | 4/2/2021 | The patient was very anxious and hyperventilating before shot. Sat in car with father and passed out. He was sweaty, pale, but otherwise okay. Patient came to and was given orange juice and squad was called. |
| 1180010 | 4/8/2021 | CT | 30 | M | 4/7/2021 | 4/7/2021 | Recipient became gray, dizzy, light-headed and fainted after receiving the vaccine. Did not hit head or fall on floor. Lost consciousness for less than 10 seconds and stated he did not eat anything that day. 911 was called but he refused to go to the ED and said he was okay. |
| 1180002 | 4/8/2021 | IN | 41 | F | 4/6/2021 | 4/6/2021 | Passed out 6 hours after shot, not normal(3rd shift worker), fever set in 10 hours after shot, headache set in 18 hours after shot, fever subsided 18 hours after shot, currently experiencing constant sweating(rarely sweat even in heat), woke up with two hives on left arm that have gone away since I noticed them itching, right arm soreness, actual pain in right armpit. |
| 1179994 | 4/8/2021 | NJ | 28 | M | 4/7/2021 | 4/7/2021 | fainted approximately 15-20minutes after injection. Happened in the parking lot getting into my car. Ems was called. i was full alert upon waking up. bp 120/60 hr 62 pulse ox 99. |
| 1179969 | 4/8/2021 | PA | 32 | F | 4/8/2021 | 4/8/2021 | the patient passed out after about 10 minutes. they came back too and feel ok now |
| 1179951 | 4/8/2021 | OR | 18 | M | 4/7/2021 | 4/7/2021 | Patient passed out and fell over. He did not injure himself in the fall. Was out for 1-2 seconds. Was a little light headed and weak as he sat in the chair, but was recovered after 15 minutes. Reported being nervous about needles and failed to eat/drink much earlier in the day. |

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| 1179812 | 4/8/2021 | IL | 31 | F | 4/7/2021 | 4/7/2021 | patient passed out a few minutes after receiving the shot. unknown if it was truly caused by vaccine or the anxiety caused by receiving it. patient said her hands and feet were tingly. she was flush and hot. we gave her water. she stayed at the store for around 45 minutes after. we used a wheelchair to get her to the car because her legs were still wobbly. contacted patient to check on her but have not heard back. |
| 1179463 | 4/8/2021 | NY | 17 | M | 4/7/2021 | 4/7/2021 | Systemic: Fainting / Unresponsive-Mild |
| 1179758 | 4/8/2021 | MN | 20 | F | 4/7/2021 | 4/7/2021 | Syncopal episode appearing as a vasovagal response from receiving the vaccine. Patient fainted and fell back onto her head. Unconscious. When patient woke up she was very confused and alarmed. EMS was called and brought her to the hospital. BP, O2, resp normal |
| 1179471 | 4/8/2021 | FL | 39 | M | 4/7/2021 | 4/7/2021 | Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Shakiness-Mild |
| 1179696 | 4/8/2021 | FL | 43 | F | 4/6/2021 | 4/7/2021 | Passed out once, and almost passed out 2 more times |
| 1179693 | 4/8/2021 | SC | 60 | M | 4/7/2021 | 4/7/2021 | Patient informed us of previous reaction (fainting) to tetanus vaccine. Covid vaccine was administered and patient remained seated for precaution. Patient fainted and was moved to the floor in a lying position. EMS was called. Pharmacist took patient's blood pressure (148/94). Patient was able to answer questions correctly when asked. EMS arrived and checked patient's vitals. Patient declined EMS transport. Patient left to go home with wife and daughter. Pharmacist called daughter at 6pm to check on patient. Patient had a headache at that time. Will follow up with patient today. |
| 1179686 | 4/8/2021 | MO | 24 | M | 4/7/2021 | 4/7/2021 | after the patient got covid shot within 2 minutes fell down on the floor/ fainted |

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| 1179639 | 4/8/2021 | MA | 30 | F | 4/7/2021 | 4/7/2021 | <p>ON 4/7/2021 AT 1600, PATIENT HAD INITIALLY REPORTED BEING OK POST VACCINE. PATIENT THEN BECAME PALE. NURSE ASKED PATIENT IF SHE WANTED TO LAY DOWN FOR A LITTLE WHILE. PATIENT REFUSED AT THIS TIME. COLORING RETURNED TO PATIENT'S FACE. PATIENT CONTINUED TO TALK WITH NURSE. THEN BECAME PALE AGAIN. AT THIS TIME, PATIENT REPORTS SHE THINKS SHE NEEDS TO LAY DOWN. NURSE ASKED ANOTHER NURSE TO RETRIEVE A WHEELCHAIR WHILE THIS NURSE STAYED WITH PATIENT. AFTER OTHER NURSE WALKED AWAY, PATIENT STATED SHE FELT LIKE SHE WAS ABOUT TO PASS OUT. PATIENT THEN SLUMPED OVER IN CHAIR TOWARDS NURSE. NURSE HELD PATIENT'S HEAD AND UPPER TORSO AND ASKED FOR FURTHER ASSISTANCE FROM OTHER STAFF. PATIENT HAD A PULSE. VS TAKEN. SEE VITALS. PATIENT HAD NO RESPONSE TO VERBAL CUES. STERNAL RUB GIVEN. PATIENT IMMEDIATELY WOKE. PATIENT SET UP AND WAS ORIENTED X3. PATIENT REFUSED TO LAY DOWN ON STRETCHER. PATIENT SET AT NURSES STATION. PATIENT WAS GIVEN ORANGE JUICE AND CRACKERS. COLD PACK APPLIED TO PATIENTS NECK. UPON FURTHER ASSESSMENT, PATIENT REPORTS FAINTING IN PAST TO BLOOD DRAWS AND REPORTS LOW BP AND HEART RATE AS NORM. PATIENT CONTINUED TO BE AS COHERENT AS PRE VACCINE. PATIENT SET WITH NURSE FOR 30 MINUTES POST EPISODE. PATIENT DID EAT MORE CRACKERS AND ATE MORE JUICE BUT REFUSED ANY MORE POST INTERVENTIONS OR ASSESSMENT. PATIENT ALSO REFUSED TO CALL OR LET STAFF CALL ANYONE TO REPORT EPISODE AND ALSO REFUSED ANY TRANSPORTATION TO HOME STATING SHE JUST HAD A 10 MINUTE WALK PATIENT WAS AGREEABLE TO AT LEAST TEXT COWORKERS OF HER WHEREABOUTS. PATIENT WAS INFORMED OF RISKS. PATIENT REPORTS UNDERSTANDING BUT LEFT ON HER OWN ACCORD AT THIS TIME ON 4/7/2021 AT 1631.</p> |

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| 1179620 | 4/8/2021 | IN | 23 | M | 4/6/2021 | 4/6/2021 | 5 minutes after the shot, I began experiencing severe hot flashes, sweating, paleness, and vasovagal syncope. This continued for 10-15 minutes while the fire department and physician on site checked my vitals. After being laid down at roughly 10 minutes after the shot, I began to regain consciousness. An ambulance was called, but was not needed. |
| 1179612 | 4/8/2021 | OH | 23 | F | 4/1/2021 | 4/1/2021 | Patient fainted approximately 10 minutes after receiving dose 1 of Pfizer covid vaccine LOT ER2613 on 4/1/21. She hit her head on the desk in the room. This was unwitnessed by any staff member. There were no bumps or open areas on patients head. Patient was immediately alert and oriented upon assessment when writer walked into room. After assessment advised patient she should go to the ED for further evaluation. Patient called her mom to come take her to the ED. Further follow up documents patient was not seen in ED. |
| 1179572 | 4/8/2021 | VA | 38 | F | 4/6/2021 | 4/7/2021 | 35 weeks pregnant, I had no side effects after first vaccine. Less than 24 h after second vaccination, began to experience mild chills and mild lightheadedness. Within 30 minutes of symptoms onset, I had a near syncope with transient hypotension with blood pressure measured 70/40. I required some assistance from coworkers before my husband was able to pick me up. Once home, symptoms evolved to fever over 100°F, chills, mild nausea, mild headache, and moderate to severe back, hip, and leg pain. Myalgias and joint pain particularly back pain 24-36 h after vaccination was debilitating and prevented sleep overnight. Symptoms as described in the context of acetaminophen use, 500-650 mg every 4-6h. |
| 1179511 | 4/8/2021 | FL | 17 | M | 4/7/2021 | 4/7/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Fever-Mild, Systemic: Flushed / Sweating-Medium |

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| 1179503 | 4/8/2021 | NJ | 17 | M | 4/7/2021 | 4/7/2021 | Site: Redness at Injection Site-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Medium, Systemic: FAINTED AND SCAR ON FACE-Mild, Additional Details: PATIENT SEATED AT SEAT 5 FELL AFTER FAINTING AND INJURED ON HIS FACE WITH BRUICE ON RIGHT SIDE AFTER HITTING GROUND WITH HIS GLASSES. PATIENT GOT CONSCIOUSNESS IMMEDIATELY AFTER. OFFERED MEDICAL HELP AND ATTENTION. GAVE WATER TO DRINK. HE WAS MONITORED FOR 30 MINUTES AND LEFT PHARMACY HIMSELF. |
| 1179500 | 4/8/2021 | NY | 26 | M | 4/7/2021 | 4/7/2021 | Systemic: Fainting / Unresponsive-Mild |
| 1180167 | 4/8/2021 | | 21 | M | 4/8/2021 | 4/8/2021 | Vasovagal syncope VS BP:118/51, HR 71 bpm RA 98% |
| 1179770 | 4/8/2021 | CT | 42 | F | 4/7/2021 | 4/8/2021 | Woke up in middle of night with intense chills and could not breathe. Fainted. Woke up on floor disoriented. Partner was ready to call 911 until I was able to breathe again. |
| 1182892 | 4/8/2021 | CA | 29 | M | 4/7/2021 | 4/8/2021 | After two weeks straight of processing herring in seafood plant, exhausted at 0200 he took a shower and fainted in the shower. He was found semi-responsive, shivering with labored breathing and flu like symptoms. EMS was called and taken to ER for evaluation. He was released from local hospital within two -four hours when symptoms resolved. |

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| 1182691 | 4/8/2021 | NC | 26 | M | 4/8/2021 | 4/8/2021 | Patient came in for vaccine. After vaccination, I had patient sit in a chair in case of any adverse reactions. About 5 minutes after vaccination, another patient came over and said that was not feeling well. When going out to patient I noticed he was very pale and sweating. The patient then proceeded to pass out. I was able to hold the patients head and the other customer was able to hold his shoulders to make sure he did not fall out of the chair. The patient then got very stiff and proceeded to push back in his chair, after about 10 seconds he relaxed. The patient was passed out for about 3 mins, during that time I was able to remove his mask and hold his head. After gaining consciousness, I was able to make sure he was ok. We were able to give him some water and he stated he felt better. I asked the patient to stay for another half hour to monitor. After giving the patient another bottle of water, and having him sit he was able to get up and leave. |
| 1183071 | 4/8/2021 | CA | 65 | M | 4/8/2021 | 4/8/2021 | we administer Janssen Covid-19 Vaccine , 5 to 10 minutes later the patient fainted in the waiting area. the associate who is watching our patient notified me that the patient is dizzy. I went outside and I noticed that the patient is leaning on the table and he fainted i put him down on the floor and lifted his feet up. he woke up in few seconds we also called 911 and they took the patient to the ER |
| 1183059 | 4/8/2021 | HI | 20 | M | 4/8/2021 | 4/8/2021 | Patient briefly fainted after covid vaccination administered by pharmacy technician. Patient was sitting down. EMT arrive but patient refused ambulance transport to hospital. No anaphylaxis or other symptoms. |

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| 1183057 | 4/8/2021 | NM | 29 | M | 4/8/2021 | 4/8/2021 | gave patient vaccination in designated vaccine area after going over possible side effects. vaccine was given in left arm. I asked patient if he felt ok to move to observation area. patient said yes and stood up and walked to observation area. he sat down and I told him I would be right back. I turned around and was walking back into the pharmacy when I heard a loud crash. I turned around and patient was slumped side ways about to fall out of chair. He had fainted or had a seizure (he was very stiff, redness to face, eyes open and fixed). I ran over to him and a pharm tech and I got him to the floor immediately. He regained consciousness within 5-10 seconds after placing him on floor. he asked how long was he out. he stated he had this seizure happen before but never after a vaccine. he said he has had multiple vaccines like hepatitis b and this never happened. he states it happens when he has something done to him that causes intense pain. he said it happened after hurting his ankle or when he hit his hand in a fan. checked his BP-172/100 pulse-65. paramedics came to check him out. BP still elevated. he walked out with paramedics. |
| 1183056 | 4/8/2021 | | 29 | F | 4/8/2021 | 4/8/2021 | Post-vaccine syncope. Patient recovered in observation. |
| 1183052 | 4/8/2021 | GA | 43 | F | 4/7/2021 | 4/7/2021 | Right at the time I got my vaccine. Three people in the group started fainting and having seizures immediately after. I had my vaccine at 1:46pm I wanted to report it since Im not sure the facility or nurses will. One you g lady fainted, then and old man passed out, then another young man in his 30s had a violent seizure. Even ripped his shirt. The organizers stopped the vaccinations until the ambulances left. I was left horrified, as was everyone else there. Im not sure what kind of poison. We have been injected with. Please send more information about the ingredients of this vaccine to me. Thanks |
| 1183049 | 4/8/2021 | | 29 | F | 4/8/2021 | 4/8/2021 | post vaccine syncope, recovered in observation area |

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| 1183028 | 4/8/2021 | CA | 39 | M | 4/8/2021 | 4/8/2021 | Found passed out inside car 5 mins post vaccination, c/o nausea, feeling tired when he came to senses, MD on site and CalMed responded, vital signs obtained @347PM, BP 93/62, pulse 67, 96% sats on room air. BSugar 86. Standing blood pressure 107/69, normal sinus rhythm, rate 74. Agreed to be trasferred to Hospital via Fire Dept Ambulance at 411PM. |
| 1182971 | 4/8/2021 | NH | 34 | F | 4/8/2021 | 4/8/2021 | Lightheadedness, dizziness, loss of hearing, then laid down before I fainted. |
| 1182941 | 4/8/2021 | PR | 47 | M | 4/7/2021 | 4/7/2021 | Patient stated he was feeling "heavy", dizzy, nauseated and feeling chills prior to fainting. Once he was attended to, he was evaluated and taken to the local SEARHC ER. He was released a few hours later when his symptoms resolved. This patient had worked over two weeks straight with Herring as a seafood processor with little sleep and exhaustion. |
| 1183086 | 4/8/2021 | NE | 25 | M | 4/8/2021 | 4/8/2021 | Patient fainted a few minutes after vaccination. He was caught as he was losing consciousness and gently lowered to the ground. He regained consciousness within 10 to 15 seconds. Remained on the ground with feet slightly elevated until rescue squad arrived. |
| 1182909 | 4/8/2021 | FL | 41 | M | 4/7/2021 | 4/7/2021 | Patient received vaccine and went in the waiting area for the 15 minute observation. He passed out and fell on the floor. He was sweating but was conscious. We put a bag of frozen blueberries on his neck and wiped his face with a damp towel while waiting for EMS to arrive. He did not require CPR. |
| 1183089 | 4/8/2021 | OH | 85 | F | 3/17/2021 | 3/19/2021 | Friday 3/19 Confusion, did not know her granddaughter, which grandchild she was kept confusing family names. That was very unusual for her. Saturday 3/20 didn't feel good that day, Sunday 3/21 around 3am got up to go to the restroom got very light headed and fell/fainted hitting her head on the night stand and falling to the floor. When EMS arrived she was in A-fib. That had never happened before. No known heart problems. |

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| 1182878 | 4/8/2021 | NC | 31 | M | 4/8/2021 | 4/8/2021 | Patient is 31 year old male who came in today to get his Janssen Covid-19 vaccine. He came with his wife and father-in-law. He verbalized ahead of time that he has a history of fainting due to his fear of needles. He does not have any allergic reaction to vaccine components. After reviewing his PQCF and possible side effects of the vaccine, patient verbally consented to get vaccinated. I administered the vaccine into the deltoid muscle of his right arm. I gave him an ice pack. Right after the vaccine was administered patient said he felt fine. He relocated from the immunization booth to a Post Vaccine waiting chair with his wife by his side. He fainted into his wives's arms for about 30 seconds. His father-in-law helped place him on his back on the floor and we raised his legs up on a chair. Patient came to immediately when placed on supine position and said he just needed to rest. We called Code White and assistant manager came to the scene. Patient was conscious and verbalized that he was feeling fine but should just rest. Patient continued to use ice pack and rested for about 30 minutes. |
| 1182844 | 4/8/2021 | IL | 20 | M | 4/5/2021 | 4/5/2021 | About 3 mins after Janssen vaccine was given, pt was very white and faintish. I rushed out of pharmacy and had a tech call 911. As I was running to him pt started slipping out of his chair, as a women, who I later found out was his mother and I helped keep pt in chair as he fainted and then seized for about 2 seconds and then gained consciousness. Upon awakening pt said , what just happened?" The mother answered "oh you just had a little seizure, you're fine." To my surprise, I asked the mother is this has happened before and she said yes when he sees needles/get shots. I told them the ambulance was on it's why and the mother asked "why?!" I told her because your son just fainted/had a seizure and we want to make sure he is ok. The pt refused to go to the hospital. I did go back out there and mentioned to them that it is very important to answer questions truthfully any time they are asked as they failed to honestly answer our questions about ever feeling faint after receiving a vaccine. His blood pressure normalized and once the paramedics left so did they. |

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| 1182839 | 4/8/2021 | WA | 31 | F | 4/5/2021 | 4/5/2021 | Felt faint 5 minutes after vaccination. Profusely sweating, ears ringing, blurred vision. Needed to lay on the ground immediately for fear of fainting. Ice pack and water was given to me |
| 1182825 | 4/8/2021 | OH | 18 | F | 3/30/2021 | 3/30/2021 | About 4 hours after getting the injection she reported pain in her arm , right side of chest, and passed out. She was trying a dress on in a store and a woman was adjusting it and she all of a sudden said mom I don?t feel good I think I?m going to pass out. She reports everything going black. She go so pale almost blue and passed out immediately she started sweating and had a slight rash on her back. EMS was called she was alert before they arrived they checked vitals and all were normal. The rash went away within a day. |
| 1182814 | 4/8/2021 | CA | 56 | M | 4/7/2021 | 4/7/2021 | Passed out in chair after vaccination, then muscles contracted for 5 seconds |
| 1182790 | 4/8/2021 | | 23 | F | 4/8/2021 | 4/8/2021 | Pt became light-headed with blurred vision while walking to her car. Pt stated has history of syncope post injection or blood draw. Pt vitals were evaluated. Pt declined transport to ED. |

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| 1182744 | 4/8/2021 | IL | 21 | F | 3/25/2021 | 3/25/2021 | lost consciousness and fainted two times; lost consciousness and fainted two times; This is a spontaneous report from a contactable consumer (patient) reported for herself that a 21-year-old female received bnt162b2, dose 1 via an unspecified route of administration, administered in right arm on 25Mar2021 15:00 (Lot Number: 10350) as single dose for COVID-19 immunization. Facility where the most recent COVID-19 vaccine was administered: Pharmacy or Drug Store. Patient was not pregnant at the time of vaccination. Medical history included asthma, attention deficit hyperactivity disorder (ADHD), Bipolar II and post-traumatic stress disorder (PTSD). Prior to vaccination, patient was diagnosed with COVID-19 on an unknown date. No allergies to medications, food, or other products. Concomitant medications included ethinylestradiol, ferrous fumarate, norethisterone acetate (BLISOVI 24 FE), methylphenidate hydrochloride (CONCERTA), aripiprazole (ABILIFY) and escitalopram oxalate (LEXAPRO). On 25Mar2021 15:00, the patient lost consciousness and fainted two times. Paramedics were called and she was released. The events result in doctor or other healthcare professional office/clinic visit and emergency room/department or urgent care. No treatment was received for the events. The patient underwent lab tests and procedures which included Nasal Swab: positive on 06Jan2021. The outcome of the events was recovered in Mar2021. The events lost consciousness and fainted occurred in a country different from that of the reporter. This may be a duplicate report if another reporter from the country where the event occurred has submitted the same information to his/her local agency. |

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| 1182739 | 4/8/2021 | MN | 59 | F | 3/19/2021 | 3/1/2021 | passed out; bad stomach ache; Tired; not normal; This is a spontaneous report from a contactable consumer (patient). A 59-year-old non-pregnant female patient received second dose of BNT162B2 (brand=Pfizer), lot no. EN60207, via an unspecified route of administration (left arm) on 19Mar2021 10:15 at a single dose for COVID-19 immunisation. The patient had no relevant medical history. She had no known allergies. No covid prior vaccination. Concomitant medications included levothyroxine, simvastatin, calcium, and multivimi (as reported). Historical vaccine included first dose of BNT162B2 (brand=Pfizer, lot no EN6203) on 26Feb2021 10:15 AM, left arm at age of 59 years. No other vaccine in four weeks. On 20Mar2021, the patient got up to go to bathroom at 4:00am Saturday and passed out. Bad stomach ache Saturday (20Mar2021), Sunday (21Mar2021). On Mar2021, tired and not normal til Thursday. No treatment for the events. No covid test post vaccination. The patient recovered from bad stomach ache on 21Mar2021 and from other events on Mar2021. |
| 1182722 | 4/8/2021 | | 28 | M | 4/8/2021 | 4/8/2021 | Presyncope |

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| 1182717 | 4/8/2021 | | 23 | F | 4/6/2021 | 4/6/2021 | Client received the COVID vaccine (Janssen, Lot# 1808980) complained of feeling dizzy at 1424, EMT and RN responded. The client was sitting in a chair with her head in her hands, stated that she felt dizzy and was having a "hot flash." The client stated that she is anxious around needles and has a history of syncope after blood draws. She also complained of experiencing tunnel vision and hearing. The client's vital signs were a temperature of 96.7, blood pressure of 122/82, heart rate of 92, and O2 of 99%. The client stated she did eat that morning, and refused a set of repeat vitals, but agreed to wait 30 minutes for observation after her symptom onset. Per the client, she has no allergies or medical conditions, and takes no medications. At 1435, the client accepted some water to drink. At 1440, the client stated that she no longer felt dizzy. The client's color had returned and she was no longer dizzy. She agreed to have repeat vital signs at this time: blood pressure of 118/82, heart rate of 90, respiratory rate of 16, and O2 99%. The client refused benadryl at this time. At 1454, the client's vital signs were as follows: blood pressure of 116/82, heart rate of 90, respiratory rate of 12, and O2 of 99%. The client stated that she felt "back to normal" and called her sister to drive her home. She was escorted to her car by the EMT, she ambulated with a steady gait. Education provided regarding emergency response, V-safe, and the importance of following up with a primary care provider. |
| 1182699 | 4/8/2021 | WI | 32 | M | 4/8/2021 | 4/8/2021 | Patient had an episode of fainting about 10 mins after vaccine administration. after regaining consciousness he had rolling eyes and seizure and 2nd episode of fainting. The fainting episodes were for few seconds (30-45 sec). Patients feet were elevated and paramedics were called. while waiting for the paramedics we had patient drink water and orange juice as he was on diet and had taken only 300 calories per patient. Used cold compress on his face and neck, patient was comprehending well afterwards. paramedics arrived and examined the patients vital and asked if he would like to go to the hospital even though patient seemed fine. Patient denied going to the hospital and paramedics left afterwards. patient waited for 30 minutes afterwards and then left. we called the patient later and he was doing fine. |

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| 1182916 | 4/8/2021 | WI | 43 | M | 4/8/2021 | 4/8/2021 | PATIENT RECIEVED VACCINE 9:49 AM, MOVED TO POST VACCINATION AREA. BECAME DIZZY AND FAINT, WAS MOVED TO FLOOR FROM CHAIR. PASSED OUT AT 9:50 AM. CAME AROUND 9:55AM WITH NAUSEA THAT DID NOT RESULT IN VOMITTING. PATIENT SAT FOR AN ADDITIONAL 30 MINUTES WITH WIFE UNTIL FELT FINE TO LEAVE POST VACCINATION AREA AROUND 10:30AM. NO INJURY RESULTED. PATIENT ADMITTED AFTER VACCINATION THAT THIS IS A COMMON REACTION TO VACCINATION AND NEEDLES IN GENERAL. |
| 1183259 | 4/8/2021 | WV | 53 | F | 4/8/2021 | 4/8/2021 | Pt went to stand up right after receiving the vaccine and immediately passed out on the floor. Upon examining the pt, pt stated she was dizzy after receiving the vaccine and we thought she just stood up too fast. Observed pt for several minutes, pt vomited shortly after and remained dizzy and sweaty. After about 30 minutes, pt stated she felt better and wanted to go on to work. While walking down the hallway to leave, pt passed out again. Contacted 911, pt had blurred vision, dizziness, slurred speech. Ambulance arrived, BP and HR were normal, but pt couldn't stand up unassisted. Pt was taken to the ER by ambulance. |
| 1181664 | 4/8/2021 | TX | 23 | M | 4/8/2021 | 4/8/2021 | The patient passed out (Syncope) for less than 5 minutes after administration of the shot. |
| 1180624 | 4/8/2021 | CA | 30 | M | 4/8/2021 | 4/8/2021 | fainted before getting shot in the vaccination area brought to EMS via gurney and was given vaccine there on the gurney @ 9:09am. Tolerated well and was discharged in stable condition @ 930am. |
| 1183486 | 4/8/2021 | IA | 31 | F | 4/1/2021 | 4/1/2021 | Fever, chills, muscle aches, hip joint pain, dizziness, vomiting, fainting, high heart rate |
| 1183469 | 4/8/2021 | CO | 17 | F | 4/8/2021 | 4/8/2021 | A few minutes after receiving the vaccine, the patient fainted in the pharmacy wait area. She woke up a few seconds later and was alert. She was able to answer questions like "what is your name?" "where are your?" " etc. She denied a history of fainting but did say she fainted once about 8 years ago. She remained seated in the pharmacy waiting area for another 30 minutes and said she felt fine. She denied feeling dizzy, short of breath, and any allergic reaction symptoms. |

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| 1183457 | 4/8/2021 | IL | 33 | M | 4/8/2021 | 4/8/2021 | Pt received vaccine; then stated that he felt nauseated, dizzy, and had increased anxiety due to his fear of needles. While sitting in observation he passed out momentarily while sitting in his chair. He awoken quickly and was assisted to a wheelchair for one on one observation. Pt states this has happened before and he always quickly awakens. Water given. Pt observed for 30 minutes and left in stable condition. |
| 1183420 | 4/8/2021 | IL | 19 | M | 4/8/2021 | 4/8/2021 | Pt received vaccine and they started to feel dizzy and then passed out in his chair momentarily. Pt began to feel better and then patient fainted again. Pt also complained of ringing in his ears. EMS was called to the bedside where they found patient to be hypotensive. Pt was resolved quickly. Once he began to feel better he was sat up at the side of the bed and monitored for a short while. Pt no longer had any symptoms or concerns and went home with his girlfriend |
| 1183387 | 4/8/2021 | AZ | 16 | F | 4/8/2021 | 4/8/2021 | Patient showing symptoms (closing/opening of eyes. fall back on chair. pale face) of fainting tendency within 5 minutes of vaccines. Pharmacist instructed patients to take slow, deep breaths and try to open eyes. Patients was able to stabilized. |
| 1183361 | 4/8/2021 | TN | 21 | F | 4/8/2021 | 4/8/2021 | At approximately 10 minutes after receiving vaccine, patient developed dizziness, fainted for approximately 2-3 seconds patient then came too, patient then fainted again and began seizing, seizure symptoms last 5-10 seconds, patient then came too and stayed stable and alert, 911 was called and patient was monitored until ambulance arrived, patient was transported to emergency room, for additional evaluation and treatment |
| 1183310 | 4/8/2021 | FL | 45 | F | 4/3/2021 | 4/3/2021 | Nearly passed out, dizziness, light headed, sweating, chills, nausea, diarrhea. |
| 1183297 | 4/8/2021 | TX | 26 | F | 3/31/2021 | 3/31/2021 | Less than five minutes of receiving vaccine: Eyes rolling back, feeling of fainting, tinnitus, blue lips, blue fingers, really hot, Thirty minutes after receiving the vaccine: bad chills/shakes/shivers/teeth chattering, diarrhea, confusion |

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| 1183083 | 4/8/2021 | IL | 20 | F | 4/8/2021 | 4/8/2021 | When I got the vaccine, I had almost passed out and felt like I needed to vomit. Later, I started getting really cold and shivering, and there was nothing I could do to make it stop. I started getting a headache, nausea, and weakness around that time too, maybe a bit sooner, like 3:00pm. The chills started at around 5:00pm. |
| 1183277 | 4/8/2021 | CT | 26 | M | 4/7/2021 | 4/7/2021 | Nausea after about 1 minute, fainting, low blood pressure lasting 15 minutes, cold chills lasting ~1 hour. Fever over 103F recorded ~11 hours after injection. |
| 1183349 | 4/8/2021 | PA | 19 | F | 4/8/2021 | 4/8/2021 | I fainted about 2 minutes after receiving the vaccine. |
| 1183249 | 4/8/2021 | MI | 28 | M | 4/8/2021 | 4/8/2021 | fainting approximately 5 seconds and hypotension 85/41 cold packs rest 30 minutes |
| 1183242 | 4/8/2021 | OH | 23 | F | 4/8/2021 | 4/8/2021 | Patient fainted within 15 seconds after receiving the vaccine. Patient came too within 15 seconds after passing out. Patient was observed for approximately 30 minutes after fainting and felt well enough to go home without the pharmacy contacting the local EMS .Patient called the pharmacy when she arrived safely at home per the pharmacist's request. |
| 1183223 | 4/8/2021 | FL | 30 | F | 4/8/2021 | 4/8/2021 | slouched in chair and almost passed out, starting shaking and slumping |
| 1183217 | 4/8/2021 | OH | 19 | F | 4/5/2021 | 4/5/2021 | Patient fainted within 15 seconds of receiving vaccine. Patient came too approximately 15 seconds after passing out. Patient was nauseated and dizzy for another 10 to 15 minutes. Pharmacy called local emergency squad to evaluate patient. Patient refused to be transported to local hospital. pharmacy made your patient had someone take her home. Contacted patient the next day and patient said she was feeling better. Patient believed it was "needle anxiety" and does not believe it was caused by the vaccine itself. |
| 1183200 | 4/8/2021 | NY | 37 | M | 4/7/2021 | 4/7/2021 | Syncope |

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| 1183194 | 4/8/2021 | CO | 64 | F | 4/5/2021 | 4/5/2021 | Patient was in waiting area for 15 minutes post-vaccination, told me she was feeling dizzy. I gave her water and took her BP (117/84) and pulse (69). I asked her to wait an additional 10 minutes. Checked on her again, said she was doing better. Asked my associate to take her BP one more time before we sent her home about 5 minutes later. Associate went to go take her BP and patient fainted for a few seconds, woke up and vomited. At this point the paramedics were called and we were monitoring the patients. |
| 1183189 | 4/8/2021 | FL | 27 | M | 4/8/2021 | 4/8/2021 | Patient stated was anxious before getting vaccine. About 5 minutes after vaccine given stated upset stomach, hands sweaty, hands tingling, felt like fainting. After about 10 minutes patients symptoms resolved. |
| 1183174 | 4/8/2021 | NM | 19 | F | 4/8/2021 | 4/8/2021 | Patient fainted about 7 minutes after the vaccine was administered. Was observed, and monitored till she felt comfortable to get up. was monitored for about 30-45 minutes |
| 1183131 | 4/8/2021 | NY | 42 | M | 4/7/2021 | 4/7/2021 | Dizziness, heart rate up and down between 62-118 while doing nothing physical. Had to sit down numerous times because I almost passed out. Heart rate would rave then drop and I'd break out in cold clammy sweat. Did not seek treatment tried to rest and had friends and kids keep an eye on me. Day 2 better but still times heart would race. |
| 1183109 | 4/8/2021 | NY | 38 | M | 4/8/2021 | 4/8/2021 | Patient received injection, told to remain in store for observation for 15 minutes. several minutes later patient briefly collapsed and fainted for a few moments. no recollection of fainting. but alert and oriented upon waking up. Patient later claimed he had fainting spells when drawing blood, never from vaccine. woke up pale and very sweaty. |
| 1183100 | 4/8/2021 | OR | 19 | M | 4/8/2021 | 4/8/2021 | Patient fainted a few minutes after the vaccination. Slumped over in chair. Woke up within about 10 seconds. Was pale and very shaky. Recovered over the course of 15-20 minutes. |

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| 1183279 | 4/8/2021 | OH | 30 | M | 4/8/2021 | 4/8/2021 | Patient fainted within 15 seconds of receiving the vaccine. Pt came too within 30 seconds after fainting. Pateint was observed for approximately 45 minutes by the pharmacy staff and the local EMS , which was contacted less than 2 minutes after the patient had fainted. EMS checked patients BP and pulse and everything was normal. Patient refused to be transported to the local hospital and a family friend came and picked the patient up to take him home. |
| 1181931 | 4/8/2021 | NJ | 18 | F | 4/8/2021 | 4/8/2021 | Patient is an 18 year old female with no PMHx that presented with lightheadedness and three subsequent episodes of syncope approximately 3-10 minutes post-vaccination. Patient was found to have an abrasion to the outer corner of her right eyebrow following an unwitnessed. It was unknown if patient was seated or standing at the time. The nurse first on scene states the patient lost consciousness briefly again and experienced approximately 10 seconds of upper extremity muscle contractions (described as convulsions). Patient experienced a loss of bladder control upon loss of consciousness. Patient was lowered to the ground to be in a supine position by healthcare staff. At this time, patient was alert and oriented without agitation or confusion. Patient denies memory of the event. She states she had prior episodes of fainting after blood draw. Patient has no allergies to medication or food. No past surgical history. No prior hospitalizations. Denies personal and family history seizure disorders, cardiac disturbances, and hypoglycemic or hyperglycemic events. Patient was hooked up to cardiac monitor and found to be in normal sinus rhythm with a heart rate of 64bpm. Vitals Orthostatic BP measurements Lying supine - 110/72 Seated - 124/76 Standing - 128/72 HR: 64 bpm RR: 16 breaths/min without distress SO2: 99% On examination, patient was A&Ox3 without lethargy, agitation, or confusion. Patient has an abrasion to the superior aspect of the right orbit (outer eyebrow) without laceration or bleeding. Patient was diaphoretic and pale following event. Normal cardiac rate and rhythm. Radial pulses intact, strong and equal bilaterally. No obvious nystagmus. Upon standing, patient steady on her feet without abnormal gait. |

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| 1182034 | 4/8/2021 | UT | 36 | F | 4/8/2021 | 4/8/2021 | Pt was give vaccine and was not nervous or anxious. About 1 to 2 minutes after receiving the shot pt passed out for about 20 seconds. The technician held the pt up and supported her head and neck while asking pt if she was OK. When pt came to she was happy and said "hi" to the technician. Soon after she laid on the floor and started crying and saying her hands were cramping and in pain. She also stated she was very nauseous and felt like she was going to throw up. Pts husband agreed that we should call an ambulance which we did. When paramedics arrived pt was feeling better and refused a ride to the ER. Pt's husband took her to the car and drove her to the ER. |
| 1182029 | 4/8/2021 | GA | 55 | M | 4/8/2021 | 4/8/2021 | Patient has had fainting issues in past with vaccinations. About 5 seconds after injection, the patient fainted, fell asleep, started to snore, then had seizure symptoms. After about one minute, the patient woke up and said he was okay. He was observed in the room for 2 hours, given hydration, towels, a pillow, and a fan to keep him comfortable. Signs and symptoms were normal when before he was allowed to leave after 2 hours. |
| 1182015 | 4/8/2021 | FL | 21 | M | 4/8/2021 | 4/8/2021 | Syncope and heart rate 42, sweating |

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| 1182011 | 4/8/2021 | MD | 35 | F | 4/6/2021 | 4/6/2021 | I got the vaccine, then was asked (due to having previous allergic reaction to Levaquin in the past, I was asked to wait 30 minutes) I got up and walked a total of 30 feet to sit in a chair. I felt completely normal, up until this point. I sat down and began to text my Mother that I had just got the vaccine & I was told to wait 30 minutes, at this point (2 mins in) I felt normal. I sat my phone down on my lap and was just looking about. I began at that point (2 1/2-3 mins mark) seeing the tile floor morph; the blue tiles and the green tiles kept merging together and forming one color. Then my heart raced, immediately and I started having hot flashes that shot out my ears. My heart raced even more and at that point I had realized something wasn't right. A National Guards member came up to me and had asked if I were okay, I explained I was not and something was not right. They took me to a medical area and made me take deep breaths, and made me drink some water. My BP was high, and my Pulse Ox had dropped slightly, and then went straight back to normal once they had asked me to stick my head between my knees and keep breathing deeply. Also, both of my ears had turned deep red/purple and they were VERY warm to the touch. They felt as if heat were tunneling out of them. The only way I can explain truly how I felt, and I have NEVER done it fully, I felt as if I was fainting. Out of nowhere I felt as if I was going to pass out ? but it didn't happen. The entire ?spell? lasted about 20 mins? I was monitored for an additional 40 minutes and was allowed to leave. |
| 1182005 | 4/8/2021 | VA | 18 | F | 4/8/2021 | 4/8/2021 | Patient fainted 5 minutes after receiving the vaccine |
| 1181979 | 4/8/2021 | TN | 34 | M | 4/7/2021 | 4/7/2021 | Syncope and fell out of chair, vital signs stable, first aid provided, EMS called, injured right side of face in fall |
| 1181961 | 4/8/2021 | | 32 | M | 4/7/2021 | 4/8/2021 | received vaccine 9am. started feeling under the weather 10pm. woke up next day 3am with headache. fainted on his way to the bathroom to get Tylenol. hit his head. |

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| 1181957 | 4/8/2021 | MD | 32 | F | 4/6/2021 | 4/7/2021 | Muscle and joint aches starting approximately 9:15 AM 04/08, dizziness and syncope at appx 10:00 AM, followed by nausea. I was transported via ambulance to given Zofran and started on LR IV en route. At Suburban I was next placed on normal saline IV and given Tylenol. I was feeling pain in my back left hip and on the back left side of my head so I had hip and chest x-rays and a head CT done. All imaging and labs were normal and I was feeling well enough to be discharged at appx 2:30 PM. Following the visit to the ER I continued to feel muscle and joint aches, but no longer any dizziness or nausea. I also started having a headache. I continue to have a headache through today, 04/09. I followed up with my primary care provider this afternoon who said it was possibly a lingering concussion from hitting my head during syncope episode. |
| 1181955 | 4/8/2021 | MA | 32 | F | 4/5/2021 | 4/8/2021 | Light headed was and fainted about 48 hrs after vaccine was administered |
| 1181941 | 4/8/2021 | OH | 19 | M | 4/8/2021 | 4/8/2021 | Patient was sitting in post-vaccination waiting area in front of the pharmacy and fell off his chair. He regained consciousness right away and didn't remember passing out. I asked him to recline and elevate his legs and he held that position for several minutes and then seemed fine after that. He said he has an extreme fear of needles and felt he passed out from the anxiety he was feeling prior to getting the shot. He remained in the post-vaccine waiting area for an additional 15-20 minutes and did not have another episode of syncope. |
| 1182061 | 4/8/2021 | PA | 32 | F | 4/5/2021 | 4/5/2021 | Vomiting, almost fainting |
| 1181934 | 4/8/2021 | SC | 24 | M | 4/8/2021 | 4/8/2021 | THE PATIENT PASSED OUT AND HIT HIS NOSE ON THE FLOOR FOLLOWING ADMINISTRATION OF THE VACCINE. HE CUT HIS NOSE AND HIS EYEBROW. THE EMS CAME AND HE REFUSED TO GO TO THE HOSPITAL. HE LATER WENT TO THE EMERGENCY ROOM WITH HIS FAMILY AND HE WAS RELEASED. HE IS RESTING COMFORTABLY AT HOME. HIS FAMILY SAYS HE DOES NOT HAVE A PRIMARY CARE PHYSICIAN TO REPORT THIS TO |

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| 1181769 | 4/8/2021 | FL | 56 | M | 4/8/2021 | 4/8/2021 | Pt. walked to the front of the Pharmacy from the post vaccination waiting area (4 feet) asking for help because he was dizzy. He was sweating and having shortness of breath. Pt. was taken to the seat where he fainted. Pt. was laid on the floor with his legs up in a step. He gained consciousness in less than 1 min. Pt was pale. Pt. was given an alcohol swab to smell. 911 was called. First responders took his blood pressure again and blood sugar. Uncle's pt. was called and came to the Pharmacy to pick him up to avoid pt. having to drive his car back home. |
| 1181889 | 4/8/2021 | RI | 32 | F | 4/6/2021 | 4/6/2021 | Immediately following the injection, felt immediate metallic taste in mouth, warm sensation from head to toe, lightheaded that almost lead to fainting (did not ever actually pass out), tachycardia... this lasted for about 5 minutes. Later that day I continued to feel flushed and had localized hives that went away on their own. |
| 1181879 | 4/8/2021 | SD | 17 | M | 4/8/2021 | 4/8/2021 | Shot given around 1125 am. Pt and pt's mother went to sit in front of pharmacy. At around 1135, pt fell out of chair, sounded/looked like he may have hit his head on blood pressure machine that he was sitting near. We thought he had fainted. Pt woke within 10 or so seconds after fall and was confused. Said his head didn't hurt. His skin did lose it's color and he was looking "white as a sheet". We had pt lie on floor and elevated his feet. After a few minutes he was feeling better and was able to sit in a chair. Pt and his mom left the pharmacy area about 15-20 minutes after pt fainted. Upon looking at video of the event, it appears that before the patient fell out of his chair that his right arm raises up and his elbow is bent in a very stiff way. A split second later his whole body appears to stiffen and bend to the left, then he falls out of the chair and is lying on the floor. When on the floor, his legs appear to be fairly stiff as well. This whole episode seems to last about 10 seconds or less. The video makes it look more like a seizure than a case of syncope. |
| 1181854 | 4/8/2021 | | 27 | M | 4/8/2021 | 4/8/2021 | Fainted and fell on the floor, non responsive for thirty seconds . |

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| 1181838 | 4/8/2021 | CT | 33 | F | 4/8/2021 | 4/8/2021 | On 4/8/21 Physician was administering Covid-19 vaccines at our clinic in the lawn and garden center. She had a patient who was there to receive her first dose of the vaccine. After the vaccine was administered, she was okay and went to sit in the waiting area. Shortly later she came back up to the pharmacist table and reported feeling dizzy, lightheaded and nauseous. Physician then told the patient to sit right by her so she could keep a better eye on her. The patient said she was okay and then suddenly she passed out. Physician was able to catch her as she was falling out of the chair and was able to lay her down on the floor. She may have bumped her head slightly on the ground during this process. Physician then reports that the patient's breathing sounded labored, and the patient was not conscious. At that point Emergency department was called. Physician removed the patients mask and was preparing to administer an EpiPen due to the labored breathing but then the patient regained consciousness. The Emergency operator advised her to keep the patient on the ground until EMS arrived on scene. Patient was conscious and okay on the ground. EMS then came and took care of the patient. It was deemed that the patient gets lightheaded when she gets bloodwork done usually and believes this may have been an anxiety event. She did not want to go to the hospital. She felt a bit dizzy once she was sitting back upright and EMS approved the patient drinking some water. This seemed to help, and the patients color came back. The patient sat with Physician for a while and then felt back to normal and left on her own accord. |
| 1181785 | 4/8/2021 | MI | 17 | F | 4/8/2021 | 4/8/2021 | Patient fainted. She faints after all immunizations according to her and her father. She was fine, laid down, raised feet, ice pack on forehead/neck. She rested and left after 15 minutes |
| 1181669 | 4/8/2021 | NY | 21 | M | 4/6/2021 | 4/6/2021 | Patient became dizzy and lightheaded with blurred vision after receiving first dose of Pfizer vaccine. Patient stated he had a history of dizziness and fainting from shots. He also stated he had not eaten that morning. Patient laid down for 15 minutes. Vitals were monitored and improved. He refused transport and left clinic on his own. |

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| 1181768 | 4/8/2021 | PA | 50 | F | 3/3/2021 | 3/10/2021 | Dizziness began 7 days after first dose and as of 5 weeks later still has not stopped. Lightheaded every day, sometimes heavy dizzy spells. Almost fainted once. The lightheadedness sometimes clears after a short walk outside, but then returns the next day. I was completely fine and extremely active physically up until receiving the first dose. In addition to the dizziness, my energy has been effected. It took an extreme downturn 5 days after the first dose. I have not regained my normal health or routine since receiving the first dose. |
| 1181729 | 4/8/2021 | MI | 23 | F | 4/8/2021 | 4/8/2021 | Patient experienced light headedness and felt as if she was about to faint. she had to sit down on the floor because she could not stand. This occurred about 5 minutes after administration of the vaccine. prior to receiving the vaccine the patient stated that they have had a history of fainting when she sees needles. patient was offered water for hydration, and given a cold rag and water bottle to put on her face and neck. Patient was advised to sit with her chest down to her thighs. after about fifteen minutes the patient felt better and wanted to go home with her mother |
| 1181716 | 4/8/2021 | WI | 67 | F | 4/6/2021 | 4/7/2021 | Woke with body aches, 102.6 fever, horrible headache. Lasted the whole day after injection. Around 5:30 pm I started feeling woozy and passed out. Neighbor couldn't bring me around. 911 was called. I started vomiting and very nauseous by 6:00 pm. All vitals were ok by medics. I went in my house, went to sleep and woke the next day fine. Wasn't sure about the passing out and vomiting, nor the fever for the day being normal. |
| 1182666 | 4/8/2021 | TN | 30 | M | 4/8/2021 | 4/8/2021 | Severe nausea, dizziness, fainted, severe blood pressure drop |

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| 1183370 | 4/8/2021 | OR | 20 | F | 4/6/2021 | 4/6/2021 | Immediately after the vaccine was injected, I felt like I got slugged in the arm. I also had a momentary hot flash. Then, I went to go sit in the waiting area, and I continued to get warmer and warmer. After 5 minutes, I went up to the front desk, and told them I didn't feel well and that I felt like I was overheating. They put me in a wheelchair, and I immediately passed out and hallucinated for a minute or two. I felt incredibly weak, and I had sweat completely through my shirt. A paramedic came and put me in a stretcher in a cornered off area of the clinic. After 30 minutes or so, I started feeling better, but I got several spurts of cold flashes. All of my vitals came back normal. |
| 1181937 | 4/8/2021 | | 58 | F | 4/3/2021 | 4/3/2021 | Patient with known fear of needles reported lightheadedness and fainted after receiving her vaccine. She was seated at the time, and was guided from chair to floor by her husband. She did not sustain any trauma and did not lose consciousness. After several minutes, she transferred independently to a chair and remained under observation for 30 minutes. She reported all symptoms resolved, she left the clinic independently |
| 1182526 | 4/8/2021 | | 23 | F | 4/8/2021 | 4/8/2021 | 20 minutes after receiving vaccine patient walked up to pick up counter to tell someone she did not feel well-sweating and headache. Patient could not speak and passed out. EMS was called and responded. Vitals checked out ok. Patient was not transported. Patient's mom was called and came to pharmacy. Patient rode home with mom. |
| 1181752 | 4/8/2021 | GA | 38 | F | 12/21/2020 | 1/12/2021 | I experienced hypersensitivity, arm pain dizziness, chills, and joint pain after my second dose vaccine after 24hours. I went to the ER twice because I almost passed out. On 03-15-21, went to the ER, was told I was dehydrated. At the ER labs were elevated also MRI and CT scans were performed. I was placed on steroids for ten days. For two weeks I could not do my normal activities. I saw my endocrinologist. I felt so sick and had to ask for time off at work. I was told to follow up with my endocrinologist. |

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| 1182634 | 4/8/2021 | KY | 37 | M | 4/8/2021 | 4/8/2021 | This morning I gave a patient a moderna vaccine. During administration the patient expressed his fear of needles. After the vaccine I asked the patient to have a seat and wait in the waiting area for 15 minutes. He went and sat down for just a couple minutes and stood up to look for his spouse and when he stood up he passed out and hit the floor face first. I ran out there to check on him and he was unresponsive and bleeding a lot. My team immediately called 911. I started tapping him and slightly shaking him and after a few minutes he woke up. He told me the only thing he remembers is feeling dizzy then woke up on the floor. EMS showed up a few minutes later and took the patient to the hospital. |
| 1182642 | 4/8/2021 | | 25 | M | 4/7/2021 | 4/7/2021 | Patient passed out |
| 1182615 | 4/8/2021 | CA | 18 | M | 4/8/2021 | 4/8/2021 | Patient at Vaccination table, just received dose of vaccine when patient's arm went limp. Also developed generalized weakness. Mother stood in front of him and held his head with both hands. Patient then passed out with eyes rolling in back of head. Also had convulsions for a few seconds that mimicked seizure. Patient soon became alert. Vitals obtained with BP 92/52, HR 34, O2 96% on RA. Patient also diaphoretic to touch. EMS activated and arrived at 1:30pm. Placed in reclining wheelchair and taken to private area. Started to feel better after given cold water. Suggested ER due to having seizure first time. Declined ambulance but mother will take to ER in private car. Patient and mother left with no further incident. |
| 1182599 | 4/8/2021 | MD | 63 | M | 4/8/2021 | 4/8/2021 | POSSIBLE SYNCOPE-PT FELT DIZZY PULSE WAS 51, BP WAS 133/91. FRONT ASSOCIATE CALLED 911 AND AMBULANCE CAME AND REFUSED TO GO AND WAS ABLE TO GET UP AND WALK OUT |
| 1182555 | 4/8/2021 | WI | 21 | M | 4/8/2021 | 4/8/2021 | Vaccine administrator (mother) was well aware of patient's vaso-vagal response. Patient sat in chair, Pfizer #1 vaccine given in LD. 5 minutes later patient stated he was about to pass out. Patient then passed out. Patient laid on the ground with 3 RN's assisting. Feet were elevated, cool cloth to forehead, and remained on the floor for 10 minutes. Recovered in the chair for 30 minutes of observation. |

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| 1182652 | 4/8/2021 | | 29 | M | 4/8/2021 | 4/8/2021 | Pt became lighted, diaphoretic and confused. Pt had a near syncopal episode. Pt stated has a history of syncope post injection or blood draw. Pt's vitals evaluated and Pt refused transport to ED. |
| 1182069 | 4/8/2021 | MI | 25 | M | 4/8/2021 | 4/8/2021 | Patient passed out and hit his head on the floor cause a laceration above left eyebrow which needed medical attention at local hospital. Also may have needed a concussion test done. |
| 1182527 | 4/8/2021 | CA | 50 | M | 4/8/2021 | 4/8/2021 | At 1314 client receive his first shot of moderna vaccine. At 1319 client complained of feeling fainting, hot and sweating. Noted client to be pale and diaphoretic. 1320 BP 60/? HR 46, O2 sat 92% on RA, RR 18, sitting, still diaphoretic. 1324 BP 90/? HR 55, O2 sat 95% on RA lying down. 1329, BP 120/80, HR 55, O2 sat 97% on RA. 1331 HR 60 lying down. 1334 BP 118/88,HR 60, O2 sat 97%on RA lying down. 1335, HR 64, O2 sat 97% on RA. at this time client said he has not eaten all day, worked last night, smooks cigarete and has the same reaction with blood draws. 1339 BP 130/70, HR 62. Client verbalized feeling good and that all symtompts has resolved. No further treatment is needed as standing BP aws 138/70 with no dizziness at this time. Total treatment time was 30min. Client left at 1349. Wife will be driving client home. |

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| 1182618 | 4/8/2021 | OH | 50 | F | 3/19/2021 | 3/1/2021 | Syncope; Vomiting; uncontrollable water diarrhea for almost 12 hours.; Severe stomachache; intestinal cramping; Low grade fever; Chills; Sweats; This is a spontaneous report from a non-contactable consumer (patient). A 50-years-old female, non-pregnant, patient received the first dose of BNT162B2 Pfizer-BioNTech COVID-19 mRNA Vaccine at pharmacy or drug store via an unspecified route of administration, administered in left arm on 19Mar2021, at 50 years of age, (Batch/Lot number was not reported) as single dose for COVID-19 immunization. Medical history included fibromyalgia from an unknown date. Prior to vaccination the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. Concomitant medications included nifedipine, clonazepam, estradiol and propranolol, all taken for an unspecified indication, start and stop date were not reported. In Mar2021 the patient experienced syncope, assessed as medically significant, vomiting, uncontrollable water diarrhea for almost 12 hours, severe stomachache, intestinal cramping, low grade fever, chills and sweats. No treatment was received for the events. All the events were resolving at the time of the report. No follow-up attempts are possible; information about lot/batch number cannot be obtained. |
| 1182503 | 4/8/2021 | OK | 49 | M | 4/8/2021 | 4/8/2021 | Pt reported feeling dizzy and light headed. He laid down with feet up with cold pack. He felt better after about 10 minutes and he sat up. He then fainted within about 5-10 minutes. We again got him safely to the ground with feet up and cold pack. He remained pale and dizzy for about 10 minutes. He then sat up and left after about 20 more minutes after reporting that he felt better. |

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| 1182474 | 4/8/2021 | PA | 53 | F | 2/13/2021 | 2/14/2021 | vasovagal response; nausea; stomach pains; vomited; diarrhea; severe headache; neck and shoulder aches; neck and shoulder aches; 100.5 fever; tired; slept all day next day; This is a spontaneous report from a contactable nurse. A 53-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Solution for injection, Lot Number: EN5318), via intramuscular route of administration in the right arm on 13Feb2021 09:30 (at the age of 53-year-old) as a single dose for COVID-19 immunisation. The patient's medical history included hypothyroidism. Concomitant medications included levothyroxine (manufacturer unknown), at 25 ug, daily, escitalopram (manufacturer unknown), 5 mg, daily, fish oil (manufacturer unknown) and calcium carbonate, colecalciferol (VITAMIN D 2000). The patient previously took first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, lot number EL8982), via intramuscular in the right arm on 23Jan2021 at 10:30 AM After administration of 2nd vaccine, the patient developed nausea, stomach pains, vomited, diarrhea, severe headache, neck and shoulder aches, 100.5 fever, tired, slept on 14Feb2021. Also had vasovagal response 14Feb at 1:00 pm and almost passed out. The patient underwent lab tests and procedures which included Body temperature: 100.5 on an unspecified date. The reported events were considered as non-serious by the health authority. The outcome of the events were recovering. No follow-up attempts are needed. No further information is expected. |
| 1182147 | 4/8/2021 | CA | 28 | M | 4/1/2021 | 4/1/2021 | Pre-syncope - BP 94/59 recovered after 10 min of laying down. |
| 1182078 | 4/8/2021 | | 43 | M | 4/8/2021 | 4/8/2021 | sweating reports ringing in ear passed out for less than a minute Given 1 dose of epi to Right Thigh |
| 1182082 | 4/8/2021 | MA | 20 | M | 4/7/2021 | 4/7/2021 | Patient fainted about 1 to 2 min after getting vaccine. Patient felt very hot and was given an ice pack and began to sweat. After about 10 min patient was helped to a sitting position. |

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| 1182143 | 4/8/2021 | OH | 27 | M | 4/8/2021 | 4/8/2021 | THE PATIENT PASSED OUT A FEW MINUTES AFTER RECEIVING THE VACCINE. HE FELL OUT OF HIS CHAIR AND WAS FULLY CONSCIOUS WHEN I CAME TO HIS SIDE A FEW SECONDS LATER. WE HAD THE PATIENT STAY LAYING DOWN AND HE SAID HE FELT COMPLETELY FINE. THE PATIENT DID NOT WANT US TO CALL AN AMBULANCE. AFTER A FEW MINUTES, WE TOOK THE PATIENT TO OUR PRIVATE CONSULTATION ROOM AND CONTINUED TO MONITOR HIM FOR AT LEAST 30 MINUTES. THE PATIENT'S MOM ARRIVED AT THE STORE, WE EXPLAINED THE SITUATION, AND THEY LEFT TOGETHER. WE CALLED THE PATIENT A FEW HOURS LATER AND HE WAS DOING FINE. |

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| 1182438 | 4/8/2021 | CA | 60 | F | | 4/4/2021 | <p>FAINTED; QUALITY OF SLEEP WAS LOW/DID NOT SLEEP WELL; FELT VERY RESTLESS; CHILLS; FEVER (UNKNOWN TEMPERATURE); EXTREME NAUSEA; This spontaneous report received from a patient concerned a 60 year old female. The patient's weight, height, and medical history included the patient had several comorbidities. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1808978) dose was not reported, frequency 1 total, administered on 03-APR-2021 at left Arm for prophylactic vaccination. No concomitant medications were reported. It was reported that, On 04-APR-2021 at approximately 04:00 a.m. in the morning, the patient experienced chills, extreme nausea, fever (unknown temperature, felt like she had a fever, hot) and she fainted. She also stated that when she went to sleep her quality of sleep was low and poor as she felt very restless. She stated that before fainting she called out to her husband who then carried her back to her bed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the quality of sleep was low/ did not sleep well, chills, fever (unknown temperature), fainted, extreme nausea and felt very restless was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0-20210408190-Covid-19 Vaccine ad26. cov2.s-Fainted. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p> |
| 1182246 | 4/8/2021 | MD | 39 | M | 4/8/2021 | 4/8/2021 | <p>vasovagal episode less than 20 seconds w rapid return to baseline. History of syncope w ?needles? 2x in past.</p> |
| 1182261 | 4/8/2021 | FL | 25 | M | 4/8/2021 | 4/8/2021 | <p>PATIENT FAINTED FOR 3-4 MINUTES...CALLED 911..PATIENT WAS TAKEN TO HOSPITAL</p> |
| 1182277 | 4/8/2021 | IL | 43 | M | 4/7/2021 | 4/7/2021 | <p>20 mins after shot, I nearly fainted - but subsided within minutes. About 6 hours later, had aches, striking headaches, dizziness throughout the entire evening. subsided by the time we woke up - took tylenol.</p> |

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| 1182293 | 4/8/2021 | KY | 22 | M | 4/8/2021 | 4/8/2021 | Patient left pharmacy and passed out on the sidewalk. Unknown if vaccine or fall caused Nausea, Headache, Memory loss. |
| 1182294 | 4/8/2021 | CO | 35 | F | 4/8/2021 | 4/8/2021 | I really think this was a result of my anxiety regarding needles rather than from the actual vaccine. I have had fainting spells after blood draws. After about 5 or 10 minutes from receiving the shot I started feeling warm and nauseous. The on site nurse came over and I did vomit. I felt better almost instantly. She was wonderful, but had me stay in the supervision area for an additional 20 minutes to make sure I didn't have any more nausea or other symptoms. |
| 1182309 | 4/8/2021 | | 42 | M | 3/11/2021 | 3/11/2021 | Patient received Janssen lot#1805020 with expiration of 05/25/2021 at 1420 sitting in upright chair. Vaccinator was notified that he has a history of vasovagal response with needles. This response presents itself as sweating (and possible fainting) and is alleviated by lying down. Client mentioned that previous nurse advised him to smell an alcohol pad to distract and prevent a vasovagal response, as this had worked previously on a glucose check. No medications were disclosed or history of anaphylaxis reported. With this background information, RN offered to have vaccine administered in reclined position, however client refused. RN conferred with co-lead about administration recommendations. Vaccinator then checked in with patient at 1423 to see if patient was okay and patient did not answer the question. RN then felt the client's hand and noticed hand was clammy. At 1425 the reclining chair was brought to the station and patient was transferred into chair, appearing diaphoretic. RN palpated pulse and noted patient was not tachycardia, but RN did note tachypnea and uneasiness. RN then provided distraction and promoted relaxation. Then at 1426 patient reported feeling okay and RN noted patient no longer felt clammy. At 1440 patient was asked if he would prefer if EMS should be called, patient declined and stated that he was able to drive home. Then at 1447 patient left the site appearing well, alert and oriented x3 leaving by self in private car. |

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| 1182320 | 4/8/2021 | OK | 30 | M | 4/8/2021 | 4/8/2021 | Patient reported feeling dizzy about 5 minutes after receiving vaccination. He then fainted immediately after reporting that. We got him to the ground safely with feet up and used a cold pack. He regained consciousness quickly. He sat up about 10 minutes later and left about 15-20 minutes later. |
| 1182338 | 4/8/2021 | | 24 | M | 4/8/2021 | 4/8/2021 | Syncope for 15-30 sec. head trauma. Neg. concussion screen test. |
| 1176209 | 4/7/2021 | NC | 25 | F | 4/6/2021 | 4/6/2021 | Patient had passed out and had woken back within minutes. Patient requested coke and water. She waited in the vaccine area until she felt better and was able to walk and leave store. |
| 1176175 | 4/7/2021 | TN | 70 | F | 4/3/2021 | 4/4/2021 | Patient passed out 24 hours after vaccination. Dose 2 of Moderna. She has recovered from the event and no additional treatment was necessary. |
| 1176158 | 4/7/2021 | | 34 | M | 4/5/2021 | 4/5/2021 | The patient experienced syncope about 10 minutes after injection. The patient recovered and left on own accord. |
| 1176153 | 4/7/2021 | IN | 20 | M | 3/31/2021 | 3/31/2021 | Patient received vaccine around 1255 pm on 3/31. Upon standing after waiting the recommended 15 minute observation period, patient became dizzy, lightheaded. Patient's symptoms proceeded leading to brief loss of consciousness and pallor consistent with syncope. Patient was gently aided to the floor at 110pm. The patient's mother was present and accompanied the patient. Patient was given general supportive care from pharmacy and team members consisting of feet elevation water, and head support. At no point did the patient nor his mother request for emergency services to be contacted. A witness had EMS on the phone during supportive care. Before being able to inform EMS not to dispatch, they had arrived around 115pm. EMS took over care upon arrival. Blood pressure reading per EMS was 102/56. Patient was transported to hospital at 1325. |
| 1176123 | 4/7/2021 | NH | 41 | F | 4/6/2021 | 4/7/2021 | Patient reported waking up with arm soreness at 2:30am. She got out of bed to get a pain reliever, felt lightheaded and passed out. She woke up and passed out again, but feels fine now. |

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| 1176117 | 4/7/2021 | | 38 | M | 4/7/2021 | 4/7/2021 | The patient experienced syncope and fell out of chair. The patient was unconscious for about 15 seconds. The patient was observed in medical tent and had two episodes of bradycardia and fainted twice more. The patient was transported to Hospital. |
| 1176116 | 4/7/2021 | NV | 47 | M | 4/6/2021 | 4/6/2021 | Patient received the vaccine. Immunizing tech stated: the patient seemed fine at the time of the shot. After administration of the shot the patient began to bleed out of injection site (like normal). The immunizing tech swabbed the area with cotton and placed a Band-Aid on the patient then stepped back into the pharmacy to grab another band aid while the patient remained at the immunization chair. The tech applied another band aid and told the patient to wait 15 minutes after the immunization and directed him to a waiting chair. The tech came back into the pharmacy and was cleaning the immunization basket when the patient's wife yelled for help. At this point I went out to the patient. Another tech called 911, another grabbed a nearby EpiPen. The immunizing tech grabbed the e-kit while I was out with the patient while he was unresponsive. Patient was unresponsive and slouched in chair. His wife and I supported the neck of the patient and laid him on the floor. I checked pulse and breathing to which both were present. Patient was still unresponsive and making strange movements. Pulse and breathing remained present and then the patient became responsive relatively quickly. At this point patient responsive and answering questions and moving fine. He asked if he had passed out then stated, he had a phobia of needles and said he felt nauseated. (wife previously stated he had a fear of injections). Soon after the ambulance showed up and I told the paramedics the above story. After a few more minutes I checked in with the paramedics and they said the patient was doing fine. Lastly, he was taken out of store with paramedics. |
| 1176190 | 4/7/2021 | MD | 57 | F | 3/17/2012 | 3/18/2021 | Vasovagal syncope: suddenly felt extremely sick the next morning. Went to bathroom, thought I might vomit. Passed out, hit face on floor, needed stitches in brow and chin, split lip, broke tooth. The sick feeling lasted maybe 10 minutes before passing out. Did not notice it again after regaining consciousness. |

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| 1176115 | 4/7/2021 | FL | 53 | M | 4/7/2021 | 4/7/2021 | Patient received vaccine approx 5-10 minutes patient fainted in his chair. A cardiac nurse was waiting to receive their vaccine and rushed over to help too. Patient began to convulse. We tried to get patient to respond approx 2 min later patient woke up and complained about being thirsty. We gave him Apple juice and placed a cold pack on his neck. Called 911, We took BP it was 77/49 pulse 45, we laid patient down and retook BP 123/73 Pulse 68. After 5 more min BP 135/85 pulse 72. EMS arrived and took patient away |
| 1176102 | 4/7/2021 | CA | 40 | F | 3/23/2021 | 3/23/2021 | Woke Up to use restroom after sleeping a bit. Fainted (full loss of consciousness) while seated on toilet, and ultimately landed on my head on the bathroom floor. |
| 1176047 | 4/7/2021 | | 20 | M | 4/7/2021 | 4/7/2021 | Came in for his Janssen COVID-19 vaccine and reported no allergies. Within 5 minutes of vaccination he briefly passed out. He was back up on his feet and reported feeling normal within 30 seconds. About 5 minutes later he began to have slurred speech, excessive perspiration and reported feeling warm. An ambulance was called and arrived within less that 5 minutes and took over care. |
| 1175940 | 4/7/2021 | DC | 53 | F | 4/5/2021 | 4/7/2021 | Dizzy spell where I almost fainted (Day 2 after vaccine) |
| 1175938 | 4/7/2021 | IN | 18 | F | 4/7/2021 | 4/7/2021 | Pt received vaccine and approximately 5 minutes later pt got light headed fainted and hit head on the floor of the waiting room. Pt begun to seize for approximately 30 seconds then regained consciousness. Pt was stabilized and monitored. 9-1-1 contacted immediately and handled pt care once they arrived. |
| 1175905 | 4/7/2021 | WA | 35 | F | 4/6/2021 | 4/6/2021 | Brief Syncope, sitting position, no fall. |
| 1175903 | 4/7/2021 | | 50 | F | 4/7/2021 | 4/7/2021 | BP at 1105 154/105, Pulse 86, O2 Sat 100%. Near syncope, hand numbness and itchiness |

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| 1175902 | 4/7/2021 | IL | 29 | M | 4/7/2021 | 4/7/2021 | Within 5 minutes of administration, patient began to experience some nausea and alerted pharmacy staff. The pharmacist gave patient trash can and began monitoring patient condition. Patient stated has anxiety and has experienced this before. Patient was pale at this time. After 10 minutes from vaccination, patient began to get sweaty. pharmacist gave patient an ice pack for forehead and helped patient to the floor. Patient sat on floor and remained conscious. After several minutes on the floor. patient's color returned and he stated was feeling much better. Patient returned to his chair at this time (about 15 mins post vaccination). Patients condition continued to improve from there on. Patient waited at the pharamcy for 30 more minutes to ensure syncope event had past and no other issues arose. Patient left after 45 minutes stating they feel normal. |
| 1176226 | 4/7/2021 | CO | 35 | F | 4/7/2021 | 4/7/2021 | Light headed, convulsions , vasovagal, then passed out, then convulsion for second time. Nausea Anxiety around needles Diaphoretic Vitals 140/95, HR -70, Oxygen -98 |
| 1175824 | 4/7/2021 | OH | 19 | F | 4/6/2021 | 4/6/2021 | Received COVID-19 vaccine (Pfizer dose 1) at 6:05PM. She was then instructed to wait in the waiting room for 15 minutes. Notified by PCT that patient had ask for an ice pack stating that "she felt like she was going to pass out." PCT retrieved water for pt and informed NP of situation. Upon entering waiting room patient appeared to be passed out in chair. Patient unable to speak, pale in color, and limp in chair. Placed cool paper towels on pts forehead - continually ask patient to speak or respond - patient was unable to. Call placed to 911 at 6:11PM. Patients vital signs BP 86/58, pulse 79, O2sat 97%. Sternal rub performed. Patient regained consciousness while PCT was on the phone with EMS. Patient then stated that this happens to her with medical procedures such as drawing blood. Assisted patient into exam room. Upon assessment lung sounds clear throughout, heart sounds normal. EMS arrived and discussed situation with NP and pt. Decision was made by pt to decline further workup at this time stating that she "feels fine now." Repeat vital signs at 6:39 BP 92/70 Pulse 115, and o2sat 97%. |

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| 1176735 | 4/7/2021 | PA | 18 | F | 4/7/2021 | 4/7/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Severe, Systemic: Hypotension-Mild, Systemic: Shakiness-Mild, Additional Details: Patient fell out of chair #7 in pharmacy. This author caught patient and brought to floor. EMS called at 12:44. Nurse on site took patients BP 108/66. Could not get HR. EMS arrived at 12:52. EMS evaluated patient. Gave patient cold water. Patient declined hospital transfer. Patient was over 18 and EMS gave her paper that stated she declined hospital care. EMS left 12:57. |
| 1175818 | 4/7/2021 | PA | 20 | M | 4/6/2021 | 4/6/2021 | Syncope/near Syncope |
| 1175811 | 4/7/2021 | OH | 54 | F | 4/5/2021 | 4/6/2021 | Fainted at 3:30am 4-6-21, fever 100 degrees, body and neck ache, migraine |
| 1175853 | 4/7/2021 | MA | 18 | F | 4/7/2021 | 4/7/2021 | Fainted |
| 1176751 | 4/7/2021 | AZ | 32 | M | 4/7/2021 | 4/7/2021 | Patient fainted within 15 minutes of receiving vaccine. Patient was responsive and did not have trouble breathing. Gave patient supportive care (had patient continue to lie down, gave water, stayed with patient). Patient was able to get back up after a few minutes. Told patient to stay an additional 15 minutes as a precaution. Patient was able to leave safely afterwards. |
| 1176910 | 4/7/2021 | TX | 42 | F | 3/6/2021 | 3/19/2021 | On 03/19/2021 She felt dizzy and went to sit down. She ended up passing out and fainting. Now her platelets have dropped 120 points. |
| 1176900 | 4/7/2021 | | 25 | F | 4/7/2021 | 4/7/2021 | a few minutes after patient received vaccine she told us she did not feel well. a few seconds later she passed out for a few seconds before she came back to. her bp was low upon monitoring |
| 1175792 | 4/7/2021 | IN | 31 | M | 4/7/2021 | 4/7/2021 | Passed out within 5 minutes of receiving the vaccine. Dizziness, skin pale, b/p 80/48. Transported to Hospital for treatment. |
| 1176895 | 4/7/2021 | AK | 22 | M | 4/7/2021 | 4/7/2021 | Fainted while standing in line to check-out minutes after getting the vaccine; Blood pressure was low so transported by med unit; Laceration on the bottom of chin and chipped two front top teeth; IV was started on scene to administer fluids. |

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| 1176893 | 4/7/2021 | MI | 18 | M | 4/7/2021 | 4/7/2021 | Fainting about 2-3 minutes after shot was administered. Could have been anxiety. He has never fainted from just a shot but has when he has had blood drawn. |
| 1176861 | 4/7/2021 | NJ | 46 | F | 4/2/2021 | 4/3/2021 | Passed out the next morning |
| 1176836 | 4/7/2021 | PA | 24 | M | 4/7/2021 | 4/7/2021 | patient passed out after shot |
| 1176810 | 4/7/2021 | AZ | 63 | F | 4/5/2021 | 4/5/2021 | I had the second dose of Moderna at 11:30 a.m. on April 5, 2021. By 8:30 p.m. on April 5, 2021, I was running a temperature and had chills for hours. At around 2 am., I got up, fainted and fell. Had a blow to my head. Fainted a second time and fell. Went to the ER with a 101 temperature. I was admitted to ICU. The CT scan didn't show any brain bleeding. Hurt my lower back when I fell. |
| 1176686 | 4/7/2021 | FL | 18 | F | 4/7/2021 | 4/7/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium |
| 1176789 | 4/7/2021 | FL | 31 | F | 4/7/2021 | 4/7/2021 | Patient had a tonic-clonic seizure approximately five minutes after receiving the first dose of the Moderna covid-19 vaccination. Post seizure the patient reported feeling a fever leading up to seizure. Patient had no history of seizure but has experienced fainting in the past. 911 was called immediately and paramedics cared for her. |
| 1176231 | 4/7/2021 | VA | 23 | F | 4/7/2021 | 4/7/2021 | Syncope, no trauma, BP. 105/61. P 80. 98% Released to home |
| 1176747 | 4/7/2021 | FL | 27 | M | 4/7/2021 | 4/7/2021 | Site: Redness at Injection Site-Mild, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Additional Details: Patient "swooned" when the observer was getting the timer. He was responsive after 2 minutes. sat upright after 5 minutes. |
| 1176698 | 4/7/2021 | WI | 22 | M | 3/9/2021 | 3/9/2021 | The patient fainted shortly after the vaccine. Patient stated that this has happened twice in the past with other vaccinations. He feels this had nothing to do with the vaccination its self. |

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| 1176684 | 4/7/2021 | MN | 17 | F | 4/2/2021 | 4/2/2021 | Patient passed out, fell out of her chair and hit her head hard after receiving her shot. Once she went down, two nurses ran to her assistance where they propped the patient's feet up on a chair and got her some water. Patient reported blurred vision, had a goose egg on the back of her head but did not appear to be mentally foggy. |
| 1176679 | 4/7/2021 | IL | 31 | F | 4/6/2021 | 4/6/2021 | Patient stated she had a history of fainting with blood draws. Patient stated she did eat before vaccination. Nurse on hand as well as another person to assist if needed. Patient was administered vaccination by medic within 3 min started feeling nauseated and sweating she lost consciousness. Medic and public health nurse able to lie on floor patient safe and did not hit her head. Ambulance staff paramedic on site. B/p taken 90/58, O2 98% 66 Pulse. Cool cloth to head and ice packs to neck. Within a minute Patient regained consciousness. Juice given. Patient was able to eat a cookie. Stated she was feeling better. Assisted transfer to wheelchair to monitoring station for additional 30 min. Patient declined to be taken to local hospital via medics. B/p reassessed at 0112 10/98 100% o2 68 pulse. Patient able to talk and drink water without any problems. Patient was present with husband. Patient monitored an additional 30 min. before leaving. Patient gait steady and no slurring of speech. Patient was advised if any problems arise to seek 911. Patient stated she would not be driving home her Husband would. |

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| 1176525 | 4/7/2021 | NY | | F | | 3/25/2021 | ALMOST PASSED OUT; LOW BLOOD SUGAR; A LOT OF GAS; VOMITED; PEED ON HERSELF; NAUSEATED; HALLUCINATION; FEVER; FELT COLD AND SAID SHE WAS FREEZING; PAIN IN LEFT KNEE; VERY WEAK, COULD HARDLY GET TO BED; EYES HURT WHEN TOUCHED; FELT MEDICATION GOING IN; SHALLOW BREATHING; HEADACHE; SHAKINESS; This spontaneous report received from a patient concerned a 51 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included diabetes and depression, and other pre-existing medical conditions included patient had no known allergies. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805022, and batch number: 1805022 expiry: UNKNOWN) dose was not reported, administered on 25-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On MAR-2021, Laboratory data included: Body temperature (NR: not provided) 101.7 Degree. On 25-MAR-2021, the subject experienced shallow breathing. On 25-MAR-2021, the subject experienced eyes hurt when touched. On 25-MAR-2021, the subject experienced felt medication going in. On 25-MAR-2021, the subject experienced shakiness. On 25-MAR-2021, the subject experienced very weak, could hardly get to bed. On 25-MAR-2021, the subject experienced headache. On 25-MAR-2021 18:30, the subject experienced pain in left knee. On 25-MAR-2021 19:30, the subject experienced felt cold and said she was freezing. On 26-MAR-2021, the subject experienced hallucination. On 26-MAR-2021, the subject experienced low blood sugar. On 26-MAR-2021, the subject experienced vomited. On 26-MAR-2021, the subject experienced peed on herself. On 26-MAR-2021, the subject experienced a lot of gas. On 26-MAR-2021, the subject experienced nauseated. On 26-MAR-2021, the subject experienced fever. On 26-MAR-2021 01:00, the subject experienced almost passed out. Treatment medications (dates unspecified) included: paracetamol. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from felt medication going in, peed on herself, shakiness, a lot of gas, pain in left knee, and nauseated on 26-MAR-2021, was recovering from felt cold and said she was freezing, |

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| | | | | | | very weak, could hardly get to bed, almost passed out, and fever, had not recovered from headache, and eyes hurt when touched, and the outcome of vomited, shallow breathing, hallucination and low blood sugar was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210354256-JANSSEN COVID-19 VACCINE Ad26.CO2. S- Hallucination. This event is considered not related. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event than the drug. Specifically: Medical History of Depression. | |
| 1176306 | 4/7/2021 | IL | 48 | M | 4/7/2021 | 4/7/2021 | Patient fainted shortly after administering vaccine. Patient lost consciousness about 2 minutes following the vaccine. Patient regained consciousness and then felt like they were going to faint again. Pt reported some chest tightness and then chills after regaining consciousness. |
| 1176299 | 4/7/2021 | OH | 62 | F | 4/1/2021 | 4/6/2021 | Severe chills followed by vertigo presyncope and fainting. Could not stand. Fell when I fainted and landed very hard. It is now 1 p.m. and I am just now able to sit up in a chair. Last night, hands and feet were blocks of ice, couldn't stand to take temp. Barely able to get to bathroom, rocketed off walls and furniture. Extreme weakness in legs. |
| 1176272 | 4/7/2021 | | 25 | F | 4/3/2021 | 4/3/2021 | Felt light-headed, passed out and recovered within 1 to 2 minutes |
| 1176236 | 4/7/2021 | FL | 32 | F | 4/6/2021 | 4/6/2021 | Syncope, weakness, cold clammy 69/36, HR 58, 115/80, 120/80, O2Sat 100% |

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| 1176800 | 4/7/2021 | TX | 27 | F | 3/27/2021 | 3/27/2021 | <p>Symptoms of Patient: Complaint of feeling light headedness and not being able to see. Patient then passed out. 14:55 P-126, SaO2 85 Treatment: Offered patient fluid prior to her passing out. Patient was able to take a few sips of water and was alert and oriented prior to passing out. Patient was lowered to the floor from chair. Patient head was protected as she was lowered to the floor. Patient legs were elevated. Patient Blood pressure checked B/P110/70, P-70, SaO2 99%. Cool gauze was placed on client forehead. Emergency services were called to assist in care of patient. Upon elevation of patients legs patient states, was able to see. Patient alert and oriented x 3. Per patient states, is able to get back in chair. Patient states no longer dizzy. Emergency services arrived. Pulse and oxygen saturation maintaining continuous until they arrived. Patient blood pressure, oxygen saturation pulse rechecked by Emergency services. Patient B/P 110/80, P-67, O2 sat-93%, per emergency services, paramedic services came and assess patient. Per paramedic patient did not need to be placed on monitor. Client was not taken by ambulance. Client signed document with Emergency services patient declined transfer. Per patient feeling better, Patient denies feeling lightheaded and dizzy as if she was going to passout. If repeated and severe side effects reviewed with patient. Patient escorted to car by staff and friend Patient left location at 15:30.</p> |
| 1174978 | 4/7/2021 | NJ | 24 | F | 4/6/2021 | 4/6/2021 | <p>Systemic: Confusion-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Visual Changes/Disturbances-Medium, Additional Details: Pt arrived to receive Pfizer vaccine. Pt reported that they experience fainting with vaccines and blood draws. Vaccine given. Mother of pt present. Pt passed out and was not responding to name. Pt regained clear vision and was able to respond normally within 5 minutes. Pt stayed and left with mother after 30 minutes.</p> |

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| 1175165 | 4/7/2021 | WA | 60 | M | 3/9/2021 | 3/1/2021 | lightheaded; stomach pain; feeling like fainting; that happened parallel to erratic high blood pressure 199/98.; nausea; Arm pain first day.; fatigue; palpitations; shakes; joints and muscle pain; joints and muscle pain; headache; Chills; night sweats; This is a spontaneous report from a contactable consumer. A 60-years-old male patient received bnt162b2 (BNT162B2), dose 1 via an unspecified route of administration, administered in Arm Left on 09Mar2021 10:30 (Batch/Lot Number: EN6199) as SINGLE DOSE (at the age of 60 years) for covid-19 immunisation . Medical history included immune thrombocytopenia from an unknown date and unknown if ongoing , hypertension from an unknown date and unknown if ongoing , drug hypersensitivity from an unknown date and unknown if ongoing , covid-19 from Mar2020 to Sep2020, (COVID 19 Long-Hauler from Mar-Sep2020). Concomitant medications included amlodipine besilate, benazepril hydrochloride (AMLODIPINE BENAZEPRIL); simvastatin (SIMVASTATIN). The patient previously took aspirin [acetylsalicylic acid] and experienced anaphylactic reaction, zantac and experienced rash and experienced peripheral swelling. The patient experienced feeling like fainting (medically significant) on 13Mar2021 14:30 with outcome of recovering , that happened parallel to erratic high blood pressure 199/98 on 13Mar2021 14:30 with outcome of recovering , palpitations on Mar2021 with outcome of recovering , lightheaded on 13Mar2021 14:30 with outcome of recovering , stomach pain on 13Mar2021 14:30 with outcome of recovering , shakes on Mar2021 with outcome of recovering , joints and muscle pain, headache on Mar2021 with outcome of recovering , chills on Mar2021 with outcome of recovering , night sweats on Mar2021 with outcome of recovering , nausea on 13Mar2021 14:30 with outcome of recovering , arm pain first day on 09Mar2021 with outcome of recovering , fatigue on Mar2021 with outcome of recovering. The patient underwent lab tests and procedures which included blood pressure measurement: 120's-30's/70's, blood pressure measurement: 199/98 on 13Mar2021, platelet count: 99, sars-cov-2 test: Several negative tests on unspecified date. The patient went to Urgent Care twice. The patient took no other vaccine in four weeks and the patient was not COVID tested post vaccination. |

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| 1175075 | 4/7/2021 | FL | 29 | M | 4/6/2021 | 4/7/2021 | On the night of the vaccine: Fever of 101.5. and headache(6/10). Morning after vaccine: Fever 100.5, headache (6/10), pallor, diaphoretic, nausea. Stood up and then passed out for approximately 2 minutes, hitting his head on the wall. Regained consciousness on his own. |

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| 1175028 | 4/7/2021 | CA | 59 | M | 2/19/2021 | 3/18/2021 | 3 days of intense diarrhea, lost about 10 pounds; Weak, no appetite, lethargic, sleeping a lot; Still just don't have the energy to this day; Chills all the time, fever of 102 for 5 days - went up every time after eating; Friday, got worse, by afternoon, was in bed. Got up to use restroom, next thing I remember was that I was on the floor and could not get up; Thursday, started not feeling great; 3 days of intense diarrhea, lost about 10 pounds; Chills all the time, fever of 102 for 5 days - went up every time after eating; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of SYNCOPE (Friday, got worse, by afternoon, was in bed. Got up to use restroom, next thing I remember was that I was on the floor and could not get up) in a 59-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 040A21A and 023M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No medical history reported). Concomitant products included ESCITALOPRAM OXALATE (LEXAPRO), LEVOTHYROXINE SODIUM (SYNTHROID) and FINASTERIDE for an unknown indication. On 19-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 16-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 18-Mar-2021, the patient experienced FEELING ABNORMAL (Thursday, started not feeling great). On 19-Mar-2021, the patient experienced SYNCOPE (Friday, got worse, by afternoon, was in bed. Got up to use restroom, next thing I remember was that I was on the floor and could not get up) (seriousness criterion medically significant). On an unknown date, the patient experienced DIARRHOEA (3 days of intense diarrhea, lost about 10 pounds), WEIGHT DECREASED (3 days of intense diarrhea, lost about 10 pounds), ASTHENIA (Weak, no appetite, lethargic, sleeping a lot), DECREASED APPETITE (Weak, no appetite, lethargic, sleeping a lot), LETHARGY (Weak, no appetite, lethargic, sleeping a lot), HYPERSOMNIA (Weak, no appetite, lethargic, sleeping a lot), ASTHENIA |

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(Still just don't have the energy to this day), CHILLS (Chills all the time, fever of 102 for 5 days - went up every time after eating) and PYREXIA (Chills all the time, fever of 102 for 5 days - went up every time after eating). The patient was treated with Bed rest for Feeling abnormal. At the time of the report, SYNCOPE (Friday, got worse, by afternoon, was in bed. Got up to use restroom, next thing I remember was that I was on the floor and could not get up) and DIARRHOEA (3 days of intense diarrhea, lost about 10 pounds) had resolved and FEELING ABNORMAL (Thursday, started not feeling great), WEIGHT DECREASED (3 days of intense diarrhea, lost about 10 pounds), ASTHENIA (Weak, no appetite, lethargic, sleeping a lot), DECREASED APPETITE (Weak, no appetite, lethargic, sleeping a lot), LETHARGY (Weak, no appetite, lethargic, sleeping a lot), HYPERSOMNIA (Weak, no appetite, lethargic, sleeping a lot), ASTHENIA (Still just don't have the energy to this day), CHILLS (Chills all the time, fever of 102 for 5 days - went up every time after eating) and PYREXIA (Chills all the time, fever of 102 for 5 days - went up every time after eating) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In March 2021, Diagnostic procedure: all normal (normal) All normal. The patient has taken acetaminophen (TYLENOL), loperamide (IMMODIUM), and an unspecified prescription nausea medication to alleviate his discomfort. The patient saw a doctor who ran unspecified tests and they were all normal. This case was linked to MOD21-065196 (Patient Link).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

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| 1175022 | 4/7/2021 | NY | 76 | F | 2/26/2021 | 3/26/2021 | <p>passed out; she fell down; bruised her lower back; her back is killing her; she felt cold inside; really hot while in bed; This spontaneous case was reported by a consumer and describes the occurrence of SYNCOPPE (passed out) in a 76-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 014M20A and 006A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included COVID-19. On 26-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 26-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 26-Mar-2021, the patient experienced SYNCOPPE (passed out) (seriousness criterion medically significant), FALL (she fell down), CONTUSION (bruised her lower back), BACK PAIN (her back is killing her), FEELING COLD (she felt cold inside) and FEELING HOT (really hot while in bed). On 26-Mar-2021, SYNCOPPE (passed out), FALL (she fell down), FEELING COLD (she felt cold inside) and FEELING HOT (really hot while in bed) had resolved. At the time of the report, CONTUSION (bruised her lower back) and BACK PAIN (her back is killing her) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, SARS-CoV-2 antibody test: positive. Concomitant medications taken by the patient were not provided. Treatment activities was done with paracetamol, ibuprofen, a shot and pill. This case was linked to MOD21-064155 (Patient Link).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested</p> |

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| 1175019 | 4/7/2021 | FL | 66 | F | 3/24/2021 | 3/25/2021 | I passed out; dizziness; I was out; I was sweating profusely; This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (I passed out) in a 66-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 047A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (no medical history reported). On 24-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 25-Mar-2021, the patient experienced LOSS OF CONSCIOUSNESS (I passed out) (seriousness criterion medically significant), DIZZINESS (dizziness), FEELING ABNORMAL (I was out) and HYPERHIDROSIS (I was sweating profusely). At the time of the report, LOSS OF CONSCIOUSNESS (I passed out), DIZZINESS (dizziness), FEELING ABNORMAL (I was out) and HYPERHIDROSIS (I was sweating profusely) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications provided. No treatment information provided. Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded. |

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1175006 4/7/2021

F

Faint; Shaking; Jawclenching; Neck spasms; Don't have interest in eating or drinking; TMJ; Groggy; I can't balance; Face is pouring sweating; Maybe I'm dehydrated; Pain in cheek; Dislocated my finger; Head is still full of fog; Vertigo; Get really tired; Chills; Bad joint pain; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of SYNCOPE (Faint) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No medical history provided.). On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced SYNCOPE (Faint) (seriousness criterion medically significant), TREMOR (Shaking), BRUXISM (Jawclenching), MUSCLE SPASMS (Neck spasms), DECREASED APPETITE (Don't have interest in eating or drinking), TEMPOROMANDIBULAR JOINT SYNDROME (TMJ), SOMNOLENCE (Groggy), BALANCE DISORDER (I can't balance), HYPERHIDROSIS (Face is pouring sweating), DEHYDRATION (Maybe I'm dehydrated), FACIAL PAIN (Pain in cheek), JOINT DISLOCATION (Dislocated my finger), FEELING ABNORMAL (Head is still full of fog), VERTIGO (Vertigo), FATIGUE (Get really tired), CHILLS (Chills) and ARTHRALGIA (Bad joint pain). At the time of the report, SYNCOPE (Faint), TREMOR (Shaking), BRUXISM (Jawclenching), MUSCLE SPASMS (Neck spasms), DECREASED APPETITE (Don't have interest in eating or drinking), TEMPOROMANDIBULAR JOINT SYNDROME (TMJ), SOMNOLENCE (Groggy), BALANCE DISORDER (I can't balance), HYPERHIDROSIS (Face is pouring sweating), DEHYDRATION (Maybe I'm dehydrated), FACIAL PAIN (Pain in cheek), JOINT DISLOCATION (Dislocated my finger), FEELING ABNORMAL (Head is still full of fog), VERTIGO (Vertigo), FATIGUE (Get really tired), CHILLS (Chills) and ARTHRALGIA (Bad joint pain) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. This case concerns a female with serious unexpected syncope, and nonserious unexpected

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| 1174998 | 4/7/2021 | IL | 28 | M | 4/6/2021 | 4/6/2021 | <p>somnolence, bruxism, muscle spasms, temporomandibular joint syndrome, facial pain, joint dislocation, balance disorder, tremor, decreased appetite, feeling abnormal, vertigo, hyperhidrosis, dehydration and expected fatigue, chills, arthralgia. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. This case was linked to MOD-2021-056963 (Patient Link). Reporter did not allow further contact; Sender's Comments: This case concerns a female with serious unexpected syncope, and nonserious unexpected somnolence, bruxism, muscle spasms, temporomandibular joint syndrome, facial pain, joint dislocation, balance disorder, tremor, decreased appetite, feeling abnormal, vertigo, hyperhidrosis, dehydration and expected fatigue, chills, arthralgia. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.</p> <p>Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Additional Details: patient fainted and regained consciousness very quickly. patient refused 911. Nurse and pharmacist checked on patient periodically. pt was under monitoring for 30 minutes and reported feeling well after drinking orange juice and some crackers.</p> |
| 1174995 | 4/7/2021 | MO | 40 | M | 4/6/2021 | 4/6/2021 | <p>Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: PT HAS HISTORY OF FAINTING WHEN GETTING ANY INJECTIONS-Severe, Systemic: Flushed / Sweating-Medium, Additional Details: THE PATIENT SAID HE HAS A HISTORY OF FAINTING WHEN GETTING ANY INJECTIONS (BLOOD DRAWS, IMMUNIZATIONS, OR ANY INVOLVING NEEDLES). THIS WAS NOT AN ACTUAL REACTION TO THE VACCINE.</p> |

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| 1175169 | 4/7/2021 | ME | 70 | F | 3/5/2021 | 3/6/2021 | fatigue; mild diarrhea; abdominal pain; gas; runny nose; diarrhea with blood; Sneezing; watery eyes; orange bowel movement; near syncope; lightheaded/lightheadness; chills; body aches; decreased appetite/poor appetite; This is a spontaneous report from a contactable Other-HCP (healthcare professional) in response to HCP letter sent in cross reference case. A 70-year-old female patient received the second dose of BNT162B2 (COVID-19 MRNA VACCINE BIONTECH; Lot Number: EN6201) intramuscularly on 05Mar2021 (at the age of 70-years-old) as a single dose in the deltoid left for COVID-19 immunisation. Medical history included ongoing HTN (hypertension; onset date: years ago; pertinent details: well controlled) from an unspecified date and menopause from an unspecified date and unspecified if ongoing. Concomitant medications included ongoing hydrochlorothiazide orally taken for HTN from an unspecified date, ongoing estradiol benzoate (ESTRADIOL) vaginal taken for menopause from an unspecified date and ongoing multivitamin orally taken for health maintenance from an unspecified date. The patient previously received the first dose of BNT162B2 (COVID-19 MRNA VACCINE BIONTECH; Lot Number: EL9261) intramuscularly on 12Feb2021 as a single dose in the deltoid left for COVID-19 immunisation and experienced sore arms and should injury. Prior vaccinations were reported as none. On 07Mar2021 the patient experienced diarrhea with blood (medically significant), sneezing, watery eyes, orange bowel movement, on 06Mar2021 the patient experienced near syncope, lightheaded/lightheadness, chills, body aches and decreased appetite/poor appetite, on 08Mar2021 the patient experienced fatigue, mild diarrhea, abdominal pain, gas and runny nose. It was reported that the event near syncope was non-serious, did not require treatment. It was also reported that the events near syncope and diarrhea with blood required a visit to the emergency room. The clinical course was reported as follows: "05Mar2021 Vax. 06Mar2021- Lightheadedness onset day after COVID vax #2. Lightheaded, chills, body aches, decreased appetite. 07Mar2021- Sneezing, watery eyes, orange bowel movement, poor appetite, diarrhea with blood. To ER. 08Mar2021- Fatigue, poor appetite, mild diarrhea, abdominal pain and gas, sneezing, runny nose. 09Mar2021- Improved." The patient underwent lab tests |

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| 1174980 | 4/7/2021 | FL | 21 | F | 4/6/2021 | 4/6/2021 | and procedures on 07Mar2021 that included: EKG, CBC and comprehensive metabolic panel which were all normal. The clinical outcome of the event near syncope was recovered/resolved on an unspecified date while the clinical outcomes of the events diarrhea with blood, lightheaded/lightheadness, chills, body aches, decreased appetite/poor appetite, sneezing, watery eyes, orange bowel movement, fatigue, mild diarrhea, abdominal pain, gas and runny nose were all unknown.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of event Diarrhea bloody cannot be excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate. |
| 1175226 | 4/7/2021 | IL | 33 | F | 3/25/2021 | 3/25/2021 | Systemic: Chills-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Medium, Additional Details: PATIENT FAINTED AND HIT HER HEAD ON THE FLOOR. SHORTLY AFTERWARDS, SHE GOT UP AND SAT DOWN ON THE CHAIR FOR 30 MINUTES AND DRANK WATER AND JUICE BEFORE BEING DRIVEN TO EMERGENCY ROOM. |
| 1174974 | 4/7/2021 | CT | 29 | F | 4/6/2021 | 4/6/2021 | Shortness of breath 5 minutes after, fainting, and severe migraine with aura 1.5 hours after. Muscle pain and aches for 24 hours after. low-grade fever. |
| | | | | | | | Systemic: Confusion-Medium, Systemic: Flushed / Sweating-Mild, Systemic: Visual Changes/Disturbances-Medium, Additional Details: Pt recieved Pfizer vaccine. Pt sat in waiting area afterwards. Pt passed out and experienced sweating and vision impairment. Within 5-10 minutes pt able to respond in usual manner and vision clear again. Pt reports having similar incidents in the past with blood draw. |

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| 1174968 | 4/7/2021 | MA | 32 | F | 4/6/2021 | 4/6/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild |
| 1174957 | 4/7/2021 | MI | 16 | F | 4/6/2021 | 4/6/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Severe, Systemic: Shakiness-Medium, Systemic: Tachycardia-Mild |
| 1174287 | 4/7/2021 | CA | 28 | F | 4/6/2021 | 4/6/2021 | Client received Janssen COVID vaccine @ 2:11pm, reported not feeling well @ 2:23pm. Stated, "I can't get enough oxygen". Client placed in zero gravity chair, was noted to be shaky and diaphoretic. Oxygen saturation 100% on room air, pulse 47, BP 122/68. At 2:28pm, client states she's not dizzy anymore, able to drink water, vital signs stable. Client also reports she has fainted before with other vaccines and blood draws. 2:37 pm, client states she feels better. 2:56pm, client able to stand and leave observation area with steady gait and fiancé present. |

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| 1174035 | 4/7/2021 | FL | 67 | M | 1/26/2021 | 2/1/2021 | Lightheaded; almost fainted; dizzy; dizziness; Almost passed out; Very light headache; This is a spontaneous report from a contactable consumer (patient). A 67-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot Number: EL9263), via an unspecified route of administration in left arm (shoulder), on 26Jan2021 at 12:00, at a single dose, for COVID-19 immunization. The patient's medical history included blood pressure, acid reflux, and multivitamin. The patient's concomitant medications included amlodipine for blood pressure, esomeprazole for acid reflux, and ascorbic acid/ biotin/ boron/ calcium/ calcium pantothenate/ chloride/ chromium/ colecalciferol/ copper/ cyanocobalamin/ folic acid/ iodine/ lycopene/ magnesium/ manganese/ molybdenum/ nickel/ nicotinamide/ phosphorus/ phytomenadione/ potassium/ pyridoxine hydrochloride/ retinol acetate/ riboflavin/ selenium/ silicon dioxide/ sodium metavanadate/ thiamine mononitrate/ tocopheryl acetate/ xantofyl/ zinc (CENTRUM SILVER ADULTS 50+) as multivitamin, all were ongoing; omeprazole for acid reflux; and an unspecified multivitamin. The patient really had no issues going on prior to onset of these events. The patient has been administered both first and second doses of Pfizer-BioNTech COVID-19 vaccines. The patient had been having some strange things that he didn't know if its COVID-19 shot related but they're symptoms he never had before. About 8 to 11 days after first dose of the vaccine (Feb2021; maybe 09Feb2021 or 10Feb2021), the patient had a very, very lightheaded episode where he almost passed out or almost fainted. The patient clarified he thinks one event was like 8 days and the other was like 10 days after the vaccine doses were administered, but is not sure, so left it as about 8 to 11 days. Also, in Feb2021, the patient had almost a very light headache where he almost fainted. The patient went to the emergency room in Feb2021 and was admitted to hospital from about 13:00 that day, overnight and discharged about 17:00 to 18:00 the following day. The patient spent the night in hospital, they sent him the next day. While in hospital (Feb2021), the patient had electrocardiograms (EKGs) of his head (as reported), magnetic resonance imaging (MRIs) of his head, computed tomography (CTs; CT scan with contrast) of his head, and echocardiograms of his heart |

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(microcardiogram). All of those tests came back normal (okay), nothing abnormal on results. They were relating this to a stroke-like symptom; however, the results were normal, also his blood test results were fine. The patient had blood work done the first time he was in the emergency room when he was admitted to the hospital in Feb2021; they took his blood 3 to 4 times while he was there overnight and blood work results all came back normal. The patient was not sure what they were testing for, but thinks they were looking for stroke type things because the event almost made him pass out. They did not draw more blood the second emergency room visit. Because of the first episode, the patient then went to his family doctor and the doctor ordered some other testing done. The patient was scheduled to get a nuclear stress test and an exercise stress test (stress test of heart), his results on 10Mar2021 came back normal (not performed until after the second reported event following second dose of Pfizer-BioNTech COVID-19 Vaccine). The patient believed that the results of those tests both came back good, family doctor emailed him the results which were normal. The patient was continuing to have some lightheaded episodes or symptoms just about daily but nothing really; continued to have symptoms which was not normal for him. Sometimes, they last for 30 minutes or more, multiple times a day. Sometimes, the patient had a good day, but he had those lightheaded episodes and he never had it before he got the shot. As therapeutic measures in the hospital, the emergency room gave the patient something for dizziness when he was there, but he was no longer taking it. Currently, the patient was really taking nothing. The patient had also gone to the ear, nose, and throat (ENT) doctor where he had a balance test or a videonystagmography (VNG) test done on 17Mar2021. The patient will get results of balance test on Wednesday (24Mar2021). Every year (unspecified), the patient goes and get his yearly test in which they had his blood work done and this and his glucose levels were always good, cholesterol level was always good. All the patient's other tests come back as normal on an unspecified date. The patient had never had these symptoms before, he hasn't changed his medications or habits and it's odd that this happened 9 to 10 days after both doses of the vaccine. The patient would like to know if this has been reported before as a

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side effect related to the vaccine. The patient was not sure if the events are Pfizer-BioNTech COVID-19 Vaccine related, but they never happened to him before those doses were administered. He does not know if this is vaccine related or just coincidence that they popped up at the same time as the vaccine doses. Also, he does not know if events could be age related, the medical community can't figure it out so he is trying to get information on if events could be related to the vaccines. So the patient doesn't know if anybody else is reporting this but he had 2 sorts of severe episodes both of them around days after each shot and he was continuing to have lightheaded episodes but not severe as those 2 but he had lightheaded (dizzy) episodes daily, since the COVID-19 vaccine. But they didn't know what brought these episodes on, other than timing wise it was during the COVID-19 shot. And he never had anything like that, and he was not blaming it on the COVID-10 shot. That was the only thing changed in his lifestyle. There might be a possibility, because that's the only thing changed, his medication has not changed, and diet doesn't change. Nothing has changed other than the patient got COVID-19 shots. The patient wanted to report it, so the company had a report file and other people reporting it. The patient wanted to know if the company was having any other report or something like this so that he would know if it might be related to the shot. The patient had not recovered from "Lightheaded; almost fainted; dizzy; dizziness". The outcome of the other events was unknown.

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| 1173842 | 4/7/2021 | TX | 77 | M | 3/18/2021 | 3/18/2021 | Passed out approximately 6 hours after receive COVID-19 injection; This is a spontaneous report from a contactable consumer (patient). A 77-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 1 via an unspecified route of administration, administered in Arm Left on 18Mar2021 09:30 (lot number: ENU204) at the age of 77 years old, as single dose for covid-19 immunisation. The patient's medical history was not reported. The patient was not diagnosed with COVID-19 prior to vaccination. No known allergies. No other vaccines received four weeks prior to COVID vaccination. The patient took other unspecified medications two weeks prior to COVID vaccination. The patient passed out approximately 6 hours after receipt of COVID-19 injection on 18Mar2021 16:00. There was no warning, dizziness nor weakness of the knees, prior to passing out. The patient landed on his forehead (out less than a minute). There was no reoccurrence. His wife had shot same time, no effects. No treatment was received for the event. The patient has not been tested for COVID-19 post vaccination. The patient recovered from the event on an unspecified date. |

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| 1173813 | 4/7/2021 | NJ | 59 | M | 3/19/2021 | 3/19/2021 | passed out; i may have had a TIA; This is a spontaneous report from a contactable consumer (patient). A 59-year-old male patient received the first dose of bnt162b2 (BNT162B2, Lot number and expiry date were not reported), via an unspecified route of administration, administered in left arm on 19Mar2021 11:15 (at the age of 59-year-old) at single dose for COVID-19 immunization. Medical history included high blood pressure. The patient had no known allergies. Concomitant medication included losartan. No other vaccine in four weeks. No COVID prior vaccination. On 19Mar2021 11:15 AM, the patient immediately passed out and was taken by ambulance to hospital. They said that he may have had a TIA (even though the CT scan and MRI were clean). The patient will not get the 2nd vaccine because of his reaction. The adverse events resulted in Emergency room/department or urgent care, Hospitalization. He was hospitalized on 19Mar2021. The patient had nasal swab test on 19Mar2021 with negative result. The patient received treatment for the events. The outcome of the events was recovering. Information on the lot/batch number has been requested. |
| 1176939 | 4/7/2021 | IA | 51 | M | 4/6/2021 | 4/6/2021 | Patient became anxious and passed out. ambulance called and performed evaluation of patient at that time he informed EMT that this had happened with previous vaccine |
| 1175110 | 4/7/2021 | IL | 67 | F | 3/29/2021 | 3/29/2021 | Approximately three hours after receiving the vaccine I became nauseated. I had been sitting with my legs extended, as I attempted get up from the chair I experienced a severe cramp to my left anterior leg and my knee was locked. After several minutes I was able to stand and the cramp subsided and my knee was no longer locked. As I began walking I became extremely hot and sweaty and felt light headed. I then fainted. No injury, with my husband's help and the wall I eased to the floor. After approximately 30 seconds I was able to get up and walk an additional eight feet to my bed. I still felt nauseated, hot and sweaty for 10 minutes longer. This sequence of events lasted about 15 minutes. I then felt fatigued and slept for 45 minutes. When I woke up I felt fine. |

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| 1174986 | 4/7/2021 | OH | 58 | M | 4/4/2021 | 4/6/2021 | I woke at 6:30am on 04/07/2021 in a state of complete confusion and disorientation. It was a level of disorientation I have never experienced before in my lifetime. I fainted one time and was having extreme difficulty getting my bearings and walking and was simply in total "mental disarray". I was having difficulty producing words, a prolonged stutter, you might say. I was shaking. The local paramedics came and I was taken to the local ER. Because I was having difficulty speaking, the paramedics (and later the physicians) thought I might have had a TIA. An MRI on 04/07/2021 at 5pm produced a negative result. So i can only attribute my reaction to the vaccine. It was very significant, and i thought it made sense to report it. |
| 1175503 | 4/7/2021 | IL | 38 | M | 4/7/2021 | 4/7/2021 | Patient got very faint and passed out. Patient came to shortly after. 911 was called and they took patient to hospital. |
| 1175753 | 4/7/2021 | NY | 33 | M | 4/7/2021 | 4/7/2021 | PATIENT RECEIVED FIRST DOSE OF MODERNA COVID 19 VACCINATION. AFTER VACCINE PATIENT FELT DIZZY AND FELL ONTO THE FLOOR AND PASSED OUT. PATIENT THEN QUICKLY WOKE UP AND WAS CONFUSED AND DISORIENTED. PARAMEDICS WERE CALLED AND PATIENT WAS TRANSPORTED TO HOSPITAL FOR FURTHER EVALUATION. |
| 1175747 | 4/7/2021 | NY | 27 | M | 4/7/2021 | 4/7/2021 | Individual had witnessed syncope. Temporary Loss of Consciousness Was sitting in observation area and dropped books and cell phone on floor Noted to be cold and diaphoretic BP 102/64 Pulse 64/ min |

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| 1175727 | 4/7/2021 | NY | 25 | M | 4/7/2021 | 4/7/2021 | He was ok right after administering vaccination. 10 minutes later he stood up and said he was feeling hot and collapsed on the floor. Seemed like he was having difficulty in breathing. Called 911 and administered chest compressions. He was partially alert during chest compressions and after 2 minutes of administering chest compressions he gained full consciousness and requested me to stop chest compressions and requested an ice pack to place on his forehead and also requested some electrolyte drink and they were provided. He sat up on the floor after a few minutes. He also said this fainting happens to him all the time when he gets any shot (injection). He was responsive and sat on a chair until paramedics arrived. on arrival they asked his couple of questions and checked his blood pressure and monitored his heat for a few minutes. He left with paramedics about 30 minutes from the time of vaccination. |
| 1175723 | 4/7/2021 | PA | 46 | M | 4/7/2021 | 4/7/2021 | Patient had 2 syncope episodes |
| 1175720 | 4/7/2021 | FL | 21 | M | 4/6/2021 | 4/6/2021 | After receiving the vaccine while in the observation area patient's vision started getting blurry and he started feeling dizzy. (about 10 minutes after vaccine) He walked back to talk to us, while pharmacist was asking him questions he swayed and fainted. Pharmacist caught him and lowered him to the floor. Called 911 and paged MIC. Pharmacist stayed with the patient who gained back consciousness and placed him in recovery position until paramedics arrived. |
| 1175698 | 4/7/2021 | IN | 41 | M | 4/7/2021 | 4/7/2021 | PT PASSED OUT HAD LOW PULSE AND VASOVAGIL SYMPTOMS. WE CALLED 911 ELEVATED HIS LEGS AND GAVE HIM O2. PT REFUSED TO GO TO ER WITH THE AMBULANCE HAD A FAMILY MEMBER COME PICK HIM UP. |
| 1175671 | 4/7/2021 | IN | 30 | F | 4/1/2021 | 4/2/2021 | Started with nausea, then fever/sweating. Had help getting up to walk and then passed out. Followed with chills and a temperature of 93. Reaction was from about 2:00AM to 4:00AM |
| 1175618 | 4/7/2021 | PA | 20 | F | 4/6/2021 | 4/6/2021 | Syncope. |

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| 1175617 | 4/7/2021 | NY | 34 | M | 4/6/2021 | 4/6/2021 | At 1651, patient was in recovery area and sustained a period of syncope lasting roughly 10-15 seconds. Patient awoke slightly disoriented and diaphoretic. Symptoms resolved in 30 minutes |
| 1175171 | 4/7/2021 | CA | 46 | F | 3/9/2021 | 3/9/2021 | patient fainted as lost consciousness; patient fainted as lost consciousness; patient urinated in her pants; Felt dizzy after 12 hours; patient had problems with concentrating; massive headache; This is a spontaneous report from a contactable consumer (patient). A 46-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 1 via an unspecified route of administration, administered in Arm Left on 09Mar2021 09:30 (lot number: 1; pending clarification) at the age of 46 years old, as single dose for covid-19 immunization. Medical history included allergy to metals (titanium metal). Concomitant medications were none. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No other medications received within 2 weeks of vaccination. The patient was not pregnant at the time of vaccination. The patient was not diagnosed with COVID-19 prior to vaccination. On 09Mar2021 21:00, the patient experienced massive headache. After 12 hours (09Mar2021 21:30), the patient felt dizzy. On 10Mar2021, around 10 am, the patient fainted as lost consciousness, urinated in her pants and had problems with concentrating. No treatment was given for the adverse events. Since vaccination, the patient has not been tested for COVID-19. The patient was recovering from all the events. |

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| 1175510 | 4/7/2021 | NY | 16 | F | 4/7/2021 | 4/7/2021 | <p>Patient presented for her first COVID-19 vaccine. Approximately a minute after vaccine was given, she was noted to be seated upright in the passenger seat of her car, with head bent forward and eyes open. She was unresponsive, stiff posture, and was placed into a reclined position. She then had some posturing with head turned to the left, no eye deviation or nystagmus, no tonic-clonic movement. Radial pulse was thready, bradycardia was noted, with normal respirations. She was noted to become diaphoretic and pale/ashen color noted to the face and arms. She became responsive within a few minutes, however initially was not able to answer questions clearly. She had no loss of bowel or bladder function. EMS assisted with evaluation. Initial blood pressure 78/31, HR 54, SpO2 100%. EMS then transferred her to the stretcher and she was transitioned from her car to the ambulance. She continued to improve spontaneously with BP 94/61 then 103/60 and HR 86 then 74. SpO2 remained stable at 100%. Skin color improved. She had normal responses to questions, no complaints of headache, dizziness, chest tightness, shortness of breath, numbness or tingling. She had some shaking/voluntary movement of the limbs and body noted, but she could control and stop this voluntarily, no myoclonic or tonic-clonic jerking noted. After syncopal event occurred, mom reported that the patient has a history of syncope routinely with blood draws and vaccines in the past, however this episode was slightly more prolonged and seizure-like activity was different. She has had some jerking movement previously with syncope which lasts 20-30 seconds, different from today's response. No known history of seizure disorder.</p> |

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| 1175192 | 4/7/2021 | TX | 52 | F | 3/12/2021 | 3/12/2021 | fainting; dizzy; tachycardia; high blood pressure; then numbness to left side of face swelling then progressed to left arm left leg with excessive pressure to head; then numbness to left side of face swelling then progressed to left arm left leg with excessive pressure to head; then numbness to left side of face swelling then progressed to left arm left leg with excessive pressure to head; then numbness to left side of face swelling then progressed to left arm left leg with excessive pressure to head; then numbness to left side of face swelling then progressed to left arm left leg with excessive pressure to head; This is a spontaneous report received from a contactable nurse (patient). A 52-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscularly on 12Mar2021 at 09:30 (at the age of 52 years) at a single dose in the left arm for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient had no allergies to medications, food, or other products. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination. The patient was not pregnant at the time of vaccination. On 12Mar2021, the symptoms the patient had were fainting, feeling dizzy, tachycardia, high blood pressure, then numbness to left side of face swelling then progressed to left arm left leg with excessive pressure to head. The events resulted to doctor or other healthcare professional office/clinic visit and Emergency room/department or urgent care. The patient did not receive any treatment for the events (as reported). Since the vaccination, the patient has not been tested for COVID-19. The outcome of the events was recovered with sequel in Mar2021. Information on the lot/batch number has been requested.; Sender's Comments: A contributory role of BNT162B2 to event fainting cannot be excluded based on temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate. |

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| 1175500 | 4/7/2021 | VA | 58 | F | 4/2/2021 | 4/3/2021 | Legs and arms started shaking uncontrollably and I passed out or had a seizure for several minutes. I woke/came to and my husband helped me to bed. He said I was all sweaty. I slept for about an hour and got up. I fed my dogs, made tea, sat down and fell asleep. After waking I got up and continued my day with extreme fatigue, nausea, and a headache. |
| 1175495 | 4/7/2021 | PA | 31 | M | 4/6/2021 | 4/6/2021 | Syncope |
| 1175473 | 4/7/2021 | GA | 21 | M | 4/6/2021 | 4/6/2021 | The participant passed out and had seizure-like activity, then would arouse and be coherent. No history of seizures. Several brief episodes occurred. EMS called. B/P and pulse un-obtainable. EMS arrived and assessed participant. Taken to Medical Center E.D. |
| 1175367 | 4/7/2021 | TX | 18 | F | 4/6/2021 | 4/6/2021 | Pt passed out after getting vaccinated. Her BP and pulse were normal. Pt stated that she did not eat anything since morning breakfast around 9am. Paramedics were called to verify that Pt was doing ok. Gave pt both orange juice as well and some food (chicken nuggets). After 30 minutes pt was calm and stated that she was feeling well. Called pt on 4/7/21 at 9:05am to verify that she was doing all right. She stated that other than sore arm she was doing fine and did not go to the hospital. |
| 1175318 | 4/7/2021 | CT | 37 | M | 4/1/2021 | 4/1/2021 | Patient got light-headed, pale with clammy, cold skin and passed out. EMT's were called. |
| 1175301 | 4/7/2021 | NY | 20 | M | 4/2/2021 | 4/2/2021 | Passed out. Patient approached me and said she didn't feel well and might pass out. Patient took two steps with me and passed out. Assisted patient down to the ground. When patient regained consciousness, moved patient to wheelchair and brought her to recovery cot. Vitals remained stable. Assisted patient onto cot, obtained vitals and gave her two Hi C beverages. Patient had no oral intake today. Patient sat for 17 minutes and felt better. Patient sat in general recover for 10 minutes and then left. |
| 1175299 | 4/7/2021 | PA | 29 | F | 4/5/2021 | 4/7/2021 | Vasovagal syncope, painful/inflamed lymph nodes on right side of neck/clavicle |

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| 1175274 | 4/7/2021 | MN | 41 | F | 4/6/2021 | 4/6/2021 | Patient had checked "yes" to the question about fainting, light-headedness, dizziness from previous immunizations so healthcare worker was aware of the situation. Healthcare worker told her to remain seated in her chair and to wave if she felt any issues arise. Right after the immunization she was fine, able to walk to the chair directly outside of pharmacy for observation. Approximately 5 minutes into observation, she waved healthcare worker down, healthcare worker immediately went to talk to her about her symptoms, healthcare worker grabbed an ice pack, while breaking the ice pack, patient fainted while she was sitting in the chair, healthcare worker held her head up to ensure proper breathing and spoke to patient, she came back after about 30 seconds, which is when healthcare worker assisted the patient in moving to the ground and putting her feet up. Healthcare worker or a pharmacy technician remained with the patient until her husband arrived. It took her husband approximately 25 minutes to get to the pharmacy, during that time healthcare worker did ask the patient if she wanted medical attention and she declined, knowing the feeling would subside. It did take her approximately 30 minutes to feel comfortable enough to sit up. Her husband took her out in a wheel chair. |
| 1175777 | 4/7/2021 | IA | 38 | F | 3/19/2021 | 3/19/2021 | A couple hour after vaccine, I experience hyperglycemia. I passed out and was unresponsive, Ambulance service was called to provide service. They gave me dextrose. The estimate date is 09/2/2021 |
| 1175559 | 4/7/2021 | WI | 32 | F | 4/7/2021 | 4/7/2021 | Patient received vaccine and then fainted while still sitting in chair. Vaccinator caught patient and put her head between her legs. EMS was called, and patient work up before they arrived from next room. |

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| 1178095 | 4/7/2021 | OH | 64 | F | 4/2/2021 | 4/3/2021 | On 4/3/21 at 7 AM, I tried to get up to brush my teeth, but was unable to stand. I sat down in the chair in front of my sink and called for my husband. I was very hot and sweaty. When my husband got to me I had passed out, unresponsive and was very pale. After 5 minutes I was able to respond to him. He asked if I could sit up. I said no so he put me back in bed. After 2 hours of sleep, I was able to get up and dress. I rested the rest of the day but checked and found that I had a fever of 99.6F. The fever lasted the day and was gone the next morning. The next morning I was OK. |
| 1178275 | 4/7/2021 | FL | 69 | F | 3/2/2021 | 3/2/2021 | Mild syncope; Mild syncope; Low grade fever; Arm soreness 1st 24 hours; This is a spontaneous report received from a contactable consumer (patient). A 69-year-old female patient received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot: EN9581), via an unspecified route of administration in left arm on 02Mar2021 13:30 (at the age of 69-years-old) as single dose for covid-19 immunisation. The patient was not pregnant at the time of vaccination. The patient's first dose of bnt162b2 (lot not reported) (at the age of 68-years-old) in left arm on 01Feb2021 at 14:00 for Covid 19 immunization. The facility where the most recent COVID-19 vaccine was administered was reported as other. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient did not have other vaccines within 4 weeks prior to the COVID vaccine. Medical history included mild syncope episodes and pacemaker. The patient had no allergies to medications, food, or other products. Concomitant medications included alondranate, calcium, metropolol and an unspecified multi vitamin. The patient experienced arm soreness in the first 24 hours on 02Mar2021. Mild syncope and low grade fever 20 days after dose 2 (on 21Mar2021 at 13:00). The treatment received for the adverse events was paracetamol (TYLENOL). The outcome of all events was recovered on 03Mar2021 for pain in extremity and in Mar2021 for the rest of the events. |

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| 1178268 | 4/7/2021 | | | U | | | passed out; feel faint; This is a spontaneous report from a non-contactable pharmacist. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date as single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. The patient felt faint and passed out after receiving dose, pharmacist asking if need to re administer although received dose. The outcome of the events was unknown. No follow-up attempts are possible. Information on lot/batch cannot be obtained. No further information is expected. |

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| 1178237 | 4/7/2021 | | | F | 2/16/2021 | 2/17/2021 | <p>Don't have interest in eating or drinking; TMJ; Groggy; I can't balance; Face is pouring sweating; Maybe I'm dehydrated; Pain when my cheek hit the floor; Dislocated my finger; Head full fog; Vertigo; Bad joint pain; Fatigue; Faint; Neck spasms; Shaking; Jaw clenching; Spasms / Neck spasms; Chills; This spontaneous case was reported by a consumer and describes the occurrence of SYNCOPES (Faint) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No reported medical history). On 16-Feb-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 17-Feb-2021, the patient experienced TREMOR (Shaking), BRUXISM (Jaw clenching), MUSCLE SPASMS (Spasms / Neck spasms) and CHILLS (Chills). On an unknown date, the patient experienced SYNCOPES (Faint) (seriousness criterion medically significant), DECREASED APPETITE (Don't have interest in eating or drinking), TEMPOROMANDIBULAR JOINT SYNDROME (TMJ), SOMNOLENCE (Groggy), BALANCE DISORDER (I can't balance), HYPERHIDROSIS (Face is pouring sweating), DEHYDRATION (Maybe I'm dehydrated), FACIAL PAIN (Pain when my cheek hit the floor), JOINT DISLOCATION (Dislocated my finger), FEELING ABNORMAL (Head full fog), VERTIGO (Vertigo), ARTHRALGIA (Bad joint pain), FATIGUE (Fatigue) and MUSCLE SPASMS (Neck spasms). At the time of the report, SYNCOPES (Faint) had resolved and TREMOR (Shaking), BRUXISM (Jaw clenching), MUSCLE SPASMS (Spasms / Neck spasms), DECREASED APPETITE (Don't have interest in eating or drinking), TEMPOROMANDIBULAR JOINT SYNDROME (TMJ), SOMNOLENCE (Groggy), BALANCE DISORDER (I can't balance), HYPERHIDROSIS (Face is pouring sweating), DEHYDRATION (Maybe I'm dehydrated), FACIAL PAIN (Pain when my cheek hit the floor), JOINT DISLOCATION (Dislocated my finger), FEELING ABNORMAL (Head full fog), VERTIGO (Vertigo), ARTHRALGIA (Bad joint pain), FATIGUE (Fatigue), CHILLS (Chills) and MUSCLE SPASMS (Neck spasms) outcome was unknown. Treatment information</p> |

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| 1178229 | 4/7/2021 | MN | 32 | M | 4/7/2021 | 4/7/2021 | was not reported. This case was linked to MOD-2021-056711 (Patient Link). Reporter did not allow further contact; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the eventS, a causal relationship cannot be excluded |
| 1178219 | 4/7/2021 | CO | 67 | F | 4/2/2021 | 4/3/2021 | Vasovagal syncope - occurred about 3-5 minutes after administration. Patient slouched in chair, eyes rolled back slightly and patient was snoring. Patient was guided to the floor by pharmacist and significant other and regained consciousness after just a few moments. Patient was unaware of what happened. Patient was given water and remained lying on the floor for a few minutes and then was able to sit up and recover. |
| | | | | | | | At 1 AM on 4/3/21, I got up to take some Tylenol since I woke up feeling like I had a temperature. I walked to the kitchen (which isn't very far) and had an extreme feeling of overwhelming weakness and fainted. (only fainted one other time in my life). I hit my head and eye and now have bruising from my hairline and down my cheek on my right side. My eye and eye lid are black and blue. I had 101 temp and chills and body aches. Immediately starting vomiting and had diarrhea for 6 hours. Had a temp of 100 the whole day of 4/3/21. Then 99.5 on 4/4 and 4/5/21 and still tired and achy. By 4/6, I felt better. Although my symptoms were just a few days, I would have never taken the second Moderna shot, in hindsight. In fact, lots of people I know have had strong reactions to the second Moderna vaccine. I have to say I have never gotten so sick so fast in my life. No way to fight it - I felt took weak and vulnerable. |

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| 1178160 | 4/7/2021 | MS | | F | | 4/1/2021 | SYNCOPE ONCE VACCINE ADMINISTERED/FAINTED; FALLING OUT OF CHAIR; This spontaneous report received from a pharmacist concerned an adult female. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, and batch number: 043A21A expiry: unknown) dose was not reported, administered on 01-APR-2021 for prophylactic vaccination. No concomitant medications were reported. Patient was not pregnant at the time of reporting. On 01-APR-2021, the patient experienced syncope once vaccine administered/fainted and falling out of chair. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from syncope once vaccine administered/fainted, and falling out of chair on 01-APR-2021. This report was serious (Other Medically Important Condition).; Sender's Comments: V0- 20210404291-covid-19 vaccine ad26.cov2.s-Syncope once vaccine administered/Fainted. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s). |
| 1178153 | 4/7/2021 | CA | 21 | F | 4/3/2021 | 4/3/2021 | patient fainted for 30 sec the regained consciousness |
| 1178134 | 4/7/2021 | | 70 | F | 3/19/2021 | 3/20/2021 | I felt dizzy and lightheaded stepping out of the shower (March 20, 2021 at around 10:00 am) and I fainted and landed on the floor. When I came to, I was able to use the toilet to pull myself up and sit on the toilet seat until I got back in control of myself. I was lucky- I only had a few black and blue marks on my right knee, but it had potential to be serious- head injuries etc. I am 70 years old and this is the only time in my life that I have fainted. Very scary and has caused some emotional stress for me. |

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| 1177782 | 4/7/2021 | GA | 32 | M | 4/4/2021 | 4/7/2021 | The patient got up from the vaccine and sat in the chair. He felt faint and his mother put him on the floor. She immediately contacted the pharmacist and the pharmacist checked his pulse and talked to him. His mom wanted him to be seen at the hospital so 911 was called and the ambulance took him to the ER. He never passed out only felt like he was going to. He felt better at the time he was taken away in the ambulance. |
| 1178121 | 4/7/2021 | TN | 51 | M | 4/7/2021 | 4/7/2021 | Patient passed out and fell out of chair after receiving his second dose. He hit his head when he fell. We called 911 and he was transported to our local hospital. I spoke with his brother and he was released and doing ok. |
| 1178349 | 4/7/2021 | SC | 22 | M | 4/7/2021 | 4/7/2021 | Patient immediately felt light headed and notified immunizer. He then quickly fainted. Pharmacist and technician carefully lowered him from the chair to the floor and laid him on his back. Pharmacist quickly checked for a pulse and removed his mask. Patient came to within 10 seconds and pharmacist then elevated his legs using a chair. Patient remained laying on the floor for 10 minutes and then felt ready to sit up. After sitting up, patient was given a cold water to drink and a snack, and remained under pharmacist's supervision for 30 minutes. Patient then felt back to his normal self and felt confident he could safely leave the pharmacy. |

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| 1178089 | 4/7/2021 | | | U | | | HEART WAS BEATING OUT OF MY CHEST; HOT FACE; ALMOST PASSED OUT; FULL BODY PAIN; CHILLS; FEVER OF 102.6; This spontaneous report received from a patient via a company representative concerned a patient of unspecified age and sex. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unk) dose, start therapy date were not reported for prophylactic vaccination. No concomitant medications were reported. On an unspecified date, the subject experienced heart was beating out of my chest, hot face, almost passed out, full body pain, chills, and fever of 102.6. Laboratory data (dates unspecified) included: Body temperature (NR: not provided) 102.6 (units unspecified). Treatment medications (dates unspecified) included: paracetamol. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the fever of 102.6, hot face, almost passed out, chills, full body pain and heart was beating out of my chest was not reported. This report was non-serious. |
| 1178083 | 4/7/2021 | FL | 24 | F | 4/6/2021 | 4/6/2021 | Patient had just received covid vaccine. She was still seated in immunization room and said she felt dizzy and then passed out. She then started having a seizure a few seconds later. She seized for about 2 minutes. Patient was breathing but unconscious. |
| 1178066 | 4/7/2021 | IL | 23 | M | 4/7/2021 | 4/7/2021 | Patient received vaccine and moved to observation chair. Within about 5 minutes, patient proceeded to experience a syncope episode. Total episode lasted about 30 seconds, and patient spontaneously awoke. Upon awakening, patient requested water, and we also offered crackers and he accepted both. Patient waited in observatory for a total of 30 minutes. At time of departure, skin color was normal and patient was not experiencing weakness or confusion. |

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| 1178058 | 4/7/2021 | PA | 26 | F | 4/7/2021 | 4/7/2021 | A few minutes after being vaccinated patient was sitting for her 15 minute observation period and walked over to the pharmacy counter stating "I just got my vaccine and I really don't feel well" the pharmacist approached the patient and caught her under both arms from behind her back as the patient fainted. Patient did not hit the ground or injure herself-she did not lose consciousness she was flushed and sweating. Pharmacist sat on floor with patient for 2-3 minutes and gave her water, patient was then able to stand up with little assistance and brought to sit down. Patient stated she felt nauseous and may vomit she was given a trash can but did not vomit she was able to drink a bottle of water and was given a soft pretzel. After about 10 minutes she stated she was feeling much better was no longer flushed or sweating she called her boyfriend for a ride home. |

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| 1178045 | 4/7/2021 | MN | 24 | F | 4/7/2021 | 4/7/2021 | <p>Patient received her Janssen COVID vaccine and was sitting in a chair in the conference room when she slumped over in her chair and became unresponsive. Patient had just received her one dose Janssen vaccine and was sitting in a chair approximately 3-5 minutes after receiving the vaccine. She began to slump over in her chair and was unresponsive. Two RNs responded to assess the patient. Patients feet were elevated and ice packs applied to her neck and axillary areas. Patient was breathing and had a pulse. Patient responded to her name once and then passed out again. Patient was unable to respond after this. Her eyes were open. Patient was lifted into a wheelchair by three nurses and brought to a private area. Patient was warm and sweat was running down her face. Her sweater was removed and ice packs again were applied to her neck and axillary area. Patient continued to have a pulse and was breathing. EMS was called. Patient slowly began to come around and could answer questions after about 5 minutes of being unresponsive. She was confused and had no memory of what had occurred. She reported feeling light headed and seeing spots in her vision. She continued to feel light headed. EMS assessed patient. Vitals were stable and blood sugar was WDL. Patient reported feeling much better. She denied feeling light headed or dizzy any longer. She was able to answer all questions asked. Patient did not want to go to the hospital and refused transport to the hospital via ambulance. She was observed for an additional 20-30 minutes at which time her boss arrived to pick her up. She was educated on calling 911 if she began to feel light headed or dizzy again. Patient verbalized understanding. She was walked to the car by an RN.</p> |

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| 1178024 | 4/7/2021 | CT | 33 | F | 4/7/2021 | 4/7/2021 | Immediately following vaccination patient passed out in the chair. Woke up approximately 10-15 seconds later, skin very pale white, clammy. Patient stated she "did not feel right". When asked to describe her symptoms, the patient said she felt "tingly and dizzy". Pharmacist gave patient water bottle and a breakfast bar. Patient ate most of the breakfast bar and then said she felt like she was "going to throw up". Patient then vomited 3 times in the trash can. Immediately after vomiting, patient's color skin color returned to normal and she stated she "felt much better". BP checked and within normal range. Patient stayed at the pharmacy for 45 min for observation and drank a second water bottle. Refused medical care and refused to have someone pick her up from the pharmacy. Pharmacist followed up with patient via a phone call at 6:20pm. Patient said she was feeling much better and had no other adverse reactions. |
| 1177979 | 4/7/2021 | PA | 29 | M | 4/7/2021 | 4/7/2021 | Syncope |
| 1177796 | 4/7/2021 | ID | 19 | F | 4/7/2021 | 4/7/2021 | Patient fainted after receiving the vaccine. She was seated at the time and immediately the chair was reclined. She did NOT hit her head and regained consciousness within a minute. Felt nauseated and dizzy. She remained laying down for ~15 minutes until feeling better. She left later feeling fine. |
| 1177787 | 4/7/2021 | OK | 31 | F | 3/10/2021 | 3/11/2021 | Passed out approximately 11 hours after receiving vaccine. Hit head on tile floor. |

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| 1178133 | 4/7/2021 | IL | 23 | F | 3/20/2021 | 3/20/2021 | Approximately 15 minutes after receiving injection, patient was sitting in chair and suddenly fell to the floor. According to witnesses, patient hit head first. Patient was wearing a thick winter coat which was immediately removed. Patient was diaphoretic, pale, BP 140/100, P 80. Boyfriend and family member accompanied patient and reported hx of anxiety and fainting with blood draws, NKA, no medications. Patient remained alert, responded appropriately to name, date and even stated time she received vaccine. Only c/o jaw pain. Denied headache, nausea and diplopia. Negative for swelling or bleeding of head and face or hives. Breathing without difficulty. BP taken 10 minutes later 156/90, P90. Activated 911, report given to paramedics, patient was transported by gurney by ambulance, accompanied by boyfriend and family member. |
| 1178729 | 4/7/2021 | CO | 57 | F | 4/7/2021 | 4/7/2021 | Passed out, threw up myself while passed out went into convulsions. Ambulance/EMTs were called. |
| 1176941 | 4/7/2021 | MN | 28 | F | 4/7/2021 | 4/7/2021 | Patient felt dizzy right after vaccine administration and fainted and collapsed into vaccinating pharmacists arms. Patient immediately regained consciousness but still hot, dizzy, sweaty. 911 called immediately and paramedics arrived to assess vitals in the ambulance, patient walked out of the store to the ambulance with assistance. |
| 1175046 | 4/7/2021 | IL | 45 | M | 4/6/2021 | 4/6/2021 | Patient became light headed and sweating approximately 10 minutes after injection. No fainting or unconsciousness. Gave water and within 5 minutes symptoms subsided. Patient left the pharmacy 30 minutes after injection and was doing well. |
| 1178937 | 4/7/2021 | AR | 19 | F | 4/6/2021 | 4/6/2021 | I had an incredibly fast heart rate, even while laying down for a long time. I fainted after walking less than a half mile to get food |
| 1178896 | 4/7/2021 | CA | 63 | M | 4/6/2021 | 4/6/2021 | Fever, dizziness, vomiting, stomach aches, fainting, all body aches., fast heart beats, injection location soreness and pain. Cannot sleep at night. I thought to call 911. |

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| 1178893 | 4/7/2021 | NY | 65 | F | 3/11/2021 | 3/11/2021 | Woke up from sleeping in the middle of the night to go to the bathroom, fainted on floor. Woke up on bathroom floor. Not sure how long I was there. Couldn't get up was sweating, nauseas and had the chills. Crawled back to bed. Slept another 8-10 hours. Woke up at 2PM. Wanted to see if I had a concussion given I'd fallen on a tile floor. Was seen at Sollis Health they discovered I was likely dehydrated so they gave me an IV to hydrate and my platelets were very low (they're usually normal). Was tired, chills, nausea, weak and slept a ton until Sunday when I woke up feeling fine. Had platelets checked later that week and they were fine. After first shot got "covid arm" on day 10. Arm still hurts in the area, thought less than it did after the second dose. |
| 1178884 | 4/7/2021 | MI | 37 | F | 3/25/2021 | 3/26/2021 | Woke up at 2am and felt dizzy, passed out, when I came to I was dizzy every time I opened my eyes I was spinning counter clockwise for the next 6hrs. Now (2 weeks later) I get dizzy every time I move too fast and I have a constant ringing in my ears. |
| 1178871 | 4/7/2021 | CO | 27 | M | 4/7/2021 | 4/7/2021 | The patient passed out cold immediately after getting the injection. He fell forward out of the chair and landed prone on his face. He came conscious quickly after we rolled him on his side. The paramedics treated him for a laceration on his nose and forehead and he left the store on his own. |
| 1178866 | 4/7/2021 | CA | 63 | F | 4/2/2021 | 4/4/2021 | I had a horrible, lengthy Charley Horse cramp (on my right leg), followed by stomach pains, dizziness, diarrhea, fever, sweats, blurry vision, nausea, then I fainted/collapsed. When I came to, I was disoriented, had more diarrhea, chills, followed by my second Charley Horse cramp, this time on my left leg. When I woke after a few hours of sleep, I was tired, weak and had a slight headache but generally felt ok. By Tuesday, other than little/mild muscle aches, I'm back to normal. |

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| 1178783 | 4/7/2021 | CA | 36 | M | 4/7/2021 | 4/7/2021 | I had an intense fever within 5 minutes of the administration of the shot. I was sweating profusely, experience nausea and then fainted and had a mild seizure. After coming to consciousness, I vomited and the pharmacy staff called the paramedics. I was extremely pale and the fever persisted for several minutes while waiting for the paramedics. I recovered and felt mostly normal after being given saline solution and anti-nausea medication. Hours after being released from the hospital, I have waves of cold chills and hot flashes. |
| 1178291 | 4/7/2021 | AR | | F | 3/19/2021 | | fainted; lightheaded; fever; feeling weak/feels weak; Sunday felt bad; glands felt swollen; body aches; headache; This is a spontaneous report from a Pfizer-sponsored program. A contactable consumer reported that a female patient of an unspecified age received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot number was not reported), via an unspecified route of administration on 19Mar2021 as a single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient had her second dose of the COVID-19 vaccine on 19Mar2021 and stated that when she woke up Saturday morning, she took acetaminophen (TYLENOL), was experiencing being lightheaded and fainted, she needed help getting back into bed, slept all day had fever 101.0 to 102.0, feeling weak. On Sunday felt bad, that night fever was 99.0. On Monday, glands felt swollen, body aches and headache. And today feels weak, but no fever. The patient underwent lab tests and procedures which included body temperature: 101.0 to 102.0 and 99.0 on an unspecified date. Therapeutic measures were taken as a result of fever and headache. The outcome of the events was unknown. Information on the lot/batch number has been requested. |
| 1178754 | 4/7/2021 | CO | 30 | M | 4/7/2021 | 4/7/2021 | Patient became light headed and fainted for a few seconds about 8 minutes after receiving the vaccine. |

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| 1178328 | 4/7/2021 | OR | 17 | F | 4/7/2021 | 4/7/2021 | PER PT, FEELING DIZZY AND AS IF SHE WAS FAINTING - PT WAS RESPONSIVE TO QUESTIONS AND HAD NORMAL BREATHING. PT GIVEN 1 DOSE OF ADULT EPI (LOT OFM501, EXP 05/22). PER EMT (ARRIVED WITHIN 10 MIN OF CALL), PT HAD NORMAL FAINTING SYMPTOMS OF HYPOTENSION AND LOOKING PALE |
| 1178627 | 4/7/2021 | NY | 16 | M | 4/4/2021 | 4/4/2021 | About 5 minutes after shot he said arm is tingling then fell off chair and hit the floor. He passed out for a couple of minutes and then opened eyes and said my throat is closing up. The EMS gave Benadryl and used the Epi Pen. He was transported by ambulance to the hospital. |
| 1178619 | 4/7/2021 | WI | 31 | M | 4/7/2021 | 4/7/2021 | The patient fainted post vaccination. He did not come to immediately and EMS was called as a precaution and the patient was assessed and found to be fine. The patient states this is common for him. |
| 1178601 | 4/7/2021 | IL | 71 | F | 4/1/2021 | 4/2/2021 | Awakened about 3 am and was nauseous. Got up to go to bathroom and passed out. I live alone. Woke up on floor. Went back to bed and in the morning there was blood on my pillow from gashes in my head. Apparently pulled something in my chest as I fell. |
| 1178530 | 4/7/2021 | CA | 18 | F | 4/7/2021 | 4/7/2021 | 17 y/o female, 5 minutes post vaccination c/o lightheaded ness, pt. Fainted for <15secs, upon assessment pt is pale, cold, clammy. Paramedics V/S taken, HR 72, BP 107/75 (sitting), standing HR 92, BP 80/50, NS bolus was given and pt still c/o lightheaded ness, dizziness, nausea. Taken to Hospital for further evaluation. Taken by Paramedics. |
| 1178504 | 4/7/2021 | GA | 19 | F | 4/7/2021 | 4/7/2021 | Patient was standing in line and started to feel light-headed and fainted. Patient fell to the ground that caused a cut above her eye. Patient was still conscious and aware. Ambulance was called for assistance. Patient received stitches and taken by ambulance to hospital. |
| 1178474 | 4/7/2021 | | 64 | F | 3/9/2021 | 3/10/2021 | Fainted |

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| 1178448 | 4/7/2021 | MO | 77 | F | 4/7/2021 | 4/7/2021 | Patient fainted after the covid shot, she was feeling hot and fell off the chair onto the floor. She hit her left eye and left temple resulting in a bump and a bruise. Patient opened her eyes when I called her name and she was not aware of where she was. Her blood pressure was 95/64 65 bpm laying down and 70/54 114 bpm when sitting. We laid her back down because she was feeling dizzy and the Ambulance arrives 45 mins after called. Because of her bump and her low BP she was taken to the hospital. |
| 1178412 | 4/7/2021 | OR | 35 | F | 4/2/2021 | 4/2/2021 | The patient presented with significant true vasovagal syncope. After evaluation, aggressive hydration, positional maneuvers, and close monitoring, she returned to baseline and was discharged home with her husband as the driver. |
| 1178623 | 4/7/2021 | FL | 28 | F | 4/6/2021 | 4/6/2021 | Fainted 5 minutes or so after receiving vaccine for unknown amount of time. Seizure-like head bobbing and hand numbness. |
| 1178759 | 4/7/2021 | CO | 50 | F | 4/5/2021 | 4/5/2021 | Was waiting in the after injection parking lot for about 10 minutes, felt fine, and then it was like a fainting switch had been flipped without much warning. Was able to roll down my window and honk horn for emt in parking lot before fainting. Woke up to emt checking blood pressure, pulse and putting oxygen mask on. Then had to throw up, continue oxygen, sat and waited about 45 minutes until I felt like I could safely drive home. Had mild flu like symptoms starting about 3 hours later, became more moderate symptoms about 8 hours after injection - headache, fatigue, fever, body aches, nausea. Slept all next day, only remained. Still feel fatigue on Wednesday |
| 1177132 | 4/7/2021 | CA | 77 | F | 4/7/2021 | 4/7/2021 | Nurse reported after vaccination patient ?passed out? Patient appeared diaphoretic, pale, lethargic Patient was able to answer questions Patient seen by medical team, The blood pressure and heart rate low, patient provided with IV fluids, patient advised and agreed to go to hospital Patient was transferred to hospital via ambulance |
| 1177368 | 4/7/2021 | | 32 | F | 4/7/2021 | 4/7/2021 | Syncopal, did not fall, disoriented, at shot table, got shot then passed out. Original BP 63/34, P 49 BP 96/53, P 65, nausea |

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| 1177348 | 4/7/2021 | CO | 22 | M | 4/7/2021 | 4/7/2021 | Patient fainted about 2 minutes after vaccine and had a seizure after falling |
| 1177331 | 4/7/2021 | TN | 24 | M | 4/5/2021 | 4/6/2021 | Headache, body aches, chills starting about 12 hours after injection and lasting until about 48 hours later; fainted in the bathroom about 20 hours after the injection |
| 1177313 | 4/7/2021 | FL | 18 | M | 4/7/2021 | 4/7/2021 | 15:40 Patient stood up and walked to escort to be checked into Observation. Turned around and returned to nurse, stating " I don't feel good" and fainted. Patient assisted to chair then floor. Diaphoretic. EMS and NP immediately on site. Smelling salts waved under his nose and he abruptly woke up. He stated he has a fear of needles . Family member here with patient. 15:50 - BP 98/35; HR 53. Sats 98% on RA. Conversant with EMT's and nursing staff 15:52- drinking water, eating breakfast bar. States he feels better 15:55 BP 117/72; HR 78- R 20. Ready for discharge home @ 1605. |
| 1177298 | 4/7/2021 | NY | 87 | F | 3/29/2021 | 3/29/2021 | 8 hours after receiving vaccine , patient had c/o chills, rigors, vertigo, lightheadedness, no syncope , Patient was seen in office 4/6/2021with unstable gait, change in speech pattern , c/o feeling unstable when standing |
| 1177283 | 4/7/2021 | IL | 25 | M | 4/6/2021 | 4/6/2021 | Pt fainted and became very diaphoretic but came to a minute later alert and orientated. |
| 1177215 | 4/7/2021 | MN | 22 | F | 4/3/2021 | 4/4/2021 | Woke up after a restless sleep not feeling well. Walked into parents room and fainted. Lost conciseness for approximately20 seconds and fell-hit head on wall on way to floor. Woke almost immediately after hitting floor. Did not remember it happening. Fell back to sleep after taking ibuprofen. Did not feel well the rest of 4/4/21. Did feel better 4/5/21. |
| 1177201 | 4/7/2021 | SC | 23 | F | 4/7/2021 | 4/7/2021 | The patient passed out for a few seconds about 5 minutes after the vaccine administration. She was very clammy, sweaty, and alert but very groggy when the pharmacists went out to her. She also stated that her throat felt swollen and sore and that she felt like she was going to throw up. We called the EMS, and she left in the ambulance about 25 minutes after being vaccinated. We don't have any further update at this time. |

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| 1177200 | 4/7/2021 | WV | 21 | M | 4/7/2021 | 4/7/2021 | Patient experienced a full syncope event after receiving his first Pfizer COVID vaccine. Pharmacy contacted EMS and patient was monitored for 30 minutes and left on his own accord (with a parent) |
| 1177397 | 4/7/2021 | | 46 | F | 4/6/2021 | 4/6/2021 | Fever -immediately and still more than 24 hours later despite taking fever reducer. Temperature going up. Almost passed out due to rising body temperature and they kept me 30 minutes. |
| 1177175 | 4/7/2021 | | 39 | M | 4/7/2021 | 4/7/2021 | lightheadedness, fainted, vs stable, transfer pt to ED for fall follow up |
| 1177141 | 4/7/2021 | RI | 64 | M | 3/18/2021 | 3/23/2021 | Dizziness, lightheadedness and a feeling of syncope. |
| 1177096 | 4/7/2021 | OK | 35 | M | 4/7/2021 | 4/7/2021 | Patient fainted about 10 minutes after receiving first dose of Moderna. Patient fell from chair with no warning. He regained consciousness within a few minutes. The paramedics came and checked patient out. He left about 30 minutes later after reporting he felt better. |
| 1177087 | 4/7/2021 | FL | 32 | M | 4/6/2021 | 4/6/2021 | Patient felt numb on hands, sweating, and fainting after receiving the covid vaccine from the pharmacy. Patient was full alert and responded to all the requests. We did call and EMS arrived. They did check patient health and everything was normal. Patient did not want to go to the hospital and felt better after drinking a bottle of orange juice. EMS crew left the pharmacy after 10 minutes. Patient sit down on a chair and drank another bottle of water. He felt very well and wanted to left the pharmacy. |
| 1177056 | 4/7/2021 | TN | 31 | M | 4/6/2021 | 4/6/2021 | Fainting, vagal reaction |

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| 1177045 | 4/7/2021 | | 17 | F | 4/6/2021 | 4/6/2021 | Patient experienced an episode of syncope almost immediately after her first dose of Pfizer covid vaccine. She was unresponsive for approximately 20-30 seconds. Her vaccinator held the patient steady until help was available. When the patient came to, her pupils were not of equal size, left being larger than right. Cap refill was about 5 seconds. She felt hazy/dizzy and was clammy. First pulse readings were 39-45 bpm. Vitals recorded 1545 BP 73/40, P 48, O sat 99 1558 BP 91/55, P 58, O sat 96 1607 BP 106/62, P 68, O sat 98 BP 111/70, P 57, O sat 100 At the time of dismissal, patient reported that she felt fully recovered. She was accompanied by her father who was her mode of transportation. It was recommended that she be scheduled for an appointment with her PCP for baseline/well visit as she had not been in some time. |

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| 1177031 | 4/7/2021 | TX | 32 | M | 4/7/2021 | 4/7/2021 | Approx. 11:40 or 11:45 Client passed out while seated in the back of the observation area Client fell to the side but landed face forward and sustained a laceration to the forehead near the hairline on the right side RN called 911 to dispatch EMS around 11:45 After the client passed out a fireman/EMT, physician and nurse were present to arouse the client and assess for further neck or brain injuries RN tended to the bleeding laceration Client gained consciousness and became alert Client able to answer questions Vaccine Administrator stated that the client mentioned that he was having chest pain but Client denied this and stated that he just felt nervous Client states that he passes out when giving blood and has a needle phobia Nurses and Fireman/EMT assisted client to a wheelchair and back to a private recovery area 11:52 Vitals obtained : O Sat 98, Pulse 56 BP 129/75 Client reports nausea, a flushed sensation, headache and dizziness No Vomiting noted Fireman/EMT took Blood sugar reading with Glucometer. Blood sugar reading is 83 Client reports feeling drowsy but he states that he did not sleep as much as he normally does last night Fireman/EMT reports Full range of motion to the neck and client reports no neck pain Ambulance arrives at 12:08 Client previous history was relayed to the paramedics : Vital assessed BP 127/80 and pulsometer in use Paramedic noted that client must have been wearing his sunglasses when he passed out because blood was present on the glasses and the laceration lined up with the sunglasses perfectly Client discussed what hospital he wanted to be transported to Client does not have a family physician Ambulance left within 10 to 15 minutes after arrival |
| 1177773 | 4/7/2021 | | 61 | F | 4/7/2021 | 4/7/2021 | patient complains that she feels dizzy. no chest pain or sob. no nausea or vomiting. no sensation of fainting. |
| 1176946 | 4/7/2021 | WI | 37 | M | 4/5/2021 | 4/5/2021 | Patient received the first dose and then felt light headed shortly after while watching his girl friend receive the shot. We had him sit down and then he passed out. A few moments later the eyes rolled to the back of his head, and then began shaking for 10 to 20 seconds, after which he immediately woke up and was aware he passed out. EMT services were called while this was happening. |

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| 1178665 | 4/7/2021 | WA | 28 | M | 4/7/2021 | 4/7/2021 | Syncope, Dizziness, diaphoretic, BP 98/56, P 58 |
| 1177010 | 4/7/2021 | OH | 23 | M | 4/7/2021 | 4/7/2021 | Patient became dizzy, passed out briefly, came to with blank appearance, diaphoretic, gray color. |
| 1177181 | 4/7/2021 | AL | 53 | F | 4/7/2021 | 4/7/2021 | Approximately 5 minutes after injection, patient started feeling faint. Pallor skin color, skin was moist. Patient then proceeded to faint, followed by a 15 second seizure. Once patient became alert, a second fainting spell occurred. |
| 1177684 | 4/7/2021 | MO | 48 | F | 4/7/2021 | 4/7/2021 | Patient fainted within five minutes of receiving the shot, she recovered about 15 minutes later. |
| 1177772 | 4/7/2021 | FL | 23 | M | 4/7/2021 | 4/7/2021 | Patient informed the pharmacist that he had needle phobia. He was doing fine during the immunization but fainted 2 minutes after. his face turn red and feel heated. He was moved to the floor for better support with his feet elevated. Pharmacist accessed his breathing and applied cold compresses to the neck. offered cold water to drink. Patient rested in the room for about 15 minutes and returned normal and left pharmacy. |
| 1177763 | 4/7/2021 | TN | 43 | F | 4/1/2021 | 4/7/2021 | At 4 am I passed out and banged my head. Dizziness might have caused this. I got the vaccine the prior day at 11 am. |
| 1177751 | 4/7/2021 | OH | 56 | F | 4/7/2021 | 4/7/2021 | Patient had a syncope episode, felt tingly, dizzy, and clammy to the touch. Patient's blood pressure dropped to 98/62. Patient legs were elevated and a cold compress was used |
| 1177749 | 4/7/2021 | WA | 46 | F | 4/3/2021 | 4/4/2021 | Symptoms of medical shock about 16 hours after vaccine dose--cold sweat and ashen complexion, dizziness, fainted, intense nausea. All symptoms except nausea and thirst subsided with bed rest and electrolyte fluids. |
| 1177122 | 4/7/2021 | IN | 17 | F | 4/7/2021 | 4/7/2021 | Patient passed out. tingling in finger. light headedness. chest pain related to anxiety. occurred after about 15 minutes |

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| 1177406 | 4/7/2021 | FL | 18 | M | 4/7/2021 | 4/7/2021 | Per the NP: 1:20pm: While in observation, patient had an episode of syncope/ hypotension. It was unclear at the time if this was a reaction to the vaccination or not. Was treated immediately by NP and EMT/Paramedic staff. 911 was called and pt was transferred to the ER via monitored stretcher for further evaluation. Prior to leaving, and as pt was being transferred from one stretcher to the transport stretcher, pt experienced another syncopal episode. No arrhythmia noted on monitor, BP running 70's/50's. Awake, sluggish but oriented to person and place upon leaving. Transported via monitored stretcher to the ER. |
| 1177729 | 4/7/2021 | MI | 74 | F | 3/27/2021 | 3/28/2021 | The morning after my 2nd shot, I got up to use the restroom. I took an item out of the bathroom vanity under the sink and then without feeling dizzy and not knowing that it was going to happen, I passed out and landed on the bathroom floor. I've never had this happen to me before and so I am questioning if it could be because of the covid shot that I had less than 23 hours earlier. I ended up with 10 staples in my head with the 2 1/2 inch injury on the back of my head. Thankfully I didn't break any bones nor have any other adverse problems. The emergency room did several tests, and they couldn't find any reason for it to happen. |
| 1177703 | 4/7/2021 | CT | 24 | F | 4/7/2021 | 4/7/2021 | The patient received the vaccine and was waiting her 15 minutes to make sure she didn't have any reactions. Approximately 8 minutes after the vaccine was administered and the patient passed out. She did not report that she was not feeling well until after she came to. She then reported dizziness and nausea. She laid on the floor in the recovery position on the floor for about 30 minutes before feeling ok enough to sit in the chair and eventually be able to walk out of the store. |
| 1177668 | 4/7/2021 | | 46 | F | 4/7/2021 | 4/7/2021 | Vasovagal syncope resulting in fall to floor. While on ground pt became rigid. Pt began to come to and was transported to medical via cot and EMS was notified. Pt symptoms resolved and EMS was refused. |

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| 1177646 | 4/7/2021 | TN | 33 | F | 4/6/2021 | 4/6/2021 | Patient reported a low grade fever starting at around 2000 hours on 4/6/2021. Her fever reached 103 F and the patient reports that she believes that she passed out. She says that she has not taken anything for her fever except for using a cold compress. She reported that she was still running a fever at 0900 when I talked to her. The patient also reported an headache and diarrhea. She reported feeling dehydrated and said that she has been drinking Gatorade. I encouraged the patient to drink Pedialyte or uncolored Gatorade. I informed the patient that she needed to take Ibuprofen (or other NSAID) or Tylenol for her fever. I also encouraged her to seek medical help if for no other reason then to receive IV fluids. |
| 1177630 | 4/7/2021 | | 32 | M | 4/7/2021 | 4/7/2021 | Syncope post vaccine. Patient taken too medic tent. No chest poison, no SOB, no weakness of extremities. No facial droop. No bowel and bladder incontinence. No confusion the following syncope. Syncopal event lasted for a brief 2 to 3 seconds. |
| 1177554 | 4/7/2021 | | 16 | F | 4/7/2021 | 4/7/2021 | POST VACCINATION SYNCOPES. DID NOT FALL, LOWERED TO GROUND. QUICKLY ALERT AND ORIENTED, ASSISTED TO WHEELCHAIR. WHILE WAITING FOR COT HAD ADDITIONAL SYNCOPAL EPISODE, NAUSEATED. MONITORED FOR 25 MINUTES AND SYMPTOMS RESOLVED. |
| 1177416 | 4/7/2021 | | 19 | M | 4/2/2021 | 4/2/2021 | vasovagal reaction with syncopes including multiple episodes of transient loss of consciousness and tonic-clonic seizure motions |
| 1177621 | 4/7/2021 | NY | 38 | F | 4/7/2021 | 4/7/2021 | Ten minutes after vaccination patient experience lightheadedness, diaphoresis, and brief syncopes at the pharmacy counter. Pharmacist assisted patient to a chair. Patient was responsive but sweating profusely, experiencing tremors, and appeared lethargic. No signs of anaphylaxis, however upon checking patients vitals - heart rate and blood pressure were below normal for patient. Paramedics arrived and monitored vitals for about 20 minutes. Patients condition appeared to improve and walked out of the pharmacy with the paramedic personnel. Patient was not taken to the hospital. |

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| 1177489 | 4/7/2021 | | 30 | M | 4/7/2021 | 4/7/2021 | post vaccination syncope. assisted to wheelchair and observed, immediately felt better |
| 1177509 | 4/7/2021 | CA | 35 | M | 4/6/2021 | 4/6/2021 | Dizziness, Facial swelling, syncope, altered consciousness, fatigue, pain at injection site |
| 1177608 | 4/7/2021 | UT | 19 | M | 4/7/2021 | 4/7/2021 | Pfizer shot given. Patient felt ok immediately after shot, but approximately 5 minutes later told his mom he felt weird. He passed out and was helped to a sitting position. When I was called out to the lobby patient was still feeling a little lightheaded but he was conscious and breathing normally. He sustained a small cut on his hand which we cleaned up promptly. Patient told mom he felt like his vision was blurry. Mom wanted him checked out so I called emergency help. |
| 1177524 | 4/7/2021 | TX | 34 | M | 4/7/2021 | 4/7/2021 | PATIENT COMPLAINED OF LIGHT HEADEDNESS AND THEN PASSED OUT TURNED COMPLETELY PAL ONCE AWAKEN STARTED HYPER VENTELATING AND URINATED ON SEL. AFTER BEING ASSESED BY EMS AND MP HE WAS STILL FEELING DROWSY |
| 1177600 | 4/7/2021 | CO | 26 | F | 4/7/2021 | 4/7/2021 | Patient fainted in her chair approximately 3-5min after I administered vaccines, patient feel the need to vomit but did not actually vomit, patient was really pale and lightheaded. EMS was called and arrived in approximately another 5 min. Gave patient water and cold rags for neck. |
| 1177628 | 4/7/2021 | CO | 74 | F | 4/6/2021 | 4/7/2021 | Patient received the COVID-19 Moderna vaccine on 4/6/21 at 2:18pm. The following day on 4/7/21 at about 2:15pm, the patient was shopping in the store and fainted at self checkout. An associate caught her before she hit the ground and lowered her down gently. Store management alerted the pharmacy and I, the pharmacy manager, went to assist the patient. She said she felt fine yesterday after receiving the vaccine but did not feel well this morning. An ambulance was called and EMS arrived at the scene. One of them reported that her pulse was low but did not report a specific number. EMS took her to a local hospital. I spoke to her husband and let him know that I would call to follow up with them tomorrow. |

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| 1177538 | 4/7/2021 | VT | 51 | F | 4/3/2021 | 4/3/2021 | I fainted while on the toilet. Woke up on the bathroom floor with a smashed, bleeding nose. I also bit my tongue, split my lip and banged up my knee and hand. As a result I now have two black eyes. |
| 1177704 | 4/7/2021 | KY | 29 | M | 4/7/2021 | 4/7/2021 | PT came in to get his first Moderna Covid shot. After patient was done, patient walked out and sat in the waiting room chair. 7 minutes into sitting down patient passed out and fell out of the chair and hit the floor. When the pharmacist came out to the patient, to assure their safety, moments after getting his safety assured. Pt informed the staff that he had not eaten anything in 12 hours before getting the shot. Pt was given Orange juice, to get his sugar back up. The Pharmacist check his blood pressure and it was 117/78. Pulse was 53 so it was low as expected post- syncope episode. Pt waited for his mother before leaving allowing him to be safe afterwards. |
| 1171846 | 4/6/2021 | | 28 | M | 4/6/2021 | 4/6/2021 | Syncope with low BP and low HR (46). |
| 1171827 | 4/6/2021 | ND | 27 | M | 4/6/2021 | 4/6/2021 | 11:55am received vaccine. 12:00pm fainted in general observation area. Fell out of chair and was laying on stomach. Bumped right side of head. Unconscious for short period - approx 30 seconds. Assisted him to a sitting position. 12:02 pm B/P 110/68. Pulse 82 O2 sat 97%. Sat on floor for a couple minutes then transitioned him to a wheelchair and brought to the medical observation area, where he rested on cot. 12:07 pm B/P 112/68. Pulse 92. O2 sat 96%. Has red area on right side of head - no bump noted. Denies s/sx of concussion. 12:16 pm Pulse 84. O2 sat 95%. Iced head for 15 minutes. 12:25 pm B/P 118/70. Pulse 82. O2 sat 95%. Sat up for 15 minutes. Drank water. Denies s/sx of concussion. Did recommend he go to urgent care to have head assessed. Feels better - left at 12:35pm. |
| 1171789 | 4/6/2021 | CA | 68 | F | 2/10/2021 | 3/10/2021 | Patient developed cold like symptoms on 3/10- nasal congestion, cough that progressed to left lung ache/pressure, cough worsened, chest congestion, sore throat. On day 3/17 and 3/18 patient became SOB, malaise, chills/sweats, achy, tired, nausea, emesis, anorexia, "heart tightness" with ambulation, presyncope. Right leg started to feel tight and painful behind the knee, tachycardia. |

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| 1171776 | 4/6/2021 | NY | 16 | F | 4/6/2021 | 4/6/2021 | Patient is a 16yo seen for her first dose of the COVID-19 vaccine. She was seated in the back seat of the car. Shortly after receiving her vaccine (within a few minutes), she chose to move to the front passenger seat of the car, and after sitting in the passenger seat she became lightheaded and lost consciousness. Syncopal event was witnessed and lasted a few seconds. She spontaneously regained consciousness, and complained of some lightheadedness and tunnel vision. No significant confusion was noted, her responses to questions were appropriate. Initial pulse was thready and heart rate initially difficult to auscultate. Pale color noted on the face. Initial pulse approximately 50bpm. Breath sounds clear with good air exchange. Patient was placed in a reclined position with feet on the dash. She quickly recovered and repeat heart rate was auscultated at approximately 70bpm, stronger pulse noted. She was noted to have improvement and she was then driven out of the vaccine site after obtaining consent from her mother (who was the driver) and parked beside EMS. BP was 100/50 and HR 68-72, SaO2 97%. Lightheadedness resolved and she was feeling well, at her baseline. She was monitored for 30 min then allowed to leave with her mother, she was at her baseline at last evaluation. Per history review with her mother, she has had 2 prior episodes of syncope with pin removal from hand after surgery and IV placement. |
| 1171766 | 4/6/2021 | NY | 30 | F | 4/6/2021 | 4/6/2021 | Patient said she walked two miles and didn't eat breakfast before the vaccine and doesn't do well with needles. Patient has had fainting spells in the past from vaccines. She reports feeling much better is eating, drinking and taking it easy today. If she experiences other symptoms she will contact her PCP. |
| 1171754 | 4/6/2021 | | 47 | M | 4/6/2021 | 4/6/2021 | arm pain, dizziness, passed out x2. Evaluated by EMS-Refusal to transport. |
| 1171722 | 4/6/2021 | | 31 | F | 4/5/2021 | 4/6/2021 | Syncope. She always has syncope with needle sticks since youth. |

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| 1171628 | 4/6/2021 | MN | 39 | M | 4/6/2021 | 4/6/2021 | Patient passed out about 1 second after administration of vaccine. Patient stayed in unconscious state for 10-15 seconds and was administered an epi-pen 0.3 mg and 911 was called immediately. Patient woke up immediately and stated they were feeling groggy and warm. patient was given a cold towel to place on their head to help cool down. Patient was then picked up by emergency services on a stretcher and went to local ER for observation. |
| 1171875 | 4/6/2021 | NY | 39 | M | 4/6/2021 | 4/6/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: pt complained of feeling as if passing out and when approached, he wanted us to call 911 and layed on floor to prevent from getting worse. he claimed laying down made him feel better. Pt was responsive and was breathing normal however, was getting pale. Upon the arrival of Medics, pt was back to normal and all his vitals (blood pressure, EKG, Oxygen level) were normal. Pt refused to go to the hospital and after waiting another 15 minutes he was picked up by his family member. |
| 1172371 | 4/6/2021 | CO | 18 | F | 4/6/2021 | 4/6/2021 | Syncope about 5 minutes after shot. Fell out of chair, immediately awake. Sweating, no trouble breathing. Paramedics checked her out, said she was ok. Mom picked her up. |
| 1171521 | 4/6/2021 | CT | 23 | M | 4/3/2021 | 4/3/2021 | patient stated that he had fainted once during an immunization , but has had others in past and has been fine, I told him to stay for the 15 min post immunization event and monitored him. about 10 mins later he said he was seeing black spots and asked if he could lie down, I said that was fine, 911 was called and an EMT took over, patient never actually passed out, it seemed that he was dizzy . followed up with patient later that day, he stated he was feeling fine. |
| 1171582 | 4/6/2021 | SC | 26 | F | 4/6/2021 | 4/6/2021 | Fainted and fell out of chair |
| 1171554 | 4/6/2021 | | | U | | | 32 yo male with history of allergic asthma, had a syncopal event. shortly after being vaccinated. Felt lightheaded, a little nauseated. Has had similar reactions in the past with blood draws. Did not eat breakfast. Vitals wnl. Likely vasovagal syncope. Lasted about 5 mins. Pt given juice crackers, after 30 minutes of observation in medical tent, was sent home once symptoms resolved. |

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| 1171523 | 4/6/2021 | CA | 31 | F | 4/6/2021 | 4/6/2021 | Pt fainted after 10 minutes of administration. But by the time I walked out in the waiting area, pt came back and sat up again. |
| 1171763 | 4/6/2021 | WI | 29 | M | 4/1/2021 | 4/1/2021 | Patient was given the vaccine and advised to wait 15 minutes in the pharmacy area. About 13 minutes into that time he fainted onto the chair next to him. help patient onto the floor and pharmacy staff assisted afterwards. called EMT and they came out to asses the patient. Patient was given OJ and some food and advised to remain in the pharmacy area an additional 15 minutes and to have another person drive him home. |
| 1172404 | 4/6/2021 | MI | 40 | F | 3/24/2021 | 3/27/2021 | I received the injection on Wednesday, by Saturday I was feeling very sick. I had a fever of around 102.5 on average and was feeling very weak. By Monday I was so weak I had to go to the doctor. In the dr. office I had a syncope event with tongue out, convulsions. Dr called 911 and was transported to the hospital via ambulance. The dr at the ER tested for Covid (negative) and stated this was a moderate adverse reaction to the vaccine. It took me a full 8 days to be able to not sleep all day and get some strength back. |
| 1172537 | 4/6/2021 | IN | 23 | M | 4/6/2021 | 4/6/2021 | syncope |
| 1172530 | 4/6/2021 | PA | 38 | F | 3/29/2021 | 4/1/2021 | Two episodes of sudden dizziness, blurred vision, collapsing, unable to stand first on 4/1 and second on 4/2. No history of dizziness or fainting. Not dehydrated at the time. Duration of event was approximately 30-60 seconds with trouble speaking thereafter for 10 minutes. Resumed normal activities thereafter. Made a doctor's appointment. |
| 1170831 | 4/6/2021 | FL | 32 | M | 4/5/2021 | 4/5/2021 | Systemic: Confusion-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Seizure-Severe, Additional Details: Pt was advised to set down in the waiting area for 15 minutes to be monitored, once in a sitting position patient started convulsing into a grand mal seizure, I immedietly ran to him, started restraining him and holding his head to prevent him from hitting the wall, patient was laid flat and restrained by family members and the nurse practitioner, seizure lasted for les than a minute, and patient started to regain consiousness. called 911 |

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| 1171468 | 4/6/2021 | MS | 28 | M | 4/2/2021 | 4/2/2021 | RNs x 2 responded to pt's vehicle c/o nausea, left arm tingling. RN reported pt was visibly "panicked " and self-reports he "passed out twice:" after seeing blood after getting vaccine. RN reported pt had small of blood on bandaid. Reports history of anxiety, especially r/l blood needles |
| 1172426 | 4/6/2021 | FL | 32 | F | 4/6/2021 | 4/6/2021 | Patient is a 32 year old female who presented to community Center for her first dose of the Pfizer vaccine. She admits to a history of newly diagnosed Hypertension. She currently states she takes a combination of 2 high blood pressure medications, but she is unsure of the names of her meds. She denies taking her blood pressure medications today and said she normally takes them in the evening. Patient received her first dose of Pfizer in her left arm. During observation she asked for her BP to be assessed due to c/o a pounding headache. VS were taken and the first reading was 179/120 HR 109, followed by a second BP reading of 200/120, HR 106, then final HR was 84. It was explained to the patient that she is currently in a hypertensive crisis and should be taken to ER STAT for further treatment. Patient agreed with medical advice and paramedics was called and she was taken to the ER. Patient denies diplopia, dizziness, N/V, weakness, syncope or any symptoms of COVID-19. Patient notified observation staff at 1403 hours and EMS & patient out time 1425 hours. |
| 1172326 | 4/6/2021 | UT | 23 | M | 4/6/2021 | 4/6/2021 | Patient passed out shortly after receiving the vaccine. He lost consciousness for a minute and seemed to be twitching in his eyes and his mouth. He regained consciousness after a few minutes and we monitored him for 30+ minutes. We referred him to urgent care to be monitored further. |
| 1172411 | 4/6/2021 | KS | 26 | M | 4/6/2021 | 4/6/2021 | Patient experience syncope approx 10 minutes following vaccine. Episode was lasted less than five seconds and patient was coherent nearly immediately after losing consciousness. |

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| 1171881 | 4/6/2021 | PA | 30 | M | 4/6/2021 | 4/6/2021 | Onset of dizziness & clamminess shortly after the shot. No nausea. No near syncope. He has had classic vasovagal events in the past including syncope atleast once. He thought symptoms were similar but less intense than prior V-V events. No CP, SOB, tingling. Initial BP - 132/90 P 97 O2 sat - 98% All VS remained stable throughout observation time. He felt better soon after lying down for a short time. No orthostasis occurred and he ambulated comfortably before D/C. |
| 1172341 | 4/6/2021 | NC | 28 | F | 4/6/2021 | 4/6/2021 | Patient passed out in waiting lobby within 5 minutes after receiving vaccine. Patient was hot to touch and felt hot herself. Patient lost consciousness and other patients asked for help. 911 was called due to her appearing to have a seizure. Patient taken back into Immunization Room to lay with feet elevated. Given water. in about 5 to 10 minutes patient was feeling better but still weak and now cold. EMS arrived. Patient passed out again when EMS took her blood sugar level. |
| 1172274 | 4/6/2021 | WA | 26 | F | 4/5/2021 | 4/5/2021 | After few minutes of vaccine given, Pt has passed out for a brief seconds |
| 1172262 | 4/6/2021 | CA | 39 | M | 4/3/2021 | 4/3/2021 | Syncope, BP 110/70. |
| 1172245 | 4/6/2021 | MN | 32 | F | 4/4/2021 | 4/4/2021 | PATIENT RECEIVED VACCINE- SAT FOR AWHILE THEN WALKED AROUND WITH HER HUSBAND IN THE STORE; PATIENT PASSED OUT; 911 WAS CALLED; PT REGAINED CONSCIOUSNESS WITHIN 1 MINUTE; WATER AND GLUCOSE TABLETS GIVEN. BLOOD PRESSURE AND PULSE OX CHECKED. NO PROBLEMS BREATING. PARAMEDICS FURTHER CHECKED PATIENT AND RELEASED WITHOUT ANY FURTHER TREATMENT. PATIENT REPORTS SEVERE MEDICAL PHOBIAS AND HISTORY OF SIMILAR REACTIONS |
| 1171895 | 4/6/2021 | CA | 34 | M | 4/5/2021 | 4/6/2021 | I was feverish, felt nauseous, and then passed out twice. My partner called the doctor who advised us to go to the ER. At the ER I passed out again. |

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| 1171892 | 4/6/2021 | CA | 30 | F | 4/6/2021 | 4/6/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Mild, Additional Details: patient felt dizzy/lightheaded approx 10 min following 2nd dose covid vax; she was witnessed in the observation area by the pharmacy tech as fainting in her chair. immunizer immediately was contacted; pt was shaking/shivering and not responding to her name for around 15 seconds. she then became alert/oriented, and laid down on floor for dizziness. clinic NP contacted (BP, pulse ox within normal limits). pt's dad came to pick her up following eval. has hx of fainting w/injections |
| 1172414 | 4/6/2021 | MA | 33 | M | 4/6/2021 | 4/6/2021 | PT received covid vaccine and immediately experience vasovagal syncope, showing signs of clammy skin. EMS responded to vaccination table to evaluate and treat. Pt was hypertensive as well. EMS treated PT at vaccination table until PTs condition improved and PT was able to get up on his own and walk to observation area to continue the duration of his observation period. PT declined transport. |
| 1170809 | 4/6/2021 | OK | 19 | M | 4/5/2021 | 4/5/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Mild, Additional Details: Immunization verified under (name), (name) administered, patient fainted during the 15 minute monitoring session. Patient was over-heated, fainted, responded immediately, had to prop patient up, continued to talk verbally to keep patient engaged. gave a cold water to rest behind neck, patient was sweaty, dizzy, propped a fan to cool patient, helped immediately, color returned to patient face. spoke with patient and mother of patient. counseled pt to be picked up. wfu with pt tomorrow. |
| 1170840 | 4/6/2021 | HI | 21 | F | 4/5/2021 | 4/5/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Additional Details: patient fainted after standing up to move to the observation area, she opened her eyes almost immediately after falling to the ground and was responsive, ems was alerted to check and make sure she did not hit her head. ems assessed and patient was stable, refused medical care or transport to the hospital. left with boyfriend (she was not driving herself). |

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| 1170874 | 4/6/2021 | NY | 31 | F | 4/6/2021 | 4/6/2021 | PATIENT WAS SEATED IN POST IMMUNIZATION AREA AND PASSED OUT AND FELL TO FLOOR, BECAME RESPONSIVE AFTER 30 SECONDS AND PARAMEDICS CLEARED HER TO GO. |
| 1170873 | 4/6/2021 | FL | 27 | M | 4/5/2021 | 4/5/2021 | Systemic: Chest Tightness / Heaviness / Pain-Medium, Systemic: Confusion-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Seizure-Mild |
| 1170835 | 4/6/2021 | FL | 21 | M | 4/5/2021 | 4/5/2021 | Systemic: Confusion-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Seizure-Severe, Additional Details: patient had an absense seizure immediately after sitting down |
| 1170824 | 4/6/2021 | MA | 35 | M | 4/5/2021 | 4/5/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Hypotension-Medium, Additional Details: approximately 10 minutes after dose patient blood pressure dropped, eyes dilated, clammy. sweating. First responders came, pt did not leave with them but was going to hospital to "get checked out". |
| 1170823 | 4/6/2021 | IL | 25 | F | 4/5/2021 | 4/5/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe |
| 1170891 | 4/6/2021 | CO | 56 | M | 4/5/2021 | 4/5/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Additional Details: patient passed out for a short time.....told me he normally has a vagal response to shots and not to be surprised of he passes out.....patient fully recovered prior to leaving....he was monitored closely |
| 1170812 | 4/6/2021 | IL | 25 | F | 4/4/2021 | 4/4/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe |
| 1170893 | 4/6/2021 | GA | 66 | F | 3/29/2021 | 4/2/2021 | PATIENT STATES SHE PASSED OUT THE FRIDAY AFTER GETTING VACCINATED. SAID SHE WAS GETTING READY IN THE MORNING AND WAS ABOUT TO BRUSH HER TEETH WHEN IT HAPPENED, BUT THAT SHE WAS ABLE TO CATCH HERSELF FROM FALLING. ALSO STATES HER ARM WAS MORE PAINFUL, SWOLLEN AND RED THAN THE 1ST SHOT. |

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| 1170783 | 4/6/2021 | | 61 | M | 4/6/2021 | 4/6/2021 | Patient said that soon after receiving his first COVID shot, he experienced extreme arthralgias and new onset arthritis in his knees, shoulders and arms. He said he never had this in his life and now struggles to ambulate distances > 100 feet and struggles to lift boxes at work. Today he received the second shot and that evening he experienced nausea, vomiting, and then passed out and was brought to the ED. |

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| 1170755 | 4/6/2021 | TX | | M | 1/19/2021 | 2/20/2021 | <p>Arrhythmia; Supraventricular Tachycardia; Severe cramping; Trouble equalising pressure in ears; sinking spells; Sore arm; Headache; Lethargy; Elevated Temperature; This spontaneous case was reported by a non-health professional and describes the occurrence of ARRHYTHMIA (Arrhythmia) in a 69-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 030M20A and 042L20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Arrhythmia. Concomitant products included METOPROLOL, SIMVASTATIN, OLMESARTAN and WARFARIN for an unknown indication. On 19-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 20-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 20-Feb-2021, the patient experienced LETHARGY (Lethargy), BODY TEMPERATURE INCREASED (Elevated Temperature), PRESYNCOPE (sinking spells), VACCINATION SITE PAIN (Sore arm) and HEADACHE (Headache). On 21-Feb-2021, the patient experienced SUPRAVENTRICULAR TACHYCARDIA (Supraventricular Tachycardia), MUSCLE SPASMS (Severe cramping) and BAROTITIS MEDIA (Trouble equalising pressure in ears). On an unknown date, the patient experienced ARRHYTHMIA (Arrhythmia) (seriousness criterion medically significant). On 22-Feb-2021, LETHARGY (Lethargy), BODY TEMPERATURE INCREASED (Elevated Temperature), SUPRAVENTRICULAR TACHYCARDIA (Supraventricular Tachycardia), MUSCLE SPASMS (Severe cramping), BAROTITIS MEDIA (Trouble equalising pressure in ears), VACCINATION SITE PAIN (Sore arm) and HEADACHE (Headache) had resolved. At the time of the report, ARRHYTHMIA (Arrhythmia) outcome was unknown and PRESYNCOPE (sinking spells) had resolved. Treatment information was not provided. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. However, the patient's past medical history of Arrhythmia may remain as a risk factor for this event. Further information is requested.; Sender's</p> |

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| | | | | | | | Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. However, the patient's past medical history of Arrhythmia may remain as a risk factor for this event, Further information is requested. |
| 1170602 | 4/6/2021 | | 25 | F | 4/5/2021 | 4/6/2021 | Chills, body aches, took ibuprofen to manage. Almost fainted. Nausea. |
| 1170574 | 4/6/2021 | FL | 22 | F | 4/5/2021 | 4/5/2021 | Fever, muscle ache, I almost fainted, pain at the site of the injection |
| 1172543 | 4/6/2021 | WI | 34 | M | 4/1/2021 | 4/1/2021 | NAUSEA, EMESIS, SYNCOPE |
| 1172259 | 4/6/2021 | MI | 37 | F | 4/6/2021 | 4/6/2021 | Systemic: Chills-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Severe, Systemic: Vomiting-Severe, Additional Details: Patient had chills, passed out for 20 seconds and regained consciousness |
| 1170820 | 4/6/2021 | IL | 31 | M | 4/5/2021 | 4/5/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe |
| 1171133 | 4/6/2021 | IL | 17 | M | 3/9/2021 | 3/9/2021 | Within 1-2 minutes my son passed out and started violently shaking/convulsing. His chin was pinned to his chest, he struggled to breath and was making a sound as if he was loudly snoring but seemed to be struggling to breathe. I was unable to wake him. I'm not sure how long it lasted but maybe 2 minutes or so. He woke up and asked what was going on as we had all been standing over him trying to unsuccessfully wake him. He shared that he thought he'd been asleep and had been dreaming. He also shared that his throat hurt very much. He had the shakes for about 30 minutes after and was extremely exhausted. He slept for 14 hours as soon as we arrived home. |
| 1171444 | 4/6/2021 | NC | 43 | F | 4/3/2021 | 4/4/2021 | Almost fainted twice about 23 hours after receiving the vaccine. Dizzy and nausea for 1.5 hrs. Also experienced sore muscles, fatigue and chills within 12hrs. Fatigue continued for 48hrs. All resolved. |

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| 1171406 | 4/6/2021 | FL | 68 | F | 4/5/2021 | 4/6/2021 | Achy, light headed @ 3 a.m....went to kitchen to take Tylenol , took it & then passed out on the kitchen floor. I landed on my bottom & then I was aware of what happened. Only happened once, & was feeling somewhat better by around 11. Husband was concerned, so this is why I'm sending this your was |
| 1171354 | 4/6/2021 | OH | 18 | F | 4/6/2021 | 4/6/2021 | Immediately after receiving vaccine patient fainted. Before administering vaccine, patient instructed us that she faints with every vaccine she receives |
| 1171314 | 4/6/2021 | FL | 36 | M | 4/5/2021 | 4/5/2021 | Presented cool, pale, diaphoretic. BP 119/82. HR 39. Approximately 5 minutes later he was pink, warm and dry. His BP remained the same but his HR returned to 66. He stated that he has a history of fainting from needles and hasn't had anything to eat or drink since dinner the night before. Pt was AOx4 and vitals were stable. He denied transport to the hospital and his wife said that she would drive him to be evaluated at St Joe's Hospital nearby. |
| 1171267 | 4/6/2021 | | 21 | M | 4/5/2021 | 4/5/2021 | headaches that have stayed for more than 12 hours, fainted at pharmacy minutes after receiving vaccine, blurry vision for around 8 minutes, dehydrated before fainting, a little difficulty breathing |
| 1171249 | 4/6/2021 | OH | 17 | F | 4/5/2021 | 4/6/2021 | 6 am following day (4/6) after injection on 4/5/21, my 17-year-old daughter complained of sore right arm (injection site), tinnitus, syncope, nausea, fever. Day before had also been treated for vaginal yeast infection. Treated with miconazole and fluconazole (tablet and vaginal cream). Also complained that her ovaries hurt. She self-administered Motrin and applied heat. Went back to bed. Has rested without waking, suspect fatigue as well. |
| 1170886 | 4/6/2021 | IL | 54 | M | 4/5/2021 | 4/5/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Seizure-Severe |

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| 1171143 | 4/6/2021 | OH | 37 | M | 3/31/2021 | 3/31/2021 | 3-31-21 6PM STATING PT PASSED OUT AND HAD A SEIZURE; HE WAS HOLDING HIS VACCINATION CARD IN HIS HAND - REQUESTING PHONE NUMBER. CALLED FOR TRANSPORT TO ER. 4-6-21 10AM PT STATES HE HAS A HX OF BECOMING LIGHTHEADED FOR MANY YRS. HE WAS IN THE CHECK OUT LINE AND 'FELT LIGHTHEADED AND WAS GOING TO GET SOME CANDY TO FIX IT(HADN'T EATEN MUCH THAT DAY)'. BYSTANDER STATES HE PASSED OUT AND HAD A SEIZURE. HE DID FX RT SHOULDER. HAS AN APPT TO SEE PCP FOR F/U. |
| 1171449 | 4/6/2021 | WV | 67 | F | 4/3/2021 | 4/3/2021 | Pt received #2 moderna vaccine. Pt had no problems with #1 other than fatigue for 1 day. Went to store and passed out in the parking lot after passing out and hit her head on the pavement. Pt was transported to hospital. Pt was transferred to different hospital. Pt died at Hospital ER. 3 weeks ago pt diagnosed with heart murmur. Echo showed aortic valve function at 65%. Dr states he will just watch pt. no meds given. Pt family stated pt has a heart attack while at store. |

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| 1171131 | 4/6/2021 | NC | 60 | F | 3/24/2021 | 3/25/2021 | <p>She got the vaccine, that evening she had a headache. Then her arm started hurting to the point that she could not move it. On Thursday, 3/25/21 she was tired but functional. Then around 5:30 PM she started feeling really strange, odd, felt faint, got hot/cold, her heart was racing. She laid down as she was at a friends house, they checked her BP, blood sugar and her temperature and they were all normal at that point. Around 8:00 PM she got the nausea that would not stop and took Zofran. Around 9:30 she started throwing up. She then tried Phenergan and was not able to keep that down yesterday. Then she started running a temperature, and called her doctors office and told her what to look for and to call back if things got worse. They then got worse, called them back and then around 8:00 AM on Friday they told her to go to the hospital. When she got to the hospital they started checking things as her fever was higher, her liver enzymes, her thyroid, her kidneys, iron just started going off the page. Her fever then kept getting higher and higher and at one point it was documented at 104.8, and felt like her organs hurt. 11 days prior to this visit she had just had labs done and everything was normal. So due to the new findings everything was all elevated, so they checked her for an infection, COVID which was negative, but the intensity of the symptoms got to the point they were unbearable. She stayed in the hospital for 4 days, and the doctor came in and noted that she had a severe reaction to the vaccine. They told her to stay longer than the 15 minutes as they had some issues today, and told her that they had to call a medic for 4 other people that passed out, which made her wonder if they had a bad batch or not, and wonders how many people from that day got sick as well. She still has the most dreadful fatigue, headache and cannot walk from her house to the mailbox without feeling like she is going to faint and used to walking 2-4 miles daily. Wonders how long is this going to last and that this will pass and that she will be okay, or is she going to be permanently this way. She feels like she has a bad case of mono or something and cannot stay up and has to go to bed, and also has bouts of insomnia as well. The body aches are extreme and is taking pain medicine daily due to these symptoms, which she did not have prior to the vaccine. She got the vaccine, that evening she had a headache. Then her</p> |

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arm started hurting to the point that she could not move it. On Thursday, 3/25/21 she was tired but functional. Then around 5:30 PM she started feeling really strange, odd, felt faint, got hot/cold, her heart was racing. She laid down as she was at a friends house, they checked her BP, blood sugar and her temperature and they were all normal at that point. Around 8:00 PM she got the nausea that would not stop and took Zofran. Around 9:30 she started throwing up. She then tried Phenergan and was not able to keep that down yesterday. Then she started running a temperature, and called her doctors office and told her what to look for and to call back if things got worse. They then got worse, called them back and then around 8:00 AM on Friday they told her to go to the hospital. When she got to the hospital they started checking things as her fever was higher, her liver enzymes, her thyroid, her kidneys, iron just started going off the page. Her fever then kept getting higher and higher and at one point it was documented at 104.8, and felt like her organs hurt. 11 days prior to this visit she had just had labs done and everything was normal. So due to the new findings everything was all elevated, so they checked her for an infection, COVID which was negative, but the intensity of the symptoms got to the point they were unbearable. She stayed in the hospital for 4 days, and the doctor came in and noted that she had a severe reaction to the vaccine. They told her to stay longer than the 15 minutes as they had some issues today, and told her that they had to call a medic for 4 other people that passed out, which made her wonder if they had a bad batch or not, and wonders how many people from that day got sick as well. She still has the most dreadful fatigue, headache and cannot walk from her house to the mailbox without feeling like she is going to faint and used to walking 2-4 miles daily. Wonders how long is this going to last and that this will pass and that she will be okay, or is she going to be permanently this way. She feels like she has a bad case of mono or something and cannot stay up and has to go to bed, and also has bouts of insomnia as well. The body aches are extreme and is taking pain medicine daily due to these symptoms, which she did not have prior to the vaccine.

1171115 4/6/2021 TX 30 F 4/5/2021 4/5/2021 Nausea, vomiting, dizziness, fainting, cold sweats, heat flashes, weakness. Pain.

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| 1171081 | 4/6/2021 | OH | 18 | F | 3/31/2021 | 3/31/2021 | 8pm 3/31/2021 Fever, nausea, fatigue 4/1/2021 Extreme nausea, fever, fatigue, body aches, Heightened symptoms of neurocardiogenic syncope, easily bruising on legs 4/6/2021 Continued agitation of neurocardiogenic syncope symptoms- fainting and nausea |
| 1171022 | 4/6/2021 | VA | 19 | F | 4/3/2021 | 4/3/2021 | Following the injection, I made my way to the observation room to wait for 10 minutes. After about two, my left arm began to get extremely hot and I called the nurse in the room over. I began to ask her if it was a normal side effect and began to lose my vision and hearing while talking. I passed out and was wheeling to the side of the room where the doctor was. Upon waking up (after 2/3 minutes) I threw up. The doctor took vitals and such and said everything looked okay. After about 15 minutes I was able to stand and head home. |
| 1170909 | 4/6/2021 | NY | 68 | M | 2/18/2021 | 2/22/2021 | Four days after my second vaccination, I had a severe heart arrhythmia and fainted twice. |
| 1170900 | 4/6/2021 | IL | 54 | M | 4/5/2021 | 4/5/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Seizure-Severe |
| 1171193 | 4/6/2021 | FL | 33 | F | 4/2/2021 | 4/5/2021 | I'm currently 11 weeks postpartum and exclusively breastfeeding my infant. I experienced typical vaccine adverse effects on day 0-1 (fatigue chills muscle aches weakness arm pain and fainting episode (I have a history of fainting and with other vaccines)) followed by mastitis on day 2 after my vaccine second dose. Mastitis symptoms included fever chills muscle aches weakness breast pain swelling redness and decreased milk production from blocked duct(s). I had no symptoms of blocked duct prior to the vaccine or prior to day 2. My prescriber ordered an antibiotic and ibuprofen which helped. We believe that the blocked ducts/mastitis occurred in relation to lymph node swelling that has been seen with the vaccine although we did not have a physical exam to determine if that is true. |

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| 1173605 | 4/6/2021 | TX | | F | 3/24/2021 | 3/25/2021 | I fainted; today she is feeling kind of drunk; having trouble keeping in balance; Few nights before the vaccine my I was having trouble sleeping, now I'm sleepy all the time; Today I started feeling miserable,; I had general weakness; malaise; dizziness; disoriented; confusion; I threw up; I had severe nausea,; I had muscle aches and body aches; My arm was hurting the next day; This spontaneous case was reported by a consumer and describes the occurrence of SYNCOPE (I fainted) in a 24-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 008B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event. Concomitant products included TRAMADOL and GABAPENTIN for Fibromyalgia. On 24-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 25-Mar-2021, the patient experienced VACCINATION SITE PAIN (My arm was hurting the next day). On 27-Mar-2021, the patient experienced SYNCOPE (I fainted) (seriousness criterion medically significant), FEELING DRUNK (today she is feeling kind of drunk), BALANCE DISORDER (having trouble keeping in balance), SOMNOLENCE (Few nights before the vaccine my I was having trouble sleeping, now I'm sleepy all the time), FEELING ABNORMAL (Today I started feeling miserable,), PAIN (I had muscle aches and body aches), ASTHENIA (I had general weakness), MALAISE (malaise), DIZZINESS (dizziness), DISORIENTATION (disoriented), CONFUSIONAL STATE (confusion), VOMITING (I threw up), NAUSEA (I had severe nausea,) and MYALGIA (I had muscle aches and body aches). At the time of the report, SYNCOPE (I fainted), FEELING DRUNK (today she is feeling kind of drunk), BALANCE DISORDER (having trouble keeping in balance), SOMNOLENCE (Few nights before the vaccine my I was having trouble sleeping, now I'm sleepy all the time), FEELING ABNORMAL (Today I started feeling miserable,), PAIN (I had muscle aches and body aches), ASTHENIA (I had general weakness), MALAISE (malaise), DIZZINESS (dizziness), DISORIENTATION (disoriented), CONFUSIONAL STATE (confusion), VOMITING (I threw up), VACCINATION SITE PAIN (My arm was hurting the next day), NAUSEA (I had severe nausea,) and MYALGIA (I had muscle aches and body |

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| | | | | | | | aches) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. The Treatment information included Ondansetron, Ibuprofen. |
| 1173793 | 4/6/2021 | FL | 17 | M | 4/6/2021 | 4/6/2021 | After leaving vaccination room with mother, heading towards the lobby for minimum of 15 minutes post-vaccination observation, patient collapsed/ fainted and fell to floor. Mother was able to catch and support patient's head as patient slowly fell to floor. After only seconds, patient alert again and speaking and answering questions correctly. Patient attempted and was able come to a complete unassisted standing position, but was immediately encouraged to stay lying down until EMT has arrived. EMT arrived, assessed patient vitals, and encouraged patient and mother to go with them to hospital if they were concerned, but mother declined and signed affidavit. Patient and mother left to go get late lunch, as it was revealed patient had not eaten breakfast or lunch yet and was nervous about getting the shot. |
| 1173781 | 4/6/2021 | WA | 27 | M | 4/6/2021 | 4/6/2021 | Syncope, layed the patient down and the event resolved within a few minutes. |
| 1173702 | 4/6/2021 | NV | 47 | F | 3/24/2021 | 3/25/2021 | Fatigue; shortness of breath when walking or talking; fast heartbeat; passed out twice (the second time I passed out on the floor, lost consciousness for a few seconds and hit my face and my nose on the floor. My left calf hurts as well. |
| 1173696 | 4/6/2021 | NV | 32 | M | 4/6/2021 | 4/6/2021 | Patient received COVID Janssen injection, saw blood and had a vagal response to which he passed out and was lowered to ground. Did not hit head. Laid supine with legs elevated, profuse sweating, ice packs to chest, water given. After a few minutes assisted to sitting position and then assisted to standing position with no s/s reported. Assisted to monitoring area for continued monitoring. |
| 1173688 | 4/6/2021 | NC | 20 | F | 4/5/2021 | 4/5/2021 | Patient fainted after injection. Mom was with her and stated she has done this in the past with vaccines or giving blood. Becomes very anxious and has needle phobia. Mom put cool pack on back of neck and wet cloth on forehead. Also gave water as she was waking up. She was fine and ready to go in about 20 minutes. |

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| 1173329 | 4/6/2021 | HI | 43 | F | 3/30/2021 | 4/3/2021 | Dizziness on days 5-7 Fainted on day 5 after first dose |
| 1173612 | 4/6/2021 | FL | 74 | M | 2/26/2021 | 3/2/2021 | Diarrhea mixed with blood; Almost passed out; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of DIARRHOEA HAEMORRHAGIC (Diarrhea mixed with blood) in a 74-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 001A21A.) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included COVID-19 in July 2020 and Diverticulitis since an unknown date. Concomitant products included LOPERAMIDE HYDROCHLORIDE (IMODIUM) for an unknown indication. On 26-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 02-Mar-2021, the patient experienced DIARRHOEA HAEMORRHAGIC (Diarrhea mixed with blood) (seriousness criterion medically significant) and PRESYNCOPE (Almost passed out). On 02-Mar-2021, PRESYNCOPE (Almost passed out) had resolved. At the time of the report, DIARRHOEA HAEMORRHAGIC (Diarrhea mixed with blood) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 02-Mar-2021, Blood test: normal (normal) Blood test-Normal. On 02-Mar-2021, Haemoglobin: normal (normal) Hemoglobin-Normal. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. The patient went to the ER for observation and blood tests which came back normal (including hemoglobin). For several days it cleared up, then it has come back sporadically but not to the same degree. This case was linked to (Patient Link).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. However, Further information is requested. |

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| 1173853 | 4/6/2021 | AZ | 26 | M | 4/6/2021 | 4/6/2021 | Patient sat down for the 15 minute observation period, after about 3-5minutes fainted, falling face forward. Episode lasted less than 2 minutes, sat up and stated felt better. Patient stated they have fainted before and tasted blood however mouth had no signs of bleeding. 911 was called and came within 5 -10 minutes. Patient left with first responders |

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| 1173598 | 4/6/2021 | MI | 66 | F | 2/19/2021 | 1/19/2021 | <p>passed out; couldn't move; threw up; joint pain; headache; hives; high fever; This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 24-Mar-2021 and was forwarded to Moderna on 24-Mar-2021. This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (passed out) in a 66-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 015M20A and 015M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Urticaria (chronic hives for 16 years.) since an unknown date. Concomitant products included DOXEPIN, CETIRIZINE HYDROCHLORIDE (ZYRTEC ALLERGY), FEXOFENADINE HYDROCHLORIDE (ALLEGRA) and MONTELUKAST SODIUM (SINGULAIR) for an unknown indication. On 19-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 19-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 19-Jan-2021, the patient experienced PYREXIA (high fever). On 19-Feb-2021, the patient experienced URTICARIA (hives). On 19-Mar-2021, the patient experienced LOSS OF CONSCIOUSNESS (passed out) (seriousness criterion medically significant), MOVEMENT DISORDER (couldn't move), VOMITING (threw up), ARTHRALGIA (joint pain) and HEADACHE (headache). On 19-Mar-2021, LOSS OF CONSCIOUSNESS (passed out) had resolved. On 24-Mar-2021, MOVEMENT DISORDER (couldn't move), VOMITING (threw up), PYREXIA (high fever), ARTHRALGIA (joint pain) and HEADACHE (headache) had resolved. At the time of the report, URTICARIA (hives) outcome was unknown. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Reporter's Comments: .; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p> |

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| 1173417 | 4/6/2021 | AK | 26 | F | 4/6/2021 | 4/6/2021 | Pt received a vaccine of Johnson and Johnson (Janssen) Covid-19 vaccine. She asked if it was normal that her arm hurt really bad, then she stated she was getting dizzy and light headed. I instructed her to sit on the floor so she would not fall down. She sat on the floor and immediately passed out. She remained unconscious for 60- 90 seconds. We laid her into the prone position. Her arms were twitching. She regained consciousness. 911 was alerted and responded. Pt refused to leave with them. She sat with un an additional 15 minutes before she left for a therapy appointment. |
| 1173408 | 4/6/2021 | IL | 18 | F | 4/6/2021 | 4/6/2021 | PT STATED NOT FEELING WELL AND SHE SAID SHE IS NOT ABLE TO SEE. PT FELT DIZZY AND FAINTED. SHE FELT BETTER AFTER ELEVATING FEET AND WAITED 30 MIN FOR OBERVATION. |
| 1173404 | 4/6/2021 | NH | 37 | F | 4/6/2021 | 4/6/2021 | Patient fell off chair, appeared to be having a seizure. Patient was very pale, clammy and reported nausea. Patient was given cold compress to back of neck, blood pressure and pulse monitored. 911 was called and arrived approx 10 minutes after event. Patient was conscious and aware when EMS arrived. Patient reported history of fainting and appearing to have seizures in the past. |
| 1173387 | 4/6/2021 | VA | 26 | M | 4/3/2021 | 4/4/2021 | Passed out 18 hours after vaccine, very low heart rate and blood pressure. Called 911 for ambulance to give saline solution through IV. Was taking to the emergency room and discharged 6 hours later after receiving two bags of saline solution. |
| 1173384 | 4/6/2021 | ID | 16 | F | 4/6/2021 | 4/6/2021 | Patient fainted within 5~10 seconds after the vaccine; not responding to conversations, not responding to calling her name during the fainting. Patient woke up approximately 5 minutes after fainting, and reported that she started to feel much better. Patient was seated on chair under direct help of pharmacist at the time. No observable injury, did not fell to the floor. EMS was called and arrive, and patient care handed over to EMS. |
| 1173686 | 4/6/2021 | VA | 54 | F | 4/1/2021 | 4/2/2021 | hives, passed out, rushed to er, low potassium, dehydrated |

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| 1173985 | 4/6/2021 | FL | 27 | M | 4/6/2021 | 4/6/2021 | Patient fainted, shaking while sitting (had to monitor patient for 15 minutes post vaccine) |
| 1171924 | 4/6/2021 | PA | 30 | M | 4/5/2021 | 4/5/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Given fluid and food. BP and Pulse ox monitored |
| 1172556 | 4/6/2021 | AK | 29 | M | 4/6/2021 | 4/6/2021 | mostl likely vasovagal syncope. patient fainted and woke up very quickly disoriented. was sweaty for about 10 minutes. He was given reeses candy bar and water and monitored for an additional 15 minutes after his beginning time. was released about 40 minutes after his vaccine/reaction. |
| 1174209 | 4/6/2021 | CA | 63 | F | 4/6/2021 | 4/6/2021 | Patient was getting light headed and fainted but did not lose conscienceness. Patient fell at around 2 feet but was conscience, we had patient lay down and called 9-1-1. I called patient afterward to follow up, as she denied going to hospital, she reports being fine, just a little sore on the head. She most likey had her vasosyncope |
| 1174208 | 4/6/2021 | CA | 26 | F | 4/6/2021 | 4/6/2021 | 18 45 pm, patient stated she felt fainting. Bp 116/64, SaO2 100% RA, Glucose 84, RR 20, HR 61. Patient was in lying flat position. 18:47 pm, 911 was called. Reported patient is awake and alert x 3 and VS. Followed instruction not to have patient eat or drink. 19:01 pm, O2 97% RA, HR 73, T 97.7, BP 126/76, patient is in sitting position, remains awake and alert x 3. Patient stated she does not have any friend/family to come to pick her up and she lives in San Francisco. A fire officer arrived at 19:10 pm Patient's BP 120/81, O2 SAT 99%, HR 75, RR 18. Patient signed the document not to have further treatment or to be admitted to the Hospital. Patient stated she was doing fine and left the facility with steady gait, and fully consciousness with the Fire officer to the parking lot. The Medical Professional was called in the command center and stated we did everything properly without any further questions/issues at 19:29 pm. |

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| 1174177 | 4/6/2021 | | 75 | F | 4/6/2021 | 4/6/2021 | A164 to a 75 y/o F c/c near syncope after receiving a Johnson & Johnson COVID vaccine. Pt St she has not had a vaccine since grade school due to having syncope type reactions and fear of needles. History of cardiac arrhythmia, no other medical issues. Upon arrival, Pt laying on floor with FD vaccination team members attending her. Pt a/ox4, GCS 15, St near syncope 10 minutes after injection. Pt St she is feeling much better now. FD vaccination team members St Pt was very nervous about the injection, became pale and sweaty 10 minutes post injection and had a near syncope. No falls reported today. Pt hemodynamically stable by our arrival with negative postural findings. Pt St she is feeling much better. Pt does not feel the need for TRX and agrees to wait with vaccination team for 30 minutes or until she feels 100%. Pt left in care of vaccination team. Near syncope after COVID vaccination injection Exam, vitals, history, Pt left with vaccination team. |
| 1174116 | 4/6/2021 | PA | 22 | M | 4/6/2021 | 4/6/2021 | Patient described episodes of fainting after medical procedures. After initially appearing fine after the vaccination, the patient fainted about 10-15 minutes after the vaccine was administered. Patient was let to lay on the floor as he almost fell out of the chair he was sitting. No injuries reported from falling or being moved to the floor. Patient spent approximately 10 minutes on the floor until feeling well enough to stand and move about. Once standing the patient was able to get move freely and did not have any more episodes while on site. Patients family was supportive and well educated on how to handle his situation. |
| 1173825 | 4/6/2021 | TN | 21 | M | 4/6/2021 | 4/6/2021 | Pt fainted immediately after receiving vaccine. Regained consciousness after 15-20 seconds. Got patient to floor and feet elevated. Monitored blood pressure until it returned to normal. |
| 1173991 | 4/6/2021 | CO | 24 | M | 4/6/2021 | 4/6/2021 | Pt Stated that he was not feeling well after the vaccination and wanted water. While getting him a bottle of water pet had Fainted and was out for 10 seconds before he regained consciousness. |

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| 1173833 | 4/6/2021 | CA | 35 | M | 4/6/2021 | 4/6/2021 | Vaccine Reaction: Nauseated, Syncope and sweating Description of Event: Pt found in observation chair, sweaty and nauseous and had about a 1 minute syncopal episode observed by OBS RN. Pt slow to arouse post syncope. Able to ambulate 2 steps and placed on gurney. Taken outside of the building by exit doors. Pt sleepy and sweaty, placed on vital sign machine. Dr. and multiple RN's with patient. Pt remained slightly nauseous at 1033. Pt had eaten breakfast and denies any medical history or meds. 1035 attempt sips of water, 1038 we called his girlfriend to come be with him and drive him home. Pt felt like he couldn't get enough air at 1038, we removed both of his masks at this time. Pt was sweaty again, but oxygen sats were 100%. 1056 GF arrived. 1106 we attempt to sit up patient slightly and he gets lightheaded and request to lie flat again. Sips of water causes nausea. Dr. remains at BS with patient. Pt began feeling a whole body tingle, encouraged to take nice slow easy breaths. 1111 took a bite of granola bar. 1143 tried sitting up again, gets lightheaded and laid back down. 1154 Dr. back at bedside. 1200 Pt cold bath blanket put on patient. Pt had periods of being slightly pale during observation period and dry mucuous membranes. Pt refusing to try water or granola bar at this time. 1205 pt began to vomit stomach contents. 1212 Dr. back at BS to evaluate patient. Pt feels slightly better, taking sips of water. 1220 pt has been able to lay with head up on his left side now for 20 mins. Dr. offered to send patient to ER to get IVF and be checked out, pt began to perk up and wanted to go home. Orthostatic VS done and remain stable. GF is agreeable to take patient home and monitor him, she is not going in to work today. Pt taken to car via wheelchair, assisted in car, able to walk a few steps. Advised by Dr. to eat a salty meal and drink plenty of fluids and rest. Go to ER if symptoms worsen. Also advised by this RN to follow up with his PCP and let them know of his syncope with vaccine. Pt also advised if he dose get the second vaccine to let them know up front he faints and will be given vaccine in reclining chair. |

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| 1173957 | 4/6/2021 | TX | 37 | F | 4/6/2021 | 4/6/2021 | pt (pregnant estimated about 6 weeks received vaccine around 4:30pm 4/6/21 first dose. pt stated no previous hx of adverse rxn to vaccines. was able to walk to the post vaccine area and sat down and stated they felt well and fine. around 4: 40pm, pt had fainted after getting up. states did not injure themselves or hit their head. walked pt into counseling imz booth, had feet elevated, provider water and ice packs. we monitor the patient for about an hour evaluating every 5-10 min. Patient stated they were feeling better. informed store management. pt was walked out with associate and had family member drive home. will fill out vaers |
| 1173955 | 4/6/2021 | FL | 40 | M | 4/6/2021 | 4/6/2021 | PATIENT PASSED OUT AND APPEARED TO BE HAVING A SEIZURE WITH EYES ROLLING BACK IN HEAD. HE WAS SLUMPED IN CHAIR. NON-RESPONSIVE. WAS ABOUT TO ADMINISTER EPINEPHRINE , WHEN HE CAME TO. HIS VOICE WAS WEAK AND SAID NO TO EPI. HE WAS DIAPHORETIC AND VERY PALE. EMS CAME ONTO SCENE AND TOOK OVER. BLOOD PRESSURE WAS 80/53 PER EMS. HE REFUSED FOR THEM TO TAKE HIM. WIFE WAS CALLED AND CAME TO GET HIM BUT HE HAD TROUBLE STANDING AND HAD TO SIT AWAYHILE. IT WAS ABOUT 45MINUTES BEFORE HE EXITED WITH ASSISTANCE. ATTEMPTED TO CONTACT HIM LATER AND HAD TO LEAVE MESSAGE |
| 1173914 | 4/6/2021 | | 35 | F | 4/6/2021 | 4/6/2021 | syncope/near syncope |
| 1173893 | 4/6/2021 | PA | 36 | M | 4/6/2021 | 4/6/2021 | Pt experienced syncope about 10 minutes after the dose. He became very light headed and began to sweat. He fell to the ground and remained there for about 5 minutes until he "came to" fully. He was able to stand on his own and get into a chair. He refused medical treatment stating that he was fine. |

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| 1173873 | 4/6/2021 | VA | 32 | F | 4/6/2021 | 4/6/2021 | Patient had received vaccine 5 minutes prior and gone to the bathroom. She came back to sit in the waiting room and then passed out in the chair. She reported that she had been nauseous prior to sitting down. She came back too quickly and stated that she was just thirsty and her chest was tight. 911 was called and they asked us to give her 4 chewable baby aspirin as a precaution. Before EMS arrived she was sitting up and talking with her husband. |
| 1174012 | 4/6/2021 | WI | 21 | F | 4/6/2021 | 4/6/2021 | Patient fainted shortly for a few seconds after receiving the vaccine. no other known effects |
| 1173997 | 4/6/2021 | CO | 20 | M | 4/6/2021 | 4/6/2021 | about 5 minutes after vaccine pt asked for a bandaid due to some heavy bleeding at injection site. He then asked for water. When I brought the water to him he was very pale and said he felt like fainting. We had him lay down and elevate feet which helped him feel better but was still hot so I applied a cold ice pack on head to help him feel less hot. After about 10-15 minutes he felt better and stayed with us for about 45 minutes until he felt well enough to drive home. I checked on him about 2 hours later and he was feeling much better. |
| 1172710 | 4/6/2021 | OH | 22 | F | 4/6/2021 | 4/6/2021 | Pt fainted in waiting area chair - was on floor - had her lie down and elevate feet, once she felt better we moved to IMZ booth for privacy and she fainted again and did not fall out of chair - called 911 |
| 1172812 | 4/6/2021 | VA | 35 | M | 4/5/2021 | 4/5/2021 | Patient was asked to sit for 15minutes after vaccination. After sitting, patient Walked approximately 15 feet and fainted onto concrete floor. Sustained head injury with laceration. Pt was alert and oriented. Was immediately attend to former EMS and nurse. Stated he had only eaten a banana that morning. Ambulance called and received head staples at the ER. |

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| 1172764 | 4/6/2021 | VA | 21 | M | 4/6/2021 | 4/6/2021 | Felt anxious about the shot and got it at 10:48, started feeling dizzy at around 10:55 during the 10 minute waiting period, then started to black out and I immediately told the nurse who's quick actions prevented me from fully fainting (laying me down and giving me food/water and elevating my legs). Blood pressure was fine she said along with O2 levels. Left around 11:25 after I felt able to. We both think this was likely related to the anxiety about getting the shot itself (I have anxiety in general so it was not paired with a mistrust or anything about the vaccine) and began fainting 7 minutes after getting the vaccine. I was anxious about any possible symptoms and needles/shots/blood draws make me feel uneasy. However, this issue was not present with the first shot. |
| 1172756 | 4/6/2021 | CA | 25 | F | 4/6/2021 | 4/6/2021 | patient was in the observation area and fainted from her chair to the floor. Observation nurses were able to arouse her immediately and transferred her from the observation area to the EMS room via wheelchair. Patient reported that she has "issues" when she gets her blood drawn bur has never passed out before. She denies chest pain, shortness of breath or nausea at this time. She was given H2O and allowed to rest on the gurney, all vitals were WNL 128/87 pulse 75 pulse ox 100%. Pt was discharged in stable condition to father who was driving her home @ 12:35pm. |
| 1172744 | 4/6/2021 | ID | 29 | M | 4/6/2021 | 4/6/2021 | Patient was waiting 15 minutes after receiving the vaccine and before the 15 minutes were up, he stood up to ask a question to the staff. While walking to the counter patient fainted hitting neck on a stand as well as head on ground. Staff members came out to approach patient at which time he was conscious. He was able to identify his name/age and speak normally but reported dizziness. Emergency services were contacted and while waiting for them to arrive patient had requested to sit up and was moved slowly to chair. Emergency services evaluated patient and determined he was ok and didn't need to go to hospital and was ok to leave when comfortable. |
| 1172729 | 4/6/2021 | IL | 25 | F | 4/6/2021 | 4/6/2021 | Patient fainted approximately 5 minutes after vaccination. Patient regained consciousness immediately. Patient also reported cold sweats. |

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| 1172846 | 4/6/2021 | KS | 22 | M | 4/6/2021 | 4/6/2021 | Two minutes after the vaccination, PT walked up to the counter and said he feels dizzy. I asked him to sit down and started walking around the counter to check on him and check his blood pressure. At that moment he fainted and lost consciousness. Another patient caught his head and he did not hit his head. He remained unconscious for 30 seconds and we were preparing to start CPR breaths as he had a pulse but was not breathing. His eyelids were fluttering. He regained consciousness at that time and we waited with him until EMS arrived. His blood sugar was very low when EMS arrived. |
| 1172712 | 4/6/2021 | KY | 19 | F | 3/22/2021 | 3/22/2021 | syncope, eye twitching |
| 1172695 | 4/6/2021 | OR | 24 | M | 4/6/2021 | 4/6/2021 | vasovagal syncope Elevated legs Call 911 |
| 1172700 | 4/6/2021 | MN | 72 | M | 4/5/2021 | 4/6/2021 | Dizziness, nausea, headache, passed out briefly |
| 1172667 | 4/6/2021 | CA | 16 | F | 4/6/2021 | 4/6/2021 | Patient fainted shortly after shot |
| 1172558 | 4/6/2021 | ME | 45 | F | 4/5/2021 | 4/5/2021 | Minutes after getting the vaccine patient said she was feeling lightheaded. We went to check on her and she fainted. EMS was called. Patient was unconscious for roughly 15 seconds. We checked pulse and positioned on the floor. Once responsive patient said she was feeling okay. She said she faints when she gets anxious (this was not disclosed before vaccine was given). She spoke with EMS who determined she did not need immediate care. She waited another roughly 30 minutes and was able to leave the pharmacy. |

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| 1173312 | 4/6/2021 | CO | 42 | M | 4/6/2021 | 4/6/2021 | Patient was given first dose of Pfizer COVID-19 vaccine. I counseled the patient on side effects and asked him to wait 15 minutes afterwards in our waiting area. After about 5 minutes, the patient starting complaining of feeling dizzy. We asked him to sit back in the chair and brought him a bottle of water. I asked the patient if he had eaten today and he replied no. I offered a snack and also a glucose tablet to help with shakiness. As I went to get a bottle of glucose tablets off the shelf, the patient fainted and fell out of his chair. I immediately ran to get an Epipen while my technicians called for a Code White and 911. I was about to inject the patient with the Epipen when he came to about 10 seconds later. He said he was really hot, sweaty, dizzy, and nauseous. Paramedics and AP arrived to evaluate him and take a statement. Patient left on his own will and received a ride home from his mother-in-law, who is an associate at our store. |
| 1174140 | 4/6/2021 | MN | 43 | M | 4/6/2021 | 4/6/2021 | Patient fainted 5-10 minutes after the shot. He was seated and fell to the floor. Pharmacist came out immediately to ask him if he had labored breathing. He laid flat on the floor claiming he was dizzy. I called 911 and they took him by ambulance to the hospital |
| 1172584 | 4/6/2021 | MS | 18 | F | 4/6/2021 | 4/6/2021 | Within 5-10 minutes after receiving vaccine, patient began to become very pale. Her symptoms included dizziness, syncope, stomach ache, foaming at the mouth, vision disturbances. 911 was called and paramedics arrived.. Her vital signs were all normal. Patient did not wish to go to hospital, and her mother took her home. Other pertinent information is that patient has a history of seizures and had been off of her seizure medication for 4 weeks. I believe that I understood her mother to say that her neurologist knew she was getting the vaccine today. Patient reported no allergies to any other vaccine, medication, or other. |
| 1172718 | 4/6/2021 | CA | 35 | M | 4/5/2021 | 4/5/2021 | Syncope, dizziness, BP 130/90 (pulse 61), O2 sat 99%. Hit left forehead, 1.5 inch gash along eyebrow. Sent to ED. |

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| 1173134 | 4/6/2021 | VT | 61 | M | 4/2/2021 | 4/2/2021 | After feeling well and dinner I passed out. I came to after a minute or so. Everything was spinning and I was sweating profusely and had pretty strong chills and shivering. I stood on the floor until I felt better. I was able to go upstairs and I went to bed. I did continue to shiver for about 15 minutes. I have felt ok since then. I am not sure if I will get the second dose after that experience. |
| 1173297 | 4/6/2021 | IN | 32 | F | 4/6/2021 | 4/6/2021 | POST ADMINISTRATION SYNCOPES |
| 1172640 | 4/6/2021 | VA | 38 | F | 4/6/2021 | 4/6/2021 | Covid vaccine administered to patient in her right arm at 2:34 pm and patient fainted. Staff administering the vaccine immediately provided assistance and patient did not fall out of chair nor was there any injury as a result the syncope episode. Patient recovered quickly and was given water. Initial BP and heart rate 93/43 and 64, At 2:53 pm vital signs were BP{ 98/53, HR 64, T 98.6, R 18 and BG 108. Vital signs at 3:10 pm BP 102/53 and HR 59. Patient was alert and oriented. Patient stated she feels okay, and denied lightheadedness or dizziness. Gait noted to be steady without stumbling, swaying, or falling. Patient was observed from 2:34 pm to 3:15 pm. |
| 1172868 | 4/6/2021 | PA | 65 | F | 4/6/2021 | 4/6/2021 | Patient reported previous nausea after receiving vaccines in the past as well as fainting. Monitored the patient for 30 minutes after her vaccination, and she vomited within 30 minutes. The patient reported she felt well after vomiting and denied needing any further attention or assistance |

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| 1173298 | 4/6/2021 | AL | 21 | M | 4/6/2021 | 4/6/2021 | Patient received vaccination sitting down. Stood up to move out of the vaccination room went to be seated outside the door. Patient said he felt like he was about to faint and went to sit down and immediately started to slid out the chair once seated. Patient was out for no less than 15 seconds. Paramedics was called during the fainting. He was responsive and able to breath. Patient was kept on the floor in supine position. no difficulty in breathing and knew who he was and where he was located. No signs of distress just very pale and shaky. Paramedics arrived at scene and O2 stats and HR was normal BP was normal. Patient was taken to hospital for further test. Pharmacist called for follow up at 5:30 with fiancé and she stated that they had diagnosis of vasovagal syncope and that they were running more test. She stated that he was doing fine and that he seemed to be better. They were still in the ER at 5:30 pm. |
| 1173136 | 4/6/2021 | WI | 65 | F | 3/31/2021 | 4/1/2021 | Noted lt. arm soreness at 3 a.m. (more than dose 1), noted chills at that time and body aches. Got up at approximately 8 a.m. and walked to the bathroom but felt nauseous. Sat on toilet, had diarrhea and felt like I was going to faint. I knew I needed to get my head down inorder to feel better. I stood up to pull my pants up and passed out. My husband heard the clunk as I hit my left forehead on wall - he came rushing in - I was face down on the tile which actually felt cool but good on my face. he helped me sit up while sitting on the floor but I still felt faint and needed to keep my head down. I quickly felt another bout of diarrhea before he and I could get back up to the toilet. I was able to wash up with him handing me washcloths and towel and clean lower extremity clothing - still felt nauseous. Had gatorade which improved how I felt quickly - temp was 96.5. rested most of the day. Completely fine on 4/2/2021. Bruise on left forehead about size of quarter and small bruise left side of nose. |

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| 1173308 | 4/6/2021 | GA | 29 | F | 4/6/2021 | 4/6/2021 | Patient began to feel lightheaded and proceeded to lie on the ground immediately after I gave her the vaccination. Her mother was present and stated that her daughter has vasovagal syncope and that this always occurs whenever her daughter gets nervous about something (even at the eye doctor when receiving eye drops). The patient's eyes rolled into the back of her and began to shake uncontrollably and lost control of her bladder. The patient came to about a minute or so later and drank some orange juice. She was monitored for an additional 30 minutes. The mother told me not to call 911 since this has happened to her daughter before. |
| 1173119 | 4/6/2021 | | 20 | M | 4/6/2021 | 4/6/2021 | Pt. passed out, diaphoretic and nauseated. Pt fell to floor hit left side of head. Pt given water and snack then recovered went home with mother |
| 1173083 | 4/6/2021 | NY | 29 | F | 3/25/2021 | 3/27/2021 | Dizzy spells and fainting. No warning that it is coming and happens at random times of the day. One or twice daily thus far. |
| 1173064 | 4/6/2021 | CO | 37 | M | 4/6/2021 | 4/6/2021 | Patient was asked to remain in store for 15 minutes after immunizing and was seated in lobby at pharmacy. After about 5 minutes patient said he stood up to tell pharmacy he was feeling dizzy and he fainted and fell down. Pharmacy immunizing technician immediately attended to patient as well as store management. Pharmacist called 911 and monitored patient. Patient did not require CPR, he was awake after a few seconds. We had patient remain face down on the floor and still on the floor talking to him until paramedics arrived. Paramedics arrived about 5 minutes after calling 911. Patient was taken to the ER by paramedics. |
| 1173016 | 4/6/2021 | NC | 54 | F | 3/15/2021 | 3/15/2021 | Zero pain with injection. Immediately upon the needle leaving my arm I began to feel dizzy and really weak. Thought I was going to pass out but didn't. My tongue felt funny almost electric. Then my heart took off and raced for a good bit. Just felt really washed out. It was a drive through clinic we did not alert anyone. Felt my husband would get someone if I passed out. Felt really tired for the rest of the day and had heart palpitations throughout the following week. I'm now fine. Called in to my primary and they advised I should report |

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| 1172889 | 4/6/2021 | | 45 | F | 3/6/2021 | 3/8/2021 | severe weakness, low blood pressure, tachycardia, feels faint/near syncope, mild but new dyspnea on exertion and severe tremor of hands interfering with activities such as feeding herself, occasional mild headache. admitted to observation in emergency center, discharged home |
| 1172955 | 4/6/2021 | ID | 38 | F | 4/1/2021 | 4/1/2021 | Withing 5 minutes hand went tight, which sometimes happen anyways your condition but became very heavy. Left side of face was pulling to her ear, looked like a stroke but it was not. Could have been Dystonic reaction. Took benadryl . Paramedics 911 was called. She fainted, then came to. BP was 185/something. Heart was beating out of her chest, was having a hard time taking a full breath. They took her to the hospital and then she could not breathe. Paramedics then gave her oxygen because she was wheezing and gave her a nebulizer treatment. They did EKG and blood tests all were normal. Medication was given for her to calm down. They think it was related to anxiety (Panic Attack). Her Dr thinks it related to her condition and that the vaccine set it off, maybe MS or immune problems. |
| 1172927 | 4/6/2021 | GA | 50 | F | 3/24/2021 | 3/25/2021 | Paranoia - yelling at people talking to her on shoulder - gave night meds early - helped Unsteady walking - had sit down then to bed Passed out twice - blood pressure down to 70/40 when paramedics took to hospital - IV fluids |
| 1173068 | 4/6/2021 | | 32 | F | 4/2/2021 | 4/4/2021 | Chest/sternal pain, syncope |
| 1172910 | 4/6/2021 | TX | 16 | F | 4/6/2021 | 4/6/2021 | Patient passed out for about 2 minutes upon receiving immunization. The patient was caught by her father and placed in a seated position. As the pharmacist went to call for assistance, the patient's father realized that she was awake again. The whole incident occurred within a few minutes. We had the patient sit in observation for 30 minutes, and we gave her water. |
| 1172925 | 4/6/2021 | CA | 51 | F | 4/6/2021 | 4/6/2021 | patient fainted after receiving Janssen Covid 19 vaccine. Patient was sitting down after the vaccine but fainted about 5 minutes after injection. Patient loss consciousness for a minute and woke up after husband was calling her name. EMT arrived and escorted patient to hospital. |

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| 1168670 | 4/5/2021 | KY | 73 | M | 4/2/2021 | 4/3/2021 | presents with difficulty breathing associated with dizziness/presyncope. Called EMS and received duoneb and solumedrol PTA with improvement. Has had generalized body aches and dyspnea for three days. Dyspnea worsened this morning. Felt like was going to black out. No fever. Of note, received first COVID vaccine 4 days. otherwise complains of calf cramping bilaterally, left greater than right. Diarrhea twice yesterday. No vomiting, no abdominal pain. Complains of bloating and acid reflux. All other systems negative |

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| 1168986 | 4/5/2021 | TX | | M | 2/13/2021 | 2/14/2021 | <p>Taken to ER where had EKG, blood tests and low blood pressure; Vaccine Poisoning; Fainted 2 times; Sweating; This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 02-Mar-2021 and was forwarded to Moderna on 03-Mar-2021. This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of SYNCOPE (Fainted 2 times) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No adverse event reported.). On 13-Feb-2021 at 10:00 AM, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 14-Feb-2021, the patient experienced SYNCOPE (Fainted 2 times) (seriousness criterion medically significant) and HYPERHIDROSIS (Sweating). On an unknown date, the patient experienced HYPOTENSION (Taken to ER where had EKG, blood tests and low blood pressure) and TOXICITY TO VARIOUS AGENTS (Vaccine Poisoning). At the time of the report, SYNCOPE (Fainted 2 times), HYPERHIDROSIS (Sweating), HYPOTENSION (Taken to ER where had EKG, blood tests and low blood pressure) and TOXICITY TO VARIOUS AGENTS (Vaccine Poisoning) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood pressure measurement: low (Low) low. On an unknown date, Blood test: unknown unknown. On an unknown date, Electrocardiogram: unknown unknown. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. This case was linked to (patient link). Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p> |

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| 1168985 | 4/5/2021 | CA | 74 | M | 2/19/2021 | 2/20/2021 | passed out; Blood sugar was 60; A spontaneous report was received from a consumer concerning a 74-years-old male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced passed out and blood sugar was 60. The patient's medical history included diabetes and high blood pressure. Concomitant medications included human insulin(Novolin 70/30). On 19Feb2021, the day before the onset of the events, the patient received first of two planned doses of mRNA-1273 (Lot: not reported) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 20Feb2021 at approximately 1 am, the patient experienced a blood sugar of 60. He drank orange juice and ate half an orange but passed out in the kitchen. He got up but passed out again. He states that he took his insulin and passed out due to his insulin and not the vaccine. and his health care provider switched him to dulaglutide. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events, passed out and blood sugar was 60 were unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. However, since the patient is known diabetic and is on insulin may remain a contributing factor to this event. Further information is requested. |
| 1168774 | 4/5/2021 | OK | 33 | F | 4/5/2021 | 4/5/2021 | Patient received the vaccine and apprx 5 minutes into waiting period she passed out and fell out of her chair. Patient hadn't reported any previous similar reactions on first ask. when the paramedics arrived to check her out, she state that she's been known to pass out while giving blood, admitted a fairly strong aversion to needles and when asked if she felt it was a reaction to the vaccine or anxiety she said anxiety quoting "as soon as I got the shot I started thinking about a chemical being in my body and my brain took it from there and the next thing I knew, I was on the ground~~ |

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| 1168741 | 4/5/2021 | WI | 60 | F | 4/1/2021 | 4/1/2021 | Pt stated her "tongue felt thick" and felt her "heart racing" immediately after injection. Pt moved to observation area and offered oral diphenhydramine, pt declined. Pt BP and HR were initially elevated at 168//80 and 129. BP decreased to 140/80 and HR to 100 after five minutes of observation. Pt reported gradual improvement with symptoms for 30 minutes, until reporting a sudden worsening of angioedema, "tingling all over", tachycardia, and syncope. RN administered 0.5 mg of epinephrine IM to L upper thigh and called 911 for ambulance transport. Pt reported some improvement in symptoms after administration of epi, but symptoms not resolved. RN considered administering second epi dose, but deferred when ambulance and EMTs arrived five minutes after first dose of epi. Pt transported to local hospital for further follow up. |
| 1168735 | 4/5/2021 | OH | 16 | M | 4/5/2021 | 4/5/2021 | Eight minutes after receiving his vaccination, he developed lightheadedness and had a brief episode of syncope. He had a small laceration on his right for head. |
| 1168656 | 4/5/2021 | MA | 60 | F | 3/27/2021 | 3/27/2021 | Pt got a pfizer COVID vaccine on Saturday 3/27 States that she was out in the sun over an hour to get a vaccine and then waited another 40 mins inside a warm building before she got her vaccine States that she had nothing to drink and barely anything to eat and prior to her appt she had been doing yard work States that about 10 mins after she got her vaccine she blacked out, clinic staff noted seizure like activity which resolved prior to EMS arrival. States that this is not the first time she was outside in the sun without water and she passed out before States that the vaccine site thought that this was a reaction to her getting the vaccine but she thinks it was due to her being in the sun for over an hour waiting to get the vaccine States that she has never had any reaction to any vaccines before States that the vaccine site informed her to call her PCP to inform them of what happened States that once she got a few sips of water she felt normal again. Was refereed to PCP who felt most likely related to orthostasis and cleared patient to receive dose # 2. |

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| 1168676 | 4/5/2021 | NC | 25 | F | 4/5/2021 | 4/5/2021 | Patient received 1st dose of Pfizer COVID vaccine and subsequently fainted roughly 5 minutes after receiving dose. Patient never lost consciousness but did suffer a minor bruise on head once after fainting. |
| 1168665 | 4/5/2021 | GA | 60 | F | 3/13/2021 | 3/14/2021 | Fever and extreme lethargy. One episode of syncope. as of today 4/5/2021 I have a mouth sore and 4 cold sores. |
| 1169077 | 4/5/2021 | FL | 23 | F | 4/3/2021 | 4/3/2021 | dizzy with syncope |
| 1168637 | 4/5/2021 | AZ | 70 | F | 3/31/2021 | 4/1/2021 | fainted, fell off chair onto floor. |
| 1168595 | 4/5/2021 | VA | 31 | M | 4/1/2021 | 4/2/2021 | vaso event after shot. Pt with no history of issues with injections. After waiting 15 mins, stood up to leave and felt wea; had near syncope event and was evaluated for vaso event. There was no food intake; given water and advised to hydrate prior to 2nd dose. 09:51-Bp-115/82 p 74 Resp 12; 10:00a-118/73 P 66 resp 12; 10:10 BP 112/76 P 62 Resp 12. Pt released to father. Pt was evaluated by on-site NRP. |
| 1168697 | 4/5/2021 | TN | 16 | M | 4/5/2021 | 4/5/2021 | Syncope and vomiting. Symptomatic treatment |

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| 1168987 | 4/5/2021 | AZ | 69 | F | 2/13/2021 | 2/13/2021 | <p>Passed out; Dehydrated; kept vomiting; Chills; her arm was swollen, itching and caused pain; arm was swollen; caused pain; A spontaneous report was received from a consumer, concerning a 69-years-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced arm was swollen (peripheral swelling), itching (pruritus), and caused pain (pain in extremity), passed out (loss of consciousness), kept vomiting (vomiting), chills and was dehydrated (dehydration). The patient's medical history was not provided. Concomitant medications reported included ascorbic acid/biotin/dl-alpha tocopheryl acetate, nadolol, acetylsalicylic acid, sertraline, levothyroxine sodium and spironolactone. On 13 Feb 2021, prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 (Batch number: 030M20A) intramuscularly in the left deltoid for prophylaxis of COVID-19 infection. On 13 Feb 2021, the patient's arm was swollen, itching and caused pain for about 2 days. On 14 Feb 2021, the passed out. The patient stated that she did not know how long she was out and that the event did not happen again. Since 14 Feb 2021, the patient kept vomiting where she couldn't eat or drink at all and she could eat on 20 Feb 2021. On 14 Feb 2021, the patient had the chills and was dehydrated which lasted for 7 days. The patients' doctor told her not to get the second Moderna COVID-19 vaccination. Treatment information was not provided. The patient was advised by her doctor to avoid getting the second dose of mRNA-1273. The outcome of the events, arm was swollen, itching and caused pain, were considered resolved on 15 Feb 2021. The event, passed out, was considered resolved on 14 Feb 2021. The outcome of the events, kept vomiting and could not eat or drink at all, were considered resolved on 20 Feb 2021. The events, chills and was dehydrated, were considered resolved on 21 Feb 2021.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p> |

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| 1168988 | 4/5/2021 | NV | 21 | F | 2/9/2021 | 2/9/2021 | Fainting; Injection site soreness in arm; nauseous; A spontaneous report was received from a consumer concerning a 21-year-old, female patient, who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced, fainting (syncope), injection site soreness in arm (vaccination site pain), and nausea (nausea). The patient's medical history included vasovagal condition that cause heart rate and blood pressure to drop due to stress on body and dehydration resulting in fainting. Concomitant product use was not provided by the reporter. On 09 Feb 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: 013M20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 09 Feb 2021, the patient was fine until about 11 pm after which she experienced arm soreness on the injection site and felt nauseous. On 10 Feb 2021, at 5 am in the morning, the patient fainted. The patient assumed that shot might have added stress to her body which most likely caused her to faint. No treatment information was provided. Action taken with mRNA-1273 in response to the events was unknown. There was no change planned to the dosing schedule of mRNA-1273 in response to the event as patient would be receiving second dose on 09 Mar 2021. The outcome of events, fainted (syncope), injection site soreness in arm (vaccination site pain), and nauseous (nausea), were considered as unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the onset date of the reported events of syncope, vaccination site pain, and nausea, a causal relationship cannot be excluded. Patient's prior medical history of vasovagal reactions is considered a contributing factor to syncope. |

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| 1169005 | 4/5/2021 | OH | 63 | F | 3/9/2021 | 3/9/2021 | went into seizure; felt a metallic taste; felt dizzy; nearly fainted; not able to walk; had chest tightness; did not feel like she could breathe; did not feel well; her face was flushed like she was on fire; A Spontaneous report was received from a phycsian concerning a 63 Year old Female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced Dysgeusia/Felt like metallic taste, Dizziness/Dizzy, Presyncope/ Near fainting, Gait Disturbance /Walking difficulty, Chest discomfort/ Chest tightness, Dyspnoea/ Breathing difficult, Malaise/ Feeling unwell, Seizure, Blood pressure abnormal, Blood sugar abnormal and Flushing. The patient's medical history included Asthma. No relevant concomitant medications were reported. No information on allergies were provided. The reported stated that the patient was physically and mentally healthy before vaccination. On 9 Mar 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: unknown) via intramuscular route and unknown location for prophylaxis of COVID-19 infection. had chest tightness and she is an asthma patient. She did not feel like she could breathe and did not feel well. She went back to the pharmacy and they did not want to give her EpiPen. She went into seizure because she already had seizure disorder. Her blood pressure went to 162/80 and her blood sugar went to 152 when she was on her way to the hospital and her face was flushed like she was on fire. She took Zofran during her 5 hours of hospitalization and got a CT scan. They diagnosed her with a post vaccination reaction but she still wants to get the second dose. Action taken with mRNA-1273 in response to the events was not reported. The outcome for the event Dysgeusia, Dizziness, Presyncope, Walking difficulty, Chest discomforts, Dyspnoea, Malaise, Seizure, Blood pressure abnormal, Blood sugar abnormal and Flushing was considered unknown.; Sender's Comments: Based on the current available information which includes a strong temporal association between the use of the product and onset of the events, and excluding other etiologies but for history of asthma, causal relationship cannot be excluded. |

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| 1169010 | 4/5/2021 | PA | 73 | F | 3/20/2021 | 3/21/2021 | Went black, did not lose consciousness, but hit the head on the tiles; Hit head on the tiles; Woke up and could not even walk; Heart was in a fast heartbeat; Weakness; Slept whole day; Dizziness; Tired; Freezing; This spontaneous case was reported by a consumer and describes the occurrence of SYNCOPE (Went black, did not lose consciousness, but hit the head on the tiles) in a 73-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 007B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Immune disorder (NOS) and Knee surgery NOS in 2019. Concurrent medical conditions included Macular degeneration. Concomitant products included ACETYLSALICYLIC ACID (BABY ASPIRIN), VITAMIN D3, MAGNESIUM and TURMERIC [CURCUMA LONGA RHIZOME] for an unknown indication. On 20-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 21-Mar-2021, the patient experienced FEELING COLD (Freezing) and FATIGUE (Tired). On 22-Mar-2021, the patient experienced SYNCOPE (Went black, did not lose consciousness, but hit the head on the tiles) (seriousness criterion medically significant), HEAD INJURY (Hit head on the tiles), GAIT INABILITY (Woke up and could not even walk), HEART RATE INCREASED (Heart was in a fast heartbeat), ASTHENIA (Weakness), SOMNOLENCE (Slept whole day) and DIZZINESS (Dizziness). At the time of the report, SYNCOPE (Went black, did not lose consciousness, but hit the head on the tiles), HEAD INJURY (Hit head on the tiles), GAIT INABILITY (Woke up and could not even walk), HEART RATE INCREASED (Heart was in a fast heartbeat), FEELING COLD (Freezing), ASTHENIA (Weakness), SOMNOLENCE (Slept whole day), DIZZINESS (Dizziness) and FATIGUE (Tired) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. This case was linked to US-MODERNATX, INC.-MOD-2021-056437 (E2B Linked Report).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. US-MODERNATX, INC.-MOD-2021-056437:Crosslinked case |

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| 1169065 | 4/5/2021 | MO | 39 | M | 4/5/2021 | 4/5/2021 | Nausea, flushing, dizziness, and syncope lasting about 15 minutes, patient was given water and an ice pack until symptoms subsided. |
| 1169090 | 4/5/2021 | KS | 36 | F | 4/5/2021 | 4/5/2021 | Patient experienced syncope, nausea, cold skin, pale, slow response but still conscious less than 5 minutes after receiving 1st dose of Moderna Covid 19 vaccine. EMS was contacted and arrived in about 5 minutes. Patient didn't need first aid response by pharmacy until EMS arrival. EMS personnel checked her vital signs (oxygen, blood pressure). Her blood pressure was 62/39 on first measurement. She was placed on stretcher. Her condition improved in several minutes. She was responsive and able to answer questions by EMS personnel. Her Systolic blood pressure went back up to 90 on 2nd measurement. She was taken out to ambulance to give her some fluid orally. Her husband stated that her condition was stable and she was able to go home with him without any needs to transport to hospital. She has history of anxiety attack, mild anemia, hypothyroidism. |

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| 1169097 | 4/5/2021 | CA | 52 | M | 4/1/2021 | 4/1/2021 | Pt got his first dose of Covid 19 vaccine with a Pfizer brand administered intramuscular at left arm at 01:11 PM. Pt sat down at 01:20 PM and pt verbalized that he is feeling light-headed/ dizzy. The EOA, RN stayed with the pt and asked admin to help patient lay on the floor. At 01:22 PM pt passed out. Admin placed pt laying on the floor with legs elevated and head on the side. Pt was unconscious with pulse and with breathing. Vital signs was checked BP 102/60 mmhg; PR 83 ppm; RR 18cpm, T 97.6 F, Oxygen sat 98% at room air, Blood sugar 128 as taken by RN. After 30 seconds pt regained consciousness, pt is alert oriented to self, time, place, date and location. Pt stated no complaints of chest pain or SOB. EOA assesses muscle strength in both upper and lower extremity and is 5/5. EOA assigned RN to continuously monitor pt every 15 mins until stable. Pt was advised to call family for us to inform and EOA highly recommended to have a family member stay with him. Admin called the wife and wife stated that she will here in an hour. Pt refused to call 911 as well but pt was advised to have a follow up appointment with primary care doctor. Pt stated he has an appointment the next day. Pt also stated he has no history of him passing out after any vaccination. Pt was transitioned from laying to sitting with latest vitals of 110/ 68mmh, oxygen sat 99% at room air, PR 72 ppm, RR 10, T 97.6 F. No complaints of dizziness. RN (EOA), and a admin stayed with the patient until family member arrives. By the time family member arrives, RN (EOA) discharged pt without any discomforts. |
| 1169156 | 4/5/2021 | VA | 19 | F | 4/5/2021 | 4/5/2021 | Patient didn't think she fainted. Thought she fell asleep. However, a customer saw her phone and personal items fall. She did state she has a history of fainting from taking blood, so it's possible she fainted. She was feeling light headed and woozy and her ears were ringing just before the episode. I asked her if she wanted me to call 911 and she said no because when it had happened in the past, she had been fine. I took her blood pressure and it was 95/52. She waited in the area till 12:25 and I took her blood pressure again and it was 115/60. She did not have any other incident. She left with her companion. I called her at 1:27p. She had arrived home and was still doing ok. |

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| 1169165 | 4/5/2021 | WI | 89 | M | 3/1/2021 | 4/2/2021 | Pt originally tested positive for COVID -19 10/19/2020. PT received both doses of the pfizer COVID-19 vaccine on 2/8 and 3/1. Pt was hospitalized on 3/31 for syncope with pacemaker implantation. Appeared to be asymptomatic for COVID-19, but had a positive SARS-CoV-2 PCR test on 4/1. |
| 1169218 | 4/5/2021 | NC | 23 | M | 4/1/2021 | 4/1/2021 | PT, A 23 Y.O, RECEIVED VACCINE IN LEFT DELTOID. UPON STANDING AND WALKING AWAY, PT ALMOST IMMEDIATELY FELL FACE-FORWARD AND SMACKED HIS FACE/HEAD ON A TALL WOODEN STOOL IN OUR PHARMACY. A FAMILY PHYSICIAN WHO WAS ACTUALLY PRESENT DURING THIS EVENT SAID THE FALL WAS MOST LIKELY DUE TO A VASOVAGAL RESPONSE (VASOVAGAL SYNCOPE). |
| 1167606 | 4/5/2021 | FL | 67 | M | 4/4/2021 | 4/4/2021 | Systemic: pt fell but was still coherent-Severe, Additional Details: pt fainted in lobby after receiving vaccine pt has chf, and dm with a recorded bp at the time of 102/70 event most likely caused by reduced bloodpressure leading to dizziness |
| 1169232 | 4/5/2021 | VA | 66 | M | 4/2/2021 | 4/3/2021 | 20 hours after receiving the vaccine, I got out of bed (~ 6 AM) to use the bathroom and while in the bathroom and on my feet, I fainted and fell to the floor. I came to a few moments later when I heard my wife calling my name. For the next two minutes or so I was very nauseous, but I did not vomit. The nausea quickly passed and there were no further fainting episodes or dizziness. I was a bit achy over the next 24 hours, but no further or additional symptoms to report. |

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| 1169244 | 4/5/2021 | ND | 29 | M | 4/5/2021 | 4/5/2021 | UPON RECEIVING THE IMMUNIZATION, PATIENT REPORTED FEELING LIGHT HEADED. HE WAS GIVEN WATER AND REMAINED SEATED. AFTER A COUPLE MINUTES HE BEGAN TO PERSPIRE AND WAS PALE. ROUGHLY 5-7 MINUTES AFTER RECEIVING THE VACCINE, THE PAINTED FAINTED AND DID NOT RESPOND TO HIS NAME FOR 90 SECONDS. HE DID ALSO HAVE SOME BRIEF SHAKING MOVEMENTS OF HIS ARMS. UPON WAKING UP, THE PATIENT REMAINED SWEATY AND PALE. HE WAS ASSESSED IN THE PHARMACY (LOCATED IN A HOSPITAL) BY AN EMERGENCY ROOM PHYSICIAN AND WAS CLEARED TO LEAVE WHEN HE WAS COMFORTABLE. |
| 1169034 | 4/5/2021 | OH | 21 | F | 4/5/2021 | 4/5/2021 | Approximately 10 minutes after vaccine administration the patient told her mother she was dizzy while sitting in a chair outside the pharmacy. I, the pharmacist, ran to the scene and the patient was regaining consciousness as I approached. Her skin was red, and she was disoriented for a moment before asking what had happened. Her mother state she began shaking, and her head slumped as she fainted momentarily. EMS arrived and determined the patient was well enough for her mother to drive her home. The patient reported nervousness, and stated before vaccination that she had dizziness and fainting with Guardasil, but that it did not occur until 3 hours after administration while she was at home. |
| 1167608 | 4/5/2021 | PA | 35 | F | 3/29/2021 | 3/29/2021 | nausea, chills, body ache, dizziness Got shot in the afternoon, nausea, chills and aches set in that evening. Nausea and chills worsened overnight. Got dizziness overnight and passed out. The next morning, chills and aches had passed. Nausea and dizziness had worsened. I passed out in my kitchen and hit my head. Went to the ER for a broken nose, possible concussion, staples in my skull and stitches in my chin from the fall. |
| 1169952 | 4/5/2021 | NC | 34 | M | 4/5/2021 | 4/5/2021 | patient fainted about 60 sec after the vaccine |

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| 1169264 | 4/5/2021 | MA | 66 | M | 4/1/2021 | 4/1/2021 | Approx. 5 min after receiving vaccine, patient lost consciousness, fell out of the chair and hit his head. Patient was moved to a stretcher and regained consciousness, was able to say where he was. HR and BP were low, patient given apple juice and water. When EMS arrived they gave additional fluid and patient was transferred. Patient was admitted to cardiology for observation, Cardiology diagnosed patient with syncopal episode 2/2 vasovagal reaction. Patient has history of vasovagal syncope related to needles. |

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| 1167466 | 4/5/2021 | TX | 32 | F | 1/12/2021 | 1/23/2021 | Fainted; Dizzy and lightheadedness; Arm was huge; Swollen at the injection site; Arm was red at the injection site; A spontaneous report was received from a 33-year-old female consumer who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced events fainted, dizzy, huge arm, red and swollen arm at the injection site. The patient's medical history was not provided. No relevant concomitant medications were reported. On 12 Jan 2021, at 05:00 pm, prior to the onset of the events the patient received their first of two planned doses of mRNA-1273 (lot batch: 025L20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 23 Jan 2021, the patient experienced delayed reactions where the patient fainted which is a medically significant event, while walking up the stairs and felt dizzy. The injection site was about 3 inches tall and 2 inches wide and raised which remained the same for about 4 days. The patient fainted again on Monday and felt dizzy and light-headedness at the time of report. Treatment medication included diphenhydramine cream for arm. Action taken with mRNA-1273 in response to the events was unknown. The outcome of the events fainted, dizzy, huge arm, red and swollen arm at the injection site was considered as unknown.; Reporter's Comments: This case concerns a 32-year-old female who had serious unexpected events of syncope and NS unexpected dizziness, peripheral swelling and expected vaccination site swelling, vaccination site erythema. Event onset occurred 12 days after the first dose of mRNA-1273. Treated with Benadryl cream. Event outcomes unknown. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. |

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| 1167480 | 4/5/2021 | NJ | 52 | M | 4/2/2021 | 4/3/2021 | Pfizer-BioNTech Covid-19 Vaccine. I received the 1st dose at approximately 11am on April 2nd. I went to sleep and woke at approximately 4am on April 3rd with a sharp pain/ache in my side. I went to the bathroom and began to experience chills and started sweating. I was sitting on the toilet and passed out. My wife heard me hot the ground and I came to. I had had another experience passing out while on the toilet a month earlier, for which I went to the ER and was discharged. Test run on the early occasion were all negative. I did not seek any medical attention immediately following this event but will be following up with my primary physician. |
| 1167506 | 4/5/2021 | CA | 28 | F | 4/4/2021 | 4/4/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Nausea-Mild, Systemic: Vomiting-Medium |
| 1167513 | 4/5/2021 | CA | 23 | F | 4/2/2021 | 4/2/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Pt recovered fully and was picked up by brother. |
| 1167514 | 4/5/2021 | CA | 29 | M | 4/4/2021 | 4/4/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Nausea-Mild, Additional Details: Patient fainted after receiving his first dose of COVID vaccine (Moderna). The patient woke up after a few minutes. He confirmed that he's okay, didn't hit his head, and had no difficulty breathing. He mentioned that he has fainted before after a vaccination due to nervousness. We gave the patient some water to drink and let him stay for an additional time for monitoring. |
| 1167516 | 4/5/2021 | CA | 29 | M | 4/4/2021 | 4/4/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Nausea-Mild |
| 1167524 | 4/5/2021 | CA | 19 | F | 4/3/2021 | 4/3/2021 | Site: Pain at Injection Site-Mild, Systemic: Fainting / Unresponsive-Medium, Systemic: Headache-Mild, Additional Details: Patient stated that she last ate around 10 am and had no extensive activity prior to vaccine at 6 pm. Per vaccinating pharmacist, patient had been fasting and fainted 5 minutes following vaccine administration. |

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| 1167545 | 4/5/2021 | KY | 78 | M | 4/2/2021 | 4/4/2021 | went to ED c/o chest pain, Pain was non-radiating, intermittent substernal aching. It improved with sublingual nitroglycerin and PO ASA 324mg. Mild SOB was noted. No syncope reported. After arrival to the ED and administration of the above meds, symptoms improved. This AM he described mild worsening SOB during his stress test and an episode of chest tightness shortly thereafter which has now resolved. He also reports anxiety about his stress test result. A 1/2019 stress test was a normal, low risk study. Today's stress test was read as an intermediate risk study with a medium-sized fixed perfusion defect suggestive of infarction, with associated mild hypokinesia. |
| 1167548 | 4/5/2021 | IL | 32 | M | 4/2/2021 | 4/2/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Tinnitus-Medium, Systemic: Visual Changes/Disturbances-Severe |
| 1167613 | 4/5/2021 | PA | 26 | M | 4/4/2021 | 4/4/2021 | Systemic: Confusion-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Vomiting-Mild |
| 1167595 | 4/5/2021 | NY | 35 | M | 4/4/2021 | 4/4/2021 | Systemic: Confusion-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Severe, Systemic: Hypotension-Severe, Systemic: Shakiness-Severe, Additional Details: Patient was lightheaded and fainted post vaccine. He was non responsive for a few seconds. 911 was called and EMS treated patient on site. Patient denied hospital visit. |
| 1168542 | 4/5/2021 | NY | 79 | F | 4/2/2021 | 4/3/2021 | The day after the vaccine I was tired, sleepy and "groggy". I went to the toilet and passed out after standing up and turning toward the sink to wash my hands. My husband (retired internist) heard a thump and found me on the floor. It took him calling my name 10 times before I woke up. My pulse was strong and heartbeat regular. I don't remember being dizzy or lightheaded, only remember going to the toilet and then waking up and wondering why I was lying on the bathroom rug. I would very much like to know if other people have passed out the day after getting the vaccine. |

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| 1167617 | 4/5/2021 | AL | 21 | M | 4/4/2021 | 4/4/2021 | Systemic: Fainting / Unresponsive-Medium, Additional Details: Patient passed out immediately after receiving vaccine. Woke up disoriented but became alert and aware within 2 minutes. Gave food and water and observed for 30 minutes. |
| 1167676 | 4/5/2021 | TX | 22 | M | 4/1/2021 | 4/1/2021 | I got the injection then went and sat down in a chair at the back of the room and started getting light-headed about 3 minutes after I sat down, so I called a nurse over. Then the inside of my chest started getting really hot and my vision started going white in both of my eyes, it took about 10 seconds for me to completely lose vision. Then I passed out, I have no idea how long I was out for but when I came too I had a sort of epileptic-type seizure but I do not know how long it lasted. I woke up completely disoriented, had no idea where I was at and had a severe cognitive dysfunction. I still have moments where I just can't follow or complete a thought or just kind of go blank. |
| 1167680 | 4/5/2021 | NC | 49 | F | 4/3/2021 | 4/3/2021 | Within a few minutes of receiving the shot I passed out and possibly had a seizure and threw up. |
| 1167824 | 4/5/2021 | MI | 42 | M | 4/2/2021 | 4/2/2021 | Patient suddenly became diaphoretic eyes rolled back in head, almost passed out . Onsite EMS was called vitals HR 42 BP 95/59 98% O2 refused glucose check. Patient felt better and reluctantly was transported to local hospital. No reaction to 1st vaccine on 3/12/21 |
| 1168075 | 4/5/2021 | MD | 16 | F | 4/5/2021 | 4/5/2021 | She almost fainted. BP dropped to 72/30. flushed pale skin. Pulse ox 96. Alert and felt dizzy throughout the stay. Paramedics arrived onsite and as requested by parents EMTs transported the client to the parents' vehicle. |
| 1168225 | 4/5/2021 | UT | 21 | M | 4/5/2021 | 4/5/2021 | Patient experienced vasovagal syncope. Treated conservatively with recumbent position and feet elevated. Awake and alert within 15 seconds. Observed for 30 minutes with no sequellae. Patient has history of syncope with IM injections. |

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| 1168273 | 4/5/2021 | WI | 19 | F | 4/1/2021 | 4/1/2021 | Approximately 15 minutes after receiving her vaccine, patient reported feeling "light headed". When I was called to help her, she had fainted. She was able to slowly respond to us and was breathing. We placed her on the floor laying on her side. A cold compress was placed on the back of her neck and a pillow was placed under her head. 9-1-1 was called. When EMS responded, she had normal blood pressure and blood sugar, but was still feeling "out of it". She was placed on a stretcher and taken to the ambulance, but did not get transported. She had a family member pick her up from the clinic. She was able to walk from the ambulance to the car on her own. |
| 1168276 | 4/5/2021 | MN | 38 | M | 4/5/2021 | 4/5/2021 | FAINTING AFTER RECEIVING DOSE OF PFIZER OCCURRED IMMEDIATELY AFTER ADMINISTRATION, PATIENT PASSED OUT IN CHAIR. THEN WAS MOVED TO THE FLOOR IN A PRONE POSITION WITH LEGS ELEVATED FOR 5-10 MIN. THEN MOVED TO SITTING POSITION WHERE HE PASSED OUT AGAIN. WE MOVED HIM BACK TO PRONE POSITION WHEN THE PARAMEDICS ARRIVED WE MOVED HIM TO A CHAIR WHERE HE PASSED OUT FOR A THIRD TIME. PATIENT DID REPORT SEVERE ANXIETY WITH VACCINATIONS AND HAPPENED TO PASS OUT WITH THE FIRST SHOT BUT DID NOT REPORT THIS TO THE PHARMACIST ADMINISTERING OR ON THE CONSENT FORM. |
| 1168353 | 4/5/2021 | NJ | 84 | F | 3/27/2021 | 3/30/2021 | On Saturday March 27, 2021 the patient was fine on the actual day of second shot which she received at approximately 11:30am. The next day she had a fever of 102, chills, body aches, and severe headache. Tylenol was given with little relief. Symptoms persisted until Monday morning and she reported feeling ?much better.? On Tuesday 3-30-21 at about 3pm she passed out n was taken to an urgent care center where a CT scan of the head was done and was negative. She was discharged to home. The next morning she felt ok but as the day went on she developed facial drooping and slurred speech. She was taken back to the ER and admitted where she remains. An MRI confirmed an ischemic stroke on 4-1 -2021 |

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| 1168411 | 4/5/2021 | SD | 23 | F | 4/1/2021 | 4/2/2021 | Patient passed out in morning |
| 1168420 | 4/5/2021 | OH | 38 | M | 4/2/2021 | 4/2/2021 | Pt passed out after receiving vaccine. He became pale in color and was talking. Wife provided Gatorade since we noticed he wasn't feeling well. Pt then laid back in the chair and became unresponsive, but still conscious. Pharmacy team, moved patient to the floor, where he immediately became responsive and color came back to skin. It is noted that the patient was sweating at the time of the event, and he stated he does not do well with shots. All of this took place within 15 minutes of receiving the Janssen Covid-19 vaccine. |
| 1168498 | 4/5/2021 | OH | 23 | F | 4/2/2021 | 4/2/2021 | Patient stated in VARS form that she "might" pass out after receiving shot. She said that she has anxiety when receiving vaccination shots. Patient received vaccine and about one minute later the patient passed out and fell forward. I was able to catch her and lower to the ground safely. I called for pharmacist on duty to assist in the care of the patient. Less than a minute after the patient passed out she was awake and alert. The patient was asked multiple times if she needed to go to the hospital and asked if she was okay to drive home. She insisted that she faints frequently from vaccines and denied any further care. She stayed in the waiting area while being checked on several times. The patient left after she said she was "100% good." She thanked us for taking care of her and apologized for what happened. |
| 1167553 | 4/5/2021 | NJ | 30 | M | 4/4/2021 | 4/4/2021 | Systemic: Fainting / Unresponsive-Medium |

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| 1170144 | 4/5/2021 | NY | 30 | M | 4/5/2021 | 4/5/2021 | CPT administered Janssen COVID-19 vaccine to the pt 4/5. While sitting in the pharmacy area for his 15 minute observation period, he fainted. He said that he was texting on his phone and the next thing he knew, he was on the ground with people around him asking if he was ok. He stated that he was very sweaty, nauseous, and a little dizzy. We called a code white, provided the pt with a cold compress and elevated his feet. Pt did not want us to call 911. Pt did not have PCP and has not been to a doctor in about 5 years. He said he was very nervous getting the shot and is afraid of needles so that may have contributed. Pt stayed in the pharmacy area for about 45 minutes until he started to feel better and his mom came to get him. I tried calling pt again at 7:10pm to check in, but there was no answer and I could not leave a voicemail due to mailbox being full. |
| 1169945 | 4/5/2021 | MA | 24 | F | 4/5/2021 | 4/5/2021 | PT received covid19 vaccine. PT had anxiety to needles, experienced vasovagal syncope. PT was immediately seen and treated by EMS and Fire/Rescue on scene. PTs condition improved over the course of 15 minutes. PT declined transport. PT was wheeled into the observation area for a remainder of 15 minutes. PT left observation area accompanied by mother. |
| 1169954 | 4/5/2021 | PA | 35 | M | 4/5/2021 | 4/5/2021 | Vasovagal syncope 5 minutes post vaccination. Patient regained consciousness in chair in observation room 2 minutes after fainting. Vital signs at baseline: blood pressure 59/34, heart rate 44, respiration 22. Vital signs at patient discharge 40 minutes later: blood pressure 105/80, heart rate 74, respiration 18. |

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| 1169283 | 4/5/2021 | MD | 20 | F | 4/3/2021 | 4/3/2021 | Following the vaccine, I was perfectly fine and was able to go about my day as normal. However, while doing dishes at 11:30 at night (about 10 hours after I received my second dose of the Moderna vaccine) exhaustion and dizziness suddenly hit me, and my vaccine went black and my ears started ringing. I managed to lie down but I fainted and blacked out for a minute. After I regained consciousness, I had these muscle contractions/shivers (although I took my temperature and had no fever). I felt really exhausted, and went to sleep after that. However, other than that I had no other vaccine side effects. I was told by my doctor to report this though since they had not heard of anyone else fainting, and I have no history of fainting (other than once following blood donation). I also was not thinking about anything remotely related to the vaccine at the time of fainting, and I had no qualms with being vaccinated so I highly doubt it was psychological, especially considering I have no history of fainting, and I had an injectable medication so I have no issues with injections. |
| 1170020 | 4/5/2021 | CT | 60 | F | 4/2/2021 | 4/4/2021 | Dizziness, passed out, diarea, throwing up, chills, headache, body aches |
| 1169916 | 4/5/2021 | VA | 43 | M | 4/5/2021 | 4/5/2021 | Patient passed out in their seat in waiting area. Struck back of his head on window behind him. Responsive after 20 seconds. Ambulance called to assess patient further. No treatment required and patient's wife drove him home. |
| 1170040 | 4/5/2021 | IA | 17 | F | 4/5/2021 | 4/5/2021 | Fainted for 2 seconds. Sweating. Pale lips but the color got back on after few minutes. Tingling. Could not lift up her arm (but could feel squeezing thumb). Shaken hands and feet. Lied down on the ground around for 10 minutes and elevated feet. Had her to keep breathing in/out. Kept drinking water and gave orange juice. Called 911. EME arrived and took care of patent. Pt didn?t want to ride on the ambulance and said fine. Was able to walk in the end. Left the scene with her mom. |
| 1170052 | 4/5/2021 | TX | 22 | F | 4/5/2021 | 4/5/2021 | Patient received the vaccine and upon standing fainted. She came to in about 30-45 seconds. EMS was called, pt was monitored for 45 minutes and released. |

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| 1170057 | 4/5/2021 | TX | 61 | M | 3/19/2021 | 3/19/2021 | 1307- I heard a car horn, located the patient in the driver's seat, put the car in park. Pt was completely passed out. He regained consciousness after approximately one minute after contact. Pulse weak at 68, I laid the seat back. Paramedics took over care. Unknown disposition by nurse, to her knowledge ambulance was not called. - RN |
| 1170062 | 4/5/2021 | IA | 24 | M | 4/5/2021 | 4/5/2021 | Had fainted for few seconds. Started to have seizures. Gave Epipen autoinjector. Called 911. EMS arrived. |
| 1170074 | 4/5/2021 | NM | 36 | M | 4/2/2021 | 4/2/2021 | Patient fainted and head slumped back and body went limp. |
| 1170119 | 4/5/2021 | NY | 74 | F | 4/2/2021 | 4/3/2021 | Nausea, sweating, chills, then fainted. Woke up on kitchen floor. Felt sick all day. Next day much better and able to eat normally. |
| 1169907 | 4/5/2021 | IL | 34 | M | 4/5/2021 | 4/5/2021 | Felt nauseous and out of breathe right away. Fainted and hit head on pavement within 15 minutes of shot. Admitted into ER with concussion and found bleeding in brain within 3 hours of shot. |
| 1170131 | 4/5/2021 | NC | 42 | M | 4/5/2021 | 4/5/2021 | Patient fainted about 2 minutes after vaccination. Was awake and alert within 2 seconds after fait and falling from observation chair. |
| 1169973 | 4/5/2021 | PA | 17 | F | 4/5/2021 | 4/5/2021 | Following the vaccine admin patient felt a wave coming over her and passed out she experienced tunnel vision and was clammy. She was placed on the floor and was then placed on a back board and taken to medical observation, patient wears a continuous glucose monitor and her mom reported that her bld glucose was 129, patients vital signs upon arrival was 120/65, P 71, O ₂ 98% on room air @ 10:35, at 10:40 her blood presure was 120/78. she was then placed in a sitting position and bp was 119/79 and then standing after 1 minute was 121/74- patient was released from observation via wheelchair she was taken to the exit with her mom and she exited the building. |

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| 1170150 | 4/5/2021 | OH | 17 | F | 4/5/2021 | 4/5/2021 | Pt had reaction in the waiting room. Pt became pale, diaphoretic, passed out and had brief seizure x 3-5 seconds. She suddenly became aware again with no recollection of what happened. She continued to be pale and diaphoretic and c/o confusion and blurry vision. Pulse ox 98-100, HR dropped to 40's and BP 90/60. Squad was called, they assumed care and transported pt to ER with her mother present. |
| 1170197 | 4/5/2021 | NV | 21 | F | 4/5/2021 | 4/5/2021 | Patient stated she felt like fainting post immunization. Pharmacists quickly grabbed adverse event protocol and followed directions as stated. Called code white on intercom to alert store management. Asked patient about symptoms and she reported symptoms of sweating, coldness, dizziness and nausea. Assessed patient blood pressure and asked patient if she wanted us to call 911. Patient did not want us to call 911. Patient never lost consciousness but had low blood pressure on initial reading. Instructed patient to lay down with feet elevated. We gave patient a pillow to assist in elevation of feet and gave her cold compresses to apply to neck and face. After a few minutes, patient blood pressure was normal and patient stated that she was feeling better. We requested that she sit for an addition 15 minutes before she can leave. After 15 minutes patient, patient was feeling ok and left with her boyfriend. She was exhausted from work and this was likely the main factor for the feeling of syncope. |
| 1170200 | 4/5/2021 | NH | 33 | F | 4/5/2021 | 4/5/2021 | Patient became dizzy and fainted |
| 1170224 | 4/5/2021 | NY | 36 | F | 4/5/2021 | 4/5/2021 | A few minutes after vaccination the pt had what appeared to be a seizure with momentary loss of consciousness. Profuse sweating, tunnel vision and syncope also present. EMS was called and patient was transported to hospital directly from the pharmacy. |

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| 1170290 | 4/5/2021 | FL | 54 | F | 4/5/2021 | 4/5/2021 | Administered vaccine at 12:40pm Pt during administration of vaccine started to pull away but full dose was administered, pt was nervous about the needle. After instructing pt to sit in the post vaccine chair for 15 minutes I noticed visible distress at around 12:50pm. I rushed to her aid and asked her how she was feeling and she reported feeling dizzy. I then helped her out of her chair onto the floor to ensure she would not fall and hit her head - told her to lay supine. I then asked my technician to give me the bp monitor. I then checked her bp and it was below 80/60. I informed her this could be contributing to her dizziness and then asked for consent to help raise her bp. She consented and then I told her I would be lifting her legs in the air to raise her BP. I held her legs in the air for 10 minutes or so and then reassessed her BP and it was 110/48. She started to feel better but reported feeling as if ants were all over her left arm which is where I gave her the vaccine. I assessed once again for angioedema, anaphylaxis, hives, redness, swelling, but didnt see anything. Since the pt was dizzy I did not offer her benadryl liquid but instead offered clairitin. The pt was merely having a panic attack post immunization and said she could swallow tablets and was feeling better. I gave her one clairitn tablet etc. She wanted to sit up so I assisted her to a sitting position while she was on the floor. She sat there for additional ten minutes then moved into a chair and was brought food by her husband because he said she did not have breakfast and thought that could be why she was dizzy. She was not a diabetic so I was not concerned about her BG. She said that this never happened in the past when I reviewed her PCQF form prior to giving her the vaccine. She has had zero history of syncope so this was rare for her. After an additional 10 minutes she had a bp reading of 98/60 and left the store feeling much better |
| 1170320 | 4/5/2021 | WA | 37 | M | 4/5/2021 | 4/5/2021 | Patient experienced vasovagal syncope approximately 2 minutes after receiving vaccination. Patient's spouse was with him with the anticipation of him having an event. He was pre-screened on our VAR. After it was determined that his experiences in the past were no longer an issue, we proceeded to administer the vaccine. He rested with cool compress and fluids for 30 minutes before leaving on his own accord. |

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| 1170332 | 4/5/2021 | NM | 25 | F | 4/5/2021 | 4/5/2021 | After getting the Covid imz (Janssen) pt felt like fainting, she layed on the floor for a few minutes, since she was feeling light headed. then she sat for several minutes, pt was conscioius at all times, she drank a little bit of water. Pt stayed for additional 15 min for observation. |
| 1170342 | 4/5/2021 | CA | 33 | F | 4/5/2021 | 4/5/2021 | around 5 minutes after vaccination patient fainted in our waiting area. The patient wife and myself we held the patient and laid him down on the floor and elevated his feet. patient woke up a couple minutes later. we called 911 by the time 911 showed up patient got better and left with her wife. |
| 1170355 | 4/5/2021 | CA | 33 | F | 4/5/2021 | 4/5/2021 | 1 minute after vaccine was administered I felt faint and fainted. Blood pressure remained low for 45+ minutes after. |
| 1170469 | 4/5/2021 | FL | 34 | M | 4/2/2021 | 4/2/2021 | Patient received vaccine and five minutes after injection he began to see dots, slowly progressed to the floor and passed out. Patient reports hitting his head. After recovering patient states he woke up with healthcare personnel making sure he was ok. He describes his experience as taking deep breaths, he felt chills, sweats and nausated. He refused further treatment. |
| 1170503 | 4/5/2021 | CA | 60 | F | 4/5/2021 | 4/5/2021 | Nausea - Not Diaphoretic Reports being "lightheaded" No Emesis No Syncope No rash Reports being cold Reports tightness in throat - EMS activated |
| 1170124 | 4/5/2021 | CO | 16 | M | 4/5/2021 | 4/5/2021 | Pt was sitting down, and mother was standing by patient. Pt fainted and fell out of chair, Did not hit head per mother. Patient was awake and aware right away and sitting up. EMS came to evaluate patient. |

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| 1169530 | 4/5/2021 | AL | 22 | M | 4/5/2021 | 4/5/2021 | Patient passed out, syncope episode while waiting in lobby after vaccine administration. Technician alerted pharmacist. Pharmacist immediately got red immunization emergency bag and approached patient. I introduced myself and prepared to activate the emergency response system (as recommended during CPR) but he had good pulse and respiration and immediately he spontaneously recovered! We asked him to stay to be observed and offered him some water and food. He accepted the water. We did a wellness check phone call with him later in the afternoon to confirm that he was doing well, and he was. |
| 1169343 | 4/5/2021 | WA | 34 | M | 4/5/2021 | 4/5/2021 | Patient passed out about 5 minutes after receiving the Janssen vaccine. Patient recovered after a few minutes and applied ice pack to left side of face that hit the ground. |
| 1169386 | 4/5/2021 | GA | 20 | F | 4/2/2021 | 4/2/2021 | Patient appeared to faint. She said everything became black and then she came to. She apparently passed out but recovered extremely quickly. This occurred within 5 minutes of receiving the immunization. We provided her orange juice and observed her for another 20 minutes. |

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| 1169398 | 4/5/2021 | DE | 48 | F | 4/5/2021 | 4/5/2021 | Pt received her 1st dose of Pfizer vaccine in her left deltoid. Pt came to the first aid area asking for a new bandaid, and stated that the bandaid was not covering over the injection site. Client fainted and this nurse assisted patient to the floor. This nurse called for additional support of workers to help assist patient to the first aid lying area. Vital signs were obtained at 1405 and are as follows: 96.6, 63, 143/88, 18, patient denied any pain. Pt reported that prior to fainting she felt dizzy and lightheaded. Pt reported daily medications are vitamin D supplement PO daily and metoprolol PO 10mg daily. PMH includes HTN. Pt was observed in the first aid area for an additional 30 minutes. Vital signs rechecked at 1424 and are as follows 97.1, 72, 112/73, and 17, no pain. Pt was assisted to an upright sitting position and provided a bottled of water after stating that she no longer felt dizzy or lightheaded. Pt was accompanied by her daughter who will be driving the patient home. Nurse assisted patient to schedule her 2nd appointment for 4/26 at 1pm, and daughter stated that she will be coming with her mother for the 2nd appointment as well. Patient was assisted to a standing position slowly and patient denied having dizziness or lightheadedness while standing. Patient exited the facility accompanied by her daughter at 1433, vital signs prior were within defined limits. |
| 1169413 | 4/5/2021 | CA | 52 | F | 4/2/2021 | 4/2/2021 | Arm soreness and presyncope immediate reaction. Severe Chills, Fever, Body aches, Nausea, headaches, dry mouth, mild cough nightmares onset delayed 12 hours and lasted 24 hours. Persisted with mild symptoms of aches, headache and vivid dreams x 3 days. I had Covid December 9, 2020 and it felt like that. |

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| 1169416 | 4/5/2021 | NE | 22 | F | 4/5/2021 | 4/5/2021 | Patient experienced fainting approximately one minute following administration of vaccine. Patient reported hearing ringing in ears prior to fainting. Patient did not fall or experience any physical injury during fainting episode. Patient returned to consciousness and reported feeling hot and sweaty. Patient consumed apple juice and was monitored for thirty minutes. Patient denied the need of emergency medical care and reported feeling better throughout the 30 minute monitoring and prior to leaving the facility. Patient was given a ride home with family members. Patient blood pressure prior to leaving the facility was 113/69 with pulse of 61. Patient denied feelings of dizziness, lightheadedness, ringing in ears and difficulty with breathing prior to leaving facility. |
| 1169447 | 4/5/2021 | WI | 58 | F | 3/31/2021 | 4/1/2021 | Muscle aches, fever, rash, fatigue, fainting, sweats, throat tightening for 30 minutes, vomiting, inability to lift arms, jaw pain. |
| 1169455 | 4/5/2021 | MO | 57 | M | 4/5/2021 | 4/5/2021 | 10 mins after receiving vaccine, pt fainted and fell out of chair |
| 1170030 | 4/5/2021 | GA | 40 | M | 4/3/2021 | 4/3/2021 | Fainted with cold sweats and chills |
| 1169508 | 4/5/2021 | CT | 32 | F | 4/5/2021 | 4/5/2021 | patient passed out and fell down on the floor . Patient was alert and oriented, no swelling of lips or tingling on tongue . We had called 911 they came and checked her vitals. |
| 1169890 | 4/5/2021 | AL | 26 | F | 4/5/2021 | 4/5/2021 | Patient has a fear of needles. After her injection, she tried to stand up to tell me she does not feel good but fainted before getting to the counter. She hit her head at some point. We gave her some water and called the paramedics. After checking her out she was instructed by the paramedics to go to hospital. She went to the student health center and given information regarding head injury. She later return to collect her Vaccine record card. |
| 1169554 | 4/5/2021 | CA | 64 | F | 3/23/2021 | 3/24/2021 | Nausea, dizziness, fainting x 3 weeks, "cyst in arm that something came out of, like a little ball, I pinched it to try to squish it, and it was hard". Per patient, arm then bled. |

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| 1169614 | 4/5/2021 | NY | 38 | F | 4/5/2021 | 4/5/2021 | Patient had Moderna Vaccine dose #1 administered and was waiting for approximately 15 min in the post vaccination area. She stated to the nurses in the area she was feeling light headed and dizzy @ approx. 12:23pm. Nurses arrived on scene with Emergency kit and stretcher. EMS called at 12:24pm by security team. Vitals 125/81 pulse 71. She appeared diaphoretic. Patient denied any type of anaphylactic reaction, denies any difficulty breathing, shortness of breath, fast heart rate, closing of the throat, itching or generalize rash. Denies any medical history, or current medications. Allergies to PCN (rash). States she has a history of vasovagal syncope in stressful situations. Vitals at 12:27pm 119/75 pulse 79 EMS arrived 12:34pm. Patient with stable vital signs, Alert oriented x 3. Upon arrival of EMS patient refused to be transported to hospital stating this has happened to her before. She denies any SOB, chest pain, palpitations, allergic reactions. She refused to have any friends or family members contacted stating she was ok. She was advised not to drive however she refused medical advice. No medications or supplemental oxygen was needed during this encounter. |
| 1169827 | 4/5/2021 | CA | 51 | F | 4/3/2021 | 4/3/2021 | Patient c/o chest tightness, audible wheezing with use of stethoscope, tongue appears to have mild swelling, patient restless, agitated and not following commands. Near syncope, did not go completely out. Epinephrine 0.3mg given IM in R thigh. Patient tolerated well. EMS initiated Epinephrine _ Lot number OFM502, Expires: 05/03/2022, NDC 49502 10201 |
| 1169476 | 4/5/2021 | MD | 26 | M | 4/5/2021 | 4/5/2021 | Pt. had an episode of fainting in the observation hall 5 mins after receiving the pfizer biontech covid-19 vaccine. he regained full consciousness after 15 seconds, was verbal. V/S - bp 131/87, rr 14, hr 64, temp 96.3, pulsox 99% RA. He was assisted to a wheelchair and wheeled to a cubiclePt where he was asked to lay down on a cot for further observation and monitoring Pt was offered water and apple juiced - 625 mls and he finished the fluids. The ambulance team called when the incident occurred arrived but left soon after when the pt. refused to be taken to the hospital At 2:35 pm pt walked out of the premises unassisted. no c/o pain or any injuries resulting from incident noted at the time. |

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| 1169843 | 4/5/2021 | | 29 | M | 4/5/2021 | 4/5/2021 | Pt passed out, fell to floor and hit right side of head. Tachycardia 250 pulse, vagal response low 80's at end of event. EMT called pt refused to go to hospital. |
| 1169635 | 4/5/2021 | WI | 17 | M | 4/5/2021 | 4/5/2021 | Patient passed out, complained of being lightheaded and having loss of vision post 2nd COVID-109 vaccine. EMS was called. EMS evaluated patient and recommended going to the hospital for observation. Patient's father denied transfer to hospital and patient left with father to go home. |
| 1169824 | 4/5/2021 | | 22 | F | 4/5/2021 | 4/5/2021 | Pt passed out, diaphoretic, anxious. Quickly came to. Left with mother to go to urgent care for evaluation. |
| 1169808 | 4/5/2021 | MO | 69 | F | 3/25/2021 | 3/25/2021 | Fainted 5 times in 1 hour starting 4 hours after receiving vaccine Fainted in bathroom and was injured. Called 911. Went to ER. Treated at hospital for 5 days - repeated fainting spells. Released 3/30/21, Remains very weak. |
| 1169779 | 4/5/2021 | MA | 56 | M | 4/5/2021 | 4/5/2021 | Pt received covid 19 vaccine. Few minutes later, pt was feeling dizzy and syncope. EMS responded to evaluate, however PT's condition was unchanged. Fire/Rescue was called in to assist. Fire/Rescue evaluated PT on scene at 17:25 hours. Pt declined transport. |
| 1169767 | 4/5/2021 | WA | 21 | F | 4/5/2021 | 4/5/2021 | Near syncope. |
| 1169747 | 4/5/2021 | WA | 41 | F | 3/25/2021 | 3/25/2021 | 12 minutes after getting the shot my heart started to tighten, I got a burning sensation down my shoulders, chest, neck and head. I felt like I was on fire. It went away and then came back. Went away and came back. I got light headed and passed out. I work up throwing up. I was taken to the ER. I was told I had a reaction to the vaccine. I?m still having symptoms and have a burning sensation off an on. |

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| 1169739 | 4/5/2021 | NY | 67 | F | 3/26/2021 | 3/30/2021 | Patient is a 67 yo F with PMH of HTN, HLD, depression/anxiety who presents with subjective fever & chills, bifrontal non-radiating HA, myalgias, non-productive cough, diarrhea since 2nd covid vaccine (03/26/21) x 4 days. Patient also endorsing SOB, chest pain only when coughing. No sudden vision changes, focal extremity weakness/numbness, syncope, palpitations, N/V, abd pain. No known prior DVT/PE, recent long distance travel/immobilization/hospitalization. +covid exposure (patient has had 23 family members die of covid). Patient endorses active suicidal ideation. Patient tested positive for covid after two doses of vaccine. Upon arrival to the hospital, patient was febrile to 38.1, hemodynamically stable, but hypoxic and placed on supplemental O2. Patient continued to require oxygen throughout hospitalization, administered remdesivir, anticoagulation and steroids. Patient discharge planning occurring. Patient will require oxygen upon discharge. O2 sat on room air at rest is 88%. Psych following patient. |
| 1169726 | 4/5/2021 | CA | 59 | F | 4/5/2021 | 4/5/2021 | Patient received 1st Covid vaccine on left deltoid muscle. Patient advise the need to wait 15 minutes for any adverse reaction. Patient verbalized understanding. Once patient was in the waiting room, she stated to the staff in the business office, she felt nauseated and dizziness and sat on the waiting floor per patient. provider was made aware. Patient was brought to patient room and was laid down on examination room Per patient she has history of fainting in the past but recently been fine. Vital sign as follow at 01:13 PM BP 128/67 HR 40 RR 16 SPO2 98%, vital sign repeated at 01:25 BP 131/72 HR 40 SPO2 96% RR 16 Per patient heart rate is always in the low side. Provider was made aware. At 01:36 patient stated she felt better, and vital sign take BP 136/75 HR 41 RR 16 Spo2 96%. At 01:41 vital sign as follow BP 128/74 HR 46 Spo2 97% RR16. Vaccination record card and Fact sheet for vaccine provided to patient. Patient monitor for 30 minutes no adverse reaction noted. Patient left clinic stable with steady gait. |
| 1169677 | 4/5/2021 | CA | 16 | F | 4/5/2021 | 4/5/2021 | Anxiety Felt like fainting Dizziness Tingling and cramping in hands Weakness EMT came to Observation area Vitals BP #1) 173/133 Pulse 86 O2 Sat 100% #2) 95/72 Patent refused transport to hospital |

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| 1169652 | 4/5/2021 | IA | 29 | M | 4/5/2021 | 4/5/2021 | Patient experienced episode of syncope |
| 1169854 | 4/5/2021 | NH | 39 | F | 4/5/2021 | 4/5/2021 | Pt was sitting in observation area and suddenly passed out and fell to the floor and hit her head. She stayed and received an ice pack, and once she felt better ended up leaving. We took her blood pressure and had her stay here for awhile. We also gave her some water while she waited. |
| 1166423 | 4/4/2021 | FL | 37 | M | 4/3/2021 | 4/3/2021 | JANSSEN COVID-19 VACCINE EUA I received the vaccine on 3rd April, 2021, at approximately 9:30 am. There were no immediate side effects. Approximately 10 hours later I began to feel EXTREME cold and chills. So much so that I had to put on 3 layers of clothing, socks and cover myself with 3-4 blankets. I also experienced a fever and body soreness. My wife tended to me with two ibuprofen tablets, 200 mg each and continually to put cold presses on my forehead. I drank a lot of water but my fever continued to spike to 102.8. The symptoms continued for another 3 hours. Out of concern we called the emergency room to ask if we should be concerned about the fever. We were advised to take two Tylenol tablets. My wife gave me two Tylenol PM tablets. About 30 mins after taking the Tylenol tablets and continuing to hydrate, my cold and chills began to subside and I began to shed all of my layers. About 30 minutes after that, my fever levelled out to about 100.8. Then I passed out. The following morning, I woke up with cold, chills and fever gone. I had a mild headache and took 2 Extra Strength Tylenol tablets. It's been four hours since then and I feel fine, just a little weak. |
| 1166534 | 4/4/2021 | NJ | 44 | M | 4/3/2021 | 4/3/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: After awakening patient said he felt like he couldn't breathe but was. EMS came to take him to the hospital. His parents who were with him said he does have anxiety around needles and may have a history of fainting with shots. |
| 1166527 | 4/4/2021 | NJ | 30 | F | 4/3/2021 | 4/3/2021 | Systemic: Fainting / Unresponsive-Mild |

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| 1166515 | 4/4/2021 | | 25 | F | 4/3/2021 | 4/3/2021 | Sweatiness and shortness of breath immediately after vaccination, stood up to go get snack & walked a short distance before getting blurred vision/ringing in ears and then fainted |
| 1166499 | 4/4/2021 | CA | 52 | M | 4/2/2021 | 4/2/2021 | Flushing/sweating, dizzy. History of fainting with shots. BPs 154/92, 121/74 (pulse 52). O2 sats 97%, 100%. |
| 1166494 | 4/4/2021 | NV | 34 | M | 4/3/2021 | 4/3/2021 | Fever of 101F-102.3F for 14 hours, onset 7 hours post-vaccination (given acetaminophen) Full body aches onset 7 hours post-vaccination, ongoing Fatigue, onset 7 hours post-vaccination, ongoing Nausea, onset 10 hours post-vaccination, sustained 4 hours Dizziness and pre-syncope, onset 3 hours post-vaccination, sustained for 20 hours |
| 1166488 | 4/4/2021 | TX | 28 | M | 4/4/2021 | 4/4/2021 | The patient passed out after receiving the vaccine. The patient received one dose of ammonium as the second time he passed out his eyes rolled back in his head. He has a history of fainting with vaccines. An ambulance was declined by the patient and the female who came with him. He was instructed to wait for 30 minutes at the pharmacy . A phone number was obtained to check on him later on. |
| 1166486 | 4/4/2021 | MO | 21 | M | 4/3/2021 | 4/3/2021 | Patient had vasovagal response. passed out in waiting area. Pt immediately laid on his back by pharmacist and another patient, legs were propped up and patient started to come to. He was aware of all surroundings and had no trouble breathing. no rash was noted and no other injection site reactions were apparent. |
| 1166460 | 4/4/2021 | CA | 41 | M | 4/4/2021 | 4/4/2021 | Patient c/o dizziness after vaccine was given. The same happened on his first dose. He was diaphoretic and passed out for few second. He was medically cleared to receive vaccine. He declined to be taken to the hospital. |
| 1166541 | 4/4/2021 | IN | 23 | M | 4/2/2021 | 4/2/2021 | A few hours after receiving the shot I started feeling extremely feverish with hot and cold chills throughout my body. Feeling on the verge of vomiting but with no nausea just occasionally dry heaving. I passed out around midnight and woke up feeling fine |

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| 1166427 | 4/4/2021 | WA | 25 | F | 4/2/2021 | 4/3/2021 | The whole night after the injection I was sweaty, couldn't get comfortable. Woke up feeling sore and dizzy with a terrible, painful headache. When I attempted to take a shower, I fainted for a few seconds and it was a struggle to move. Only felt comfortable when I was laying down. My muscles all felt painful and sore, had a painful headache, felt very disoriented and woozy. It was a struggle to walk or move, and couldn't talk loud or for a long time at once. Had to go home from work and spent the rest of the day sleeping. Around 4pm, 24 hours after the injection, my muscles felt less sore and was feeling better. The next morning, I was back to being completely normal. |
| 1165738 | 4/4/2021 | FL | 43 | M | 4/3/2021 | 4/3/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Shakiness-Medium, Additional Details: After patient had vaccine sat down, then felt light headed and broke out into a sweat. Pulse very shallow = 60bpm. Would get better than worse again. Called emt's, came w/i 15 minutes. Said had high bp, but on no meds. when emt's came he passed out and pulse down to 40bpm, emt's gave epinephrine. pulse back up to 60, put on stretcher, passed out again. Took to local hospital/ER |
| 1166403 | 4/4/2021 | MA | 72 | M | 3/13/2021 | 3/13/2021 | Evening of 3 March 2021 around 7 pm started to feel chills with fever and cold sweats. Left arm beginning to feel very sore at injection site. Drank water before retiring to bed. Woke up around 9 am and was not feeling well at all. Felt like heart was beating fast but was very light headed and nauseous. Next is very hard to describe, my wife and daughter found me passed out on the kitchen floor. This lasted approximately 20 minutes until EMT arrived. I do not remember anything from that point. EMT told me I passed out again while enroute to the hospital. Do not remember arrival to hospital nor admittance over night. |
| 1166218 | 4/4/2021 | MO | 62 | F | 4/1/2021 | 4/1/2021 | Vasovagal Syncope. Called 911, transported by ambulance to Hospital emergency room. |
| 1166029 | 4/4/2021 | ID | 22 | M | 4/4/2021 | 4/4/2021 | Hx of presyncope with needles who had recurrence of presyncope. Also had nausea and one episode of emesis. |

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| 1165935 | 4/4/2021 | MA | 27 | F | 4/3/2021 | 4/3/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium |
| 1165912 | 4/4/2021 | CA | 21 | M | 4/3/2021 | 4/3/2021 | Systemic: Confusion-Mild, Systemic: Fainting / Unresponsive-Medium, Additional Details: VS X 3- 1st BP 122/90, HR 100, RR 20, SATs 98% RA; 2nd bp126/92, hr 81, RR 18, O2 SATs 98 RA; 3rd BP130/82, HR 80, RR 20, O2 SATs 98% RA. delayed syncope episode < 5 minutes after IM injection, reported dream-like feeling before fainting, confused but recovered quickly. |
| 1165746 | 4/4/2021 | CA | 32 | F | 4/3/2021 | 4/3/2021 | Site: Swelling at Injection Site-Mild, Systemic: Patient fell off and fainted for 1 minute-Mild, Additional Details: EMT came and checked on her vitals. Everything was normal. Pt left and drove home safety |

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| 1165580 | 4/4/2021 | OH | 65 | F | 2/27/2021 | 2/28/2021 | I sat down on floor passed out for 5 mins; light headedness, dizzy; Sweaty; arm soreness; legs felt achy; A spontaneous report was received from a consumer who was also a 65-year old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced sat down on floor passed out for 5 mins/ loss of consciousness, legs felt achy/ pain in extremity, light headedness, dizzy/ dizziness, sweaty/hyperhidrosis, and arm soreness/ vaccination site pain. The patient's medical history was not provided. Concomitant medications included fluticasone propionate and salmeterol xinafoate and salbutamol. On 27 Feb 2021, prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 (Batch number: 025A21A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 28 Feb 2021, the patient had arm soreness and in night her legs felt achy. On 01 Mar 2021, the patient suddenly had light headedness, dizzy, and sweaty. The patient sat down on floor passed out for five minutes. The patient reported feeling better. Treatment for the events included Ibuprofen and paracetamol. Action taken with mRNA-1273 in response to the events was not provided. The outcome of the events, the patient sat down on floor passed out for five minutes was considered as resolved on 1 Mar 2021. The outcome of the events, the patient suddenly had light headedness, dizzy, and sweaty was considered recovering.; Reporter's Comments: This case concerns a 65-year-old female with serious unexpected events of loss of consciousness along with nonserious unexpected dizziness, hyperhidrosis, pain in extremity and expected vaccination site pain. Event onset occurred 2 days after the first dose of mRNA-1273. Treatment included Motrin and Tylenol. Events resolving. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. |
| 1167087 | 4/4/2021 | AZ | 60 | F | 4/2/2021 | 4/3/2021 | Fainted morning after 2nd Pfizer shot and needed 8 staples for gash on back of my head. Second day after shot I woke up with 102 fever and general malice. |

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| 1166429 | 4/4/2021 | SC | 65 | F | 3/27/2021 | 3/29/2021 | Woke up feeling very full. Didn't feel good when standing. Sat down and continued to feel bad. Stood up and started to walk to restroom and passed out. Was not unconscious as I was aware of family responses. Put a cold wash rag to forehead. Within a few minutes I felt fine. |
| 1167031 | 4/4/2021 | WI | 57 | M | 4/4/2021 | 4/4/2021 | Patient had syncope related symptoms. Main symptoms were dizziness and hot sweats. |
| 1165245 | 4/4/2021 | UT | 34 | F | 3/2/2021 | 3/2/2021 | Within five minutes I experienced a hot wave, rapid heart rate, syncope, dizzy, light headed, dip in pulse, headache, nauseous, chills, shaking, body ache especially back, fatigue, out of it/dreamlike, worse standing/sitting up. Was kept for monitoring at facility for three hours then sent home. Next day I had my opposite arm from the shot and neck itching, rash on chest. Felt ill for many days afterwards. |
| 1166559 | 4/4/2021 | IA | 22 | F | 3/25/2021 | 3/25/2021 | Patient fainted immediately following vaccine. She was seated and did not fall. She was unconscious for only a few seconds. The technician administering asked the pharmacist for help. The patient was given water to drink. She became nauseous and was given a trashcan to vomit into. She was vomiting on and off for about 20-25 minutes. The technician remained next to the patient to observe her in case she fainted again, but she did not faint again. The technician confirmed that patient's friend was driving her home and the pharmacist cleared her to leave after she spent a total of 30 minutes in the pharmacy. |
| 1167077 | 4/4/2021 | ID | 29 | M | 4/4/2021 | 4/4/2021 | Patient received vaccine at 2:20 PM and showed no symptoms initially. His wife was having syncopal symptoms and he helped care for her while paramedics were on their way. After they arrived he experienced lightheadedness and blurry vision. He was evaluated by they team and they determined the cause to be vasovagal syncope. He recovered and declined transport. He left on his own accord after 40 minutes feeling back to normal. |

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| 1167015 | 4/4/2021 | NC | 30 | M | 4/4/2021 | 4/4/2021 | Patient given 0.5ml dose of covid-19 vaccine by Janssen. Patient stated was scared of needles. He immediately stated he thought he was going to pass out. Patient passed for approximately 30 seconds and jerked/like a seizure then came back but still felt dizzy, passed out again and jerked came back but still felt bad, Patient stated he did not feel right was not wanted to lie down on floor. 911 was called made patient comfortable until EMT's arrived and patient was taken to ambulance and released. |
| 1166994 | 4/4/2021 | KS | 71 | M | 2/23/2021 | 3/20/2021 | 28 days (March 20th) following 1st Moderna shot which was given on Feb 23rd, felt dizzy, weak and lightheaded leading to fainting (syncope). Ambulance arrived and determined to take me to hospital after having 2nd syncope in their presence. Remained in hospital overnight. All vitals, heart and bloodwork were fine as seen by cardiac doctor and determined it was dehydration. Followed up with primary physician and told him I was urinating excessively. He put me on Flomax 0.4 mg. I had the 2nd Moderna shot on March 23rd and again was taken to the hospital on March 31st with same symptoms and near syncope and again was told it was clinical dehydration. They told me to drink a combination of pedialite and water which I have been doing and I am still experiencing the dizziness, lightheadedness and weakness. Woke up on April 4th and felt like my soul was being ripped from my body. I honestly thought I was going to die. Looked on line and found forums of people experiencing similar symptoms. Went to pharmacy and they recommended meclizine and have taken a clonipin for anxiety. I am feeling better now, but worried about how long I will be experiencing these symptoms. |
| 1166894 | 4/4/2021 | CA | 58 | M | 4/4/2021 | 4/4/2021 | Shortly after leaving the facility, after waiting the required 15 minutes post vaccine, I was driving back home on the freeway when I suddenly felt light-headed and as though all the energy had left my body (as though I was about to pass out). Then, without warning, I passed out, while driving on the freeway. Fortunately, I did not hit anyone, or was hit by anyone, and must have bounced off guardrails after crossing traffic twice and going off the freeway into the middle of an off ramp, where I finally came to. I did not suffer any injuries in the accident. |

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| 1166878 | 4/4/2021 | TX | 39 | F | 4/4/2021 | 4/4/2021 | Patient took the vaccine, was moved to the post vaccination waiting area. Patient had a fainting event approximately 5 to 6 minutes after the vaccine being administered. It was a sudden onset. |
| 1166877 | 4/4/2021 | CA | 41 | F | 4/4/2021 | 4/4/2021 | PATIENT STATED HAVING HISTORY OF FAINTING. UPON ASKING, PATIENT STATED FAINTING ON THE SIGHT OF BLOOD, AND SHE WAS NERVOUS. WITHIN 5 MINUTES OF THE VACCINATION, PATIENT WAS SHAKING AND WARM/ SWEATING. SHE WAS BREATHING WAS NORMAL. PATIENT SAT DOWN IN A CHAIR, WE GAVE HER SOME WATER AND AN ICE PACK. PATIENT THEN DECIDED TO LAY DOWN AFTER 5 MINUTES. HER HUSBAND WAS CALLED, SHE STARTED FEELING BETTER. SHE STAYED SITTING/LAYING DOWN FOR AT LEAST 30 MINUTES. PATIENTS HUSBAND TOOK HER HOME. |
| 1166854 | 4/4/2021 | MN | 67 | F | 3/11/2021 | 3/12/2021 | Moderna COVID-19 Vaccine EUA 7PM 3/11/2021 hands and body were very cold 2:30AM 3/12/2021 rose to use the bathroom. Felt dizzy and weak. Could not make it back to the bed. Felt like I was going to faint, so just laid down on the floor for 5 minutes. Got really hot and sweaty. 3/13/2021 extremely tired (30% capacity) and back ached 3/14/2021 felt fine Since I've had fainting issues in the past, I realized I had to get to the floor, but if I hadn't been aware of that, I would have fainted. I have to be careful with the Lisinopril because I get dizzy when I get up too quickly. I did not get up too quickly that evening, though. I rested on the bed before I tried to walk. I had hydrated a LOT that day as the nurse advised me to do. Because I get dizzy with viruses, I it didn't seem unusual for my body to respond this way, but I thought I should report this. |
| 1166817 | 4/4/2021 | | 74 | M | 4/1/2021 | 4/2/2021 | said woke up middle of night went to bathroom and passed out for a few hours. was weak for a few days, also a known diabetic and was unaware of BG at the time. |

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| 1166674 | 4/4/2021 | WI | 28 | F | 4/4/2021 | 4/4/2021 | vaccine was administered around 1115am patient was fine before and during vaccine. known history of fainting. after vaccine was administered patient was seated on chair for post vaccine observation and fainted. so signs or symptoms patient was going to faint. patient was alert and oriented within seconds. no signs or symptoms of any injury or severe reaction. |
| 1166791 | 4/4/2021 | IA | 23 | F | 4/1/2021 | 4/1/2021 | Pfizer COVID-19 Vaccine EUA Patient was in medical monitoring and started to wave nurse down. Stated she was feeling light headed. Got her in a wheel chair was hot sweaty and looking like she was going to faint. Got her jacket off and cooled down never fainted. Patient stated she ate lunch. Vitals. BP 116/68, pulse 88 bpm, pulse ox 97%, RR 16 brpm. Patient monitored and then discharged to home. |
| 1166789 | 4/4/2021 | OH | 25 | M | 4/4/2021 | 4/4/2021 | About 30 seconds after administering the vaccine the patient began to feel light headed. About a minute after the first symptoms started, the patient lost consciousness for about 20-30 seconds. I provided support for about 20 minutes and he recovered without complications. I walked with him to the store exit and he walked un-aided the entire way. Situation resolved without incident. The patient had also stated that he had fainted upon receiving another vaccine in the past (meningitis vaccine) he did not know which one. |

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| 1166781 | 4/4/2021 | OH | 42 | F | 4/2/2021 | 4/2/2021 | First day nothing really happened just I developed a Bad headache that I needed to sleep a little bit. Was a little bit weak. Did not take anything but felt hot but no fever. Second day I had to work so I woke up very early in the morning tried to go down to pick up some thing and I passed out. I waited 15 minutes and I tried to wake up back again wash my face and I close my eyes and your eyes and my blood pressure played around again and ran to the bed and went back to sleep. All through the day It was impossible for me to get up because of my blood pressure. I stayed sleeping all day almost was watching TV. I canceled school or work you can call it. Every time I would be watching TV I would be sleeping without knowing. So basically all throughout the day I fell asleep. I felt very weak And could not walk at all. The headache would not go away. I felt like I had a cold I felt hot but no fever at all throughout the whole day. My shoulder pain got really bad and my neck but then at the end of the night all that subsided and I got better that was way at night at 8 PM. I then went back to sleep Took a muscle relaxer to make sure that I would sleep throughout the whole night I woke up the third day and I still feel not myself but much way better. When I first got up it was very hard to walk but then I kept going and I survived lol. Just thought to share my story because my first vaccine was not like this at all actually the first date was the hardest for me for my first vaccine this time it was my second day for my second vaccine |
| 1166770 | 4/4/2021 | IA | 21 | M | 4/1/2021 | 4/1/2021 | Patient was in medical observation fell on floor and passed out. Moved back to cc part of building where we kept for 30 plus minutes. Asked patient if he hit his head he stated no- no neck problems just right knee was hit when he fell. BP 115/72 mmHg, pulse 72 bpm, pulse ox 99%, RR 16 brpm. Patient was monitored for 30 minutes and then discharged home. |
| 1166752 | 4/4/2021 | AZ | 27 | M | 4/3/2021 | 4/3/2021 | Pt fainted while waiting for 15 minutes after the vaccination was given |

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| 1166695 | 4/4/2021 | LA | 37 | F | 3/31/2021 | 4/1/2021 | Janssen COVID-19 Vaccine EUA 12 hours after receiving the vaccine (4/1/21 at 3am), I fainted and collapsed at home. Hit my head and landed on back. Had about a 2 second warning that I was going to faint. I felt perfectly fine prior to fainting. After fainting where I was unconscious for 15 seconds, I was dizzy. Today (4/4/21) - I am very tired and weak and have lower neck pain due to fall. |
| 1166596 | 4/4/2021 | | 28 | M | 4/4/2021 | 4/4/2021 | Patient experienced post-vaccination syncope within two minutes of receiving vaccine. Patient was sitting and got lightheaded and sweaty and fell out of chair. Patient denied any pain but was assisted to wheel chair and brought to medical observation tent where he was given juice and monitored for 15 minutes. Patient BP was checked twice (110/60 and then 102/64) with a heart rate of 86 BPM. Patient declined EMS eval and was sent home |

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| 1166645 | 4/4/2021 | NJ | 32 | M | 4/3/2021 | 4/3/2021 | Felt a bit odd on the couch, little shiver and what felt like adrenaline. I got up and went into the bathroom where the incident occurred. I used to be on 10mg of Ramipril years ago and moved to 5 due to light headedness when standing up. Yellow tinted vision, bright and sparkly. Getting up too fast with heart pressure meds prescribed for albumin /T1D and not for heart pressure. The secondary use of Ramipril is normal for type 1 diabetes after 20+ years. So I went to 5mg and haven?t had that issue since. I should also mention that when this used to happen to me I would lay down and recover with no problem. Back to the incident it felt exactly like that but on steroids. I was in the bathroom looking for Tylenol and I got light headed, yellow tinted vision, bright and sparkly, ringing in the ears, dizzy, and confused. I remember thinking I should probably get down on the tile floor and lay down like I?m used to from the episodes years ago with 10mg Ramipril causing the same symptoms but never anything so extreme. Next thing I know I?m on the ground waking up where I fainted and hit my head pretty hard on the way down. I probably have a minor concussion. Iced my head in the back where I hit it last night and this morning. Surprisingly 0 bumps, etc other than a little bit sore. Trying to remember going down is impossible. There is a strange, I guess it?s not strange as I fainted, but to me being 1 moment thinking what I should do then the next moment still thinking that same exact thing but coming to on the bathroom floor with parents yelling over top of me as I was at their house is strange. I recall what almost felt like a dream while I was out but I was wondering why everyone was asking if I was ok, of course I?m ok I thought. Then I realized what happened and crawled around on the floor the rest of the night if I needed anything and was checked every hour through the night which was horrible but necessary. Also my blood glucose was a 220 at the time of the incident according to my CGM so it didn?t have to do with low blood sugar. In any case I feel better today but in a fog with a slight headache. |
| 1166811 | 4/4/2021 | NY | 68 | M | 3/31/2021 | 4/1/2021 | Passed out . Went to hospital to be evaluated. Released. |

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| 1167100 | 4/4/2021 | ID | 25 | F | 4/4/2021 | 4/4/2021 | After vaccination the patient looked to be doing well, good color in the face and communicating freely. After providing the same immunization to her spouse she lost color in her face, began sweating, and became faint. She did not lose consciousness but was drowsy, diaphoretic, pale and stated she lost hearing for a couple minutes. I kept her awake and asked her questions to assess for alertness. She was aware of date, location, name, year. She was not improving after 5 minutes so paramedics were called to evaluate her. She was cared for by the paramedic team and recovered after 40 minutes. She was diagnosed with vasovagal syncope due to the vaccine. She refused transport to the ER and left of her own accord. |
| 1167254 | 4/4/2021 | TX | 21 | M | 3/23/2021 | 3/24/2021 | 8:00 woke up very tired and decided to stay in bed and rest. 11:00 When woke up again I felt sick to the stomach and had the urge to throw up. While rushing to the bathroom I lost consciousness and fainted. Hit my face against the tub and the wall. My nose was bleeding and went to the emergency room. 11:45 in the emergency room they took blood samples, a head scan and put me on an I.V. for 45 minutes. |
| 1167245 | 4/4/2021 | CA | 35 | M | 4/4/2021 | 4/4/2021 | PATIENT FAINTED AFTER VACCINATION. PARAMEDICS WERE CALLED AND PATIENT VITAL SIGNS WERE NORMAL. |
| 1167238 | 4/4/2021 | OR | 37 | M | 3/19/2021 | 3/19/2021 | Syncopy repeated twice after first initial collapse/fainting |
| 1167225 | 4/4/2021 | CA | 45 | F | 4/4/2021 | 4/4/2021 | patient received her moderna covid vaccination first dose in the consultation room (she had stated that she was nervous and wanted her husband to come in with her and I assured her it would be fine -she - was fine at first but a few minutes later she stated she was feeling nervous so I had her go and sit in the waiting area with her husband in case the consultation room was claustrophobic. a few minutes later the technician called me stating that she had passed out. I asked her to cAll 911 whilst I checked her breathing. she came around shortly thereafter and the paramedics arrived and attended to her - she had come Around by the time the pAramedics arrived, and wanted to go home They however advised her to go the ER, to get checked and she and her husband left with them |

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| 1167183 | 4/4/2021 | CA | 29 | M | 4/4/2021 | 4/4/2021 | After receiving the COVID vaccine, the patient was instructed to have a sit in the clinic for 15 minutes in order to be monitored for any adverse reactions. Within that time period, the other patients in the waiting area reported to the staff that the patient has fainted. The patient woke up shortly after fainting. He was visibly pale but he confirmed that he is okay and not in distress (no difficulty breathing, etc). He reported that he's fainted before after a vaccination due to nerves. We gave him some water to drink and had him stay for another 30 minutes so we can monitor him closely. After 30 minutes, we determined that he's well enough to leave the store and no other further care was needed at the time. |
| 1167131 | 4/4/2021 | FL | 31 | M | 4/4/2021 | 4/4/2021 | Passed out, low blood pressure, extreme sweating |
| 1167102 | 4/4/2021 | | 16 | F | 4/4/2021 | 4/4/2021 | Patient received Pfizer vaccine at 2pm, went to coffee shop, and then went out to car to wait. Became dizzy 5 minutes after coffee shop order. Patient fainted approximately 15 minutes after receiving pfizer vaccine on 4/4/21. Mom came into store to alert courtesy clerk, alerted pharmacy who brought E-kit out to car, brought patient into store to take blood pressure. Took patients blood pressure. ~83/63 mmHg pulse 109. EMTs were called and arrived within 5 minutes. EMTs arrived and stated vitals were normal but recommended mother take patient to be checked out by a doctor at a nearby hospital. Patient saw Dr who determined she can get the second dose, but must remain seated for 15 minutes after vaccination |
| 1163846 | 4/3/2021 | IL | 43 | M | 4/3/2021 | 4/3/2021 | Fainted about 7 minutes after receiving the vaccine. Came up to consciousness again after 1-2 minutes, but felt lightheaded and nauseas. Vomited 45 minutes after receiving the vaccine. |
| 1163802 | 4/3/2021 | CA | 16 | F | 3/30/2021 | 3/30/2021 | Syncope, dizziness. BP 55/30 (pulse 56). Final BP 111/54, 100% O2 sat. |

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| 1163770 | 4/3/2021 | IL | 29 | M | 4/2/2021 | 4/2/2021 | Patient fainted approximately three minutes after his vaccination. He regained consciousness immediately and we moved him to the floor with his feet elevated. We asked him a series of questions to assess his health. He was pale and sweaty but his blood pressure and pulse were stable. We monitored him for roughly 20 minutes after the incident while continuously checking his pulse and blood pressure. He denied any further intervention/assistance and insisted that he felt fine. He left on his own accord. |
| 1163741 | 4/3/2021 | MO | 70 | F | 4/1/2021 | 4/1/2021 | After shot was received went to have breakfast and then to grocery store. Came home and put a few things away and began to feel nauseous and a little dizzy so laid down. Needed to use bathroom so went into bathroom and became very dizzy. Attempted to make it back to bed and called for husband. Husband heard me yell and when he came to bedroom I was laying in floor passed out. He called paramedics and they came immediately. When I came to I had a feeling of extreme heat over my entire body and then broke out into a bad sweat (I was still lying in floor). After that I had a feeling of extreme heat (like fire) in my feet that rushed up to my calves. Paramedics checked me out and during that time I had I believe 2 more episodes of the heat and sweat. Paramedics stayed for maybe 20 minutes and I seemed to be okay. I did not go to ER. Remainder of Thursday I was dizzy when I got out of bed. Dizziness improved on Friday and was better by Friday evening. Still some dizziness today (Saturday 4/3) when I move around but not bad. Blood pressure has sometimes been a little low (105/68) but sometimes more normal (118/70). |

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| 1163566 | 4/3/2021 | CA | 40 | M | 3/20/2021 | 3/20/2021 | Patient came in to the clinic to receive his dose of the Janssen COVID vaccine. Within the 15 minute post-vaccine period, the patient reported feeling warm, sweaty, having clammy hands, and the feeling of almost "passing out". Patient was taken to a patient room to rest, vitals were taken at 13:16 PM with readings of BP: 91/57, HR 72, SpO2 98%, temp 98.5. Patient denies any past medical history, reports he only takes vitamin supplements, and denies any past history of anxiety. He denied any chest pain or SOB. Patient was provided water and was told to rest for a few minutes. Vitals at 1:42 PM were noted to be: BP 108/71, HR 72, SpO2 99%, and temp of 98.1. He says he feels much better and denies any symptoms at this time. ER precautions were given to the patient. Called patient again 4/2/21 at 09:59 AM - pt denies any ER visits, hospitalizations, or any visit to any other healthcare provider since his vaccine. The day after his vaccine, he says he developed a headache with left arm soreness (injection site was left upper arm) which was all improved by Monday, 3/22/2020. He says he took Advil, drank plenty of fluids, and rested for his symptoms of headache and arm soreness. He denies any other symptoms of near syncope after his near syncopal episode at the clinic. He denies any symptoms of fevers, CP, SOB, swelling, drainage, or pain at injection site, abdominal pain, dizziness, lightheadedness, or any other side effects/averse effects of the vaccine. He says he is doing well overall |
| 1163442 | 4/3/2021 | MD | 61 | F | 3/26/2021 | 3/28/2021 | I was having the stated symptoms of fever (102); chills, fatigue starting the evening after receiving the vaccine (3/26/21). Felt these symptoms all day on 3/27/21. Got up to go to the bathroom at 3:00AM on 3/28. Started feeling weird while going to the bathroom. Finished and tried to make it back to bed but passed out before I could get to the bed. This woke my husband up and he wanted to get me up but I could not--too weak. Laid on floor for about 30 minutes before I felt strong enough to get up with assistance. Pregnancy History: 1 Child (9lbs. 1ox.) via C-Section |
| 1163950 | 4/3/2021 | | 36 | M | 4/3/2021 | 4/3/2021 | Syncope, apple juice, observation, VSS, home care |

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| 1163393 | 4/3/2021 | MA | 69 | M | 4/2/2021 | 4/3/2021 | at midnight I felt queasy and very thirsty, trying to drink water, passed out momentarily and spilled water all over bedding. then felt buzzing and faint; fainted and crashed to the floor where I lay unconscious for a short time (up to a minute). regained consciousness and had pain in neck and left arm. |
| 1163460 | 4/3/2021 | TX | 63 | F | 3/5/2021 | 3/5/2021 | Extremely sore arm - I had to hold it as though in a sling for 2 days as letting the arm hang naturally was too painful. Vasovago occurred during the night during which I was nauseous, fainted and vomited. The injection itself was very painful (only the second one, not the first). I felt as though the doctor punched my arm. I still have a slight pain in my muscle several weeks later. |
| 1163862 | 4/3/2021 | SC | 29 | F | 4/3/2021 | 4/3/2021 | pt had shot, walked to waiting area, sat for a few minutes, then passed out very briefly (about 10 seconds). Came too and was fine |
| 1163894 | 4/3/2021 | NY | 65 | F | 4/2/2021 | 4/3/2021 | Fainted |
| 1164019 | 4/3/2021 | NY | 22 | F | 3/31/2021 | 3/31/2021 | Pt reports that she has a history of fainting whenever she gets vaccinated and it happened this time, too. She was wheeled to the EMS area via wheelchair, where she could rest for a period of time. She received a bottle of water and cookies and she felt better. |
| 1163948 | 4/3/2021 | MA | 24 | M | 4/3/2021 | 4/3/2021 | Vasovagal. Fainted, hit head. Small head laceration |
| 1163989 | 4/3/2021 | PA | 28 | M | 4/3/2021 | 4/3/2021 | pt was extremely anxious about getting the vaccine. pt was fine during the administration. 5 minutes after pt sat in the observation area he felt light headed and clammy . we eased him down to the floor before he passed out. We then put ice packs around his neck and hand. he came too and after resting for 15 minutes in a supine position he had some water and seemed to feel better and left on his own accord. |

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| 1164014 | 4/3/2021 | CA | 31 | M | 4/2/2021 | 4/2/2021 | Pt presents with syncopal episode 5 minutes post vaccination of 1 dose Janssen vaccine to left deltoid. Pt was in his vehicle when he started to feel lightheaded and had +LOC. His girlfriend who was sitting next to him states that he was unconscious for about 15 seconds before regaining consciousness. He had no head injury or other trauma. On immediate evaluation he is conscious and endorses diaphoresis and lightheadedness. He states that he has had similar episodes of syncope in the past following vaccinations. He denies medical problems, medications, or any Hx of allergies. Pt denies swelling of the face, throat tightness, difficulty swallowing, itching of the skin, SOB, CP, nausea or vomiting. Following evaluation by EMS, Pt refused medical transport and signed out AMA. Pt felt improved and was driven home by his girlfriend. |
| 1163320 | 4/3/2021 | NH | 62 | F | 3/30/2021 | 3/31/2021 | Awoke the next day, drank water, immediate lightheadedness led to syncope (likely vasovagal) and emesis, diaphoresis, followed by several hours of chills. Local erythema, edema and pruritus distal to injection site appeared several days later (also following first injection on right arm) lasting about one week. Treatment: bed rest, benadryl, hydrocortisone |
| 1163167 | 4/3/2021 | NC | 26 | M | 4/2/2021 | 4/2/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild |

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| 1164029 | 4/3/2021 | CA | 26 | F | 4/3/2021 | 4/3/2021 | Patient is a 26 year old female who presents immediately following administration of a single dose of J&J COVID19 vaccine in the left deltoid. Patient was walking with her mother to their vehicle when she lost consciousness. Per patient?s mother, the patient has a developmental delay and can be a poor historian. Patient states that she has never experienced syncope. She denies allergies to medications and foods. She has never had a vaccine in the past. Patient denies a medical history. Patient states that she takes Concerta and Lexapro on a daily basis. She denies chest pain/tightness, shortness of breath, wheezing, swelling of the face/lips/mouth/tongue/throat, skin rash/itching, cramping abdominal pain, nausea, and vomiting. Vasovagal syncope with loss of consciousness. Patient not displaying active signs and symptoms of anaphylaxis. Patient was transferred to a cot and very quickly regained consciousness. Patient was A&O x 4 and in NAD. EMS was called to the scene for further evaluation due to limited resources. EMS called to the site for further evaluation due to vasovagal syncope with loss of consciousness. EMS related patient was experiencing orthostatic hypotension. EKD and blood sugar levels were within normal limits. Patient transported to ER. |
| 1163926 | 4/3/2021 | TX | 21 | F | 3/31/2021 | 3/31/2021 | 12 hours after injection there was increase swelling around the injection site and spreading into the Lt shoulder and upper back. Nausea, tightness in left neck and left upper back with swelling. Went to bed with ibuprofen and ice on swelling. Woke up 18 hours (5am) feeling sweating, difficult breathing, chest was tight with more swelling in left arm and left upper back. Got up to ask for help and fainted. Called father, mother we checked blood pressure was low (98/40), and was heart rate was low (46). Got her sitting up and blow pressure and heart rate returned to normal. |
| 1163173 | 4/3/2021 | FL | 39 | M | 4/2/2021 | 4/2/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient passed out. Patient was responded to immediately. Blood pressure was checked and 911 was called. EMS evaluated patient and determined that the patient is okay. |

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| 1163625 | 4/3/2021 | | 38 | M | 4/2/2021 | 4/2/2021 | Patient experienced post-vaccination syncope and fell out of chair. Patient denies any pain and/or injuries. EMS was called. BP was within normal limits before EMS arrival. Patient declined juice and crackers and walked to medical tent with EMS. Patient was sent home with spouse. |
| 1164038 | 4/3/2021 | NY | 30 | M | 3/31/2021 | 3/31/2021 | Pt has a history of vasovagal responses after medical procedures - which he did not admit to until after he had been vaccinated. He has a very brief episode of syncope at the station where he received his vaccine. He was assisted via wheelchair to the EMS station and was monitored for 30 minutes. His father was with him because of his history and both agree that he will be given his second dose while laying on a cot. |
| 1162357 | 4/3/2021 | IN | 67 | F | 2/11/2021 | 2/25/2021 | Faint; Had vertigo; decreased blood pressure; increased heart rate; A Spontaneous report was received from a consumer concerning, a 67 years-old, female patient, who received Moderna COVID-19 vaccine (m-RNA-1273) and experienced vertigo and fainted/syncope. The patient medical history was not provided. No relevant concomitant medications are provided. On 11 Feb 2021, approximately 15 days prior to the onset of the events the patient received their first dose of mRNA1273(lot/batch: 030L20A) intramuscularly for prophylaxis of COVID-19 infection. On 25 Feb 2021,the patient experienced the events of vertigo, fainted, heart rate increased, and low blood pressure. The patient reported that she took blood pressure medicine and was normal now. Action taken with mRNA-1273 in response to the events was not reported. The outcome of events, faint, and vertigo, were unknown.; Reporter's Comments: This case concerns a 67-year-old female who experienced a serious unexpected event of syncope along with nonserious events of unexpected vertigo, decreased blood pressure and increased heart rate. Event onset occurred 15 days after the first dose of mRNA-1273. Treatment not reported. Event outcomes unknown. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded |

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| 1162365 | 4/3/2021 | NC | 30 | F | 3/18/2021 | 3/18/2021 | <p>Looked awful; Almost passed out; Vision was gone; Ringing in the ears; Clammy; Dizziness; Severe fatigue; Low grade fever; A spontaneous report was received from a consumer concerning for herself, a 30-year-old, female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced almost passed out/ Loss of consciousness, low grade fever/ Pyrexia, severe fatigue, dizziness, vision was gone/ Visual impairment, ringing in ears/ Tinnitus, clammy/Cold sweat, Looked awful/ Feeling abnormal. The patient's medical history included she had undergone 2 open heart surgery and was on blood thinners. Concomitant medications include blood thinners. On 18Mar2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Batch/Lot number: 037A21B) via an unknown route for prophylaxis of COVID-19 infection. On 18Mar2021, patient felt low grade fever. On 19Mar2021, patient had severe fatigue, dizziness and both were ongoing. On 20Mar2021 the patient stated that she almost passed out, my vision was gone, ringing in the ears and clammy (lasted 20 mins). On 22MAR2021 the patient was sent home from work because she looked awful. The event almost passed out was considered as medically significant. Treatment for the events was unknown. Action taken with mRNA-1273 in response to the events was Unknown. The outcome of the event low grade fever was resolved on 18Mar2021. The outcome of the events, almost passed out, vision was gone, ringing in ears and clammy, were resolved on 20Mar2021. The outcome of events severe fatigue, dizziness was not recovered. The outcome of the event Looked awful was unknown, at the time of this report.; Reporter's Comments: This case concerns a 30 Y/O F with PMH cardiac surgery, had a serious unexpected event of loss of consciousness and nonserious unexpected dizziness, feeling abnormal, tinnitus, cold sweat, visual impairment and expected pyrexia and fatigue. Event onset Day 5 after first dose mRNA-1273. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.</p> |

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| 1162487 | 4/3/2021 | FL | 42 | F | 3/15/2021 | 3/1/2021 | like blurry vision and then she lost her senses/loss of consciousness (fainting)/passed out; like blurry vision and then she lost her senses/loss of consciousness (fainting); tachycardia; mental confusion; loss of sphincter control (urinary incontinence)/pissed on herself; diarrhea; This is a spontaneous report from a contactable consumer (patient). A 42-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration administered on arm left on 15Mar2021 13:15 (Batch/Lot number was not reported) as SINGLE DOSE for COVID-19 immunization at the pharmacy. Medical history was not reported. There were no concomitant medications. The patient was not pregnant (including at the time of vaccination). On 16Mar2021 13:15, she came around to feeling really something bad in her body. She described this as she had loss of consciousness (fainting) which started to feel like blurry vision and then she lost her senses. She then passed out for 5-8 minutes and she had loss of sphincter control (urinary incontinence) as she pissed on herself. She also had tachycardia and mental confusion by that time. They called an ambulance and she was brought to the emergency or urgency department/room. The events [loss of consciousness (fainting), loss of sphincter control (urinary incontinence), tachycardia and mental confusion] were considered as serious (medically significant). She also had several diarrhea (noted in 2021) episodes during one week. She had no COVID prior vaccination and not tested post vaccination. She would like to know if the reaction that she had with first dose vaccination was normal as she was afraid of the second one. The patient did not receive any treatment for the events of loss of consciousness (fainting), loss of sphincter control (urinary incontinence), tachycardia and mental confusion. Outcome of the event of diarrhea was unknown while recovering for the remaining events. Information on the lot/ batch number has been requested. |

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| 1162489 | 4/3/2021 | | 58 | M | 3/19/2021 | 3/19/2021 | <p>Syncope episode; Lightheaded; This is a spontaneous report from a non-contactable nurse. A 58-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 1 intramuscularly on 19Mar2021 at 13:00 (01:00 PM) (Batch/Lot Number: ep6955) at the age of 58-years-old as single dose for COVID-19 immunization. The patient was vaccinated at a hospital. There was no other vaccine in four weeks. The patient's medical history and patient's concomitant medications were not reported. The patient experienced lightheaded/syncope episode on 19Mar2021 at 13:15 (01:15 PM). The events resulted in emergency room/department or urgent care. It was unknown if the patient received treatment for the events. The patient had no COVID prior to vaccination and has not been tested for COVID post vaccination. The outcome of the events was unknown. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Based on the information currently available, a possible contributory role of the suspect drug in the reported event syncope episode cannot be completely ruled out given the known suspect drug profile and/or implied temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p> |

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| 1163045 | 4/3/2021 | TX | 26 | F | 4/2/2021 | 4/2/2021 | Patient, received immunization, proceeded to post-immunization section for 15 minute observation. RN and EMT personnel noticed that individual appeared to lean in chair and then leaned forward as if experiencing dizziness. RN approached individual at which time she appeared to be on verge of fainting, and sounded incoherent, her pulse was at 45, and she was dizzy, at which time an Epinephrine pen was utilized. As patient became more coherent she indicated she felt nauseous and proceeded to vomit. She was monitored by EMT and RN for about 30 minutes and was offered further medical assistance which she declined. Patient indicated that she had history of experiencing dizziness after a previous TB immunization. |
| 1163176 | 4/3/2021 | FL | 39 | M | 4/2/2021 | 4/2/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient passed out. 911 was called. Blood pressure was checked. EMS arrived and determined that patient was okay. |
| 1163164 | 4/3/2021 | NY | 35 | M | 4/2/2021 | 4/2/2021 | Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Additional Details: Patient fainted and hit his head on the way down. Was unresponsive for <10 seconds and came to then was able to sit up and hold a conversation. Had 2 orange juice bottles and patient communicated that this was a known issue with needles. |
| 1163279 | 4/3/2021 | NJ | 26 | F | 4/2/2021 | 4/2/2021 | Systemic: Fainting / Unresponsive-Severe, Additional Details: Before vaccination, patient briefed pharmacist regarding very probable likelihood of fainting. Per patient's own account, this event occurs very frequently when receiving vaccines. Pharmacist understood and with consent of patient continued vaccination. Within a minute after administration patient did pass out into catatonic state, followed by epileptic-like convulsions. RPh provided physical support with patient as she was convulsing out of chair and onto floor. Convulsions ended within 2 minute |

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| 1163178 | 4/3/2021 | WA | 33 | F | 4/2/2021 | 4/2/2021 | Systemic: Allergic: Difficulty Breathing-Mild, Systemic: Abdominal Pain-Medium, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Severe, Systemic: Hypotension-Medium, Systemic: Nausea-Severe, Systemic: Numbness (specify: facial area, extremities)-Medium, Systemic: Stroke-Mild, Systemic: Tingling (specify: facial area, extremities)-Medium, Systemic: Vomiting-Mild |
| 1163181 | 4/3/2021 | PA | 32 | M | 4/2/2021 | 4/2/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Mild, Additional Details: PT WAS IN AISLE FOR MONITORING ADRS FOR 3-5 MINS AFTER SHOT. HE WAS SEATED AND PASSED OUT FALLING FACE FIRST OFF HIS CHAIR. HE REGAINED CONSCIOUSNESS AFTER 10-15 SECS AND SAT DOWN AGAIN BY HIMSELF. WE TOOK BP READINGS OF 80'S/60'S, 90'S/70'S. HE AGAIN LOST CONSCIOUSNESS WHILE SEATED AND LEANING FORWARD TOWARDS HIS WIFE. HE AGAIN REGAINED CONSCIOUSNESS IN 10-15 SECS. HE NOTED ONLY DRINKING A COFFEE TODAY. HE REMAINED SEATED IN THE STORE FOR ANOTHER 20-30 MINS AND BEGAN TO FEEL BETTER. |
| 1163210 | 4/3/2021 | CA | 20 | M | 4/2/2021 | 4/2/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Flushed / Sweating-Mild, Additional Details: approx 2-3 mins post vaccine states feeling hot, sweaty, and anxious. States previously fainted after injection. 1458 Assisted to lie on carpet in vaccination area. legs elevated on chair. States feeling better now. 1510 BP 117/74, P 93. Lungs clear to auscultation. Heart rate reg. No edema, pain or redness at vaccination site. enc to drink water. 1515 Assisted to sit in chair x 10 mins. 1526 Amb. in store. 1535 States he will leave to go home now. Home in stable condition. |

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| 1163234 | 4/3/2021 | CA | 44 | M | 4/2/2021 | 4/2/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Additional Details: Patient received a pfizer covid19 vaccine and sat on the floor during the monitoring period due to dizziness. Patient was given a bottle of water and reported fainting briefly before resuming consciousness. Patient waited at the pharmacy and was given a protein bar and gatorade to help because he reported not eating or sleeping. Blood pressure was taken and was 155/75 mmHg which then decreased to 119/82 mmHg a few minutes later and then normalized to 121/82 before the patient left. Full recovery |
| 1163235 | 4/3/2021 | PA | 19 | F | 4/2/2021 | 4/2/2021 | Systemic: Abdominal Pain-Medium, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Severe, Systemic: Nausea-Severe, Systemic: Visual Changes/Disturbances-Severe, Systemic: Vomiting-Severe |
| 1163242 | 4/3/2021 | PA | 58 | M | 4/2/2021 | 4/2/2021 | Systemic: Chills-Mild, Systemic: Confusion-Severe, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Severe, Systemic: Hypertension-Severe, Systemic: Hypotension-Severe, Systemic: Nausea-Mild, Systemic: Shakiness-Medium, Systemic: Visual Changes/Disturbances-Severe, Systemic: Weakness-Mild |
| 1163261 | 4/3/2021 | IL | 27 | M | 4/2/2021 | 4/2/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Headache-Medium, Systemic: Seizure-Medium, Systemic: Shakiness-Medium, Additional Details: unconscious for less than a minute.Has a history of fainting from many years ago but no incidents since.Epi pen given 4:10p and 911 called. Paramedics arrived ~4:18p.Bp was 110/80 @4:13p, 128/88 @ 4:18p, 132/86 (pulse 70) @4:21p.Was clammy, shaky, sweaty,and had a headache post.Paramedics monitored sitting and standing.Advised to followup with physician. |

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| 1163271 | 4/3/2021 | WI | 21 | F | 4/2/2021 | 4/2/2021 | Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Mild, Systemic: Tingling (specify: facial area, extremities)-Mild, Additional Details: Patient fainted shortly after injection. She recovered quickly, but felt confused, sweaty, and tingling in her arms after. She felt better after about 15 minutes, but we had to stay to observe for 30minutes after. She was feeling better by the time she left the store. |
| 1163161 | 4/3/2021 | GA | 92 | F | 4/2/2021 | 4/2/2021 | Systemic: Allergic: Difficulty Breathing-Medium, Systemic: Confusion-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Nausea-Medium, Systemic: Vomiting-Medium, Additional Details: Patient recieved vaccine and was helped to observation area. About 3-5 minutes after vaccination the patient told her son that she felt hot and then her head slumped forward. She became unresponsive to verbal/ physical stimulation. Patient vomited and would have fallen out of her chair if she had not been caught. She also made some noises from her throat that sounded concerning. EMS was immediatly called and epinephrine administration was attempted. Epi not given. Pt recovered and taken to ER. |
| 1164928 | 4/3/2021 | PA | 24 | F | 3/14/2021 | 3/15/2021 | I passed out in my bathroom the morning after the vaccine shot around 5:30am. I called the doctors and they said that was unrelated to the vaccine, but I had intense dizziness and tinnitus before I passed out. I was incredibly fatigued all day long for the rest of the day and had a migraine - both to be expected. However, I am 3 weeks post-vaccine (April 3) and have been having intense muscle cramping and fatigue in my legs during exercise. I wake up with muscle soreness that goes away throughout the day and then comes back during exercise. |
| 1164740 | 4/3/2021 | WI | 56 | F | 4/3/2021 | 4/3/2021 | fainting spells (feeling warm/hot and dizzy) 5 minutes post vaccination no loss of conciousness she was alert and coherent the whole time. treatment done placed on supine position with elevated legs- Felt a lot better few seconds after. Prior to vaccination she verbalized she is scared of shots |

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| 1164789 | 4/3/2021 | WI | 25 | M | 4/3/2021 | 4/3/2021 | Patient fainted. When I arrived patient was awake. He drank some orange juice and relaxed for about 30 minutes. Patient felt better and went home. |
| 1164794 | 4/3/2021 | NH | 26 | M | 4/3/2021 | 4/3/2021 | Shortly after injection, pt developed dizziness/near syncope. He was noted to be very pale and was reclined in his chair. He improved after appx. 5 minutes and symptoms resolved. BP 110/80, HR 72, 99%. No signs to suggest anaphylaxis. He felt completely back to normal when he drove home. Symptoms likely consistent with vasovagal response from injection. Pt notes he did not eat much during the day |
| 1164798 | 4/3/2021 | CA | 55 | F | 4/1/2021 | 4/1/2021 | Syncope, initial BP 220/126 (pulse 120). F/u BP 163/101 (pulse 74). |
| 1164803 | 4/3/2021 | FL | 36 | M | 4/2/2021 | 4/2/2021 | FAINTED AFTER FIVE MINUTES AFTER RECEIVING VACCINE. LAYED ON FLOOR. CALLED 911. |

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| 1164804 | 4/3/2021 | MN | 38 | M | 4/2/2021 | 4/2/2021 | While sitting down during the post-vaccination period, patient asked his wife for water about 10 minutes after receiving vaccine. Pharmacy staff provided water and pharmacist went over to check on the patient. Patient expressed feeling "hot" and wanted an ice-pack, which was given. Patient expressed feeling "faint," after which he briefly lost consciousness. Pharmacist immediately started checking for pulse and obtained Emergency Kit. Patient regained consciousness quickly without need of CPR or administration of Emergency Kit medications. At some point patient also released his bladder, most likely during the syncope episode. Patient expressing feeling "nauseous" and asked for something to throw up in. Pharmacist quickly got a trash can and gave to patient, shortly after which patient started vomiting. Pharmacist was attending to patient and asked patient if he wanted 911 to be called, to which he replied "No" and that he just needed some time to sit. Patient also stated he did not eat much that day. Pharmacist offered Pedialyte, to which patient agreed, in order to replenish fluids/electrolytes lost due to vomiting. Patient also asked for some crackers since he did not eat much earlier. After taking sips of Pedialyte and taking bites of crackers, patient could not hold anything down and continued to vomit. At that time patient's wife asked pharmacy staff to proceed with calling 911. 911 was called and paramedics took patient's vitals upon arrival at the scene. Vitals were all stated to be normal. Patient agreed to be taken by ambulance to the hospital. A couple hours later patient's wife informed pharmacy staff that patient was doing much better and was expected to be released from hospital soon. Before receiving vaccination, patient did share that in the past he had "felt faint" when giving blood but it was not made clear that patient had felt faint or fainted during vaccinations prior. After the incident patient's wife confirmed that patient had fainted in the past both after giving blood and after receiving vaccinations. Pharmacist called patient at 9:12 AM the following day (4/3/21) to see how patient was doing but was only able to leave a voicemail message. |

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| 1164805 | 4/3/2021 | VA | 43 | F | 4/3/2021 | 4/3/2021 | Patient felt dizzy during 15 minute wait time after given Janssen COVID19 vaccination and wanted to lay down on the floor but stressed that she was fine and just needed some water. Patient was not feeling better after 15 minutes so 911 was called at 4:59PM and a member of management was called for a Code White to report to the pharmacy. The Rescue Squad arrived at 5:08PM and started to assess the patient. BP: 100/70 and BG: 113. Patient states that this has happened before but not after a vaccination. All vitals were normal but patient was still fainting in an out, Emergency Squad recommended patient and husband to go to the hospital for further observation. |
| 1164835 | 4/3/2021 | PA | 41 | F | 4/3/2021 | 4/3/2021 | Patient was instructed to wait and sat down in observation area for 15 minutes. She fainted within first 5 minutes. I immediately got to her, felt her pulse and she was breathing so I lifted her legs. She immediately came to. We gave her ice packs and sat with her until she was able to move on her own accord. She was light headed and nauseated and had a friend take her home. |
| 1164718 | 4/3/2021 | CA | 37 | M | 3/30/2021 | 3/30/2021 | Fear of needles, syncope. Seizure-like activity for 4 seconds. Alert. Patient states this has happened before. |
| 1164927 | 4/3/2021 | OR | 51 | M | 4/3/2021 | 4/3/2021 | Patient had syncope at time of injection. Patient reported having syncope with every shot they receive. Patient slouched in chair, then within 15-30 seconds was conscious and back to normal. No additional care was needed. Patient waited in the pharmacy 30-45 minutes before mother drove home. |
| 1165020 | 4/3/2021 | NY | 71 | M | 2/4/2021 | 2/4/2021 | Numb arm, bright red hands and face, teeth chattering for 12 hours, disoriented, fainting, lack of bladder control. |
| 1164945 | 4/3/2021 | GA | 54 | F | 3/31/2021 | 3/31/2021 | Severe pain at site (burning) briefly, headache off and on, severe dizziness, light-headed, disoriented, almost passed out, arm pain on and off. Day 2 same except no burning at site, getting sick, some coughing, Day 3 Coughing, slight headache off and on. Decreased energy and sleeping more, still disoriented. |
| 1164952 | 4/3/2021 | MT | 23 | M | 4/3/2021 | 4/3/2021 | After administering the vaccine, the patient fainted. He regained consciousness after laying him down. We monitored his blood pressure for 30 minutes |

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| 1165006 | 4/3/2021 | CA | 71 | F | 3/13/2021 | 3/13/2021 | Moderna Covid 19 Vaccine EAU severe flu-like symptoms escalating to incontinence, cumulating in fainting and being unable to move any body part except one index finger. After that subsided, foggy brain, fever. Eventually a day of diarrhea. |
| 1165080 | 4/3/2021 | CA | 22 | F | 4/3/2021 | 4/3/2021 | after vaccination, patient fainted but was conscious after couple seconds. asked if she was ok she stated she was fine but felt nauseated, was given water and crackers and remained at the pharmacy for additional 20-30 minutes for monitoring. |
| 1165138 | 4/3/2021 | CA | 30 | F | 4/3/2021 | 4/3/2021 | Patient 30 y/o Female, received her first dose of Pfizer COVID-19 vaccination (Lot #ER8729, exp. 07/31/21) on 4/3/21 around 11:10am. While in the post-vaccination observation area, notified EMTs around 11:15am that she felt lightheaded, sweaty, nauseous, dizzy, had ringing in her ears, fainting, and was experiencing "tunnel-vision." EMT and responded to . had a BP of 108/60 at 11:15am. Co-lead , RN attended to after being notified. Upon assessment, is arousable, alert and oriented x 4, verbally responsive but sluggish to respond. No signs or symptoms of respiratory distress. Medical history of asthma, phobia of needles, not currently taking any meds. 911 was called. 911 instructed RN to not give any food or drink to . stated she was feeling a "little better" around 11:22am; appeared sweaty and reported mild dizziness and lightheadedness. At 11:25am, had a HR of 68 and a RR of 18 and O2 SAT OF 97%. At 11:28am reported mild lightheadedness; her symptoms of sweatiness and dizziness had resolved. At 11:30am the AMR Paramedics arrived, as well as the Fire Dept. refused to be taken by ambulance to the ER. Paramedics monitored at the site for the next 30 mins. in the post-vaccination observation area. Provided education to notify next time during vaccination that she has a history of fainting from vaccinating. left the site on her own will; accompanied by her spouse, unassisted, no complaint of nausea, fatigue, and ambulates with steady gait. VAERS report submitted. Confirmation # |

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| 1165147 | 4/3/2021 | MI | 38 | M | 4/2/2021 | 4/2/2021 | Patient Fainted few seconds after taking his first dose of the Pfizer vaccine. Pharmacy nurse was able to help patient right away where he was seated safely, patient was provided with water, orange juice, and an energy bar and within couple of minutes he regained consciousness. Patient was feeling okay after that, he was taken to the stretcher to rest where he was still monitored to make sure he is okay. Patient stayed under observation for 35 minutes. |
| 1164125 | 4/3/2021 | TN | 80 | F | 4/3/2021 | 4/3/2021 | Pt was exiting the building and became light headed and dizzy. Pt then passed out and was slowly released to the ground. Pt did not hit her head and had no hx of fainting/dizziness spells. EMS were contacted and arrived on scene approximately 5 minutes later. |
| 1163519 | 4/3/2021 | GA | 26 | F | 4/3/2021 | 4/3/2021 | Patient said that they were scared of needles. Patient was ok during her vaccine. Only after I finished the shot she passed out. We called 911 to make sure she was o.k. even though she said not to call. |
| 1164915 | 4/3/2021 | ID | 22 | M | 4/3/2021 | 4/3/2021 | Within 3 minutes of being escorted to our waiting area and starting the timer, patient made a complaint of sweating. within moments patient was heavily perspiring and lost all color. Flushed and confused. Pt starting asking "how long have I been here?". then while being escorted back to our vaccine room patient experienced a brief syncope. He fainted and was escorted to the ground. Increased pulse and continued confusion. Patient was placed in supine position with ice packs on face and nape of neck. EMS was called. we stayed with patient until EMS arrived and took over. Patient declined going with them to the hospital after his evaluation and was cleared by EMS to leave. |

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| 1164318 | 4/3/2021 | TN | 37 | F | 3/29/2021 | 3/29/2021 | I received my first dose of the Pfizer Covid vaccine in my left arm. It didn't hurt and I felt good. I walked to the area of observation and sat in a chair. I was texting friends and looking at social media when all of a sudden I felt very hot for a split second then lost consciousness. When I woke up I was on the ground in quite a bit of pain. I was told by the paramedics that I was unresponsive for 60 seconds and that I had fallen directly on my head and neck. I was immobilized and taken to the ER in an ambulance. I am very healthy and have never passed out before. I have no medical history or events that would justify this happening. In fact, I recently got an annual physical and my blood work was perfect. It was about 5 minutes after the first dose that I completely lost consciousness. |
| 1164233 | 4/3/2021 | FL | 72 | F | 3/9/2021 | 3/10/2021 | 12 hours after the second COVID vaccine was received I had chills for two hours and then started vomiting. Only took two Tylenol and water. We had to spend the night because my husband had his second shot the next day. We had a two hour drive home and almost home I started to feel nausea light headed very hot. I passed out in the car so my husband pulled over to assist me. After five or so minutes I decided I could make it home but started vomiting again. I had nothing to eat but did drink sips of Sprite. He wanted to take me to ER but I said no. Worse sickness I've had in 72 years |
| 1164239 | 4/3/2021 | PA | 30 | F | 4/1/2021 | 4/2/2021 | Fainted at 5:30am immediately after vomiting and bowel movement. Chills and assumed fever began around 1:30am. |
| 1165135 | 4/3/2021 | | 37 | M | 3/26/2021 | 3/26/2021 | 12 minutes post vaccination, the patient was sitting down and attempted to stand up to tell the observing health care staff that he was feeling "woozy." When he stood up, the patient fainted and fell to the ground. He appeared to be unconscious for 5-10 seconds and then came to. While he was confused for a few minutes, he was able to orient himself to place, time, and date. No treatment was administered. Patient's blood pressure was monitored throughout recovery time. |

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| 1164690 | 4/3/2021 | MO | 20 | F | 4/3/2021 | 4/3/2021 | Patient was given the injection and then she started feeling dizzy right after administration. She sat with her head against the wall and dropped her phone and passed out for just a moment. She had a slight tremor/shake for a few seconds. (I did not witness, unsure exactly what happened or how long) She came too fairly quickly after being yelled at, are you ok? When she regained consciousness she complained of being hot all over for a bit. We gave her ice packs to cool down. She felt hot for maybe 10-15 minutes, but felt relief with the ice packs. She also drank some sips of cool water which seemed to help her cool down. |
| 1164304 | 4/3/2021 | FL | 32 | F | 4/1/2021 | 4/1/2021 | Systemic: Allergic: Anaphylaxis-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Vomiting-Mild |
| 1164326 | 4/3/2021 | MA | 29 | M | 3/25/2021 | 3/25/2021 | Syncopal episode a few minutes after the vaccine. No injury. Reported history of fainting after vaccines. |
| 1164341 | 4/3/2021 | OR | 53 | F | 4/3/2021 | 4/3/2021 | Patient fainted 2 minutes post-vaccination. Patient reports she had a panic attack due to reading the potential side effects vaccine pamphlet. Patient reports she has had panic attacks in the past, but never from a vaccine. Patient was shaky and slightly disoriented but alert enough to answer questions about her identity and how she was feeling. |
| 1164366 | 4/3/2021 | CO | 44 | F | 4/3/2021 | 4/3/2021 | Patient was waiting in lobby for 15 observation period. During this time she started to feel faint and approached the counter. I asked her to return to her chair, she passed out. The patient fainted but did not hit her head. Her breathing was monitored, her husband was called, and I sat with her until paramedics arrived. The patient was able to walk out of the store after her examination with the paramedics. |
| 1164398 | 4/3/2021 | TX | 36 | M | 4/3/2021 | 4/3/2021 | Patient received his vaccine and was doing well, he proceeded to sit on the chair to wait for 15 mins for us to monitor him. He was with his wife and fainted and fell out of the chair. 911 was called and they came and took him to the hospital |

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| 1164404 | 4/3/2021 | WI | 30 | F | 4/2/2021 | 4/2/2021 | Severe body aches, chills and sweating. Dizziness, nausea, dehydration and stomach pain. Headache and passed out! |
| 1164684 | 4/3/2021 | MI | 18 | M | 4/2/2021 | 4/2/2021 | Patient passed out briefly a few minutes after receiving the vaccine. Nurses evaluated patients orientation, oriented x3, vitals, within normal limits. Last food or drink a banana earlier that morning Called EMS who cleared patient to leave. Patient did not go to the hospital. |
| 1164615 | 4/3/2021 | NC | 36 | M | 4/3/2021 | 4/3/2021 | Patient immediately felt lightheaded and fainted with head in lap for 5 seconds. We called 911 and he drank a lot of water and felt better and paramedics left. |
| 1164430 | 4/3/2021 | AZ | 58 | F | 4/3/2021 | 4/3/2021 | Pt received Janssen COVID vaccine. 4/2/21 at 12:20PM After the injection pt was seated in a chair for observation. Pt began feeling light headed and passed out. Her eyes never closed and she did not fall from sitting in the chair. She looked out of it for a brief period, 1-2 minutes. Afterwards, pt stated she had a burning sensation and she felt weak. We gave the pt water and she agreed to stay in waiting area for 30 minutes. Pt husband and daughter were with her while she was in waiting area. 911 was not called as pt was responding and began to feel better. Pt observed for 30 minutes. She stated she felt fine when she left the pharmacy with her husband and daughter. Told pt to seek medical attention is symptoms persist or come back. |
| 1164597 | 4/3/2021 | | 37 | F | 4/2/2021 | 4/2/2021 | Lightheaded, claustrophobic wheelchair to medical tent and passed out states "this happens with needles". Pt rested on cot and voiced she felt better. Pt refused EMS AMA upon EMS arrival. |
| 1164688 | 4/3/2021 | CA | 28 | M | 3/30/2021 | 3/30/2021 | Syncope, fear of needles, hadn't eaten meal. BP 70/37 (pulse 60), 100% O2 sat. Final BP 111/72 (pulse 82), O2 sat 100%. |

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| 1164566 | 4/3/2021 | IA | 31 | M | 4/3/2021 | 4/3/2021 | Patient was talking to a friend about five minutes after receiving the vaccine and suddenly passed out and fell to the floor. He was awake again in about a minute. The patient was sweating, pale and a little disoriented for a couple minutes but started improving steadily until he was feeling his normal self again. The EMS was called but the patient declined being taken to the hospital as he felt much better by the time they arrived. |
| 1164519 | 4/3/2021 | MD | 16 | F | 4/3/2021 | 4/3/2021 | Dizziness and near syncope |
| 1164509 | 4/3/2021 | MN | 38 | M | 4/2/2021 | 4/2/2021 | Approximately ten minutes after receiving the vaccination I got very dizzy and passed out. I was out for 3-4 minutes and came to. Subsequent to passing out I vomited a few times and could not hold anything down. I also urinated on myself at some point when out. I was not getting better so 911 was called and I was transported to the emergency room via ambulance. Once the ambulance arrived at the hospital I vomited again filling about half of the vomit bag. I arrived at the hospital and an IV was not able to be administered so I was given Zofran for nausea and Gatorade to try and hold down. I spent approximately 4 hours in the ER, was able to finally get to the point where the nausea calmed down and I was able to walk around. I was then discharged. |

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| 1164484 | 4/3/2021 | WY | 68 | F | 2/26/2021 | 2/28/2021 | <p>Tested positive for COVID-19 January 11th 2021. Feb 26th 2021 went in to get the first COVID vaccine around 1130 with Public Health. COVID vaccine manufacturer was Moderna. Given in the left deltoid, IM. Patient did stay an extra 30 minutes post vaccine b/c she has lots of allergies. About an hour After the vaccine she experienced pain in her left arm and up into her neck on the left side. Symptoms are very simular to something that she ingested and had an allergic reaction to in the past. Felt okay the first day, second day (2-27-2021) she had chills, fatigue, aches and pains. Started to feel like she was improving on Monday around the 28th of February 2021. Fever was down. Still felt fatigued. Nose felt like it was runnng, itching. Experienced dry eyes, started using the eye drops more frequently. Ear canals were itching. She noticed a tickle in her throat later. Not conscios of everything all the same time, she just didn't feel well overall. Vagina and anus were itching. Started to use the estradiol compound daily hoping that might help. Itchy all over and then realized that the reaction was sort of the same reaction she had in the past with the statin medication. Few days after that had abdominal bloating and cramping, also loose stool and finally diarrhea. Around that same time she reports that she was very dizzy and saw stars, had to sit down, did not actually faint. Denies any fainting episodes, but felt faint. Resolved after 5-10 minutes of sitting down, did not feel clear headed after that for several days. Did do her daily walk, starting on 2-28-2021, felt like she had less stamina. Feels more tired in general still now. Does regret getting the COVID vaccine now. Took some benadryl at the time of the reaction and at hs PRN, benadryl makes her feel drowsy. Takes zyrtec, flonase daily and singulair. Pt's husband is a physician, and he prescribed a Medrol dose-pak, which did not seem to help. At the time was taking all of her prescribed medications amlodipine, benazepril. Has taken pepcid for heart burn in the past, was not taking it as the time. Taking prn omeprazole. Denies experiencing any wheezing. Experienced Generalized swelling of eyelids, face, hands, feet. Tongue is kind of swollen today, and she feels like it has been swollen on and off since the vaccine. Prior to the vaccine she felt pretty good overall. Went out for a few days and went skiing with her family. Has a place out of town that she deep cleaned, felt like</p> |

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| | | | | | | maybe she over did it, but she recovered after she rested briefly. Was due for the second vaccine last week. She held off until she could discuss with her doctor, and they discussed that she should not have any further doses. Physically she felt that she should not receive the 2nd vaccine. Continued symptoms include itchy throat (tickle), vaginal and anal itching all day every day. Itching has become a little more like soreness of the tissues. No bruising. Patient has not had the shingles vaccine (Shingrix), thinks she should not get it now. She has pretty much avoided getting vaccines throughout her life b/c she has had poor reactions to flu shots in the past as well. One year, we tried a "half-dose" regimen of the flu shot, giving 0.5ml IM , waiting one month and repeating 0.5ml IM. She did tolerate this well with no reported adverse outcome and did not get influenza that year though it was very active in the community. Since the Moderna vaccine, pt describes Abd distention, bloating of small intestine, "I look 6 months pregnant." pt states her stomach has been like this since the COVID vaccine reaction. | |
| 1159933 | 4/2/2021 | DC | 43 | M | 4/2/2021 | 4/2/2021 | Patient developed signs of syncope within five minutes of receiving the second dose of the Pfizer COVID-19 vaccine. Patient stated he ate little that day and often has similar episodes after giving blood. The patient also stated a fear of needles and taking a look at the needle today caused anxiety. |
| 1159773 | 4/2/2021 | WA | 19 | M | 4/2/2021 | 4/2/2021 | Near syncope, hypotension and nausea. |
| 1159886 | 4/2/2021 | IL | 37 | M | 4/2/2021 | 4/2/2021 | Vaccine was administered at 10:25am. Patient walked over to the waiting area and as he was walking he passed out and fell to the ground. Vitals were taken at about 10:28am: B/P 132/74 HR 70 RR 18, glucose 120. Patient was able to state his name and where he was located, but kept his eyes closed and kept stated he felt "confused and dizzy" and was apologetic. EMS was called at 10:30AM and when EMS was here pt was noted to have another syncopal episode. Patient was transported to Hospital via ambulance. |
| 1159911 | 4/2/2021 | WI | 16 | F | 3/20/2021 | 3/20/2021 | Vasovagal Syncope. Awake within 3 seconds, kept her legs elevated, pushed fluids and a snack. Patient was given the Moderna Vaccine and is under the age of 18 |

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| 1159892 | 4/2/2021 | WI | 38 | M | 4/1/2021 | 4/1/2021 | Patient had a vasovagal response. Patient observed another person feeling anxious and then he fainted. Patient immediately recovered without any further concerns. |
| 1159889 | 4/2/2021 | TN | 19 | F | 4/1/2021 | 4/1/2021 | Patient sustained a vasovagal syncope event about 3 to 4 minutes subsequent to vaccine administration. Struck back of head on chair with fall to ground. Evaluated by medical staff and referred to medical center via ER non-emergent transport. Subsequent to ER staff evaluation for syncope and head injury, she was treated and released from the ER without need for further work-up or imaging. |
| 1159924 | 4/2/2021 | PA | 29 | F | 4/1/2021 | 4/1/2021 | Fainted for roughly 2 minutes |
| 1159640 | 4/2/2021 | WA | 72 | F | 2/23/2021 | 2/23/2021 | approximately 14 hours after second Moderna vaccine, developed severe shaking chills, low grade fever, nausea and fainting |
| 1159839 | 4/2/2021 | MA | 23 | F | 4/2/2021 | 4/2/2021 | near syncope |
| 1159756 | 4/2/2021 | IN | 36 | M | 4/1/2021 | 4/1/2021 | Pt received his vaccine and then went to the observation area. While he was there he started feeling lightheaded and unwell. 5 minutes after vaccination, pt was hot, diaphoretic, and went very pale. His eyes started rolling into the back of his head and he was exhibiting shallow breaths. His pupils dilated and he started foaming at the mouth. Pt was lowered to the ground and a full dose of adult epi pen (Lot#0FM406 Exp FEB 2022) was given to the left lateral thigh at 1725. 911 was also called. Pt came to almost immediately. His pupils and breathing returned to baseline. He stayed lying down but was A & O x4. He confirmed that he does not have any allergies, however he has passed out after a vaccine before. Paramedics arrived on scene and took over the encounter. Pt felt much better, however still went with the Paramedics to the ER. Also advised pt to follow up with his PCP in regards to receiving the second vaccine. |

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| 1159810 | 4/2/2021 | TX | 43 | M | 3/23/2021 | 3/23/2021 | Date: 3/23/2021 Problem: fainted Notes: Pt was being observed post Janssen COVID Vaccine when the nurse observed pt fall onto the floor from his chair. This nurse began to take VS- BP 144/77 P74 O2 100% T 98.6 RR 18 BS 105. Pt did hit head when falling to floor but answered all questions appropriately. Pt states he is afraid of needles and this has happened to him previously as well. 911 called by head nurse. Pt able to move all extremities. This nurse stayed with pt until EMTs arrived. Pt alert and oriented x4. Redness noted to left cheek, no bleeding noted. EMT found no signs of distress and pt refused to be transported to hospital. This nurse notified pt that he would need someone to take him home. Wife arrived to take pt. Pt showed no signs of acute distress aand left with wife. |
| 1159766 | 4/2/2021 | MD | 74 | F | 3/29/2021 | 3/30/2021 | syncope without prodrome within 24 hours of administration |
| 1159765 | 4/2/2021 | IL | 29 | F | 4/1/2021 | 4/1/2021 | I became very hot and couldn't breathe. I passed out and fell over. My tongue swole up so much I couldn't talk to emt. My neck and body broke out in a rash. My entire right side of my face and neck hurt like I got punched in the face. No treatments just a prescription for an epi pen. |
| 1160003 | 4/2/2021 | PA | 28 | M | 4/1/2021 | 4/1/2021 | Patient was given vaccination at the health Center. He was observed and waited for 15 minutes prior to leaving. Drove home. Close to his home, he began to feel lightheaded. However continued to try to make it home and passed out. Crashed car into a tree. Was taken to a local hospital where he had a head CT, hand Xray, CXR and "blood work." He was advised that all testing was normal and that he had a mild concussion. Evening of event, he had a mild headache. Day after the event, the only complaint was tenderness around the vaccine site. He has not had prior reactions to vaccines but states "I work construction and have noticed that I have had vasovagal symptoms with pain in the past.~~ |
| 1160242 | 4/2/2021 | OH | 35 | M | 4/2/2021 | 4/2/2021 | Four minutes after receiving his vaccination, he had a brief episode of syncope. He was alert and oriented times four. He was taken to a brief session at the arena and monitored. |

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| 1159685 | 4/2/2021 | KY | 23 | F | 4/1/2021 | 4/1/2021 | Patient stated she had previous passed out following vaccination. EMS on site in case pt passed out again. Patient passed out following vaccination and EMS was able to catch her and lower her to ground. She regained consciousness quickly and was monitored afterward. Refused any further treatment/transport as she was feeling fine upon leaving. |
| 1159723 | 4/2/2021 | NY | 68 | M | 3/31/2021 | 4/1/2021 | Syncope, minor head trauma, muscular weakness. |
| 1159832 | 4/2/2021 | TX | 43 | M | 3/23/2021 | 3/23/2021 | Date: 3/23/2021 Problem: fainted Notes: Pt was being observed post Janssen COVID Vaccine when the nurse observed pt fall onto the floor from his chair. This nurse began to take VS- BP 144/77 P74 O2 100% T 98.6 RR 18 BS 105. Pt did hit head when falling to floor but answered all questions appropriately. Pt states he is afraid of needles and this has happened to him previously as well. 911 called by head nurse. Pt able to move all extremities. This nurse stayed with pt until EMTs arrived. Pt alert and oriented x4. Redness noted to left cheek, no bleeding noted. PERLA. EMT found no signs of distress and pt refused to be transported to hospital. This nurse notified pt that he would need someone to take him home. Wife arrived to take pt. Pt showed no signs of acute distress and left with wife. |

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| 1160248 | 4/2/2021 | NY | 31 | M | 4/2/2021 | 4/2/2021 | 1040: Pt reports not feeling well. Reports has had "passed out in the past" Pt A&O and slightly diaphoretic noted on forehead. No color change at present moment. Pt instructed of breathing techniques. EMS requested by NP as pt appears to have facial paleness and lips no longer pink in color- "I'm going to pass-out" Pt remained seated upright in chair and LOC for aprx 4 seconds. Pt did regain consciousness without assistance or injury. Pt ambulated to WC without assistance and wheeled to medical evaluation room in rear of the OBS area. 1045: EMS vitals: 118/66 P-65. while lying on cot. Pt consumed a 16.9 oz water bottle intermittently without difficulty. 1100: EMS vitals: 126/85 P-63. pt able to sitting position without complication independently. 1110: Pt ambulated to OBS general sitting area without assistance-pt stable. 1115: pt reports doing better-"No problems" 1125: Pt ambulated independently to exit and instructed in 3 weeks to inform vaccination side to have pt lay down prior to injection. Pt reports someone will drive him home. Pt instructed if not feeling well-pull over and call 911. Pt verbalized understanding. |
| 1160331 | 4/2/2021 | OH | 30 | M | 4/1/2021 | 4/1/2021 | 1:29PM SYNCOPE - EASED TO FLOOR AND FEET ELEVATED. PT BECAME RESPONSIVE. MOVED TO COT PER WHEEL CHAIR. A/O, PIN W/D, RESP WITH EASE. CRACKERS AND WATER GIVEN. 2PM 'FEELS BETTER NOW'. WIFE TO DRIVE PT HOME. 4-2-21 10:30AM TC:PT STATES HE 'FEELS FINE NOW'. |
| 1160355 | 4/2/2021 | HI | 47 | F | 3/30/2021 | 4/1/2021 | fainted last night |
| 1158834 | 4/2/2021 | MA | 61 | M | 3/31/2021 | 3/31/2021 | Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Hypotension-Medium, Systemic: Nausea-Medium, Systemic: Vomiting-Medium, Additional Details: pt passed out for 10 seconds, blood pressure low, when he regained consciousness he vomited.Recovered in about a half hour. |
| 1159622 | 4/2/2021 | MA | 49 | F | 3/31/2021 | 3/31/2021 | Patient fainted in the observation area, woke quickly, alert and oriented. Able to ambulate without any assistance. |

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| 1160330 | 4/2/2021 | VA | 27 | M | 3/20/2021 | 3/20/2021 | Syncope possible seizure about 5 minutes after vaccine. Vitals stable. Refused transport to ED. Mother drove him home. |
| 1160325 | 4/2/2021 | IL | 23 | M | 4/2/2021 | 4/2/2021 | Patient passed out shortly after given vaccine. Immediately regained conscious but felt nauseous and sweaty. Monitored the patient for thirty minutes and gave a cool compress. After the 30 minutes he felt well enough to leave the pharmacy. After two hour patient had eaten and felt completely fine. |
| 1160206 | 4/2/2021 | NY | 30 | M | 4/1/2021 | 4/1/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Nausea-Mild, Systemic: Vomiting-Mild, Additional Details: Prior to vaccine administration patient reported history of passing out from any needle and injection related procedures such as blood work and injected medication. Approximately 30 seconds after administering vaccine patient said "oh my god!" and passed out shortly after with head rolled back. Patient regained consciousness approximately 2-5 minutes later. Felt nauseous and wanted to vomit for about 10 minutes. 911 was called. Patient refused further care and recovered after 15-20 minutes. |
| 1160256 | 4/2/2021 | OH | 29 | M | 4/2/2021 | 4/2/2021 | Site: Redness at Injection Site-Mild, Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient had a vasovagal reaction. He states he has had this occur previously. Orthostatic vitals: lying 176/81 HR 81, sitting 129/86 HR 82 standing BP 119/82 HR 83, Pulse OX 99% |
| 1160016 | 4/2/2021 | | 26 | M | 4/1/2021 | 4/1/2021 | around 10 pm started with chills and fatigue with a sore injection location. Around 11:30 pm he got light headed and passed out for 4 seconds. After awaking he doesn't remember the last 5 minutes. He laid down to go to sleep and was consistently hot and then cold. He does have a history of night terrors but they have remained dormant for about 2.5 years. Around 12 am he started having one of the worst night terrors I've seen. The following morning, April 2nd 2021, he was feeling incredibly sore and the injection spot was tender. He said "it feels like I got hit by a truck." Seems to be doing okay otherwise now. |

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| 1160243 | 4/2/2021 | NY | 66 | F | 3/23/2021 | 3/23/2021 | about 2 hours later I started having allergic reactions similar to ones I have had in the past with food allergies. My bottom lip started swelling, my tounge swelled, I took Benedryl which reduced the swelling but I was very tired, lightheaded, blurry vision, Brain fog could not perform normal duties, rested most of the rest of the day. The next day I still was not comfortable driving as I was still feeling lightheaded. I have Vasovagal syncope where my blood pressure drops, even 7 days later I still felt lightheaded and in the mornings my calfs burn. 7 days later blood pressure was low 94/61 and 97/59. Its now 10 days later and I still do not feel 100%. my Cardiologist recommended extra salt intake and not to take 2 |
| 1160222 | 4/2/2021 | NM | 59 | F | 3/31/2021 | 4/2/2021 | Passed out in the restroom and broke nose at 3am 2 days after receiving second shot. |

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| 1160173 | 4/2/2021 | TX | 57 | F | 3/30/2021 | 3/30/2021 | ASSESSMENT: 57 y.o. female with PMHx of HTN who presented today to the Vaccine site for her second COVID vaccine. She c/o only a sore arm for 1-2 days after her first vaccine but otherwise tolerated it well. NKDA. She states that about 5-10 min after the vaccine she developed rhinorrhea so she went to the bathroom and blew her nose and it improved some but did not resolve. She did not inform us of this until her 15 min timer went off so I completed an evaluation. I am the physician assistant on site at the vaccine clinic who monitors the patients and is there for emergencies. If a patient feels they are having a reaction I complete an exam on the patient. She states the rhinorrhea was still there but was better than it was. Associated with a sensation of "oil in my throat, like eating some butter" but denies throat itching or tightness. Associated with intermittent dry cough and throat clearing. Denies difficulty breathing, wheezing, tongue/lip swelling, mucosal or skin itching, hives, palpitations, lightheadedness, dizziness, SOB, headache, nausea, vomiting, diarrhea, abdominal pain. She has experienced similar rhinorrhea and dry cough in the past with certain medical masks like the one we provided her today. She also experiences this with her seasonal allergies. Her allergies have not been flaring up the last 2 weeks or so but they were before that. She states she has dry mouth and has to drink a lot of water or she will develop a dry cough and throat clearing like she has today. Reports she has never had an allergy to any vaccine or injectable medication in the past. ROS: Constitutional: Negative for chills, fatigue, fever, diaphoresis and weakness. Eyes: Negative for blurred vision, photophobia, vision loss and visual disturbance. E/N/T: Positive for rhinorrhea. Negative for hearing loss, ENT Pain, ear pain, nasal pain, sore throat and hoarseness. Cardiovascular: Negative for chest pain, palpitations, tachycardia, edema, dyspnea on exertion, irregular heartbeat and near-syncope. Respiratory: Positive for cough (dry, intermittent, associated with PND). Negative for shortness of breath, wheezing and sputum production. Gastrointestinal: Negative for abdominal pain, diarrhea, stool changes, nausea and vomiting. Musculoskeletal: Negative for myalgias. Integumentary: Negative for pruritus, rashes, color change and flushing. Neurological: Negative for |

dizziness, headaches, paresthesias, weakness, difficulty with concentration, disturbances in coordination, focal weakness, light-headedness, loss of balance and vertigo. Allergic/Immunologic: Positive for allergies and environmental allergies. Negative for frequent illnesses, urticaria, hives and persistent infections. Psychiatric/Behavioral: Negative for anxiety and depression. OBJECTIVE: Vitals: 15 min after vaccination B/P: 140/88 Pulse: 70 Temp: 98.2 Resp: 12 SpO2: 99% Vitals: 25 min after vaccination B/P: 148/90 Pulse: 68 Resp: 14 SpO2: 98% Vitals: 40 min after vaccination B/P: 150/92 Pulse: 67 Resp: 12 SpO2: 99% Vitals: 70 min after vaccination B/P: 142/82 Pulse: 70 Resp: 12 SpO2: 99% PHYSICAL EXAM CONSTITUTIONAL Vitals reviewed. GENERAL APPEARANCE: Well-developed. GROOMING: Well groomed. LEVEL OF DISTRESS: The patient is not distressed, nervous/anxious, diaphoretic or tearful. She appears to be well. The patient is not lethargic or toxic. The patient does not appear tired. EYES: LIDS/CONJUNCTIVA: Lids and conjunctiva are normal. PUPILS/IRIS: extraocular movement intact. ENT EXTERNAL EARS/NOSE: External ears and nose are normal. SEPTUM/MUCOSA: Negative for sinus tenderness. LIPS/TEETH/GUMS: Normal lips, teeth and gums. No lip edema. OROPHARYNX: Mucosa: Mucosa appears normal. No edema of lips, face, tongue, oropharynx or posterior pharynx NECK: Neck normal. RESPIRATORY EFFORT AND PATTERN: Effort normal. No tachypnea, intercostal retractions, accessory muscle usage, hypopnea and irregular rate. AUSCULTATION: Normal breath sounds with no rales, rhonchi, wheezes or rubs. No coarse breath sounds or decreased breath sounds. CARDIOVASCULAR AUSCULTATION: Rate: Is normal. Rhythm: regular. Heart sounds: S1 is normal. S2 is normal. S3/S4 not present. With no murmurs heard. EDEMA/VARICOSITIES: No edema or varicosities. RADIAL: radial pulses normal bilaterally PEDAL PULSE: Normal bilateral posterior tibial pulses. LYMPHATIC OTHER NODES: No neck adenopathy. MUSCULOSKELETAL STABILITY: Normal stability. INTEGUMENTARY SKIN INSPECTION: Normal. PALPATION: Normal. No diaphoresis, no flushing, no urticaria Injection site is unremarkable, no swelling or erythema NEUROLOGICAL GAIT, COORDINATION,

VAERS_ID RECVD STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

REFLEXES Gait: normal PSYCHIATRIC
ORIENTATION: She is alert and oriented to person, place and time. MOOD/AFFECT: Normal mood and affect. INSIGHT/JUDGEMENT: Normal insight/judgement. The patient has good insight with good judgment. ASSESSMENT/PLAN:
Rhinorrhea - Airway remained clear, breathing was normal, circulation was good and mentation was good. - She was monitored for 60 min after the rhinorrhea began, vitals remained stable and WNL (despite slightly elevated BP). She drank 1.5 bottles of water which improved her dry cough. She stated she was feeling back to normal before she left the clinic. - Warned her that she likely was having a mild allergic reaction to the vaccine and warned that it is possible for allergic reactions to worsen. Reviewed signs and symptoms of anaphylaxis in detail and gave strict ER warnings if any develop, especially difficulty breathing, throat/facial swelling or any worsening symptoms occur. Warned her while driving to work (15 min drive) she keep an eye on her symptoms and pull over and call 911 if any signs or symptoms of anaphylaxis develop. - Advised she take a non-sedating antihistamine like Claritin on her way to work. I advised she let her colleagues at work now to keep a close eye on her at work. - She expressed understanding and stated she was feeling well and wanted to go to work - All questions were answered. I informed her PCP and sent them my note. I called 4 hours after the vaccine to follow up but had to leave a voicemail,. I spoke with her the following day on 3/31/21 and she stated she felt great besides localized soreness at the injection site. Otherwise she felt well. The rhinorrhea, cough and throat clearing had completely resolved after taking 1 claritin. Denied shortness of breath, difficulty breathing, wheezing, fever, chills, n/v/d, chest pain, hives, itching, palpitations, dizziness, syncope, near syncope or headache. She did not require any further treatment and did not need to have a visit with her PCP and did not need to go to the ER or hospital.

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| 1160096 | 4/2/2021 | | 23 | F | 4/2/2021 | 4/2/2021 | pt received first dose of Pfizer COVID-19 vaccine. hx of vasovagal syncope with blood draws. per medical personnel in monitoring area, noted patient unconscious at 1312 for about 15-20 seconds on the chair. as patient was waking up, she was noted to have "eyes flickering and shaking." pt diaphoretic, pale, and had emesis x1 upon waking up. CODE BLUE team on scene at 1315. BP 138/91, HR 68, RR 16, SPO2: 97. pt transported to ED via wheelchair. pt a&ox3 upon transport. |
| 1160055 | 4/2/2021 | MA | 32 | M | 4/2/2021 | 4/2/2021 | Near syncope |
| 1160048 | 4/2/2021 | TN | 26 | M | 4/1/2021 | 4/1/2021 | Patient sustained a vasovagal syncope event approximately 3 to 4 minutes after their vaccination. Fell to ground sustaining abrasion to right cheek. Advised ER evaluation but patient refused. Observed for 30 minutes w/o sequelae and released at patient insistence. Spoke with patient by phone today and he notes that he feels well and has experienced no new, recurrent, or residual symptoms. |
| 1160047 | 4/2/2021 | CT | 35 | F | 3/2/2021 | 3/3/2021 | passed out/fainted at about 1am the night/early morning after the vaccine was administered |
| 1160267 | 4/2/2021 | OH | 60 | F | 4/2/2021 | 4/2/2021 | Vaccine administered 07:15, patient reported syncope approx 11:00. Patient was reclined on floor for 20-30 minutes until episode passed. |

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| 1158708 | 4/2/2021 | MI | | F | 1/12/2021 | 1/27/2021 | Passed out at work; abnormal EKG; PVCs; This is a spontaneous report from a contactable other healthcare professional (patient). A 52-year-old female patient received bnt162b2 (BNT162B2), dose 2 intramuscular, administered in Arm Left on 12Jan2021 10:30 (Batch/Lot Number: UNKNOWN) as SINGLE DOSE for COVID-19 immunisation. Patient received first dose on unspecified date. The patient medical history was not reported. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient is not pregnant at the time of vaccination. Concomitant medications included losartan; nadolol; levothyroxine sodium, all were taken for an unspecified indication, start and stop date were not reported. On 27Jan2021 16:30, the patient passed out at work, has abnormal EKG, now PVCs. The event required Emergency Room visit. The outcome of the events was recovered. Since the vaccination, the patient has not been tested for COVID-19. |
| 1158869 | 4/2/2021 | NJ | 57 | F | 4/1/2021 | 4/1/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Hypotension-Mild |
| 1158831 | 4/2/2021 | CT | 60 | F | 3/28/2021 | 3/28/2021 | Site: Pain at Injection Site-Mild, Systemic: Chest Tightness / Heaviness / Pain-Medium, Systemic: Chills-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Exhaustion / Lethargy-Medium, Systemic: Fainting / Unresponsive-Mild, Systemic: Fever-Mild, Systemic: Flushed / Sweating-Medium, Systemic: Headache-Medium, Systemic: Hypotension-Mild, Systemic: Shakiness-Mild, Additional Details: Patient reported vitals from ER BP=107/70, Liver tests were off due to dehydrated per ER , had fever ,sweats then chills and Headache followed by fatigue for a few days. Patient did notify her PCP |
| 1158829 | 4/2/2021 | TX | 17 | F | 3/29/2021 | 3/29/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient felt some lightheadness and felt she was having a panic attack. sje slumped but patient was responsive |

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| 1158812 | 4/2/2021 | MO | 36 | M | 4/1/2021 | 4/1/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: patient fainted while waiting 15 minutes after vaccination patient has abrasions on cheek nose and forehead from carpet where he fell patient received quickly staff cleaned wounds and gave water patients wife said he was better and just wanted to go home so they left the store patient walked out on own accord |
| 1158799 | 4/2/2021 | MD | 22 | M | 3/31/2021 | 3/31/2021 | pt waited 15 minutes after vaccination and 30 minutes after receiving vaccine pt passed out driving home |
| 1158785 | 4/2/2021 | NJ | 26 | F | 4/1/2021 | 4/1/2021 | Systemic: Dizziness / Lightheadness-Severe, Additional Details: vagal response - fainted |
| 1158875 | 4/2/2021 | NM | 71 | F | 3/26/2021 | 3/27/2021 | Sudden dizziness, fever & almost passed out 19 hours after 2nd Moderna Covid vaccination shot but was better by that evening. 2 days after injection the arm rash reoccurred on the injection arm and was much more intense, itchy & red in comparison to the rash after the 1st Moderna Covid vaccination shot. The rash finally started disappearing 1 week after injection. |
| 1158726 | 4/2/2021 | OK | 61 | F | 3/31/2021 | 3/31/2021 | Left arm started to hurt minutes after the injection, radiating down toward elbow and my arm started to go numb, especially the pinkie and ring finger. Difficult to hold my phone while waiting, I dropped it, then started to get dizzy. Called a volunteer over, who summoned another lady. They told me they were going to move me to another area, and attempted to help me there, but I fainted about 3 steps out. When they were lying me down on the floor, I came to and was oriented at that point. BP was somewhat low initially, but increased as I lay there, and oxygen levels increased from 94 to 99 before I left facility. |
| 1158966 | 4/2/2021 | GA | 28 | F | 4/2/2021 | 4/2/2021 | syncope related to needle stick |

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| 1158677 | 4/2/2021 | IL | 41 | F | 3/16/2021 | 3/16/2021 | <p>started feeling tired/she was starting to feel tired, then really tired and the mom said 'maybe you should pull over' and she didn't have time to process it as she fainted/blacked out right after; fainted/blacked out right after; she rear ended another car and then drove around that car and she think the car stopped itself possibly not sure but when she awoke she was directly in front of the vehicle she had rear ended; This is a spontaneous report from a Pfizer-sponsored program. A contactable consumer reported that a 41-year-old female patient received dose 1 bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in the left arm on 16Mar2021 16:00 (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunization . There were no patient's medical history and concomitant medications. The patient waited the 15 minutes at the site and felt fine. She got on the road at 6pm and started feeling tired. She was on the phone with her parents and mentioned she was starting to feel tired, then really tired and the mom said 'maybe you should pull over' and she didn't have time to process it as she fainted/blacked out right after. When she woke up, she was still behind the wheel the drivers steering wheel airbag and airbag at her legs had deployed. She has no memory of what happened but her daughter (age 9) was in the back seat of the car with the dog. The patient's daughter said that she accelerated into the intersection passed through ("I blacked out as the light was changing to green") she rear ended another car and then drove around that car and she think the car stopped itself possibly not sure but when she awoke she was directly in front of the vehicle she had rear ended. The driver in the other car was taken in an ambulance with she believes the other driver had some discomfort in the neck/back but she was not 100% sure. It was reported that the outcome of events was recovering. It was unknown if the patient receive treatment for the events. The events were considered as serious due to hospitalization. Information on the lot/batch number has been requested.</p> |

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| 1158669 | 4/2/2021 | CA | 36 | U | 3/11/2021 | | <p>DIZZINESS; NAUSEA; FAINTING; BODY ACHES; This spontaneous report received from a patient concerned a 36-year-old unspecified sex. The patient's height, and weight were not reported. The patient had no known allergies. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1802072, expiry: UNKNOWN) dose was not reported, 1 total, administered on 10-MAR-2021 17:00 to left deltoid for prophylactic vaccination. No concomitant medications were reported. On 11-MAR-2021, since 0900 the patient began feeling dizzy and nauseous and fainted, patient also complained of body aches. The action taken with JNJ78436735 (Ad26.COVID.S) was not applicable. The patient recovered from fainting, nausea, and dizziness on 11-MAR-2021, and had not recovered from body aches. The reporter considered the causality between covid-19 vaccine ad26.cov2.s and fainting, nausea, dizziness and body aches as related. Company causality between covid-19 vaccine ad26.cov2.s and fainting, nausea, dizziness and body aches was possible. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210322081-JANSSEN COVID-19 VACCINE-Fainting. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p> |

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| 1158366 | 4/2/2021 | CA | 38 | F | 4/1/2021 | 4/1/2021 | <p>On Thursday, 4/1/2021, client received her first dose of Pfizer COVID vaccine (LOT # EW0150, EXP 7/2021) at approximately 10:07 am by vaccinator RN. RN instructed client to self-monitored at the observation area. EMT found this 38 years old female in an observation chair sitting upright and requesting assistance. Due to the client needing translator, site manager present provided translation. lead RN came to assist EMT as needed. EMT reported client had a chief complaint of lightheadedness. Client stated that she felt like her head was "big" but that she did not feel like fainting. Client stated she had a history of high blood pressure and diabetes type 2 but did not take diabetes medication. Instead, she stated that she managed it strictly with her diet. Client had no known allergies. Assessment revealed no redness, hives, swelling, shortness of breath, chest pain or other signs of anaphylaxis throughout her body. Client denied having a headache but stated that she felt "hot" and that the heat was rising to her head. Client denied having a meal before her vaccination. Initial vitals were as follows: Alert and oriented x 4, Eyes were PERL (Pupils Equal and Reactive to Light) at 4 mm, pulse - 74, regular and strong at radial. O2 - 99%, blood pressure 160/98, Temperature 97 F, Respirations 20 and regular. Skins were warm and mildly sweaty. Client consented to staying present for an extra 30 minutes after incident onset. Staff present verified that client had no food allergies and was provided food to eat while under observation. Client's vitals were monitored at 5 minutes intervals after the onset of the incident as follow: 10:18 am: 160/98 (Blood Pressure), 74 (Heart Rate), 99% (Oxygen), 20 (Respiration), 97 F (Temperature); 10:23 am: 162/98, 68, 99%, 18; 10:28 : 162/98, 68, 99%, 18; 10:33 : 162/98, 72, 99%, 18; 10:38 am: 162/98, 72, 99%, 18, 98 F; 10:48 am: 162/98, 72, 99%, 18. Client reported at the end of her observation that she no longer felt hot and her head sensation was gone. Client's temperature improved from 97 degrees Fahrenheit to 98 degrees Fahrenheit and she ceased sweating at the end of her observation period. Client's husband was present and both were provided a Pfizer vaccine fact sheet and instructed to seek out medical advice or emergency care if a severe allergic reaction occurs later in the evening. Client left with husband in no apparent distress at 10:48 am with husband stating he would drive them home.</p> |

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| 1158343 | 4/2/2021 | CO | 22 | M | 4/1/2021 | 4/1/2021 | <p>Syncope. Pt fell backwards as he was leaving immunization room for waiting/observation area after receiving first dose of Moderna COVID-19 vaccine. Episode lasted roughly 15 seconds at which point patient regained alertness. It was determined no epinephrine etc was needed. Pt was observed following episode until he was clearly okay to leave on his own accord, and no further medical attention would be necessary. Discussed follow up with PCP post event and to discuss appropriateness of receiving second dose. Out of an abundance of caution, contacted patient later in the evening (about 1.5 hrs later) at home to check up and make sure he was still okay.</p> |
| 1158258 | 4/2/2021 | OR | 50 | F | 4/1/2021 | 4/1/2021 | <p>dizziness , Fainting, loss of consciousness , shaking ,chills, may be seizure</p> |
| 1160400 | 4/2/2021 | CA | 77 | F | 3/12/2021 | 3/12/2021 | <p>first shot a month earlier - sore arm, gland swollen in armpit, very cold & headache. 2nd shot - sore arm, sore back of neck from headache (muscles seemed frozen for days), really cold from 8pm to 4am with debilitating headache. left side of body was without coordination, hip, knee, ankle didn't work. Went sideways with all joints when walking. 03/18/2021 - passed out in bathroom due to pain. Hit door frame and had large lump on forehead. Bowel mess to clean up. 03/21/2021 - didn't dress, still wobbly stomach upset, neck sore, dizziness, ate squash and beans. 04/01/2021 - still have stomach upset and though day temperature is over 70 degrees, am very cold, tired as soon as do just one thing. continues</p> |
| 1160959 | 4/2/2021 | CA | 36 | F | 4/2/2021 | 4/2/2021 | <p>Patient Fainted but was conscious in observation station. Patient was resting comfortably slowly sipping on water. Was able to ask patient if she was having any trouble breathing her response was no. Also asked if she had fainted before any other vaccinations also said no. Had her remain in observation station for an additional 30 minutes. After 30 minutes symptoms did not improve and we called the paramedics. Her Mother and Husband were present. The paramedics noted low blood pressure, started IV fluids and took her to the hospital for continued care.</p> |

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| 1158751 | 4/2/2021 | FL | 37 | F | 4/1/2021 | 4/1/2021 | Pt. was sitting in waiting area and walked into the building and informed that she was feeling dizzy. Pt. then fainted and was lowered to the ground by medic before actually falling. Pt. was given sternum rub and capillary refills were done. Pt. was taken to medic area where BP/BS/EKG was performed. |
| 1159327 | 4/2/2021 | NJ | 26 | F | 4/1/2021 | 4/1/2021 | Muscle pain, headache, body chills, shaking, fatigue, fever, fainting |
| 1159545 | 4/2/2021 | MI | 31 | F | 3/31/2021 | 3/31/2021 | Patient has needle anxiety briefly passed out after receiving vaccine. Onsite EMS was called vitals HR 54 BP 110/80. She quickly recovered and went home. |
| 1159475 | 4/2/2021 | MN | 52 | M | 3/30/2021 | 3/31/2021 | Feverish chills and vomiting on day 1. On 4/1/21 at 1:00 am patient fainted and had incoherent speech and then went ?lights out? for less than a minute. He was taken to ER. They gave him fluids anti nausea medicine and ran many blood tests. Patient still feeling dizzy and groggy on day 2 |
| 1159450 | 4/2/2021 | | 31 | F | 3/30/2021 | 3/30/2021 | fainting |
| 1159439 | 4/2/2021 | CA | 19 | F | 3/31/2021 | 3/31/2021 | 3 min after vaccine given patient felt light headed and got vertigo, became green, fainted and was sweating. |
| 1159435 | 4/2/2021 | OH | 38 | F | 4/1/2021 | 4/2/2021 | Immediately following injection: sore arm, ?fuzzy? head, mild syncope, hot and cold flashes- all resolved after about 20 minutes minus arm pain. Approximately 7am the next day overall muscle soreness- especially spinal area, dizziness, nausea, bruised arm at injection site, generalized weakness |
| 1159430 | 4/2/2021 | MI | 39 | F | 3/31/2021 | 4/1/2021 | Fainted and threw up about 29 hours after the shot |
| 1158840 | 4/2/2021 | MA | 37 | M | 3/31/2021 | 3/31/2021 | Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Shakiness-Medium, Additional Details: the pt passed out 5 min after covid vaccine had possible seizure. ambulance was called at pt was given fluids by emts because of low pulse while sitting. pt was taken to er and his status unknown |

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| 1159344 | 4/2/2021 | MN | 22 | F | 4/1/2021 | 4/1/2021 | pt received the IMZ at 11:59am. instructed wait time 12:15pm in the designated chair provided. at 12:08pm she came up to the counter. As i came around the corner, I saw she was pale. she then fainted and I ran out the door. a male customer caught her and eased her to the floor. i knelt beside her checking pulse and respirations. both WNL. after 10 seconds she came to with extreme sweating. i removed BOTH masks and pull her long hair away from her face to cool her off. got a cool wet paper towel and put on her forehead. i had her raise her legs against the wall to elevate. her mom came in and said as a kid she fainted often due to a vasovagal overstimulation. her mom helped her to the chair and sat for a few more minutes. leaving at 12:20pm with her mom. |
| 1159565 | 4/2/2021 | NY | 74 | F | 1/21/2021 | 1/21/2021 | I was very achy felt like the flu for a day and 1/2. On that Saturday I fainted I woke up crawled into the room passed over. I have been to the Ear,Nose & Throat doctor doesn't know if this is from vaccine or ear inflammation. I also followed up Cardiologist and Neurologist waiting on the results. |
| 1159313 | 4/2/2021 | IL | 40 | M | 3/31/2021 | 3/31/2021 | I started to feel really tired around 7:30pm and got a head ache so I went to bed early. I couldn't sleep well because I got the chills and a fever. I went to use the bathroom around 3am. All of a sudden I got really nauseous, the room spun, everything went black and I fainted in the middle of my bathroom. My wife woke up and helped me back to bed. The next day I was very weak and tired. The chills and fever faded the next afternoon. |
| 1159283 | 4/2/2021 | | 69 | M | 2/26/2021 | 2/26/2021 | when patient got home after receiving 2nd dose he passed out |

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| 1159157 | 4/2/2021 | MI | 59 | F | 3/31/2021 | 4/1/2021 | At 4am, I woke up with a high fever (which I expected). I got up to eat a piece of toast before I took Tylenol. I ate about 2 bites of the toast and started sweating profusely. Fortunately, my husband had gotten up at that time to help me out. At about that time, I totally passed out (fainted). According to my husband, I was out about 10 seconds. I woke up to him panicking and on the verge of calling 911. I was extremely weak and could not walk without his help. I did not end up taking Tylenol since I could not keep anything down (I ended up with the dry heaves). The "passing out" side effect is not listed on the side effects. My daughter said her brother-in-law also passed out several hours after taking Moderna. I experienced all of the side effects listed: fatigue, headache, muscle pain, joint pain, chills, nausea, vomiting, fever, dizziness and weakness. |
| 1159114 | 4/2/2021 | NY | 18 | F | 4/1/2021 | 4/1/2021 | Patient reported to her friend that she felt nauseous. According to the friend she then slouched to her right and fell off her chair. She came to within a minute. 911 was called at 12:45. She stayed on her right side on the floor for approx 3 minutes before being assisted to sitting on the floor. She was alert and oriented. She was given juice. She reports she had eaten that morning before getting vaccine. She reports that she has not ever "passed out" after an injection or vaccine before. She was assisted to the chair then to a wheelchair. She was wheeled to the ambulance. EMS checked her blood sugar and it was 65. She did not go to the ER, she was treated and released. She reported that she went for lunch after leaving vaccine site. |
| 1159107 | 4/2/2021 | CO | 59 | F | 3/15/2021 | 3/16/2021 | Slight ha when woke up on 16th. Within 15 min dizzy and passed out. Heavy vomiting and no strength. Bone crushing pain, Laid on floor, partner called 1-800 suggested pepto mismol. Vommitted that. Called EMS to help Get. Me to bathroom and back laid down. No fever. Took other vs . Next thing I know I was in bed eating toast and cola. Left me still weak and trouble keeping balane. Should I get 2nd shot? |

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| 1159052 | 4/2/2021 | PA | 57 | F | 2/23/2021 | 2/24/2021 | Symptoms began the day after the injection was received. Symptoms included: high fever (103 degrees), nausea, lightheadedness (almost passed out twice), uncontrollable chills (whole bed was shaking), night sweats, headache, mental fogginess. The day after the injection I developed a UTI; was put on macrobid antibiotic. Shortness of breath began on day 3 after the injection. Difficulty breathing; out of breath going up the steps. Went to the ER on day 4 after the injection with all the symptoms listed above. |
| 1158979 | 4/2/2021 | IN | 61 | F | 3/30/2021 | 3/30/2021 | 11 hours after?intense shivering shuddering 22 hours after, awoke to?shivering, sweating, dizziness, lightheadedness, inability to get out of bed, dry heaves 23 hours after?attempted to get out of bed, fell/collapsed/fainted sustained many bruises |
| 1159384 | 4/2/2021 | AZ | 63 | F | 3/29/2021 | 3/29/2021 | During the 15 minute observation (post-vaccination), patient fainted. EMS was called and patient was transported. |

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| 1162057 | 4/2/2021 | PA | 55 | F | 3/3/2021 | 3/4/2021 | <p>her stomach was bothering her; her daughter told her the right side of her tongue looked swollen; allergic reaction to the COVID-19 Vaccine; heaviness with her headache; stroke; Facial droop; Numbness / left half of her face was numb / numbness in her left hand/numbness and tingling all over her body; Tingling; Tiredness; Pain; Headache; This is a spontaneous report received from a contactable consumer, the patient. A 55-year-old adult female received the first dose of BNT162b2 (solution for injection; Lot EN6202 and expiry information not provided) via unspecified route in the left arm on 03Mar2021 between 17:10 and 17:30 (at 55-years-old) for COVID-19 immunisation. Relevant medical history included Frozen shoulder (2020-2020), and severe migraines (especially in the past ten years). The patient further stated that she has always had migraines. She said sometimes when her migraines escalate, her blood pressure goes up, and her left side tingles. She said several times in the past, she thought her migraine symptoms may have been a stroke. She said she her doctor is checking her for any kind of things like rheumatoid arthritis, mast cells, constant (chronic) fatigue, and fibromyalgia. She said right before the COVID-19 Virus pandemic she had passed out unexpectedly. She said she doesn't know what caused her to pass out. She said she needs another neurological test done. She said she had a neurological test that maybe showed that veins were dying in her brain, but she wasn't sure. She said her doctor had been doing heart tests too, but because of the pandemic, it was taking longer to have the tests done. The patient also mentioned that her last blood work was probably in/around Nov2020. There were no concomitant medications or past drug history reported. The patient denied receiving any other vaccination within the four weeks prior to the vaccination. The patient also denied receiving any other vaccination on the same date as the vaccination. The patient reported that on 04Mar2021, approximately seventeen hours after she received the COVID-19 vaccine, she had what she thought was a kind of severe reaction. She said she had an inside numbness and tingling all over her body. She said the left side of her body, especially, had a very strong numbness and tingling, like a stroke. She said the numbness was in her left hand, and outside left shoulder. She said the left half</p> |

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| 1162637 | 4/2/2021 | TX | 24 | M | 4/2/2021 | 4/2/2021 | of her face was numb. She said at the time she felt weird. She said she was speaking to her friend on a video call and did not want her friend to think she was a cry baby. She said then her friend told her there was something happening with her face. She said the right side of her face had dropped. She said her right eye and the right side of her mouth were drooping. She said she told her friend she thought she had an allergic reaction to the COVID-19 Vaccine. She said it took about three hours for her symptoms to pass. She said afterward she was so tired, had pain, and a headache. She said it was strange for her to have a headache because she was used to migraines. She said she still had a headache today (08Mar2021). She said she had a heaviness with her headache. She said if she had a migraine, she would not be able to do anything, but with the headache she had, she was able to go about her everyday things. She said her stomach was bothering her too, but she was not worried about how her stomach felt. The events did not require any visits to a physician's office nor the emergency room. Treatment for the events included drinking a lot of water and moving around. The outcome of the events, inside numbness and tingling all over her body, very strong numbness and tingling, like a stroke, numbness was in her left hand, and outside left shoulder, half of her face was numb, right side of her face had dropped, and tongue looked swollen, and allergic reaction to the COVID-19 Vaccine was recovered on 04Mar2021 after about three hours duration. The outcome of the events so tired, and pain was recovered on an unspecified date in Mar2021. The outcome of the events, headache, and heaviness with her headache was not recovered. |
| 1162588 | 4/2/2021 | NY | 47 | M | 4/2/2021 | 4/2/2021 | Patient fainted/passed out in the waiting area after receiving the Pfizer COVID vaccine. The patient was ok after he woke up and the paramedics were called to assess the patient. The patient was fine and was allowed to go home after being assessed. |
| | | | | | | | he fainted and passed out for 1 minute as soon as I administered the J&J vaccine to him i laid him on the floor , he regained his consciousness after 2 minutes the EMT came in and handled the situation . he felt okay after 15 minutes |

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| 1162569 | 4/2/2021 | OH | 20 | M | 4/2/2021 | 4/2/2021 | Dose given 1804, band aide placed, patient states feels a little light headed 1806, as laying flat LOC for 2 seconds, BP 90/50, pale, patient states small amount of nausea, left flat, talking throughout, A/Ox4, 1815 BP 90/56, patient states feels fine, skin color pink/dry, sat up slowly, sat for another 5 minutes then ambulated to chair, states feels well, waited another 15 minutes for observation, patient states after, previous blood draw, passed out |
| 1162546 | 4/2/2021 | OH | 31 | M | 4/1/2021 | 4/1/2021 | Fainted |

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| 1162105 | 4/2/2021 | PA | 27 | F | 3/11/2021 | 3/15/2021 | <p>passed out; experienced seizure like activity; low fever; arm pain; fatigue; chills; feeling very weak and sick; feeling very weak and sick; This is a spontaneous report from a contactable consumer (patient). A 27-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), first dose via an unspecified route of administration, administered in the left arm on 11Mar2021 at 15:45 (batch/lot number was not reported) as a single dose for COVID-19 immunisation. Medical history included asthma, Ehlers-Danlos syndrome, known allergies to red food dye and sulfa; all from unspecified dates. The patient was not pregnant at the time of vaccination. Concomitant medications included celecoxib (CELEXA), lorazepam (ATIVAN), VITAMIN D NOS (VITAMIN D), cyanocobalamin (VITAMIN B12), curcuma longa (TURMERIC); all taken for unspecified indications, start and stop date were not reported. The patient previously took gabapentin, escitalopram (LEXAPRO), and promethazine and experienced known allergies to all drugs. Facility type vaccine was pharmacy or drug store. No other vaccine in four weeks. It was unknown if the patient had Covid prior to vaccination. The patient was not Covid tested post vaccination. After receiving the first shot, the patient felt the expected side effects (low fever, arm pain, fatigue and chills) but they worsened over the next several days. After feeling very weak and sick all day, she passed out for approx 30+ minutes, she was alone but was found on the floor by her mother after she attempted to call her multiple times and she didn't respond. She experienced seizure like activity and was advised by her primary care doctor to go to the emergency room, and was seen there. Start date for the adverse events reported as 15Mar2021 at 16:00. The adverse events resulted in doctor or other healthcare professional office/clinic visit and emergency room/department or urgent care. There was no treatment received for the events. The outcome of the events was recovering. Information on the lot/batch number has been requested.</p> |

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| 1162099 | 4/2/2021 | MI | 59 | F | 3/19/2021 | 3/20/2021 | Fainted; Body chills; fever; body aches; Loss of appetite; Weakness; Sleepiness; This is a spontaneous report from a contactable consumer (patient). A 59-year-old female patient received the first dose of BNT162B2 (Pfizer-BioNTech COVID-19 vaccine, lot number and expiry date unknown), via an unspecified route of administration, in the left arm on 19Mar2021 at 21:00 as a single dose for COVID-19 immunization. Medical history included COVID-19 from an unknown date to an unknown date, prior to vaccination. The patient had a nasal swab test for COVID on 18Mar2021 with a result of negative. The patient had no known allergies. There were no concomitant medications. The patient did not receive other vaccines in four weeks prior to the COVID vaccine. The patient experienced body chills, fever, body aches, loss of appetite, weakness, sleepiness and fainted on 20Mar2021 at 01:00. The patient did not receive treatment for the events. The outcome of the events was recovering. Information on batch/lot number was requested. |
| 1161220 | 4/2/2021 | AZ | 28 | F | 4/2/2021 | 4/2/2021 | Patient received vaccine at 9:10 am. Went to get a coffee, came back and stood in line, sat back down. At 9:25 am, called pt to counter to receive covid vaccination record card and id and she stated feeling dizzy. technician and pharmacist went out to assist, Pharmacist caught her as she passed out, technician pushed chair under her. We dragged chair into counseling room so that she could lay down on carpeted area. She was coherent - directed tech who to call, was able to describe how she felt (dizzy, nauseas).. She passed out for few seconds only. Ambulance was called when she was not feeling better. Ambulance arrived at 9:40am and left with patient at 9:53am. First bp taken 117/73, second bp upon sitting was 80/60 - at which point the paramedics recommended she be seen at hospital |

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| 1162060 | 4/2/2021 | NY | 45 | F | 1/26/2021 | 1/26/2021 | Tachycardia; Rash; This is a spontaneous report from a contactable healthcare professional. This is the second of two reports for the same patient with reoccurring events separated in time. A 45-years-old non-pregnant female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), second dose (Batch/Lot Number: UNKNOWN) via an unspecified route of administration on 26Jan2021 (at the age of 45-years-old) as a single dose for COVID-19 immunisation. The vaccination was received at the hospital. Medical history included asthma, clotting disorder and allergies. The patient did not receive any other vaccines within 4 weeks prior to the BNT162B2 vaccine. The patient was not diagnosed with COVID-19 prior to vaccination. Since the vaccination, the patient has not been tested for COVID-19. Concomitant medications included unspecified medications. It was reported that the patient had received other medications within 2 weeks of vaccination. The patient previously received the first dose of BNT162B2 on 05Jan2021 for COVID-19 immunisation and experienced tachycardia, rash and presyncope. The patient developed tachycardia and rash which started approximately 2 weeks after the first vaccine and worsened after the second vaccine on 26Jan2021. The tachycardia and rash required a visit to the Emergency Room and Physician Office. Treatment included steroid injections, oral steroids and Diphenhydramine (BENADRYL). The patient was not admitted to the hospital. The outcome of event tachycardia was recovered on an unknown date. The outcome of event rash was recovering. The healthcare professional reported casual effect of the events tachycardia and rash to the vaccine. The lot number for the vaccine was not provided and will be requested during follow up.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of tachycardia and rash due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including EKG, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product |

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| 1162748 | 4/2/2021 TX | 55 M | 1/29/2021 | 1/30/2021 | is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021092876 same patient/reporter, different vaccine dose and event. Muscle pain and serious fatigue. It is continuous. Every day, muscle pain in legs makes me feel like I ran a marathon, hard to climb stairs to go upstairs in my home. It is preventing me from doing any physical work or activities. Sometimes I feel like, i.e. some days and times, as if I cannot move or I am almost fainting. |
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| 1161995 | 4/2/2021 | RI | 67 | F | 2/23/2021 | 2/23/2021 | <p>weakness; noodle legs; excruciating headache; vomit; extremely nauseous; freezing cold with chills; passed out; weak tingling feeling; loose bowels; low grade temp of 96; sore arm; total, severe exhaustion; A Spontaneous report was received from a consumer concerning herself a 67-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced passed out/loss of consciousness, severe exhaustion/fatigue, sore arm/ pain in extremity, extremely nauseous, weak tingling feeling/Paresthesia , vomiting, freezing cold with chills, loose bowels/diarrhea, low grade temp of 96/body temperature decreased, excruciating headache, weakness/asthenia, noodle legs/muscular weakness. The patient's medical history was not included. Concomitant medications were not listed. On 23 Feb 2021 prior to the onset of events the patients received first dose of their two planned doses of mRNA-1273 (Batch N0:023M7) intramuscularly in the right deltoid for prophylaxis of COVID-19 infection. On 23 Feb 2021, She felt total, severe exhaustion until Saturday 27 Feb 2021. She woke up with a sore arm on 24 Feb 2021. On Sunday 28 Feb 2021, she felt extremely nauseous. She had a weak tingling feeling; she started seeing spots and passed out. When she came to, she started to vomit, was freezing cold with chills, then had loose bowels. She had a low-grade temp of 96. She had excruciating headaches. She had weakness; she has noodle legs The event passed out/loss of consciousness was medically significant and serious. Treatment information was not provided. Action taken with mRNA-1273 in response to the events was not provided. The outcome of the events, severe exhaustion was resolved on 27 Feb 2021, and outcome of event passed out resolved on unknown date. The outcome of the events sore arm, extremely nauseous, weak tingling feeling, vomiting, freezing cold with chills, loose bowels, low grade temp of 96, excruciating headache, weakness, noodle legs were unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: MOD-2021-035997:Same Reporter, Different Patient</p> |

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| 1161993 | 4/2/2021 | TX | 52 | F | 2/3/2021 | 2/3/2021 | <p>Passing out sometimes; Very dizzy for two days; Feeling very bad; Hot flashes; Fever; chills; felt like she would fall; A spontaneous report was received from a consumer concerning a 52-year-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and felt passing out sometimes/Loss of consciousness, very dizzy for two days/dizziness, felt like she would fall/presyncope, hot flashes/hot flush, feeling very bad/feeling abnormal, chills and fever/pyrexia. Medical history of the patient was not reported. Her concomitant product included rosuvastatin calcium. On 03 Feb 2021, the patient received her first of the two planned doses of mRNA-1273 (batch number: 012M20A) intramuscularly for prophylaxis of COVID-19 infection. On the same day, she developed fever and hot flashes. She took treatment with paracetamol. On an unknown date, she became very dizzy for two days and was feeling very bad. She was passing out sometimes and felt like she would fall. She became dizzy again after two weeks for a couple minutes. The event passing out sometimes was considered to be medically significant. The action taken with mRNA-1273 in response to the events was not known. The outcome of the events was not provided.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the onset date of the reported events, a causal relationship cannot be excluded.</p> |

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| 1161971 | 4/2/2021 | | 46 | M | | 3/31/2021 | <p>vasovagal syncope; This spontaneous report received from a health care professional concerned a 46 year old male. The patient's height, and weight were not reported. The patient's pre-existing medical conditions included patient had no known allergies and no significant past medical history. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number was not reported) dose was not reported, administered on 31-MAR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 31-MAR-2021, a couple minutes later of vaccination, patient experienced vasovagal syncope for which a Code Blue was called by clinic staff. 911 was also called. Patient was evaluated by ED physician on scene at the clinic, where patient had regained consciousness and responded to questions. The patient was then transported to emergency department next door by the emergency department staff where patient was monitored and ultimately discharged home. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from vasovagal syncope on 2021. This report was serious (Other Medically Important Condition).; Sender's Comments: V0. 20210401417 -COVID-19 VACCINE AD26.COV2.S-VASOVAGAL SYNCOPE. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event</p> |

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| 1161939 | 4/2/2021 | VA | | U | | 3/11/2021 | <p>FAINTING; LOSS OF CONSCIOUSNESS; HYPOTENSION; This spontaneous report received from a health care professional concerned multiple patients. Initial information was processed along with the additional information received on 17-MAR-2021. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: Unknown) dose was not reported, administered on 11-MAR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. The nurse reported on 11-MAR-2021. two patients had hypotensive episodes and fainted in clinic. On 11-MAR-2021, the patients experienced loss of consciousness. On an unspecified date, the patients had fainted. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the loss of consciousness, hypotension and fainting was not reported. The reporter provided causality between covid-19 vaccine ad26.cov2.s and loss of consciousness, hypotension, fainting was possible. This report was serious (Other Medically Important Condition).; Reporter's Comments: This case contains multiple patients.; Sender's Comments: V0: 20210324277- Covid-19 vaccine ad26.cov2.S- loss of consciousness, hypotension, fainting. This events are considered unassessable. The events have a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the events.</p> |

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| 1161936 | 4/2/2021 | GA | | F | | 3/11/2021 | <p>PASSED OUT; LIGHT HEADED; SHIVERING; HARD TIME REGULATING ITS TEMPERATURE; SENSITIVE SKIN; This spontaneous report received from a female of unspecified age reporting on self via social media. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: Unknown) dose was not reported, administered on 10-MAR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 11-MAR-2021, the subject experienced sensitive skin. On an unspecified date, the patient stated that the side effects for her were bad but short lived, got light headed and passed out in her kitchen, if she felt light headed, sat or lay down so she could not fall, her body also had a hard time regulating its temperature (temperature regulation disorder). The patient was shivering uncontrollably for about an hour, and then overheated very quickly under all blankets. On 11-MAR-2021 the patient mentioned that her skin feel sensitive, otherwise she was fine. She got the shot yesterday. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from light headed, was recovering from shivering, and sensitive skin, the outcome of passed out and temperature regulation disorder was not reported. The reporter considered the causality between JNJ-78436735, and light headed, shivering, sensitive skin, passed out and temperature regulation disorder as related. Company causality between JNJ-78436735, and light headed, shivering, sensitive skin, passed out and temperature regulation disorder was possible This report was serious (Other Medically Important Condition).; Sender's Comments: 20210322217-JANSSEN COVID-19 VACCINE-Passed out. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.</p> |

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| 1161921 | 4/2/2021 | TN | | F | | 3/1/2018 | <p>her heart went back into afib one; feeling tired; numbness in her hands and fingers; tingling in her hands and fingers; lower back pain on the right side/lower back starts to hurt sometimes; weakness in legs/legs are weak; shortness of breath; feeling off; black eye; This is an initial solicited report from a non-Pfizer sponsored program, from a contactable consumer, based on information received by Pfizer. This 79-year-old female patient was involved in a patient support program. The patient received apixaban. The report describes a case of fatigue (feeling tired), hypoaesthesia (numbness in her hands and fingers), paraesthesia (tingling in her hands and fingers), back pain (lower back pain on the right side/lower back starts to hurt sometimes) and muscular weakness (weakness in legs/legs are weak). The occurrence of additional non-serious events is detailed below. The patient's past medical history included High frequency ablation and Hospitalisation. In March 2018, the patient started apixaban (Oral), (unspecified dose, twice a day). On an unknown date, the patient experienced fatigue (feeling tired), hypoaesthesia (numbness in her hands and fingers), paraesthesia (tingling in her hands and fingers), back pain (lower back pain on the right side/lower back starts to hurt sometimes), muscular weakness (weakness in legs/legs are weak), dyspnoea (shortness of breath) and feeling abnormal (feeling off). The action taken with apixaban (Oral) was unknown. At the time of the report, fatigue, hypoaesthesia, paraesthesia, back pain, muscular weakness, dyspnoea and feeling abnormal outcome was unknown. For apixaban (Oral), the reporter did not provide any causality assessments. Patient received apixaban for the indication of Atrial fibrillation. The consumer reported that in Mar-2018 during a trip with her daughter, she began feeling tired and her legs hurt. When she returned home, she was hospitalized and diagnosed with Atrial Fibrillation. Follow-up (18Mar2021): This is a follow-up solicited report from a non-Pfizer sponsored program, from a contactable consumer, based on information received by Pfizer license party for apixaban. This 79-year-old female patient was involved in a patient support program. The patient received APIXABAN. The report describes a case of ATRIAL FIBRILLATION (her heart went back into afib one). The occurrence of additional non-serious events is</p> |

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detailed below Co-suspect products included Covid-19 Vaccine. The patient's past medical history included High frequency ablation and Hospitalization. Concurrent medical conditions included AFib. In March 2018, the patient started APIXABAN (Oral), (unspecified dose, twice a day). On an unknown date, the patient experienced ATRIAL FIBRILLATION (seriousness criterion medically significant), FATIGUE (feeling tired), HYPOAESTHESIA (numbness in her hands and fingers), PARAESTHESIA (tingling in her hands and fingers), BACK PAIN (lower back pain on the right side/lower back starts to hurt sometimes), MUSCULAR WEAKNESS (weakness in legs/legs are weak), DYSPNOEA (shortness of breath), FEELING ABNORMAL (feeling off) and EYE CONTUSION (black eye). The patient was treated with Surgery (heart monitor) for Atrial fibrillation. The action taken with APIXABAN(Oral) was unknown. At the time of the report, ATRIAL FIBRILLATION, FATIGUE, HYPOAESTHESIA, PARAESTHESIA, BACK PAIN, MUSCULAR WEAKNESS, DYSPNOEA, FEELING ABNORMAL and EYE CONTUSION outcome was unknown. The patient stated that she had the coronavirus Pfizer vaccine and a few days later she had a black eye. The patient was concerned about this because she takes Eliquis so she asked a healthcare professional for advice they then informed her that the vaccine had caused her black eye. She was told that she cannot miss her second vaccine and that she might have to stop Eliquis. Patient was concerned about having to stop and had some questions. The patient reported that, she had been on Eliquis for a while and she had been doing just fine. She recently took the Pfizer Covid vaccine and a week or two later she developed a "black eye". She described the color around her eye as eggplant purple. She remembered her mother would have blood vessels burst around her eye, so at first, she thought nothing of it. She said the day before yesterday she went with her daughter while she got the Moderna Covid vaccine. She asked the nurse administering her daughters Moderna Covid vaccine if the Pfizer vaccine could cause black eyes. The patient said the nurse did some research and told her the the Pfizer vaccine was known to cause hemorrhaging, and that the vaccine caused the black eye. The nurse told the patient she should go to her HCP as soon as possible and get blood work done. The patient did not

say anything else was abnormal about her blood work. She told the HCP what happened to her eye after she was given the Pfizer Covid vaccine. The HCP told her that no matter what the patient should get the second Pfizer vaccine, even if she had to stop the Eliquis for a few days. The patient said she did not want to stop the Eliquis because she has been doing wonderful on the medication and did not think the Eliquis was the cause of the black eye. She said she will have a talk with her normal primary care doctor as well as her cardiologist. The patient said she rather not get the second covid then stop the Eliquis. The patient started Eliquis two years ago after her heart went into "full afib" she had an ablation procedure and they shocked her heart three times to get it back into rhythm. Since starting the Eliquis the patient said her heart went back into afib one time. She wore a heart monitor and her heart went back into sinus rhythm on its own. She also mentioned that her HCP prescribed her a diuretic but she said she has a terrible reaction to it. She was prescribed the diuretic to help with the swelling around her ankles. She said the diuretic was also to help "keep congestion from her heart". The diuretic makes her feel "terrible" so her HCP allows her to cut the pill in half or quarters and take as needed to keep swelling down. She said the diuretic makes her feel faint and she even passed out one time while walking in the mall. She said she has not taken it in a while. The patient said she had a lot of allergies to medications, to many to list.

DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 17-Mar-2021, Prothrombin time: 16.2 seconds. For APIXABAN(Oral), the reporter did not provide any causality assessments. Patient received apixaban for the indication of Atrial fibrillation. The consumer reported that in Mar-2018 during a trip with her daughter, she began feeling tired and her legs hurt. When she returned home, she was hospitalized and diagnosed with Atrial Fibrillation. The strength of Eliquis was 5 mg. Most recent follow up information received on 18-Mar-2021 from Non-Health Professional incorporated above includes : New events added, lad data, concomitant drugs and narrative updated.; Sender's Comments: BMS Medical Evaluation Comment: This 79-year-old patient had atrial fibrillation after therapy with apixaban. Elderly age and underlying atrial fibrillation can be associated with increased risk of arrhythmias and

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| 1161233 | 4/2/2021 WA | 65 F | 3/31/2021 | 4/1/2021 | <p>based on the absence of etiological plausibility; the reported event is considered not related to apixaban.</p> <p>Basic Information Chief Complaint Palpitations began at 0940 today, Hx SVT, received second dose of Moderna vaccine yesterday History of Present Illness 65F with hypothyroidism and hx of SVT, who presents with palpitations. She has had palpitations reportedly since childhood and has documented SVT on cardiac monitor in 3/2017. At baseline she has palpitations 1-4x per month, but she has had more frequent palpitations since receiving the COVID vaccine earlier this month. 2nd COVID dose yesterday. Today her palpitaitons lasted 1.5 hours prompting her to present to ED. She is asymptomatic aside from palpitations. No lightheadedness, syncope, chest pain, SOB, N/V, diaphoresis. No leg swelling. She is able to walk around while having palpitations. She does not take rate control agents or anticoagulation. She has plans to see her ARNP for outpatient cardiac monitoring in mid April.</p> |
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| 1162065 | 4/2/2021 | OH | 64 | M | 3/11/2021 | 3/11/2021 | Kidney stone; Blood all over him; Falling down; Wobbliness; No energy; Could not sleep at all; Sweating like crazy; No appetite; This is a spontaneous report from a contactable consumer (patient). A 64-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), first dose (at the age of 64-years old) via an unspecified route of administration in the left arm (reported as injection in left shoulder) on 11Mar2021 at 13:00 (Batch/Lot number UNKNOWN) as a single dose for COVID-19 immunisation. Medical history included colitis ulcerative from 1982 and ongoing, ongoing seizure (he had seizures for about 6 years and they got worse, probably it has been 6 or 7 years he has had seizures), high blood pressure, heartburn and insomnia (comes and goes). Concomitant medication included atorvastatin (manufacturer unknown, Tablet) 40mg strength, oral administration, 20 mg daily (half a tablet at bedtime) taken for an unspecified indication from an unspecified start date and ongoing; cholecalciferol (manufacturer unknown, Tablets) oral administration, 2 tablets in morning taken for colitis ulcerative from an unspecified start date and ongoing; escitalopram (manufacturer unknown), oral administration, 20 mg once daily taken for seizure from an unspecified start date and ongoing; lacosamide (manufacturer unknown) oral administration, 200 mg twice daily taken for seizure from an unspecified start date (for approximately a couple of years) and ongoing; lisinopril (manufacturer unknown), oral administration, 20 mg daily taken for high blood pressure from an unspecified start date and ongoing; mesalazine (MESALAMINE, Tablet), oral administration, 4 tablets a day taken for colitis ulcerative from an unspecified start date and ongoing; omeprazole (manufacturer unknown) oral administration, 20 mg as needed (two or three pills daily as he feels like he needs) taken for heartburn and ulcerative colitis from 2001 (approximately 20 years ago) and ongoing and zonisamide (manufacturer unknown) oral administration, 100 mg twice a day taken for seizure from an unspecified start date (for a couple of years) and ongoing. The patient did not receive any other vaccines within 4 weeks prior to the COVID-19 vaccine. The patient received the vaccination on 11Mar2021. After he received his first dose of the vaccine he experienced a bunch of symptoms which he listed as sweating, he could not |

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sleep at all the first night, he was falling down, he had no appetite, and had no energy that same day. This occurred after the 15 minute window of waiting after getting the vaccination. On 11Mar2021, after the vaccination, the patient went to the store to buy groceries and started sweating like crazy. He could hardly carry the groceries to the car. He also had wobbliness. On 11Mar2021, the patient fell down and passed out coming home that night and he had blood all over him. He later clarified that he did not pass out, he got into the house and fell down and somehow landed on the recliner. He was covered in blood and all kinds of stuff. On 11Mar2021, he could not sleep at all that first night and his prescription Melatonin (Manufacturer Rugby) 3mg did not help at all. The falling down occurred roughly that same night on 11Mar2021. The patient stated that they told him they thought he was having seizures again but he was not. He had imaging which showed no seizures and Xray of his brain with unknown results in Mar2021. He had to have another Xray to make sure he did not have bleeding on the brain. Xray of his stomach showed kidney stones on 12Mar2021. The patient was not admitted to the hospital. The patient was scheduled to return for the second dose 01Apr2021. The patient inquired if he should get the second dose of the vaccine. The outcome of events kidney stone, blood all over him, could not sleep at all and wobbliness was unknown. The outcome of events sweating and falling down was recovered on 11Mar2021 and no appetite was recovered in Mar2021. The outcome of no energy was recovering. The lot number for the vaccine was not provided and will be requested during follow up.

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| 1162862 | 4/2/2021 | TN | 27 | M | 4/2/2021 | 4/2/2021 | 1744 Patient received his 1st dose covid vaccine 1802 Patient notified PCT in waiting room that he was feeling lightheaded after he witnessed another patient have a syncopal event. Patient stated that he has passed out in the past during IV procedures. Patient did become very pale and was staring off. He was able to verbally respond during the event with a few words. He reported that his hands were tingling and ears were ringing. Patient remained upright in a chair. He was given a cold paper towel and bottle of water to drink. He remained in the waiting room until 1845. He ambulated around the clinic front. He left ambulatory in no distress. He stated he felt better. |
| 1160926 | 4/2/2021 | WI | 19 | F | 4/2/2021 | 4/2/2021 | fainted briefly, pallor - happened within a couple minutes of receiving vaccine. patient recovered within 10-15 minutes, sat with ice packs, had a glass of water, and a granola bar. |
| 1162998 | 4/2/2021 | CO | 29 | M | 4/2/2021 | 4/2/2021 | Patient was sitting on the chair in front of the pharmacy and he passed out and fell out of the chair and hit his head. He said he felt dizzy. He passed out again but did not fall. The store called 911 and the paramedics came and took him away. I asked for a report but did not come back |
| 1160422 | 4/2/2021 | CA | 28 | F | 3/31/2021 | 3/31/2021 | 5hrs after dose: Fever, chills, body aches. Tried to sleep it off and go to bed 15hrs after dose: nausea, dizziness, syncope . Woke up in the early morning and fainted in the bathroom after feeling nauseous |
| 1162951 | 4/2/2021 | AZ | 35 | F | 4/2/2021 | 4/2/2021 | Patient received vaccine and about 10 minutes after administration experienced syncope. She recovered well within the following 30 minutes and her husband took her home after the fire department monitored her. |

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| 1162919 | 4/2/2021 | CA | 24 | M | 4/2/2021 | 4/2/2021 | <p>On Friday, April 4, 2021 client (DOB 5/3/1996) received his first dose of Pfizer COVID vaccine (LOT # EW0150, EXP 7/2021) at approximately 12:56pm. Per EMT report: at 1:06pm, client fell out of chair, landed on his left knee and regained consciousness immediately. Upon assessment, client stated his left knee pain was a 3 out of 10 scale. At 1:07pm, client was sat in the zero-gravity chair in supine position and given a bottle of water. Client stated he "felt pressure in ears-mainly right ear." EMT & 2nd EMT coached client to breathe normally. At 1:09pm vitals were taken: BP: 120/70, HR: 52, RR: 10, O2 sat: 95%, skin: pale, moist, cool, eyes: PERRLA, LOC: A&O x4. Lead RN was notified and advised vitals be taken every 5 minutes for an additional 30 minutes. At 1:13pm vitals were retaken: BP: 120/70, HR: 69, RR: 12, O2 sat: 94%, eyes: PERRLA, skin, pale, moist, cool, LOC: A&O x4. On assessment, client stated he has no history of fainting, no allergies, and not taking any medication. Client stated he had a small amount of food and water intake and was not currently experiencing nausea. At 1:20pm, client stated the pressure in his ear subsided and was experiencing no headache, light-headedness or dizziness. At 1:25pm vitals were retaken: BP: 120/70, HR: 69, O2: 98%, skin: warm, pink, dry, LOC: A&Ox4. At 1:35pm, vitals: BP: 120/78, HR: 72, RR: 12, O2: 96%. Client was lowered to sitting position in gravity chair. No changes in vital signs were assessed by EMTs. At 1:40pm one final set of vitals were taken: BP: 120/76, HR: 66, RR: 13, O2 sat: 97%, eyes: PERRLA, A&O x4, skin: pink, warm & dry. At 2:15pm, client was able to safely stand up. No further interventions indicated. Client was educated by Lead RN & EMT on signs and symptoms of adverse reactions and when to go to the ED/call MD. Client was also encouraged to sign-up. Client left vaccination site at approximately 2:15pm with a steady gait. A family member was able to pick him up and drive him home.</p> |

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| 1162918 | 4/2/2021 | FL | 48 | F | 4/2/2021 | 4/2/2021 | Patient complained feeling faint and felt like she was going to pass out. Patient was observed to have heavier breathing than normal. She also complained of numbness in her left arm. EMS was activated immediately. Patient's blood pressure was 51/38 mmHg . Oxygen was measured at 99 % Sp O2, PRbpm 45. Emergency contact for patient was notified. EMS arrived and took over. Patient returned hours later to pharmacy to informed us she was okay. She was told she had experienced vasovagal syncope. |
| 1162901 | 4/2/2021 | CA | 60 | F | 4/2/2021 | 4/2/2021 | syncope about 3 minutes after dose administered. Patient was in reclined chair and recovered quickly. Paramedics were called and they assessed her in the store. Patient declined further treatment, walked out of the store on her own, and a relative drove her home. |
| 1162696 | 4/2/2021 | TX | 24 | F | 4/2/2021 | 4/2/2021 | Pt got vaccine and she fainted about 5 minutes post dose. She immediately came too and was ok to go home after 15 minutes. |
| 1162867 | 4/2/2021 | OH | 24 | M | 4/2/2021 | 4/2/2021 | I did not vaccinate this patient, but I went out to the parking lot when a customer said someone fainted outside. The patient was asked to wait 15 minutes in the store. However his mom was with him and stated that he always faints after injections, so she wanted to put him in the car to lie down. When I arrived the patient was awake and feeling warm. Sitting up |
| 1162714 | 4/2/2021 | CA | 38 | F | 3/1/2021 | 4/2/2021 | While in the shower a day and a half after receiving the second vaccine, patient experienced shortness of breath and nearly lost consciousness. Body shaking. Fainting almost occurred. Light headedness. Increase in blood pressure. Increased heart rate. Increased body temperature. |
| 1162826 | 4/2/2021 | AZ | 32 | M | 3/31/2021 | 3/31/2021 | Started with sweeping of hands, feeling hot and flushed, then redness of face. Extremely itchy. Fainted once arrived to ER. |

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| 1162823 | 4/2/2021 | CA | 23 | M | | 4/2/2021 | Patient got first dose of Covid vaccine (Prizer) on 04/02/21 around 11:00am. Patient started develop adverse effects of dizziness, cold and low blood glucose. He almost passed out. He refused us calling 911. However after 20 minutes, symptoms get worse . We call 911 and AMR arrived. |
| 1162822 | 4/2/2021 | TX | 60 | F | 3/6/2021 | 3/10/2021 | I felt OK for the first 3 days and then I started having worse symptoms of my MCAS and POTS condition. Note, I had NOT had POTS symptoms for 7 years. I was originally diagnosed with POTS in 2010 but slowly got better over 3 -4 years time and have not had issues with POTS since until after the 1st dose of the Covid 19 vaccine. Once my mast cell issues seemed to improve after the first week or so then the POTS symptoms kept getting worse. I am now one month out from the first shot and my heart rate and blood pressure are so bad I'm mostly couch ridden. I'm seeing a cardiologist on Monday. Heart rate even when sleeping at night is shooting up to 125-136 without exertion, just sleeping or standing. I have almost passed out while driving 5 times. Until I improve I won't be driving on major freeways. My vision has also been severely effected. Very blurry and one time all I could see were prisms blinding my view of almost everything. Also very weak all of the time and a lot of pressure in my head, it feels like someone is pushing my head forward. Some ringing of the ears as well. |
| 1162778 | 4/2/2021 | TX | 53 | M | 3/20/2021 | 3/27/2021 | I TOOK THE SHOT ON 03/20/2021, FELT BREATHLESS WHILST TAKING A WALK ON THE TRAIL ON 03/27/2021. DIZINESS ABOUT FOUR TIMES ON 03/27/2021 AND I PASSED OUT MOMENTARILY/CHECKED INTO ER. NOT EXACTLY SURE IF THE VACCINE IS THE CAUSE, BUT IT REQUIRES LOOKING INTO BECAUSE I HAVE NEVER HAD SUCH AN EXPERIENCE IN MY ENTIRE LIFE. |
| 1162773 | 4/2/2021 | CA | 64 | F | 4/2/2021 | 4/2/2021 | dizziness, fainting feeling post vaccination, has hx DM on oral meds, no meds given, stable and DC AMA with son driving pt home |

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| 1162770 | 4/2/2021 | CA | 26 | M | 4/2/2021 | 4/2/2021 | Patient fainted after the Shot and regained consciousness .He complained about dizziness and nausea. 911 was called. He was advised to sit and be observed until they arrived |
| 1162956 | 4/2/2021 | MI | 19 | F | 3/30/2021 | 3/31/2021 | I received my second dose of the COVID 19 Moderna vaccine on Tuesday morning. By Tuesday night I started to have virtually every side effect that Moderna listed including; fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, and extreme fever. The next morning as I woke up in attempt tp get ready for work, I was not feeling any better and began to feel light headed, and felt the need to vomit. As I had the feeling of needing to vomit, I turned to do so and fainted. From accounts by my family, I was told I woke up, and quickly passed out a second time. As I was awoken, there was probably a minute before I fainted for a third time. All three times I was told I lost consciousness. I was awoken and by that point my family had contacted emergency responders. Paramedics arrived and took all necessary vitals. I did not pass out after that third time. As I expected all side effects Moderna listed, I did not expect to feel as bad as I did and I thought it was worth reporting what happened to be the next day. It caused a panic and I was scared and nervous as I was unsure why that was happening. I've tried to look up articles and links between passing out and the vaccine and all I can find is people fainting as they get the vaccine (which is common for any shot) but nothing for fainting that long after the vaccine was administered. I just wanted to report my incident. |
| 1162893 | 4/2/2021 | NJ | 24 | F | 3/31/2021 | 4/1/2021 | Low blood pressure, brief (5 minute) fainting and dizziness spell |
| 1160543 | 4/2/2021 | ME | 18 | F | 4/2/2021 | 4/2/2021 | Patient received Janssen Vaccine around 11:30 am. Patient was told to wait around 15 minutes to make sure everything was ok. Patient got my attention a few minutes later saying she felt dizzy. As i was guiding her back to the chair she passed out and i guided her to the floor. In a few minutes she was able to sit upright in the chair. EMS was called and she later went to hospital for further evaluation. |

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| 1160686 | 4/2/2021 | OH | 52 | F | 3/31/2021 | 3/31/2021 | 12:10PM 'CHEST TIGHTNESS AND SOB' PALE, RESP SHALLOW. 12:13PM EPI PEN GIVEN LT LATERAL THIGH. NEAR SYNCOPE - PLACED ON FLOOR WITH FEET ELEVATED. BP 77/68, HR118, R 20 02 SAT 97%. 12:20PM IV STARTED PER SQUAD. NO WHEEZING PER AUSCULTATION - BREATH SOUNDS DIMINISHED. BP 182/90, HR 110, R 16, 02 SAT 95%. TO ER PER SQUAD. 4-2-21 10:20AM: STATES TREATED/RELEASED FROM ER. NOW HAS RASH TO FACE/CHEST, HEADACHE AND FATIGUE. HAS APPT WITH PCP TODAY. |
| 1160678 | 4/2/2021 | DE | 63 | F | 4/1/2021 | 4/1/2021 | After the Covid shot, I was instructed to wait in my car for 15 minutes. Approx. 12 min after the shot, I got a burning sensation in my left arm that continued across my upper body, throat and into my bladder and felt like I was going to urinate. It lasted approx. 2 min and subsided. Then I felt like I was going to pass out, so I drank some water and reclined in my seat to rest. I never passed out but waited another 15 minutes to proceed home. As I was driving home approx. 6 minutes since I left the clinic, the same feeling came over me. I immediately pulled off the highway into a near by parking lot until it subsided which was again approx. 2 minutes. I waited 10 minutes then proceeded to drive home which was only. Additional information for Item 18: which was only 5 minutes away. Once home, I laid down because I was tired and uneasy about what had just happened. I had no other symptoms and that feeling never returned. I thought I should call my family doctor and let him know what happened. I called Dr. office and left a message for him about what happened. His nurse called me back and she had relayed the message to Dr., and said I should not receive the 2nd Covid shot since I had this reaction to the first shot. I have not had any other issues except a little soreness in the arm where the shot went in. |

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| 1160668 | 4/2/2021 | WV | 42 | F | 3/12/2021 | 3/22/2021 | Ten days after the vaccine was administered I woke up feeling like something was wrong. I just didn't feel right. I tried to lay down to see if I could feel better but this did not help. Even while in a relaxed state my blood pressure was up to 170/97 and heart rate of 220. I was very dizzy and felt like fainting but did not lose consciousness. I had a terrible pressure in my chest, in the left side of my neck and along the inside of my left arm. Also notable my vision was blurred. Called 911 ambulance took me to the Hospital ER and the ekg they performed was abnormal and also notable when they drew my blood my sodium level was below the normal threshold. I had taken 3 nitroglycerin tablets and my symptoms subsided enough for them to let me go home. Since coming home my bp has remained elevated much higher than normal at around 135/85. I continue to feel not quite normal and have the pressure in my left side of neck, chest and left arm. I feel very certain this is all due to the covid vaccine I received. |
| 1160667 | 4/2/2021 | NY | 40 | F | 3/27/2021 | 3/28/2021 | nausea,, light headed, fainted, chills, sweats,body aches, |

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| 1160647 | 4/2/2021 | WI | 39 | M | 3/17/2021 | 3/17/2021 | Patient reported history of fainting/getting woozy when receiving injections. Vaccinator offered for patient to lay down for injection but he refused. After the vaccine was administered the patient remained in the vaccinator's chair for a few minutes. Patient denied feeling woozy and walked to the observation station. Vaccinator informed the greeter at the observation station notified of history and that they should closely monitor him. 1700 BP 132/92 Pulse 74 Resp 16. Patient sweating. continued to be monitored. no medication administered. 1705 BP 132-80 Pulse 74 Resp 14 1710 BP 162/90 Pulse 82 Resp 16 Patient offered a breakfast bar. states "feeing fine" 1715 162/108 Pulse 78 Resp 16 Patient returned to chair (had lowered himself to the floor). No sweating. Denies SOB and difficulty breathing. 1725 BP 162/80 Pulse 64 Resp 16. Patient states he "feels OK and doesn't feel "funny" 1732 BP 144/110 Pulse 78 Resp 16 Patient denies SOB States feeling "OK" temp 97.3 Ate a cookie 1742 BP 178/106 Pulse 76 Resp 16 Patient denies HA or lightheadedness 1753 BP 172/106 Pulse 74 Resp 16 Reports he "feels normal". Patient was advised to seek medical attention. Declined EMS call/evaluation. Patient released to self. Call placed/message left for follow up on 3/26. No return call received. |
| 1160616 | 4/2/2021 | OH | 45 | M | 4/2/2021 | 4/2/2021 | Several minutes after receiving his vaccination, he had a brief episode of syncope. |
| 1160578 | 4/2/2021 | SC | 74 | F | 2/5/2021 | 2/23/2021 | Auto Accident - syncope - Ambulanced to Hospital. Passed out and hit a tree, totaled vehicle with no memory of the event. CT without contrast, blood work, EKG, fluid given IV. Stayed about 3 hours and was released. |

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| 1160718 | 4/2/2021 | MN | 34 | F | 4/2/2021 | 4/2/2021 | vaccine was administered to patient, and patient immediately fainted. Her head drooped, and she was not conscious. The technician who administered the vaccine caught the patient so she didn't fall out of the chair. The pharmacist on duty was alerted, and 911 was called. The pharmacist ran out to the patient to check vitals. Patient was already conscious again, but looked pale and weak. Pharmacist and technician stayed with patient to make sure she did not pass out again. EMT arrived shortly after call and took over the situation. Patients blood pressure was taken, and was very low 80/50 for several minutes. EMT stayed and monitored patient until she regained normal vitals, and sent patient home with her mother so did not have to drive. |
| 1160548 | 4/2/2021 | PA | 24 | M | 4/2/2021 | 4/2/2021 | I felt light headed, hot, and passed out within minutes of injection. About 10 minutes later I felt like I might pass out again, but did not. |
| 1160493 | 4/2/2021 | TX | 26 | M | 3/23/2021 | 3/23/2021 | Pt fainted in chair while being observed post vaccination. |
| | | | | | | | Date: 3/23/2021 Problem: Dizziness, fainting Notes: Pt stated he began to feel dizzy and started to lose balance in his chair. VS taken BP 113/70 P102 O2 97 T 97.1 RR 18 BS 104. Continued to monitor pt. No signs of acute distress. Pt able to communicate appropriately. A/Ox4. No bleeding or redness at injection site. Water and granola bar provided to pt. Monitored for 30 minutes. VS remain stable, pt AxO4 and states he feels good. Pt left facility in good condition. |
| 1160538 | 4/2/2021 | CA | 71 | F | 3/27/2021 | 3/28/2021 | The next morning, I fainted when I got out of bed. |
| 1160530 | 4/2/2021 | NY | 20 | F | 4/2/2021 | 4/2/2021 | Individual fainted while walking to the medical area. Patient was brought by wheelchair to medical area. Loss of consciousness was approximately 1 minute. Patient laid on cot, vital signs all within normal limits. Patient recovered quickly and signed off on further medical assistance. |

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| 1160505 | 4/2/2021 | NY | 36 | F | 4/1/2021 | 4/1/2021 | Near syncope, Shaky, Tingling in fingers |
| 1160502 | 4/2/2021 | OH | 19 | F | 4/1/2021 | 4/1/2021 | 4:10PM SYNCOPE -EASED TO FLOOR BECAME RESPONSIVE. MOVED TO COT PER WHEEL CHAIR. A/O, PINK, W/D, RESP WITH EASE. NO PAIN, NO SOB. FAMILY X 3 AT SIDE. 4:20PM 'FEELS BETTER'. CRACKERS AND WATER GIVEN. 4:31TO EXIT PER WHEEL CHAIR, MOM TO DRIVE PT HOME. NO ACUTE DISTRESS NOTED. 4-2-21 12N TC: 'FEELS FINE TODAY'. |
| 1160475 | 4/2/2021 | MA | 70 | M | 4/2/2021 | 4/2/2021 | Patient received vaccine dose 2. Waited 15 minutes in observation area. Upon leaving observation area, patient passed out. Hit eyebrow and had laceration. Patient recently dx with Shingles 3 days ago and on valcyclovir for treatment. Patient also stated he did not eat at all today. Blood Glucose was 135. |
| 1161210 | 4/2/2021 | TX | 50 | F | 3/27/2021 | 3/27/2021 | Neuropathy starting evening of shot and progressed very fast on right side. Went from arm to hip down leg to right foot then back to hip and right arm and into right neck glands to back of my head and starting back down along with shortness of breath. I called pharmacy to report it and was guided here to report. The shot was given on the left shoulder last Saturday and this is still continuing this Friday currently. Has been 98% debilitating. I just have such weird things with my neurocardiogenic syncope and healing is slow for me because of my weakened immune system , just reporting because I never know what to expect with my chronic illness. |
| 1162999 | 4/2/2021 | WA | 43 | M | 4/2/2021 | 4/2/2021 | Patient fainted after vaccine administration. 911 was called and EMTs responded, patient was observed by pharmacist on duty, did not need further medical support. |

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| 1160574 | 4/2/2021 | NC | 42 | M | 4/2/2021 | 4/2/2021 | Patient's wife exited from car screaming for help reporting patient passed out. Upon arrival of RN, patient had regained consciousness and was A&O x 3. He was sweating, pale, with active pilomotor reflex. VS: BP 80/55, temp unable to obtain, HR 67, RR 24 EMS called and repeat vitals at their arrival BP 152/121, HR 67-70, T 96.5, RR 24. Patient's brother is MD and spoke with EMS reporting extensive hx of vasovagal syncopal events at dentist in past as well as with high stress events. Patient decline transport to ER and wife elected to drive home. Patient remained at cognitive baseline without complaints at time of departure from site. |
| 1160968 | 4/2/2021 | MN | 23 | M | 4/2/2021 | 4/2/2021 | Patient indicated on consent form that he had never had a reaction after receiving a vaccine before. Pharmacist on duty administered vaccine to patient. Patient walked from the vaccine administration location to the waiting area and sat down. Pharmacist heard a loud thud, and customer yelled "call 911" 911 was called, and patient was given a pillow under his head, and a blanket covering his body. He was unconscious for about 5 seconds, then came to. He was able to answer questions correctly like his name, and what year it is. Management came to help and take care of patient also. EMT arrived and took patient's BP and blood glucose levels. EMT recommended a snack because patient had not eaten yet today. Patient was given cheetos and water. EMT stayed to monitor patient until his vitals returned to normal. Patient told EMT that he has fainted about 8 times previously after giving blood, but never after receiving a vaccine. Came to pick him up so he did not have to drive home. Patient stated he had chipped his tooth when he fell from the chair. |
| 1160767 | 4/2/2021 | IN | 57 | F | 3/26/2021 | 3/27/2021 | Diarrhea, nauseated, loss of appetite, cold, clammy, almost passed out, headache, extreme exhaustion starting @ 5:30 AM next morning lasting until noon on 3/28/21. Legs and arms hurt and generally felt week, shortness of breath, exhaustion and extreme headache. More than likely had covid-19 in July 2020 and was still suffering from covid long haul symptoms. After taking the shot long haul symptoms worsened |
| 1161160 | 4/2/2021 | CA | 19 | M | 4/1/2021 | 4/2/2021 | vasovagal syncope |

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| 1161050 | 4/2/2021 | CA | 35 | F | 4/2/2021 | 4/2/2021 | Pt passed out seated in driver's seat in idle, ran into car in front of her. Pt pale, cool diaphoretic, refused transport to hospital. Pt observed until vitals within normal limits. |
| 1161030 | 4/2/2021 | CA | 45 | F | 3/31/2021 | 3/31/2021 | 13 hours after my injection I fainted and fell. After getting up I fainted and fell again. I also had the typical symptoms of arm pain, sweating and weakness before fainting. After fainting I had the above plus chills and muscle spasms and was unable to get up for about 20 minutes. |
| 1160975 | 4/2/2021 | TX | 26 | M | 3/22/2021 | 3/22/2021 | Date: 3/23/2021 Problem: Syncope Notes: Client requested a bottle of water upon returning with the water client noted to fall out of his chair. Staff was able to reach him before he hit the ground, guiding his head downward off setting some of the impact from the fall. Client states he does not remember the fall. He also states he has a history of fainting when he gives blood. AAOx3 T 97.4 P68 R18 BP 124/72 O2 97% RA Client monitored for an additional 30 minutes. States he feels fine after 30 mins. T98.0 P72 R20 BP 126/70 O2 98% RA. Client left facility AAOx3 via personal vehicle. |
| 1161147 | 4/2/2021 | TN | 20 | F | 4/2/2021 | 4/2/2021 | Patient received 1st dose of Pfizer COVID vaccine. Upon administration, patient reported she felt as though she was having an anxiety attack. She then fainted and started falling forward in her chair. The pharmacist and technician caught the patient as she fell forward and as they were leaning her back in the chair she began seizing in their arms for approximately 5-10 seconds (no more than 20-30 seconds). At this point, the patient spoke and stated that was weird and said she felt lethargic. Another technician was on the phone with 911 at this time. We gave her a bottle of water and kept the patient seated in the immunization room until EMS arrived. She was complaining of being very hot and lethargic. EMS arrived and checked her vitals and recommended the patient go with them to the hospital due to B/P and pulse being very low (exact vitals were not communicated to us). She agreed to go to the hospital and we will be following up with the patient tomorrow. |

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| 1161181 | 4/2/2021 | PA | 38 | M | 4/1/2021 | 4/1/2021 | Patient stood up to get a drink of water after receiving his vaccine and seemed a little unsteady. The pharmacy team asked him to remain seated for at least 15 minutes and brought patient water. He experienced syncope a few minutes later. Emergency services were contacted and evaluated patient. |
| 1160953 | 4/2/2021 | CO | 46 | M | 4/2/2021 | 4/2/2021 | Client received vaccine at 12:40 and waited the required 15 minutes for observation. After leaving the building, he felt unwell and starting coming back inside where he had multiple episodes of syncope. EMS was called. The client wasn't able to make it to sitting without syncope so he was transported to the hospital via ambulance. |
| 1160915 | 4/2/2021 | CA | 28 | F | 4/1/2021 | 4/2/2021 | Arm pain after shot, no other symptoms until going to sleep. Woke up with headache around 1:45am Tried to get water at 2:20am to help headache Got nauseous next to sink - feeling like throwing up while pouring water Passed out Woke up shortly after on kitchen floor Stumbled to bedroom on super weak legs (which were kinda giving in) When laying back down ringing (like static) in ear for about 1min and tingly feet and hands for about 3min Afterwards still feeling weak and having headache but no other symptoms. Awake with headache until 6am, slept 6am-7am, woke up with slight feaver, headache persisted 8:30am took daily meds, had food and water, took sumatriptan for headaches and awake until 11:30am Slept from 11:30am to 1:30pm - woke up feeling A LOT better, little to no headache left, only still feeling weak and armpain |

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| 1160896 | 4/2/2021 | MN | 61 | F | 4/2/2021 | 4/2/2021 | Patient alerted pharmacy that she had experienced swelling and itching from influenza shots in the past, and has asthma and allergies, however has never had to use an Epi-pen in the past. Patient seemed very nervous, but insisted she was OK to receive the shot. Pharmacist on duty administered Moderna to patient, and waited next to her for several minutes to observe for possible reaction. Patient felt fine after several minutes of talking, so pharmacist advised patient and her husband to let her know if patient started feeling SOB, or itchy, or swelling of face, and went back to pharmacy to complete rxs in que. At that time a different patient who had just received the Moderna vaccine passed out, and pt witnessed this, further increasing her anxiety. 911 was called for the patient who passed out. During the next half hour, pharmacist kept checking on pt. She indicated her tongue seemed to be swelling. So pharmacist on duty asked EMT to check out pt after they had finished taking care of patient who had passed out. EMT checked pt throat, and assured her there was no swelling, however suggested diphenhydramine 25-50mg to be proactive. Pharmacist on duty asked pt if she would like diphenhydramine, and she said, "Yes, Please." So pharmacist provided the diphenhydramine to pt, and she took 50mg. After that she seemed to be fine, and her husband took her home. |
| 1160894 | 4/2/2021 | IL | 33 | M | 4/2/2021 | 4/2/2021 | Patient fainted after receiving vaccine. |
| 1160893 | 4/2/2021 | OH | 37 | F | 4/1/2021 | 4/2/2021 | Passed out in shower |

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| 1160891 | 4/2/2021 | WI | 32 | M | 3/26/2021 | 3/26/2021 | Pfizer-BioNTech COVID-19 Vaccine EUA 32-year-old male with history of anxiety and hypertension presents with possible reaction to the COVID vaccine. He was in his usual state of health and doing well until he received his first dose of the Pfizer vaccine around 0740 this morning. Around 10 minutes following the vaccine, patient became short of breath, lightheaded and had his vision gray out before losing consciousness for few seconds. Patient was sitting in a chair at that time and did not fall or hit his head. He was then given juice and was able to ambulate and felt better. Patient was directed to the emergency department for evaluation. He states that he now feels back to his baseline with no lightheadedness or difficulty breathing. Patient states that he has passed out following blood draws in the past and usually lies down afterward. Patient's presentation is overall most consistent with vasovagal syncope, especially given his history of similar events following blood draws. Patient was observed in the emergency department for nearly an hour and remained asymptomatic so he was discharged home with return precautions |
| 1160830 | 4/2/2021 | IL | 25 | F | 4/2/2021 | 4/2/2021 | Patient expressed seeing spots then fainted, hypotensive, vitals stabilized, refused of transport |
| 1160979 | 4/2/2021 | SC | 52 | F | 4/2/2021 | 4/2/2021 | Patient fainted a few minutes after receiving the vaccine. She has fainted after vaccines in the past, and fainted for about a minute after receiving the Janssen Covid-19 vaccine. After she returned to consciousness, she reported no difficulty breathing or other adverse reactions at the time. She was monitored in store for 30 minutes following the fainting episode and was feeling much better at the time of departure. Her husband safely drove her home. |
| 1155172 | 4/1/2021 | NY | 61 | F | 3/10/2021 | 3/12/2021 | Woke up very dizzy, light headed, felt like diarrhea, hot, sweaty, passed out approximately 4 times, had a harder time breathing, than normal being on oxygen. Stayed in bed for approximately 27 hours, just couldnt function well. Didnt contact Dr. About it, had family stay with me for couple days. I know it was from the vaccine. |

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| 1155082 | 4/1/2021 | FL | 48 | F | 3/31/2021 | 3/31/2021 | Systemic: Confusion-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Seizure-Medium, Systemic: Vomiting-Severe, Additional Details: none |
| 1155112 | 4/1/2021 | TX | 36 | F | 3/10/2021 | 3/10/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Hypotension-Medium, Systemic: Nausea-Severe, Systemic: Vomiting-Medium, Systemic: Weakness-Mild, Additional Details: First report failed to submit. Pt experienced a syncope event within 1-2 minutes after receiving. It took ~30 seconds for her to regain consciousness. Afterwards, she experienced significant dizziness/nausea and could not pick up her head without these symptoms intensifying. After ~30 minutes, a full bottle of water, and at least 3 BP checks (all of which read <95/60), there was no improvement in s/sx and BP was still low. Recommended pt to go to ER. Improved by next day after fluids/zofran. |
| 1155107 | 4/1/2021 | MA | 29 | M | 3/31/2021 | 3/31/2021 | Systemic: Pt was in the observation area, almost fainted, fell out of the chair-Mild, Additional Details: Pt stated he has a needle phobia. He felt faint and fell out of the chair in the observation area and hit his head on the floor. Pt did not pass out and was alert. He did not need an epi pen or benadryl. He was offered water and accepted. He stayed 20 minutes and left, fine. Manager is calling into the incident line as well. |
| 1155101 | 4/1/2021 | SC | 61 | M | 3/30/2021 | 3/31/2021 | Extreme low blood pressure - 80/40, dizziness and fainting, low grade fever - 99, headache |
| 1155096 | 4/1/2021 | MA | 29 | F | 3/31/2021 | 3/31/2021 | Systemic: Fainting / Unresponsive-Medium, Additional Details: patient fainted while receiving vaccine, 911 was called, pt was all right after sitting for awhile. did not leave by ambulance. |
| 1155086 | 4/1/2021 | IL | 20 | F | 3/31/2021 | 3/31/2021 | Systemic: Fainting / Unresponsive-Medium |

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| 1155074 | 4/1/2021 | MA | 26 | M | 3/31/2021 | 3/31/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Seizure-Mild, Systemic: Shakiness-Mild, Additional Details: patient was administered vaccine, was feeling well and walked to waiting area. patient \"lost balance\" and fell to floor, hitting his face and began bleeding from his nose and upper brow area. Technician retrieved an ice pack from pharmacy, and in the meantime, worker aided patient to sitting position, which was when patient began to seize. worker called EMS while holding patient's head steady. Patient regained consciousness and EMS arrived. Whole event lasted around 5 minutes. |
| 1155063 | 4/1/2021 | FL | 42 | M | 3/31/2021 | 3/31/2021 | Fainted for a brief moment when see needles. 11:15am Patient reported feeling better. |
| 1155059 | 4/1/2021 | MO | 17 | F | 3/31/2021 | 3/31/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Hypotension-Mild, Systemic: Weakness-Mild |
| 1155053 | 4/1/2021 | NJ | 23 | M | 3/31/2021 | 3/31/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: patient was anxious before the vaccine and is afraid of needles. 911 was called, emt arrived and assisted the patient. patient's vital signs were taken and were all within normal limits.-Mild |
| 1155052 | 4/1/2021 | DC | 27 | F | 3/31/2021 | 3/31/2021 | Site: Pain at Injection Site-Mild, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Mild, Systemic: Seizure-Medium, Systemic: Weakness-Mild, Additional Details: P/T stated she had not ate since yesterday. She has had these fainting spells in the past especially when she gets her blood drawn. Her bp & respirations were all within normal levels. Was a and O x 4. P/t stated she was feeling faint and dizzy then asked for water. Pharm tech then went to notify RN of the situation. At the moment p/t began to collapse from the chair and fell on her right upper forehead which started to bruise and swell. She then started to seize & 911 was called & emt arrived. |
| 1155049 | 4/1/2021 | MA | 16 | F | 3/31/2021 | 3/31/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild |

| <i>VAERS_ID</i> | <i>RECVDATE</i> | <i>STATE</i> | <i>AGE_YRS</i> | <i>SEX</i> | <i>VAX_DATE</i> | <i>ONSET_DATE</i> | <i>SYMPTOM_TEXT</i> |
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| 1155610 | 4/1/2021 | OH | 28 | F | 3/31/2021 | 3/31/2021 | Janssen COVID-19 Vaccine EUA Received the shot at 11 am and started feeling tired with some muscle aches at 2:45 pm. I slept from 3:45 to 4:30 pm but was still tired and felt weak. I did feel hungry and made dinner over 30 minutes. However, this wore me out. I was even more tired and started getting dizzy. I almost fainted as I made my way to a chair to sit down. I couldn't eat because of slight nausea and cold chills. I was shaking for about 20 minutes. Eventually, I made it to my bed to lay down, but my legs were shaking as I walked up the stairs. At 6:00 pm, my temperature was 98.8 F. I was freezing a shivering for the next hour in bed under 3 blankets. My hands and feet felt like ice. At 8:00 pm, I had a fever of 100.2 F that lasted all night. My body ached all over, especially at the hips. I couldn't sit still and couldn't sleep until 4:00 am. I woke at 8:30 am with some milder aches and fatigue with a temperature of 97.6 F. |
| 1155033 | 4/1/2021 | NY | 53 | M | 3/31/2021 | 3/31/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild |
| 1155029 | 4/1/2021 | NY | 54 | F | 3/31/2021 | 3/31/2021 | Systemic: Fainting / Unresponsive-Severe |
| 1155051 | 4/1/2021 | SC | 61 | M | 3/30/2021 | 3/31/2021 | Extreme low blood pressure at 80/40, fainting, low grade fever, headache, mild nausea |

| <u>VAERS_ID</u> | <u>RECVDATE</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1155832 | 4/1/2021 | OH | 25 | M | 3/30/2021 | 3/30/2021 | Patient reported to clinic for Pfizer Covid-19 vaccination. Patient did not indicate on questionnaire that he had experienced fainting or severe reactions from receiving vaccinations before. About 5 seconds after receiving vaccination patient said he would like to sit for just a minute. The clinic had a designated waiting area about 25 feet away where patients sit for 15 minutes after receiving vaccination. My technician and I agreed that patient should stay seated in the same chair he was receiving the vaccination in so we would be right next to him. After 2-3 minutes I noticed the patient had his eyes closed and then his head began to nod and he started to slump down in the chair. As I went to patient's side to stabilize him he pushed his chair backwards away from me about 5 feet which caused him to roll to the right side of the chair and fall off hitting his head on the floor. My technician immediately called 911 and EMTs arrived in about 5 minutes. A bystander who was a nurse helped me roll him onto his back and we propped his legs up with 2 cushions. We took his blood pressure and pulse. Patient regained consciousness in about 30 seconds and the EMTs cleared him to stand up after about 15 minutes. After patient had recovered, patient's mother who was there with patient and other siblings stated that the whole family has fainting episodes when receiving vaccinations. I informed patient's mother and patient to please inform any future vaccinators of these fainting episodes so they can be prepared. |
| 1155922 | 4/1/2021 | HI | 34 | M | 3/31/2021 | 3/31/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Feeling faint, on the verge of fainting-Mild, Systemic: Flushed / Sweating-Mild |
| 1155930 | 4/1/2021 | WY | 16 | F | 4/1/2021 | 4/1/2021 | patient passed out 10 minutes after receiving the Pfizer covid vaccination |

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1153998 | 4/1/2021 | NY | 21 | M | | | A spontaneous report was received from a consumer (United States) concerning a 21-year-old, male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced fell out of the chair and passed out/Loss of consciousness, fell out of the chair and passed out/Fall, may have been a seizure but unsure/seizure. The patient's medical history included psychological problems. Concomitant product use was not provided by the reporter. On an unknown date, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Batch number unknown) intramuscularly for prophylaxis of COVID-19 infection. On an unknown date, after the injection he "fell out of the chair and passed out". The reporter stated that she heard it "may have been a seizure but unsure". She reported the male was obese. The events passed out and seizure was considered as medically significant. Treatment information was not provided. Action taken with mRNA-1273 in response to the events was not provided. The outcome of the events fell out of the chair and passed out, may have been a seizure but unsure was unknown at the time of this report.; Reporter's Comments: Very limited information regarding these events has been provided at this time. Further information has been requested. |
| 1155019 | 4/1/2021 | NJ | 18 | F | 3/31/2021 | 3/31/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Mild, Additional Details: EMS arrived at the site after patient had recovered from the episode. vitals were checked. BP: 120/90. pulse: 80. Patient was fully responsive after episode. |
| 1155890 | 4/1/2021 | FL | 18 | M | 4/1/2021 | 4/1/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild |

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1155881 | 4/1/2021 | WA | 30 | M | 3/30/2021 | 3/30/2021 | Patient received his first Moderna COVID-19 vaccine dose at around 2pm at State Fairgrounds mass vaccination drive through site. Shortly after while in the observation lane, patient experienced an episode of syncope along with brief LOC and bumped the car in front of him. Medical Controller alerted the Clinical Supervisor of the incident. Clinical Supervisor arrived on the scene when EMTs were taking patient's vitals: BP (90/60), pulse, temp. (afebrile). Patient was able to state that he has a history of episodes of syncope that can be triggered by various things such as even watching a movie with blood. Patient states he feels fine, but still tingly and shaky. Patient brought to medic unit on site for stat ECG. At 2:15pm patient was offered transport to the hospital, but he refused. Patient continued recovery in the medic unit. ECG report was unremarkable, BP 104/68, pulse 99 and patient states he's feeling better. Patient released by paramedics/ EMTs. Clinical Supervisor spoke with patient prior to him leaving the vaccination site to verify that he is feeling well and able to leave. |
| 1155527 | 4/1/2021 | WI | 16 | F | 3/31/2021 | 3/31/2021 | They made initial contact with young lady when she entered the holding area (as they do with every car). Their second contact came when the mother showed up on scene. At that time the patient reported that at one point her vision began to get dark on the peripherals and she may have passed out. She stated she turned on her hazard lights (four-way flashers) at that point. Our personnel never noticed a vehicle not progressing forward at any point. Our personnel then removed her from the line for evaluation: She no longer had any complaints, vitals: BP 106/57 P-64 and regular SPO2-99% and did not want transport to the hospital. The patient and mother were given instruction of things to watch for and what warranted calling 911. They report the mother and patient had no concerns upon their departure. Further, there were 4-6 personnel in the 15-minute holding area yesterday. They are constantly on foot moving between all the cars. |
| 1155835 | 4/1/2021 | MA | 69 | F | 3/29/2021 | 3/31/2021 | COVID arm and Syncope |

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1155240 | 4/1/2021 | CT | 44 | F | 3/29/2021 | 4/1/2021 | Fainting in the middle of the night after going to the bathroom |
| 1155672 | 4/1/2021 | OH | 28 | M | 3/31/2021 | 3/31/2021 | Patient felt like he was going to faint. Patient has had history of fainting with other vaccines in the past. Patient appears pale, mildly diaphoretic. No apparent respiratory distress. Patient moved to cardiac chair, legs elevated. Cool washcloths applied to back of neck, cool water provided to drink. Patient felt better after 35 minutes and left hospital accompanied by father. |
| 1155569 | 4/1/2021 | NY | 64 | F | 4/1/2021 | 4/1/2021 | Resident had an Anxiety attack, passed out approx 5 minutes after administration. Vital signs were taken, blood pressure & pulse elevated, temperature & oxygen levels okay. Patient was sweating. Approx 2 minutes later, patient became alert & oriented x4. Patient stated that she has a fear of needles. Patient relayed having similar symptoms in the past. Patient has hx of hypertension. No further care given. 911 was called at the time the patient became unconscious. EMS arrived approx the same time as the patient becoming conscious. EMS ran vitals. EMS did not transport. Patient is stable and walking. Patient left location after 30 minutes of monitoring. |

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1155919 | 4/1/2021 | PA | 28 | M | 4/1/2021 | 4/1/2021 | Patient has a history of syncope after vaccinations (last occurred with a vaccination 10 years ago) but did not state this prior to receiving his first COVID-19 vaccine. About 1 minute after sitting down in the observation area, he fell to the ground and briefly lost consciousness. Multiple staff members came immediately to assess, rolled him over, and he immediately came to and was alert and oriented. He was taken to a medical area and laid down on a cot. He had unremarkable vitals and was breathing normally. He initially endorsed feeling lightheaded, but denied any other symptoms. He was given crackers and water given that he had not had much to eat or drink before the vaccination. He had a normal neurological exam. He was noted to have a superficial abrasion above and below the left eye (lower forehead and upper cheek), and a small Bandaid was placed on the forehead. Fire rescue on site called EMS, who assessed him. There were no immediate concerns and he refused transportation to a hospital for further assessment. After 1 hour had passed, the patient confirmed that he was feeling normal and he was allowed to leave. He was able to walk out of the facility of his own volition and did not have further symptoms when standing. His wife verified that she would drive him home. Prior to leaving, he was given strict instructions of reasons to seek immediate medical care should he have any new or worsening symptoms. The patient indicated understanding. Communication was performed via a Language Line medical interpreter. |
| 1155455 | 4/1/2021 | NY | 29 | M | 3/31/2021 | 3/31/2021 | Fainted and feel out of chair in recovery, arose when touched and spoken to, no C/O of any pain, brought to cot, monitored VS, all stable, stayed for an additional 25 minutes, he stated he felt well and would drive self home |
| 1155447 | 4/1/2021 | NC | 46 | M | 3/31/2021 | 3/31/2021 | Patient passed out and hit his head five minutes after receiving the vaccine. |

| <u>VAERS_ID</u> | <u>RECVDATE</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1155405 | 4/1/2021 | WI | 28 | M | 3/31/2021 | 3/31/2021 | Patient indicates he was feeling very anxious before receiving the shot. Reports that he is overall healthy but had a blood pressure reading of 133/86 at a wellness fair and had an appoint with a doctor to evaluate his blood pressure on 04/01/2021. Denies any known illnesses or health conditions. Reports that about one minute after receiving the vaccine he became very light-headed, dizzy and sweaty. Denies any SOB, throat swelling. The next thing the patient remembers is" waking up with a bunch of people looking at him. An ambulance on-site assessed the patient and felt he should be transported to a local emergency room to assess. The ambulance staff had blood pressure readings of 90/50 and 80/51 . The patient reports he felt "much better" after arriving to hospital. Indicates he was hydrated with fluids and had an EKG while in the ER. His blood pressure reading at the ER was 133/86. Patient reports that the ER doctor indicates that he most likely had a "Vaso vagal syncope episode.". The patient indicates that he did not receive any medications and was told to follow-up and keep his appt. on 04/01/2021 in regards to his high blood pressure. reading. |
| 1155392 | 4/1/2021 | CO | 30 | M | 4/1/2021 | 4/1/2021 | Pt fainted about 5 minutes after receiving vaccine. He was seated and fell to the ground facedown. We turned him over onto his back and he slowly regained consciousness. Paramedics arrived shortly afterwards. |
| 1155867 | 4/1/2021 | NC | 20 | M | 4/1/2021 | 4/1/2021 | Patient fainted few minutes after receiving the vaccine. EMS was called and patient was treated on site. Patient was not transported to the hospital. |

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| 1153906 | 4/1/2021 | OH | | F | 1/26/2021 | 1/26/2021 | <p>Passed out; Diarrhea; pulled leg muscles; She could hardly walk; vomiting; A spontaneous report was received on,28-JAN-2021 concerning a female patient of age 75 years old, who experienced Diarrhea, vomiting, passed out and hit the floor, she might have passed out for maybe 5 minutes, when she fell her right leg bent severely and pulled some muscles, she could hardly walk., with the use of mRNA-1273 as prophylaxis for COVID-19 infection. The patient's history was not reported. Concomitant medications such as sertraline ,Synthroid, hctz rosuvastatin trazodone, pantoprazole sodium, vitamins, fiber, aspirin, fish oil included. On 26 Jan 2021, the patient started taking first dose of Moderna COVID-19 Vaccine for COVID-19 infection. On the same day at 09:30 PM, patient experienced Diarrhea, vomiting, passed out and hit the floor, she might have passed out for maybe 5 minutes, when she fell her right leg bent severely and pulled some muscles, she could hardly walk. The action taken for the adverse events were not provided. The outcome of all events were resolved.;</p> <p>Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p> |

| <i>VAERS_ID</i> | <i>RECVDATE</i> | <i>STATE</i> | <i>AGE_YRS</i> | <i>SEX</i> | <i>VAX_DATE</i> | <i>ONSET_DATE</i> | <i>SYMPTOM_TEXT</i> |
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| 1153987 | 4/1/2021 | OK | | F | 2/27/2021 | 2/28/2021 | asymptomatic urinary tract infection; threw up; Passed out; defecated on herself; A spontaneous report from was received from a healthcare professional concerning a 64 Years-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced Passed out, defecated on herself and threw up very hard and had asymptomatic urinary tract infection. The patient's medical history was not provided. The patient was taking sitagliptin phosphate, ezetimab, dulaglutide, glipizide as concomitant medication. On 27 Feb 2021, prior to the onset of the events, the patient received her first of two planned doses of mRNA-1273 batch no: 025L20A intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 28 Feb 2021, the patient passed out, defecated on herself and threw up very hard. On 01 Mar 2021, the patient passed out again and threw up. Went to emergency room and was told she had an asymptomatic urinary tract infection. Laboratory details was not provided. The patient took antibiotic and nausea medicine administered at ER as treatment medication. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events was unknown.; Reporter's Comments: This refers to a loss of consciousness case of a 64 Years-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and patient was taking various hypoglycemic agents as concomitant medication. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |

| <u>VAERS_ID</u> | <u>RECVDATE</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1153984 | 4/1/2021 | VA | | F | 1/28/2021 | 2/26/2021 | A spontaneous report was received from a consumer, concerning a female patient of an unspecified age who received Moderna's COVID-19 vaccine (mRNA-1273) and who experienced chills, fatigue, achy/pain, couldn't get warm/feeling cold and passed out/loss of consciousness. The patient's medical history was not provided. Products known to have been used by the patient, within two weeks prior to the event were not reported. On 28-Jan-2021, the patient received first of two planned doses of mRNA-1273 (Lot number: 02RL20A) intramuscularly for prophylaxis of COVID-19 infection. She had had no reaction with her first vaccine dose. On 25-Feb-2021, the patient received her second of two planned doses of mRNA-1273 (Lot number: 02YM20A) intramuscularly for prophylaxis of COVID-19 infection. On 26-Feb-2021, the patient felt achy. About 2 weeks later, the patient experienced chills, fatigue, aches and couldn't get warm. On an unknown date, the patient blacked out /passed out and found herself on the floor when she got up to go to the bathroom. The patient weighed only 97-100 lbs. The event blacked out/loss of consciousness was considered as serious (medically significant). Treatment information was unknown. Action taken with mRNA-1273 was not applicable since the patient received both the doses of the vaccine. The outcome of the events chills, fatigue, achy/pain, couldn't get warm/ feeling cold and passed out/loss of consciousness were considered as unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded. |

| <i>VAERS_ID</i> | <i>RECVDATE</i> | <i>STATE</i> | <i>AGE_YRS</i> | <i>SEX</i> | <i>VAX_DATE</i> | <i>ONSET_DATE</i> | <i>SYMPTOM_TEXT</i> |
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| 1153970 | 4/1/2021 | MS | 65 | M | 2/3/2021 | 2/3/2021 | Fainting; Back Ache; Fever; A Spontaneous report was received from Consumer concerning 65-year-old of male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced fainting, fever, and back ache. The patient's medical history and concomitant medication was not reported. On 03 Feb 2021, 1 day prior to the onset of the events, the patient received their second dose of mRNA-1273 (Lot number: 029L20A, Expiration date: not provided) via intramuscular route in the in the deltoid muscle arm for prophylaxis of COVID-19 infection. On 03 Feb 2021, after administration of vaccine, the patient experienced fever, back ache and fainting. The fainting was considered as medically significant. Treatment information was not provided. Action taken with the mRNA-1273 in response to the events was not applicable. The outcome for all events was considered recovered.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the onset date of the reported events, a causal relationship cannot be excluded. |

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1153961 | 4/1/2021 | NC | 72 | F | 2/5/2021 | 3/5/2021 | A spontaneous report was received from a consumer, concerning a 72 year old female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) where I passed out, hit my head and skull was bleeding, lost control of my body functions, sever chills, I could hardly move, threw up, extremely tired, don't feel good and totally incoherent. The patient's medical history was not provided by the reporter, concomitant medications are losartan, baby aspirin, pill for cholesterol included by the reporter. On 05 Feb 2021, the patient received the first planned doses of mRNA-1273 on right arm and Lot number reported for the first dose was (010M20A) for prophylaxis of COVID-19 vaccination. On 05 Mar 2021, the patient received the second planned doses of mRNA-1273 on left arm and Lot number reported for the first dose was (014M20A) for prophylaxis of COVID-19 vaccination. Action taken with mRNA-1273 in response to the events was not applicable. The outcome of I passed out, hit my head and skull was bleeding and lost control of my body functions were resolved and other events like sever chills, I could hardly move, threw up, extremely tired, don't feel good and totally incoherent were unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. |
| 1153946 | 4/1/2021 | | 80 | M | 2/17/2021 | 2/18/2021 | Passed out; A spontaneous report was received from a consumer concerning an 80-years-old male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and passed out/loss of consciousness. Patient's medical history was not reported. Concomitant product use was not provided by the reporter. On 17 Feb 2021, approximately 17 hours prior to onset of the event, the patient received their first of two planned doses of mRNA-1273 (lot/batch number: 023M20A) for prophylaxis of COVID-19 infection. On 18 Feb 2021, the patient experienced medically significant event of passed out. No treatment information was provided. Action taken with mRNA-1273 in response to the event was not reported. The outcome of the event passed out was not reported.; Reporter's Comments: Very limited information regarding this event has been provided at this time. Further information has been requested. |

| <i>VAERS_ID</i> | <i>RECVDATE</i> | <i>STATE</i> | <i>AGE_YRS</i> | <i>SEX</i> | <i>VAX_DATE</i> | <i>ONSET_DATE</i> | <i>SYMPTOM_TEXT</i> |
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| 1153929 | 4/1/2021 | CA | 66 | F | 2/28/2021 | 3/1/2021 | <p>passed out; fall; Lower back pain; fever up to 102 F; Chills; nauseous; Head hurts; A spontaneous report was received from a consumer concerning a 66-year-old, female patient, who experienced fever (pyrexia), chills, nausea and had passed out (loss of consciousness). The patient's medical history was not provided. Concomitant medications were not provided. On 28-FEB-2021, the patient received their first of two planned doses of mRNA-1273(Lot number- 012A21A) in the left arm for prophylaxis of Covid-19 infection. On 01-Mar-2021, the patient experienced fever, chills, nausea and had passed out when she went to the bathroom. When she woke up, she was on her bed and reported that her lower back and head hurts after that fall. Treatment medications included acetaminophen for fever and chills. Action taken with mRNA-1273 in response to the events was unknown. The outcome of events of fever (pyrexia), chills, nausea and passed out (loss of consciousness) resulting in fall and head and back hurts thereafter were unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p> |

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| 1154007 | 4/1/2021 | AL | | F | 3/22/2021 | 3/22/2021 | <p>Patient reports of "passing out 5 minutes after getting the vaccination; felt tingly; Felt fuzzy; Blotchy skin; Itching all over; A spontaneous report was received from a consumer and concerning a 46-year-old female patient who received Moderna's COVID-19 vaccine and experienced Passing out 5 minutes after getting the vaccination while waiting in the monitor room, felt tingly and fuzzy, itching all over and blotchy skin. The patient's medical history was not provided. No relevant concomitant medications were reported. On 22 Mar 2021, prior to the onset of events, the patient received their first of two planned doses of mRNA-1273 (lot number unknown) via intramuscular route for COVID-19 infection prophylaxis. On 22 Mar 2021, after first dose of vaccine, the patient experienced Passing out 5 minutes after getting the vaccination while waiting in the monitor room, felt tingly and fuzzy was hospitalized for 3-4 hours. The event passed out was medically significant. Treatment for the events itching all over, blotchy skin included Claritin or Benadryl. No lab details were provided. Action taken with mRNA-1273 in response to the event was not reported. The outcome of the events, Passing out 5 minutes after getting the vaccination while waiting in the monitor room, felt tingly and fuzzy, itching all over and blotchy skin were unknown.; Reporter's Comments: Based on the current available information which includes a strong temporal association between the use of the product and the start date of the reported event, and excluding any other etiology, a causal relationship with the event cannot be excluded</p> |

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| 1153920 | 4/1/2021 | MD | 23 | M | 2/10/2021 | 2/10/2021 | Faint; Migraine; Dizzy; Disoriented; Joint pain; Fatigue; Muscle pain; Nausea; Slight fever; A spontaneous report was received from a consumer concerning a 23 year old, male patient, who experienced faint (syncope), migraine, dizziness, fatigue, disoriented (disorientation), joint pain (arthralgia), muscle pain (myalgia), nausea, and slight fever (pyrexia). The patient's medical history was not provided. Concomitant products known to have been used by the patient, within two weeks prior to the events, included allergy medication unspecified. On unspecified date, the patient received their first of two planned doses of mRNA-1273 for prophylaxis of COVID-19 infection. On 10-FEB-2021, the patient received their second of two planned doses of mRNA-1273 (Lot number: 013L20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 10-FEB-2021, after vaccination, the patient experienced faint, migraine, dizzy, fatigue, disoriented, joint pain, muscle pain, nausea and slight fever. Treatment for the event included Ibuprofen and Excedrin. The patient received both scheduled doses of mRNA-1273 prior to the events; therefore, action taken with the drug in response to the events is not applicable. The event of faint was considered recovered. The outcome for the events of migraine, dizziness, fatigue, disoriented (disorientation), joint pain (arthralgia), muscle pain (myalgia), nausea, and slight fever (pyrexia) was considered unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |

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| 1154006 | 4/1/2021 | PA | 58 | F | 3/24/2021 | 3/24/2021 | <p>Passed out; Bruising her head; Dizziness; A spontaneous report was received from a 58-year-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced the event passed out/loss of consciousness, bruising her head/contusion and dizziness. The patient's medical history included diabetes mellitus, blood pressure and cholesterol. Concomitant medications included glyburide, cholesterol medication and blood pressure medication. On 24 Mar 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot#: unknown) in the right arm for prophylaxis of COVID-19 infection. On 24 Mar 2021, the patient experienced dizziness, passed out and bruised her head. Treatment for the event, bruised her head included applying ice. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events; passed out, bruising her head and dizziness was not reported.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p> |

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1153901 | 4/1/2021 | UT | 51 | F | 3/9/2021 | | <p>FAINTED; LOW BLOOD PRESSURE; FEELING FUNNY; This spontaneous report received from a patient concerned a 51 year old female. The patient's weight was 72.7 kilograms, and height was not reported. The patient's concurrent conditions included primary pulmonary hypertension. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin, and batch number were not reported) dose was not reported, administered on 08-MAR-2021 for prophylactic vaccination. Batch number was not reported. The company is unable to perform follow up to request batch/lot numbers. The patient received selexipag (form of admin and route of admin were not reported, batch number: 031491701) 800 ug, every 2 days, frequency, and therapy dates were not reported for primary pulmonary hypertension. Concomitant medications included ambrisentan, and riociguat. On 09-MAR-2021, Laboratory data included: Blood pressure (NR: not provided) Low blood pressure. On 09-MAR-2021 13:00, the patient experienced low blood pressure, felt funny and she fainted. The action taken with covid-19 vaccine ad26.cov2.s was not applicable; and dose of selexipag was not changed. The outcome of the low blood pressure, fainted and feeling funny was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0 20210342442-Covid-19 vaccine ad26.cov2.s-Fainted, Low blood pressure. These events are considered not related. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the events than the drug. Specifically: CONMEDS-OTHER SUSPECT DRUGS V0 20210342442-Selexipag-Fainted. This event is considered not related. The event has a compatible/suggestive temporal relationship, is unlabeled, and is scientifically plausible. There are other factors more likely to be associated with the event than the drug. Specifically: MEDICAL HISTORY AND UNDERLYING DISEASE V0 20210342442-Selexipag-Low blood pressure. This event is labeled and is therefore considered potentially related</p> |

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| 1153897 | 4/1/2021 | MI | 35 | F | 3/17/2021 | | <p>FAINTING WHICH WAS DESCRIBED AS DIZZINESS; VACCINE EXPOSURE DURING PREGNANCY; FEVER WAS WORSE; INTERMITTENT HEADACHE; FATIGUE WAS WORSE; This spontaneous pregnancy report received from a consumer concerned a 35-year-old female. The patient's weight was 124 (unit not reported) and height was 144.78 centimeters. The patient had no known allergies. The patient had no illness at the time of vaccination. The patient had no history of allergy to vaccine, drug, or food. The patient had no past history of similar event. The patient had no pre-existing acute illness 30 days prior to vaccination. The patient had no history of hospitalization in last 30 days. The patient's grandmother had history of Hypercholesterolemia and Diabetes Mellitus. The patient's father died from Hepatitis C approximately 10 years ago. The patient's mother had no history of chronic disease. It was not reported whether the patient had been pregnant before. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration not reported, batch number: 1802072, expiry: UNKNOWN) dose was not reported, administered on 17-MAR-2021 for prophylactic vaccination in left deltoid. Concomitant medications included Prenatal Multivitamin, calcium, magnesium, vitamin D3 and vitamin K2. The date of the subject's last menstrual period was 06-JAN-2021 and expected delivery date was on an unspecified date in 2021. On 2021, Laboratory data included: Pregnancy test (NR: not provided) POSITIVE. On MAR-2021, Laboratory data included: Body temperature (NR: not provided) 99.4. The patient mentioned that the day, she took the vaccine she had not symptoms. The patient was feeling very good. The patient's gestation period was 9 weeks and 3 Days. On 17-MAR-2021 the patient experienced vaccine exposure during pregnancy. The patient mentioned that she fainted the next day after receiving the vaccine. The patient discussed this symptom with OBGYN on a phone visit in 18-March-2021. The husband stated that she had not had any fainting spells prior to receiving the vaccine. The patient mentioned her symptoms improved two days after receiving the vaccine. However, she reports she still feels an intermittent headache (pain rate: 6/10) described as "stitching pain" (Left Side temporal irradiating to occipital area. The patient stated that she was already fatigued due to the pregnancy and now her fatigue was</p> |

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worse. She had no history of headaches, and he reported a fever of 99.4, although he said his thermometer, may not be accurate. The patient's home thermometer was broken therefore she was unable to measure her fever. The patient's husband said that her side effects started on yesterday, and were worse today (as reported). The patient was resting at the time of this call. The patient mentioned that she had lab work done on 19-Mar-2021. The pregnancy result was unknown. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from fainting which was described as dizziness, fever was worse, and fatigue was worse, and had not recovered from vaccine exposure during pregnancy, and intermittent headache. This report was serious (Other Medically Important Condition). Additional information was received from consumer on 26-MAR-2021 following information was updated and incorporated into case narrative: Patient demographic details (height, weight), patient history, parent history (patient's grandmother had history of Hypercholesterolemia and Diabetes Mellitus, Patient's father had hepatitis C), concomitant medications (Prenatal Multivitamin, Calcium, Magnesium, Vitamin D3, Vitamin K2), pregnancy details (gestation, LMP date, gravida), event (intermittent headache), outcome of the events (recovering from fainting which was described as dizziness, fever was worse, and fatigue was worse; and not recovered from intermittent headache), reporter details (contact), other identification numbers and event description was updated.; Sender's Comments: V1: Follow up information received updates patient demographic details (height, weight), patient history, parent history (patient's grandmother had history of Hypercholesterolemia and Diabetes Mellitus, Patient's father had hepatitis C), concomitant medications (Prenatal Multivitamin, Calcium, Magnesium, Vitamin D3, Vitamin K2), pregnancy details (gestation, LMP date, gravida), event (RRT amended to intermittent headache), outcome of the events (recovering from fainting which was described as dizziness, fever was worse, and fatigue was worse; and not recovered from intermittent headache), reporter details (contact), other identification numbers and event description. This updated information does not alter prior causality assessment of reported event. 20210335441-JANSSEN

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COVID-19 VACCINE Ad26.COV2.S-Fainting. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.

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| 1153878 | 4/1/2021 | OH | 63 | F | 3/6/2021 | | LOSS OF CONSCIOUSNESS, FAINTED; HEART WAS RACING; DIZZY; VOMITING; CANKER SORE UNDER TONGUE; HEADACHE; NAUSEA; FATIGUE; INFLAMMATION ON LEFT EYE; FALL ON BED; SMALL HIVES UNDER EYE; This spontaneous report received from a patient concerned a 63 year old female. The patient's weight, height, and medical history were not reported. The patient's concurrent conditions included seasonal allergies, and codeine allergy. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1802068, expiry: UNKNOWN) dose was not reported, administered on 05-MAR-2021 to left arm as prophylactic vaccination. No concomitant medications were reported. On 06-MAR-2021, after vaccination, she felt fine all day and night. The next morning she woke up and felt sick. She had nausea, headache, hive under eye. She laid back down and tried to sleep. A few hours later, she woke up to use the bathroom. She was very nauseous and dizzy. She lost consciousness and fell trying to get to the bathroom. She fell on her bed and was uninjured. The paramedics took her to the hospital. She was given medication for nausea, headache, and IV fluids. She gave blood for lab tests and they came back normal. No COVID test was administered. When she felt better, she was released. A few days later, she discovered her tongue was sore and red. She called her primary care physician (PCP). PCP said the red and sore tongue was probably related to allergies. Two weeks later, her tongue was not sore, but still red. They advised her to get a second opinion with another HCP. She was going to visit her allergy specialist.. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from loss of consciousness, fainted, heart was racing, dizzy, headache, nausea, fatigue, inflammation on left eye, and small hives under eye on MAR-2021, and vomiting on 07-MAR-2021, and had not recovered from canker sore under tongue, and the outcome of fall on bed was not reported. This report was serious (Hospitalization Caused / Prolonged). Additional information was received from the patient on 23-Mar-2021. The following information was updated and incorporated into case narrative: Patient's medical history added as seasonal allergies and codeine allergy, Vaccination site as left arm added; Additional events as small hives under eye, fall |

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on bed; lab test of blood work added; Event outcome of loss of consciousness, fainted, heart was racing, dizzy, headache, nausea, and fatigue was updated to recovered/resolved.; Sender's Comments: v1: Follow up information received updates patient's medical history (seasonal allergies and codeine allergy), Vaccination site as left arm; Additional events (small hives under eye and fall on bed), laboratory test (Blood Work); Event outcome (loss of consciousness, fainted, heart was racing, dizzy, headache, nausea and fatigue was updated to recovered/resolved). This updated information does not alter prior causality assessment of reported events 20210323730-COVID-19 VACCINE AD26.COV2.S-headache, nausea and fatigue. These events are labeled and are therefore considered potentially related. 20210323730-COVID-19 VACCINE AD26.COV2.S-loss of consciousness, fainted, heart racing, dizzy, vomiting, canker sore under tongue. These events are considered unassessable. The events have a compatible/suggestive temporal relationship, are unlabeled, and have unknown scientific plausibility. There are no information on any other factors potentially associated with the events.

| <u>VAERS_ID</u> | <u>RECVDATE</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1153876 | 4/1/2021 | CA | | F | | | <p>FAINTED AFTER GETTING VACCINE; FLU LIKE SYMPTOMS; This spontaneous report received from a consumer concerned a female of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: Unknown, and batch number: UNKNOWN expiry: UNKNWON) .5 ml, start therapy date was not reported for prophylactic vaccination. No concomitant medications were reported. On an unspecified date, the subject experienced fainted after getting vaccine, and flu like symptoms. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the flu like symptoms and fainted after getting vaccine was not reported. The reporter considered the causality between JNJ-78436735, and faint and flu like symptoms as possible. Company causality between JNJ-78436735, and faint and flu like symptoms was possible. The batch number was not reported and has been requested. This report was serious (Other Medically Important Condition). Additional information was received from consumer on 12-Mar-2021 following information was updated and incorporated into case narrative: Patient demographic details (patient initials and sex) and other identification numbers was added.; Sender's Comments: V1 Follow up information updates Patient demographic details (patient initials and sex) and other identification numbers. This updated information does not alter prior causality assessment of reported events. Flu-like symptoms and fainted. This event(s) is considered related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are no other factors more likely to be associated with the event(s) than the drug.</p> |
| 1155939 | 4/1/2021 | FL | 62 | F | 3/29/2021 | 3/31/2021 | <p>vasovagal syncope after getting up in the night to use the bathroom , momentary blackout with spontaneous recovery</p> |

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| 1157543 | 4/1/2021 | MN | 87 | F | 2/11/2021 | 2/11/2021 | syncope/fainted; Dizziness; couldn't eat; Fatigue/tiredness; Sore arm; A spontaneous report was received from a consumer concerning herself, an 87-years old female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced syncope/fainted, sore arm/pain in extremity, dizziness, fatigue/tiredness, and she couldn't eat (decreased appetite). The patient's medical history included COVID-19 in December 2020. Concomitant product use was not provided. On 11 FEB 2021, 1 day prior to the onset of the events, the patient received their first dose of two planned doses of mRNA-1273 (lot/batch: 031L20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 11 FEB 2021, the patient experienced sore arm. On 12 FEB 2021, the patient experienced syncope (she fainted), dizziness, fatigue/tiredness, and she couldn't eat. Treatment for the events included paracetamol. Action taken with mRNA-1273 in response to the events was not reported. The event of syncope/fainted was considered resolved on an unknown date. The outcome of the events of sore arm, dizziness, fatigue/tiredness, and couldn't eat were unknown at the time of this report.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |

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| 1153921 | 4/1/2021 | | 81 | F | 3/1/2021 | 3/1/2021 | passed out; Fall; knee got banged up pretty bad; Got dizzy; weak; A spontaneous report was received from a consumer who was also an 81-year-old, female patient that received Moderna's COVID-19 Vaccine (mRNA-1273) and passed out/ loss of consciousness, fall, knee got banged up pretty bad/ joint injury, dizzy/ dizziness, and weak/ asthenia. The patient's medical history included knee replacement, COVID-19 in Nov 2020, and pneumonia. Concomitant product use was not provided by the reporter. On 01 Mar 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: 013h21a or 013E21a) intramuscularly for prophylaxis of COVID-19 infection. On 01 Mar 2021, the patient got dizzy. The patient was weak and passed out. She was sitting on toilet cover and was getting ready for a shower but the next thing she knew was that, she found herself laying in the shower stall. The patient did not know for how long she was passed out for. Treatment for the events included 2 Tylenol. Action taken with mRNA-1273 in response to the events was unknown. The outcomes of events, loss of consciousness, fall, joint injury, dizziness, and asthenia, were considered as unknown.; Reporter's Comments: Very limited information regarding these even/s has been provided at this time. Further information has been requested. |

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| 1154282 | 4/1/2021 | MA | 23 | F | 3/29/2021 | 3/29/2021 | 23 y.o. female has a past medical history of Anxiety and Depression. Who was a proceed out after receiving her first vaccine for Covid. Patient reports a long history of fainting with vaccines in the past. She received the first vaccine and about a minute later started to feel diaphoretic and lightheaded. She had to sit herself down and staff at the vaccine clinic lifted up her legs. Ended up doing repeat vitals with initial blood pressure of 60 over palp. She was cool and clammy at that time. She denies any nausea or flushing. At the time of my evaluation in the bouncing clinic, blood pressure had improved to 85 over palp with 2+ radial pulses bilaterally. Patient was then transferred to emergency department for observation. At the time of transfer she started to feel back to baseline. She denies any cardiac history, drug use, decreased p.o. intake, family history of cardiac disease, sudden history of cardiac death, bleeding, black or bloody stools. She is unsure of her last menstrual period. |
| 1155010 | 4/1/2021 | CA | 72 | M | 2/27/2021 | 2/27/2021 | Systemic: Fainting/Unresponsive-Medium, Additional Details: pt received vaccine and went to waiting area. Pt fell faint and went out of chair to ground and then started to get back up. I went out and helped pt up into chair and when talking to pt his head drooped and stopped talking. Pt was unresponsive. Vaccination pharmacists came over and I called 911. Pt had undetectable pulse according to (Pharmacist) Epipen administered. Pt stated was fine when came back to and that he fainted often. Ambulance assessed pt and then pt left on his own. |
| 1155006 | 4/1/2021 | CA | 36 | F | 3/31/2021 | 3/31/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Medium, Systemic: Vomiting-Severe, Additional Details: PATIENT FELT LIGHT HEADED AND DIZZY THEN FAINTED AND VOMITED INTO HER MASK AND ALL OVER HER CLOTHING. CHECKED BP WAS 108/68 AND LATER INCREASED TO 108/86. PATIENT LEFT AFTER 30 MINUTES FEELING EXTREMELY FATIGUED. COUNSELLED TO CONTACT PCP ASAP |

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| 1155005 | 4/1/2021 | CA | 20 | F | 3/31/2021 | 3/31/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient fainted while walking in store. She was found on the floor but she was still conscious. She described her symptoms are blurry vision and head spinning. She noted that she was afraid of needles and was very nervous for the appointment. She was given gatorade to hydrate and was under watch for around 20 min. She felt better and left the pharmacy on her own. |
| 1154966 | 4/1/2021 | NY | 44 | F | 3/31/2021 | 4/1/2021 | Arm pain at first but then Got up to go to bathroom, suddenly felt nausea and then numbness on left side of body, vision became blurry and I passed out. Hit head when fell. Couldn't regain consciousness for 10-20 minutes. Couldn't move, get off floor. Husband had to come carry me back to bed. Felt tingling in arms, legs on both sides. After an hour, had water, iced arm (extreme arm pain), and felt better but stayed in bed. |

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| 1154953 | 4/1/2021 | CA | 28 | F | 3/31/2021 | 3/31/2021 | <p>On Wednesday, March 31, 2021 client (DOB 4/30/1992) received her first dose of Pfizer COVID vaccine (LOT # EW0150, EXP 7/2021) at approximately 11:50 am by vaccinator RN. RN instructed client to self-monitored at the observation area. EMTs found a 28 years old female sitting up while leaning forward and waving for assistance in an observation chair. Client had a chief complaint of dizziness. Client reported dizziness and fatigue to EMTs present after having sat in the observation area for approximately 10 minutes. Client had no known allergies or major medical history. Client denied pregnancy. Client agreed to be assisted walking up to the front EMT station so that she may be assessed more closely and with greater privacy. While walking over to the EMT station, the client experienced sudden loss in weight bearing and was prevented from falling by EMT present. EMT promptly came over to assist with transferring the patient to a chair for safety. Client was kept safe in her chair by EMT. It was at this point client experienced syncope. Client was then transferred to the gravity bed and laid supine until she became more alert. Client was then transferred to sitting semi-fowlers at 45 degrees once she was alert and tracking. lead RN came to assist EMTs as needed. Assessment revealed no hives, swelling, redness, difficulty breathing, wheezing or pain throughout her body. Client's skin was free of any signs of anaphylaxis throughout her body. Client's first set of vitals at 11:50 am was as follows: blood pressure 100 / 64, O2 - 99% on room air, pulse was 64 and regular at radial, respirations was 20 and regular. Client was fully alert and oriented x 4 (person, place, time, situation) and eyes were equal and reactive to light. Client stated that she had breakfast and denied any pain throughout her body. Client agreed to stay in the observation area for another 30 minutes after the onset of the incident per lead nurse's instruction to EMT. Client's vitals were reassessed at 5 minutes intervals as follows: 11:50 am- 110/64 (BP), 20 (respirations), 64 (pulse), 99% (O2); 11:55 am- 102/64, 18, 64, 99%; 12:00 pm - 104/ 68, 72, 18, 99%; 12:05 pm - 118/ 72, 72, 16, 100%; 12:10 pm - 118/ 78, 99%, 16, 78; 12:15 pm - 118/ 78, 100%, 16, 78; 12:20 pm - 118/80, 100%, 16, 78. After approximately 10 minutes, the client was asked to sit up so that her orthostatic vitals could be reassessed. Throughout her observation, client's vitals slowly returning to normal with</p> |

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| 1154468 | 4/1/2021 MI | 93 F | 2/18/2021 | 2/19/2021 | <p>a blood pressure - 118/ 80, pulse 78, respirations 16 and 02 100% on room air. Client was provided with a fact sheet and pertinent areas of interest were highlighted for convenience. Client stated that she felt safe going home and ordered a ride sharing service. Client was encouraged to follow up with her primary and to seek medical care or the emergency room if a severe incident occurs. At 12:35 pm, the client departed the facility in a ride sharing service in no apparent distress and with all relevant information in her purse.</p> <p>Patient was found passed out on the floor of her room after family called the facility as she was not answering her phone. She was taken to the Emergency Room and admitted to the hospital.</p> |
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| 1153991 | 4/1/2021 | AR | 75 | F | 3/18/2021 | 3/19/2021 | Collapsed; head injury from hitting the corner of the cabinet; dizzy; Lumbar contusion; she didn't feel so good; A spontaneous report was received from a consumer concerning a 75 Years-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced syncope, collapsed (syncope), head injury from hitting the corner of the cabinet (head injury), didn't feel so good (feeling abnormal), dizzy, and lumbar contusion (bone contusion). The patient's medical history was not provided. No relevant concomitant medications were reported. On 19 Feb 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot/batch: 007M20A) via unknown route for prophylaxis of COVID-19 infection. On 18 March 2021, prior to the onset of the events, the patient received their second of two planned doses of mRNA-1273 (lot/batch: 040A21A) via unknown route for prophylaxis of COVID-19 infection. On 20 March 2021, she was dizzy and passed out and ended up on the floor unconscious and was taken to the ER in an ambulance. The patient had a CT scan done and was diagnosed with syncope, head injury from hitting the corner of the cabinet and lumbar contusion.No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. At the time of this report, the outcome of the event syncope, collapsed (syncope), head injury from hitting the corner of the cabinet , didn't feel so good were not reported. The events dizzy and lumbar contusion were not recovered.; Reporter's Comments: Very limited information regarding this events has been provided at this time. Further information has been requested. |
| 1154438 | 4/1/2021 | MO | 51 | F | 3/27/2021 | 3/28/2021 | Dizziness, extreme sweating, fainted-loss of consciousness (unknown amount of time) Woke up somewhere between 7am - 8:30am and went into the bathroom. Sat down on toilet and don't remember anything else. Spouse was woken up by pet barking and discovered me in the bathroom at 8:30am. After about 20-30 seconds of saying my name, I woke up and, with his help, was able to walk back to bed. Laid down, was very warm, dizzy and sweating profusely. Drank some water and went back to sleep. |

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| 1153992 | 4/1/2021 | AZ | 81 | M | 2/1/2021 | 3/2/2021 | <p>Passed out on driveway; Arm Pain; Tremors in hand; Could not get up; Headache; Nausea; Vomiting; A spontaneous report was received from a consumer concerning an 81-year-old, male patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced arm pain/ pain in extremity, headache, nausea, vomiting, passing out on the driveway/ loss of consciousness, could not get up/ hypokinesia and tremors in hand/ tremor. The patient's medical history was not provided. Products known to have been used by the patient, within two weeks prior to the event, included xylometazoline hydrochloride, simvastatin, cyanocobalamin, folic acid, metformin, lisinopril, propranol, hydrochlorothiazide and levothyroxine. On 01 Feb 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Batch number: Unknown) intramuscularly on right upper arm for prophylaxis of COVID-19 infection. On 01 Mar 2021, prior to the onset of the events, the patient received their second of two planned doses of mRNA-1273 (Batch number: Unknown) intramuscularly on left upper arm for prophylaxis of COVID-19 infection. On 02 Mar 2021, the patient experienced arm pain, headache, nausea, vomiting, medically significant event of passing out on the driveway, could not get up and tremors in hand. Treatment for the event included nausea medication. The patient received both scheduled doses of mRNA-1273 prior to the event; therefore, action taken with the drug in response to the event is not applicable. The outcome of the events, arm pain, headache, nausea, vomiting, passing out on the driveway, could not get up and tremors in hand was resolved on 06 Mar 2021.; Reporter's Comments: Based on the current available information which shows a temporal association between the use of the mRNA-1273 and the reported events, a causal relationship with the events cannot be excluded. Fever, nausea and vomiting are consistent with the product safety profile.</p> |

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| 1154275 | 4/1/2021 | | 57 | F | 3/26/2021 | 3/26/2021 | States that she was feeling dizzy and nausea. Patient states has a history of Vasovagal syncope and usually gets like this after having a shot, and that she was a little anxious getting the second shot since so many people told her it makes them sick. Patient was assessed by nurse and EMT, BP 86/39, P74, R22, was put in lying position on stretcher and BP was monitored closely. 16:19 BP 118/78 P64 R20 patient states feeling well and is ready to go home., was escorted by nurse and EMT to vehicle at 16:25, no problems noted. |
| 1154232 | 4/1/2021 | MA | 48 | F | 3/11/2021 | 3/11/2021 | 48-year-old female past medical history recurrent neurocardiogenic syncope, Mobitz 1 AV block, hypertension, hypothyroidism, history of gastric bypass (2018), and anxiety presents from vaccine clinic with an episode of presyncope. Patient was at the vaccine clinic this morning to get the second dose of her COVID vaccine. Approximately 5 minutes after receiving the second dose, she noted gradually worsening palpitations, mild nausea, shortness of breath, and a sensation that she has been to pass out. Staff in the vaccine clinic were concerned the patient was having allergic reaction, so they gave her an EpiPen. Of note, however, patient denied any cough, chest tightness, sensation of throat closing, wheezing, abdominal pain, diarrhea. She reports that today's episode is nearly identical to multiple prior episodes of syncope/presyncope. She has been worked up extensively for these episodes, including echo, stress test, and Holter monitor. In the ED, she reports feeling back to her baseline. She denies any ongoing symptoms, including presyncope, chest pain, shortness of breath, palpitations, diaphoresis, nausea/vomiting. |
| 1154171 | 4/1/2021 | NC | 20 | F | 3/31/2021 | 3/31/2021 | Patient received vaccine and experienced syncope shortly after causing her to fall. 911 was called and patient was taken to the emergency room. |

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| 1154125 | 4/1/2021 | CA | 84 | F | 2/23/2021 | 3/1/2021 | severe anaphylactic shock; High blood pressure; This is a spontaneous report from a contactable consumer (patient). An 84-year-old female patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration, administered in left arm on 23Feb2021 09:30 (Lot Number: EN6200) as single dose for covid-19 immunisation at age 84 years old. Medical history included low thyroid and allergies to grasses. The patient was not pregnant. The patient had no Covid prior to vaccination and was not Covid tested post vaccination. Concomitant medications included levothyroxine sodium (SYNTHROID) taken for an unspecified indication, start and stop date were not reported. No other vaccine taken in four weeks. The patient previously received the first dose of BNT162B2 administered in left arm on 02Feb2021 09:30 AM (lot no: EC9265) for COVID-19 immunization. On 16Mar2021 09:15 AM, 15 minutes after eating usual breakfast: avocado/toast, coffee, almond milk, the patient went into severe anaphylactic shock: extreme itching on palms, red welts on body, explosive diarrhea, dizzy/fainted, extreme blood pressure drop to 60/XX, in/out of consciousness, loss of bowel/urine. Rushed to ER. High blood pressure 7 days after (Mar2021). The events resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, emergency room/department or urgent care and were considered life threatening illness (immediate risk of death from the event). Treatment given in the emergency room includes unknown (as reported), prednisone, Pepcid. Outcome of the event was unknown. |

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| 1154093 | 4/1/2021 | NM | 74 | F | 3/16/2021 | 3/16/2021 | a little tired; passed out; weakness; disorientation when walking; headache; nausea; hand on the side that she got the vaccine was cold; Second dose: pain at injection site; This is a spontaneous report from a contactable consumer (patient). A 74-years-old female patient received BNT162B2, dose 2, via intramuscular, administered in right arm on 16Mar2021 10:00 AM (Lot Number: EN6204; Expiration Date: Jun2021) as single dose for COVID-19 immunisation. Vaccination facility type was hospital. Medical history included eczema from 2017, she had eczema all over her back and arms and had mild allergies to mold and juniper. The patient's concomitant medications were not reported. The patient previously took first dose of BNT162B2 at the age of 74-year-old on 23Feb2021 at 10:00AM (lot number: EN6198, Expiry: Jun2021) intramuscular injection in left arm and experienced pain at injection site and couldn't sleep. The patient also took Prolia shots for arthritis. The patient experienced headache, nausea, pain at injection site and hand on the side that she got the vaccine was cold on 16Mar2021, passed out, weakness and disorientation when walking on 17Mar2021, a little tired on 18Mar2021. The clinical course included: The patient was calling about the second vaccine that she got on 16Mar2021 (Tuesday). She was calling about the after effects. They were quite huge. She had a headache, nausea, weakness, and disorientation when walking. Stated she obviously had pain at the site of injection. Stated some of it was her own fault, and at first she felt fine. On the same day that she got her second dose of the covid vaccine, she had a glass of wine and was not too hungry. She ate a little that evening. The next morning she passed out. Clarified that she had two glasses of wine, not one. Caller's daughter was a doctor. Caller referd to her daughter as doctor daughter. Stated that she told her daughter about what happened. Her daughter told her it was because she was dehydrated. Her daughter told her that it was called vagus something or another. Her daughter was not there with the caller. Her daughter called it vagus something, she does not remember. Her daughter told her that it had to do with inflammation and her immune system. Caller stated she also has arthritis. Her daughter told her that she was stupid for drinking wine after receiving the second dose of the covid vaccine and not eating a full meal. Whenever |

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she passed out and fell, she did not hurt herself but it was a wake up call. She realized she was vulnerable. She was calling because she did not know why no one told her to drink a lot of water after receiving the vaccine. She got a Prolia shot in July and the nurses told her to drink a lot of water. She was asking why the nurses who gave her the covid vaccine are not saying that to people. Her daughter told her to call the doctors office about this, and she told her daughter that it was over with now, she's 95%, she was a little tired on 18Mar2021. She was unconscious for 15 seconds per her husband. Her husband was shouting her name, and she did not hear anything. She wanted to call and report that the nurses should tell people to drink water. One more thing, her daughter told her that the covid vaccine was slowly released. About 10 hours after receiving the second dose of the covid vaccine her hand on the side that she got the vaccine was cold. She got the vaccine about 10AM, and about 10PM at night is whenever her hand got cold. She had pain at the injection site where she had the first dose of the vaccine too. She had more pain at injection site after the second dose of the vaccine. It was not awful, but only if she pressed on it. Clarified that she gets Prolia shots twice a year for her arthritis. Luckily whenever she started to get dizzy, she braced her self, whenever she fell, she did not fall from an upright position. She was crouched over, and fell against trays that fell with her. Her doctor daughter told her that inflammation was because of her immune system. One other thing was that she has been stung in the past and had extreme reactions from yellow jackets in the 90's. She thought her immune system was sensitive. One other things related to her autoimmune from 3 years ago. She moved to a city in 2012. Everyone told her after 5 years she would develop allergies. In 2017, she had eczema all over her back and arms. It was not just like a topical thing where she scratched and itched, it was under her skin. She went to a dermatologist and he took a biopsy, but the results just said eczema. She went to an allergist, he finally found a space on her underarms where he could do a test. The test showed that she had mild allergies to mold and juniper. Juniper is a tree that they have there, she has one in her back yard. Her allergy was very mild. She tried everything, and in 4 months it went away. Now she just latherers her skin with coconut oil. Her diagnosis

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that this autoimmune issue was related her immune response from the yellow jacket reaction is a self diagnosis. A doctor had never told her this, this was coming from her own self. Clarified that she is calling about the second dose of the pfizer covid 19 vaccine. Headache: It was not a bad headache, it was more like pressure all across the top. Whenever she went to sleep, the headache started. She got the second dose of the covid vaccine on 16Mar2021. She had a little bit of a headache this morning. A cup of coffee with milk made it better. Nausea: It started whenever she did not want to eat dinner. She could tell her stomach was not right. The nausea and headache started together about 12 hours after her vaccine at 10:00 PM. Weakness: She noticed weakness on the next day whenever she got up to use the bathroom. Clarified as the early morning of 17Mar2021. Her weakness was about 90 percent resolved. Disorientation when walking: Clarified that her disorientation was in reference to walking only right before she fell. She was not mentally disoriented. Mentally she knew that she was not doing well. Second dose: pain at injection site: The pain only lasted for about 2-3 hours. It was now absolutely minimal. She would have to press on it to feel anything. Her hand on the side that she got the vaccine was cold: She got the second dose of the covid vaccine around 10:00 AM, and noticed her hand was cold about 5:00 PM., about 7-8 hours later. Whenever she went to bed, she was cold. She thought that it resolved by the next morning. The morning after receiving the second dose of the covid vaccine, she passed out: She passed out about 8:15 AM. The outcome of the events headache, nausea, weakness, pain at injection site was recovering. The outcome of the events disorientation when walking and her hand on the side that she got the vaccine was cold was recovered on 17Mar2021. The outcome of the other events was unknown.

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| 1154010 | 4/1/2021 | NJ | 65 | F | 3/11/2021 | 3/11/2021 | Passed out; Foggy; Dull headache; Achy; Very tired; Nausea; A spontaneous report was received from a consumer concerning a 65-year-old, female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced foggy, passed out, dull headache, achy, very tired, nausea. The patient's medical history was not provided. Concomitant medications reported included insulin, pravastatin, enalapril maleate. On an unspecified date, the patient received her first of two planned doses of mRNA-1273 (Lot number: unknown) via unknown route and site for prophylaxis of COVID-19 infection. On 11 Mar 2021, approximately 7 hours prior to the event, the patient received her second dose of mRNA-1273 (Lot number: unknown) intramuscular in right arm deltoid for prophylaxis of COVID-19 infection. On 11 Mar 2021, the patient experienced foggy, passed out, dull headache, achy, very tired, nausea. . Treatment for the events included paracetamol. Action taken with mRNA-1273 in response to the events is not applicable. The events, dull headache, achy, foggy, passed out, very tired, nausea were considered recovered after week and half.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |
| 1155013 | 4/1/2021 | CA | 23 | U | 3/31/2021 | 3/31/2021 | Systemic: Fainting / Unresponsive-Mild |
| 1154447 | 4/1/2021 | GA | 50 | F | 4/1/2021 | 4/1/2021 | after scheduling her second dose appointment patient reported feeling lightheaded, was sitting on the floor. Moved patient to an exam room for privacy and elevated her feet. She asked to lie down because she was getting ready to pass out and then did. Patient was out for approximately 1 minute, was snoring. Applied a sternal rub and eventually patient came to. Patient was very disoriented afterward and discovered patient had urinated. Patients husband was with her, but in the parking lot, brought him in. She reports a history of fainting. BP 134/87, pulse 77. Patient also reported nausea, but states she had not eaten this morning because she doesn't normally eat breakfast. Gave patient a coke to sip on. Patient was recovered when she left. |

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| 1158206 | 4/1/2021 | CA | 46 | M | 4/1/2021 | 4/1/2021 | syncope sp vaccine diaphoretic pale, VSS with EMT, monitored for 30 min, refused hospital, wife drove home. hx of syncope sp vaccines blood draw |

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| 1157628 | 4/1/2021 | MI | 63 | F | 2/26/2021 | 2/27/2021 | <p>passed out; Unfortunately hit my head.; felt light headed; slightly nauseous; intense right knee pain; temperature of 99.6; flu-like symptoms; This is a spontaneous report from a contactable Other Health Professional (patient). A 63-year-old non-pregnant female patient received bnt162b2 (Pfizer Brand COVID 19), dose 2 intramuscular, administered in left arm on 26Feb2021 12:00 (Lot Number: EN6198) as single dose for COVID-19 immunisation. Medical history included hypothyroidism from an unknown date and unknown if ongoing. The patient was not diagnosed of Covid prior vaccination and has not been tested for Covid post vaccination. The patient has no known allergies. Concomitant medication included levothyroxine, liothyronine (NP THYROID) taken for an unspecified indication, start and stop date were not reported. The patient previously received bnt162b2 (Pfizer Brand COVID 19), dose 1 intramuscular, administered in left arm on 05Feb2021 11:30 AM, (Lot Number: EM9810) for COVID-19 immunisation. There was no other vaccine in four weeks. On 27Feb2021 07:45, the patient passed out, unfortunately hit head, felt light headed and slightly nauseous. It was also reported that patient had intense right knee pain, a temperature of 99.6 and flu-like symptoms. The events were also described as follows: 18hrs after the injection, I had intense right knee pain that lasted for 24hrs. Also in that same time period, I felt a huge rush of energy come over me and passed out. Unfortunately hit my head. I had a temperature of 99.6 and flu-like symptoms that lasted 24hrs. For 4 days I felt light headed and slightly nauseous but that could have been due to hitting my head. Called 911, EMT evaluation and the patient received treatment for events. Outcome of the events was recovered on an unspecified date.;</p> <p>Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events and other events. There is limited information provided in this report. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any</p> |

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| 1157625 | 4/1/2021 | ID | | M | 3/15/2021 | 3/1/2021 | <p>appropriate action in response, will be promptly notified, as appropriate.</p> <p>His nape and upper back area felt sunburnt and tender.; felt dizzy and almost fainted; felt dizzy and almost fainted; severe allergic reaction; broke out in cold sweat; fatigued; slept 60% of the time; His nape and upper back area felt sunburnt and tender.; This is a spontaneous report from a Pfizer-sponsored program. A contactable consumer (patient) reported that a male patient of unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number: Not reported) via an unspecified route of administration on 15Mar2021 as single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. On 15Mar2021, 10 minutes after the vaccination the patient broke out in cold sweat, he felt dizzy and almost fainted, experienced severe allergic reaction. He was given Benadryl by his vaccination provider and made him stay for another 20 minutes. He felt better after that and drove home and slept for 4 hours. After 54 hours after getting the shot that was on Mar2021, he was fatigued and he slept 60% of the time. His nape and upper back area felt sunburnt and tender on an unknown date in Mar2021. The patient received Benadryl as a treatment to felt dizzy and almost fainted, severe allergic reaction, broke out in cold sweat. He wanted to know if his adverse reactions are expected of the vaccine and if his immediate adverse event would warrant him not getting the second dose of the vaccine due to severe allergic reaction. The outcome of the event felt dizzy and almost fainted, severe allergic reaction, broke out in cold sweat was recovering while for other events was unknown. Information on Lot/Batch number has been requested.</p> |

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| 1157609 | 4/1/2021 | LA | 75 | M | 1/20/2021 | 2/22/2021 | Spinal cord issue; Weakness; Parkinson's disease flare up; Hallucination; Syncope; Balance disorder; Movement disorder; Abnormal sleep related event; Musculoskeletal disorder; dyskinesia; Back pain; Limb discomfort; Musculoskeletal stiffness; Neck pain; Fall; Confusional state; Abnormal dreams; Orthostatic hypotension; Livedo reticularis; Somnolence; Dizziness postural; Gait disturbance; A spontaneous report was received from a pharmaceutical provider concerning a 75-year-old, male patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced events spinal cord disorder, parkinson's disease flare-up, asthenia, balance disorder, movement disorder, abnormal sleep related event, musculoskeletal disorder, dyskinesia, back pain, limb discomfort, musculoskeletal stiffness, neck pain, hallucination, fall, confusional state, abnormal dreams, orthostatic hypotension, livedo reticularis, somnolence, syncope, dizziness postural and gait disturbance. The patient's medical history included Parkinson's disease, dyskinesia, arthritis, heart disease, spondylitis, body height decreased and two cardiac stent placement. In 2020, after starting Gocovri, the patient experienced hallucinations, falls, balance issues, confusion, jerky movements and weird and intense dreams. The concomitant medications on use included amantadine/gocovri used for dyskinesia associated with Parkinson's disease, levodopa, carbidopa, entacapone, tamsulosin, magnesium, cholecalciferol, vitamin C (ascorbic acid), paracetamol, cetirizine hydrochloride, fluticasone propionate, acetylsalicylic acid, pravastatin, clopidogrel, ropinirole hydrochloride, rasagiline mesylate, macrogol 3350, methyl cellulose, cyanocobalamin and multivitamin, all used for unknown indication. On 20-JAN-2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA (Batch/Lot number: unknown) through unknown route of administration for prophylaxis of COVID-19 infection. On 25-JAN-2021, patient had gotten worse, had difficulty walking, his legs felt very heavy and he was high stepping when he walked, he could hardly walk, weakness in legs, muscle stiffness and weakness, neck and back pain. Visited doctor. These events were considered to be not resolved. On 17-FEB-2021, prior to the onset of the events, the patient received their second of two planned doses of mRNA (Batch/Lot number: |

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unknown) through unknown route of administration for prophylaxis of COVID-19 infection. On 22-FEB-2021, patient experienced balance disorder, movement disorder, abnormal sleep related event, musculoskeletal disorder, dyskinesia, back pain, limb discomfort, musculoskeletal stiffness, neck pain, hallucination, fall, confusional state, abnormal dreams, orthostatic hypotension, livedo reticularis, somnolence, syncope, dizziness postural and gait disturbance. On 25-FEB-2021, patient experienced spinal cord disorder, weakness/asthenia and Parkinson's disease flare up/Parkinson's disease. The patient was hospitalized on 25-FEB-2021 and was discharged on 01-MAR-2021. The patient received both scheduled doses of mRNA-1273 prior to the events, therefore action taken with the drug in response to the events was not applicable. The events spinal cord disorder, weakness and Parkinson's disease flare up were recovered on 01-MAR-2021. The outcome of the events balance disorder, movement disorder, abnormal sleep related event, musculoskeletal disorder, dyskinesia, back pain, limb discomfort, musculoskeletal stiffness, neck pain, hallucination, fall, confusional state, abnormal dreams, orthostatic hypotension, livedo reticularis, somnolence, syncope, dizziness postural and gait disturbance were unknown.; Reporter's Comments: Very limited information regarding these events has been provided at this time. Patient's advanced age along with concomitant medications and underlying conditions may have been contributory for the occurrence of the events. No further follow-up information is expected.; Sender's Comments: Very limited information regarding these events has been provided at this time. Patient's advanced age along with concomitant medications and underlying conditions may have been contributory for the occurrence of the events. No further follow-up information is expected.

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| 1157589 | 4/1/2021 | | 78 | F | 3/16/2021 | 3/16/2021 | <p>passed out; feeling strange; started sweating; sore arm; A spontaneous report was received from a consumer concerning a 78-year-old female patient, who received second dose of Moderna's COVID-19 vaccine (mRNA-1273) and experienced sore and tender right arm, feeling strange, started sweating and passed out. The patient's medical history was not provided. No relevant concomitant medications were reported. On an unspecified date, the patient received their first of two planned doses of mRNA-1273 (Lot number: unknown) through an unknown route in an unknown arm for prophylaxis of COVID-19 infection. On 16-MAR-2021 the patient received their second dose of two planned doses of mRNA-1273 (Lot number: unknown) through an unknown route in an unknown arm for prophylaxis of COVID-19 infection. On 16-MAR-2021 patient had a sore and tender right arm. On 19-MAR-2021, she started feeling strange, started sweating and passed out. The adverse event of passed out was assessed as medically significant. Action taken with mRNA-1273 in response to the events was not applicable. Outcome of the events of sore and tender right arm, feeling strange, started sweating and passed out was unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p> |

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| 1157576 | 4/1/2021 | | | F | | | Passed out; Zero appetite; Arm was very painful; Fatigued; Major chills; Fever; A Spontaneous report was received on 16 Mar 2021 concerning a female patient of unspecified age. On unspecified date she had her first Moderna COVID-19 vaccine and developed events include Fever, Major chills, Zero Appetite, Severe Fatigue which resulted in passing out, Painful Arm. On the next day morning or after 24 hours she was said to be completely all right. Patient age, pregnancy information, concomitant medications, other relevant history, current condition or lab data is not specified as this report was taken up from the social media source. The outcome of the above listed events were said to be resolved.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |

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| 1157568 | 4/1/2021 | NY | | F | 3/16/2021 | 3/16/2021 | Fainted; Bad stomach pain; Feeling Light headed; Chills; Nausea; A spontaneous report was received from a Consumer concerning a 69-years-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced nausea, chills, bad stomach pain/abdominal pain, feeling lightheaded/dizziness and fainted/syncope. The patient's medical history was not provided. Concomitant products used by the reporter were lansoprazole, simvastatin and famotidine. The patient received the first dose of two planned doses of mRNA-1273 (batch no: 023M20A) for prophylaxis of COVID-19 infection on an unknown date. On 16-Mar-2021, prior to the onset of the events, the patient received the second of two planned doses of mRNA-1273 (batch no: 006B21A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 16 Mar 2021, same day of vaccination, the patient experienced nausea, chills, bad stomach pain, felt lightheadedness and fainted (medically significant). Laboratory details were not provided. The treatment medication included acetaminophen for the events. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events fainted, nausea, chills, stomach pain, feeling lightheaded were considered as not resolved.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |
| 1157127 | 4/1/2021 | AR | 19 | F | 4/1/2021 | 4/1/2021 | pt fainted then threw up, felt better, gave water and made her stay in pharmacy area for 30 more minutes |

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| 1157513 | 4/1/2021 | MI | | F | | 3/22/2021 | <p>BLACKED OUT/FAINTED AGAIN; BODY ACHE; CHILLS; NAUSEA; FEVER; HEADACHE; This spontaneous report received from a patient concerned a female of unspecified age. The patient's height, and weight were not reported. The patient's concurrent conditions included non alcoholic, and non smoker. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1802068, expiry: Unknown) dose was not reported, administered on 22-MAR-2021 11:00 on right arm for prophylactic vaccination. No concomitant medications were reported. On 22-MAR-2021, patient experienced chills, body ache, nausea, Fever, Headache. On 23-Mar-2021, Tuesday patient woke up in am - had few glasses of water, went back to bed, at 10 am had cup of tea and around 2 pm setting in chair and blacked out. Patient did not fall, daughter tried to wake up however after no response daughter called ambulance, when EMT (Emergency Medical Technicians) came patient woke up and told EMT that she did not want to go to hospital however patient fainted again in front of EMT and they took her to ER (emergency room), checked vitals, boold work, urine test , CAT Scan, moitored heart, IV saline administered twice. All reports came to negative so ER concluded it as reaction to COVID vaccine. Patient was in ER for total 6 hours. On 24-Mar-2021, patient felt much better. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the chills, body ache, nausea, fever, headache and blacked out/fainted again was not reported. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: V0: 20210349895-COVID-19 VACCINE AD26.CO2.S -Blacked Out/Fainted Again. This event is considered Unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.</p> |

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| 1157844 | 4/1/2021 | ID | 21 | M | 4/1/2021 | 4/1/2021 | Pharmacy staff was alerted by patient's girlfriend that he had passed out. I went to the waiting area where she was propping him up in a chair. Patient was not responsive and completely limp. Together we lowered him to the floor where he quickly began to regain consciousness and tried to sit up. Patient was fairly alert within 1-2 minutes. Patient was given water, ice packs for the back of his neck and forehead, and ED was called. Patient stated he was feeling much better and did not need EMS, but due to store policy they were called. Patient relayed a history of fainting after receiving tattoos, that was not notated on his form. Patient remained on floor until EMS arrived about 20 minutes later and checked on patient. Patient's heart rate and BP were taken by EMS laying down, sitting, and standing and was cleared by EMS to leave. |

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| 1157493 | 4/1/2021 | | 70 | M | | 3/1/2021 | <p>PASSED OUT ABOUT 15 MINUTES; DOES NOT REMEMBER ANY OF IT; RASH ALL OVER HIS BODY; This spontaneous report received from a patient concerned a 70 year old male. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, once in total administered on 18-MAR-2021 for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. In MAR-2021, the patient broke out in a rash all over his body and passed out and was out for about 15 minutes or more. The patient's neighbor helped to get into bed. The patient does not remember any of it and don't know if it was vaccine or whatever was wrong with him. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the rash all over his body, does not remember any of it and passed out about 15 minutes was not reported. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to 20210347765 and 20210347766. Version created to amend previously reported information on 21-MAR-2021. Upon review, following information was amended: The case upgraded to serious and new event passed out about 15 minutes added in case.; Sender's Comments: V1: Version created to upgrade case to serious with event (passed out about 15 minutes added). 20210342307-Covid-19 vaccine ad26.cov2.s-passed out for about 15 minutes or more. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p> |

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1157483 | 4/1/2021 | FL | 50 | F | 3/11/2021 | | <p>LIGHTHEADEDNESS; PASSED OUT ONCE; COUGHING OUT; ACHINESS THROUGHOUT THE BODY; CHILLS; NAUSEA; FEVER; HEADACHE; This spontaneous report received from a patient concerned a 50 year old female. The patient's weight was 165 pounds, and height was 162.56 centimeters. The patient's past medical history included passed out, and concurrent conditions included allergy to bactrim. The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, and batch number: 1805025 expiry: UNKNOWN) dose was not reported, administered on 11-MAR-2021 14:00 for prophylactic vaccination. No concomitant medications were reported. On 11-MAR-2021, after getting the vaccine, the patient experienced achiness throughout the body, coughing out, chills, fever, headache and nausea. Later, she was having lightheadedness. On 12-MAR-2021, she passed out once. Reporter stated that, she might had passed out due to lightheadedness. She has passed out before, but it doesn't happen often and she was fine now and has no issues. The action taken with Covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from passed out once, and fever on 12-MAR-2021, coughing out, achiness throughout the body, nausea, headache, and lightheadedness, and chills on MAR-2021. This report was serious (Other Medically Important Condition). Additional information received from patient on 26-MAR-2021 The following information was updated and incorporated into the case narrative: patient details (age, height, weight, medical history and drug allergy), outcome of the events and event description updated.; Sender's Comments: V1: Additional information received updates patient details (age, height, weight and drug allergy), medical history (passed out), outcome of the events and event description. This updated information does not alter prior causality assessment for previously reported event. 20210327370-Covid-19 vaccine ad26.cov2.s-Passed out once.. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p> |

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| 1157278 | 4/1/2021 | CA | 55 | F | 4/1/2021 | 4/1/2021 | Following administration of dose 2 of moderna covid vaccine. pt has syncope episode and fell landing on butt and hitting head on floor. LOC elapsed 30 seconds. No seizures. Pt evaluated by onsite MD and placed on gurney to be evaluated at triage bay area. 1020am: BP 220/126 P120. No meds and no previous allergies. 1050am: BP 176/104 P=85 . Pt was monitored and symptoms improved. Pt ambulated and was stable prior to d/c from vaccination site. onsite MD recommended for patient to follow-up with outside PCP if persistent elevated BP or symptoms. |
| 1157191 | 4/1/2021 | CA | 36 | F | 3/28/2021 | 3/28/2021 | Vaccine on 3/28. 45 min after vaccine felt cold sweats, nausea. 3/29 ongoing cold sweats, nausea, fatigue, mild body aches. Went to work, symptoms worsened and developed severe body aches, headache, photophobia, gasping for air (but could breathe ok). Got up from a chair and syncopized, unknown amount of time unconscious. Taken to ED, normal exam, diagnosed with vasovagal syncope, went home to rest remainder of day. 3/30 still fatigued, tried drinking coffee and it spilled out right side of mouth. Looked in mirror and thought right eye and lip were drooping. Touched face and could not feel anything on right side. Also noticed splotchy red rash bilateral cheeks and left arm (same as injection) that was itchy. Saw PCP (via tele) who documented decreased right smile, forehead elevation, cheek puff and decreased sensation on face. Prescribed 7 day course of Valtrex TID and Prednisone 60mg daily which she began on 3/31. Seen by neurology (via tele) 4/1, patient indicating 50% improvement in symptoms but states she cannot feel entire right side of face or ear. When talking appears to only be talking out of left side of mouth but no flattening of right nasolabial fold, normal smile, cheek puff, questionable asymmetry of right forehead elevation but symmetric eyebrow furrow. Unable to assess forced eye closure. States she cannot feel pinch or nail on right side of face. |

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| 1157188 | 4/1/2021 | TN | 21 | M | 4/1/2021 | 4/1/2021 | Shortly after vaccination, patient passed out while sitting, he fell out of the chair, hit his head on the floor, regained consciousness within 10-15 seconds, patient stayed laying down with legs elevated, patient vitals taken (pulse rate 60 blood pressure 120/70 respirations were 18) patient given juice and granola bar, monitored for about 40 minutes at which time he reported his symptoms had greatly improved, he was also offered transport with EMS but patient declined, patient has someone to transport him home, he was advised to follow up with his doctor as soon as possible or to go to the ER if he were to develop any symptoms. |
| 1157185 | 4/1/2021 | | 46 | F | 3/31/2021 | 3/31/2021 | Vasovagal syncope resolved when placed supine patient monitored vitals remained stable |

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| 1157561 | 4/1/2021 | MI | | F | 2/11/2021 | 2/11/2021 | Died; Unresponsive; Shortness of breath; Not able to eat; Sick; Nauseous; Vomiting; Passed out on kitchen floor; Blood sugar increased; A spontaneous report was received from a consumer concerning an unspecified age, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced raised blood sugar/blood sugar increased, passed out on kitchen floor/loss of consciousness, nausea, vomiting, sick/illness, not being able to eat/decreased appetite, shortness of breath/dyspnea, unresponsive/unresponsive to stimuli and died/death. The patient's medical history included diabetes. Products known to have been used by the patient, within two weeks prior to the event, included unspecified insulin. On 11 Feb 2021, the patient received their first planned doses of mRNA-1273 (Batch number: unknown) intramuscularly for prophylaxis of COVID-19 infection. On 11 Feb 2021, the patient had a rise in her blood sugar (blood sugar 208, 212, 199 up until her bedtime of 9:45PM). On 12 Feb 2021, the patient passed out on the kitchen floor and the patient's blood sugar took a dive (blood sugar was 304 9:00AM, blood sugar was 260 10:30AM then stayed over 200/280 all day even with insulin). That evening, the patient experienced nausea and vomiting. On 13 Feb 2021, the patient's blood sugar was up and had nausea and vomiting throughout the night. The patient spoke with her doctor, who told her to regulate it with insulin if she needed too. Per the report, the doctor informed the patient that there have been studies that say the vaccine has shown to mess with blood sugars. The patient's blood sugar remained between 144-179 all day even with insulin. The patient had nausea and vomiting. On 14 Feb 2021, the patient reported still being sick. The patient reported a weight loss of 5 pounds and reported not being able to eat. Blood sugar was 174-292 all day even with insulin. On 17 Feb 2021, the patient's blood sugar was bouncing between 53-151 all day even with insulin. On 18 Feb 2021, the patient reported shortness of breath and was using Vicks to help clear the nasal passage. On 19 Feb 2021, approximately at 6:00AM, the patient's spouse found patient breathing but unresponsive. At approximately 7:25AM, the patient died. Treatment information included, unspecified insulin and Vicks. Action taken with the drug in response to the event is not applicable. The outcome of event, passed out on kitchen |

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| | | | | | | <p>floor/loss of consciousness, was considered resolved on 12 Feb 2021. The outcome of events, raised blood sugar/blood sugar increased, passed out on kitchen floor/loss of consciousness, nausea, vomiting, sick/illness, not being able to eat/decreased appetite, shortness of breath/dyspnea, were considered unknown. The outcome of events, unresponsive/unresponsive to stimuli and died/death, were considered fatal. The cause of death was not provided. Plans for autopsy was not provided.; Reporter's Comments: Very limited information regarding these events has been provided at this time. Patient's history of uncontrolled diabetes with recent fluctuations may have been contributory for the occurrence of the death. Further information has been requested.; Reported Cause(s) of Death: Unknown cause of death</p> | |
| 1158026 | 4/1/2021 | CA | 44 | F | 3/29/2021 | 3/30/2021 | <p>Common side effect occurred later in the day of vaccination date 3/29/21 which includes local redness, pain and swelling on vaccination site. It progressed to low grade fever, headache and body aches that evening. Tylenol ES prn provided relief. However, around 5pm the next day, I started having nausea, vomiting, near syncope , weakness and headache. My husband had to pick me up from work, drive me home. This lasted until midnight. Day 4 still with nausea and localized pain and swelling on arm. No more redness on site.</p> |

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| 1157500 | 4/1/2021 | | | U | | | <p>FAINTED; SLOW MIND; BODY ACHE; CHILLS; FATIGUE; This spontaneous report received from a patient concerned a patient of unspecified age and sex. The patient's weight, height, and medical history were not reported. The patient's past medical condition included patient typically faints after receiving vaccines. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unk) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the patient experienced fainted, slow mind, body ache, chills, and fatigue. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the fainted, chills, body ache, fatigue and slow mind was not reported. This report was serious (Other Medically Important Condition); Sender's Comments: 20210346239-covid-19 vaccine ad26.cov2.s-Fainted. This event(s) is considered not related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: MEDICAL HISTORY</p> |
| 1155958 | 4/1/2021 | MN | 24 | M | 4/1/2021 | 4/1/2021 | <p>syncope post vaccination. Mother was there expected this to happen said he does not do well with vaccinations. gave water, let patient rest in chair for greater than 30 minutes left in good health stable.</p> |
| 1158191 | 4/1/2021 | AK | | U | | | <p>Patient fainted in the observation area about 5 minutes after receiving the vaccine. She was on the floor and we treated her for syncope. Her first blood pressure reading was not recorded but it was low around 100/60. Subsequent measurements were 128/78 then 145/87. She could respond to verbal commands but she felt weak and nausea. She recovered after about 5 minutes. We observed her for another 15 minutes before we released her.</p> |

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| 1158158 | 4/1/2021 | CA | 54 | F | 3/18/2021 | 3/18/2021 | Thursday, March 18, 2021, 11:00 pm Around 12 hours after the vaccine, I started having stomach cramps and began having diarrhea. About an hour later (around midnight), I fainted while seated on the toilet and fell face first into the tiled floor. My forehead and mouth/teeth apparently broke my fall and I realized when I came to, I had chipped my two front teeth. There was a good amount of blood and soon after my house mates came to find me, they got me up to lean over the toilet as then I began getting sick and throwing up. They called the paramedics as I kept throwing up. The paramedics tended to me and after two does of an anti-nausea pill, I was able to at least keep a bit of water down. |
| 1158140 | 4/1/2021 | AK | 18 | M | 3/31/2021 | 3/31/2021 | patient passed out a few minutes after receiving his second moderna dose, he recovered quickly but opted to be transported via ambulance to hospital and released with a diagnosis of syncope. |
| 1158101 | 4/1/2021 | MA | 21 | F | 3/25/2021 | 3/25/2021 | Patient received vaccine morning of 3/25/21. She developed severe abdominal pain, dizziness, and near syncope starting 11pm, prompting emergency department evaluation around 1:30am on 3/26/21. Symptoms were self-limiting and resolved without intervention or treatment. She was feeling better several hours later |
| 1157708 | 4/1/2021 | WI | 32 | F | 4/1/2021 | 4/1/2021 | Patient got light headed and fainted. Was eased to the ground by RN. Elevated legs. She regained consciousness in 1 mins and remained laying down with legs elevated for 10mins. BP 138/68 at 14:20. Given water and candy. BP 118/68 at 14:26. Observed for 15 more mins and feeling well to leave with husband who was had no adverse reactions. |

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| 1158073 | 4/1/2021 | CA | 23 | F | 4/1/2021 | 4/1/2021 | Patient received vaccine at 6:03 pm, patient was in recovery area and experienced syncope at 6:07 pm, patient fell to the group face down, nurses responded turned patient on left side, patient had 5-10 second seizure with full body seizing and eyes rolled backed. EMS called. Right frontal area hematoma due to hitting head on floor. Patient confused at first, BP 98/64, HR 80 at 6:10, patient diaphoretic, reassessed BP 105/60 HR 82, EMS assessed, patient LOC returning A&Ox4, able to remember she does have seizures and takes seizure medications but cannot remember medication name. Nurses advised patient to be transported by EMS, patient refused, patient boyfriend and mom also refused and stated they would take her themselves. Boyfriend to drive patient to ER for follow up per patient and family. |
| 1157774 | 4/1/2021 | UT | 33 | M | 4/1/2021 | 4/1/2021 | Numbness in left arm and face, overheating, fainting, Medical personal fist on site noticed shaking due to Seizure. |
| 1158020 | 4/1/2021 | NJ | 24 | F | 4/1/2021 | 4/1/2021 | Patient fainted. We sat her down. Offered to call an ambulance. gave her some orange juice to drink. We monitored blood pressure and made sure she was not driving home. |
| 1158006 | 4/1/2021 | TN | 81 | M | 4/1/2021 | 4/1/2021 | Patient waited the 15 minutes in front of the pharmacy and then started shopping in the store and passed out on one aisle in the store. I was called to look at patient and they had already placed him in a chair and he was alert but weak and was able to answer questions coherently. His son that was with him call EMS to come. I called the son later in the day to see how everything was going and the son said that EMS told him all vitals were normal and he did not go with them. He then told me that his dad and him were having dinner at the time I called and that he felt fine. He also said his dad did not have breakfast that morning which could have contributed to it since he had T2DM. |
| 1158000 | 4/1/2021 | NH | 19 | F | 3/30/2021 | 3/31/2021 | fainting following day, muscle aches, headaches, nausea (no vomiting), tiredness, weakness |
| 1157967 | 4/1/2021 | OH | 28 | F | 4/1/2021 | 4/1/2021 | Patient fainted after receiving vaccination during observation time. |

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| 1157924 | 4/1/2021 | MI | 19 | F | 4/1/2021 | 4/1/2021 | Syncope, fever, tachycardia |
| 1157904 | 4/1/2021 | | 61 | F | 4/1/2021 | 4/1/2021 | PATIENT FAINTED IMMEDIATELY AFTER RECEIVING THE VACCINE. WAS MONITORED AND BLOOD SUGAR CHECKED BECUASE SHE REPORTED NOT EATING THAT DAY |
| 1158167 | 4/1/2021 | WI | 38 | M | 3/22/2021 | 3/23/2021 | 12 hours after the vaccine around 3:30am I got up to use the bathroom and was a bit unsteady but after peeing I was walking back to my bed I grabbed the door and my wife woke up and helped me Collapse to the sitting position, about 3 minutes later completely passed out. I was out for 30-40 seconds then startled awake. I laid in the floor for about 10 minutes and my wife helped me get back to bed. The rest of the week I was kind of dizzy and off balance On Saturday 27th I almost passed out again and again on Tuesday March 30th. |
| 1158088 | 4/1/2021 | OR | 38 | F | 4/1/2021 | 4/1/2021 | Patient become light-headed and fainted while sitting in a chair after the vaccine. Her friend was with her and supported her until we were able to get to her. She regained consciousness within a few seconds and was disoriented for about a minute. Claimed she was anxious and didn't sleep well the night before. Started to feel nauseous. Her family was in the store and everyone sat with her for about a half an hour after the event until she felt good enough to leave. Said she had fainted during a blood draw in the past but told us this after the incident. |
| 1156150 | 4/1/2021 | FL | 56 | F | 3/26/2021 | 3/26/2021 | Within 15-minutes of vaccination, the patient had a syncopal event. EMS evaluated the patient on-site. The patient reported a history of syncope with the sight of needles and blood. EKG demonstrated sinus brady, rate 48 bpm, no ST elevation. The patient was hypertensive (155/88) and bradycardic. EMS administered 4mg Ondansetron PO. EMS transported the patient to Hospital Emergency Department. In the ED, the patient reported that they were currently asymptomatic after suffering a syncopal event following vaccination. The patient was normotensive (121/80). Given the patient's improvement in transit to the ED, the physician discharged the patient with a diagnosis of syncope. |
| 1156359 | 4/1/2021 | IN | 47 | F | 3/30/2021 | 4/1/2021 | Dizzy and fainted at 6:00am on April 1, 2021 |

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| 1156338 | 4/1/2021 | CA | 55 | F | 4/1/2021 | 4/1/2021 | After vaccination, while waiting the recommended 15 minutes post vaccination, around 10 minutes, patient fainted and eyes rolled back, patient was limb and could not stand. Patient was breathing and talking, however was disoriented, did not know where she was. |
| 1156279 | 4/1/2021 | CA | 26 | M | 4/1/2021 | 4/1/2021 | 26by/o male, c/o lightheaded ness, dizziness, buzzing in the ears, stated ?I think I passed out?. Pt was pale, cold, clammy, diaphoretic but able to answer questions appropriately. PARAMEDICS came to check pt. V/S HR 51, BP 107/70, O2 sat 98%. NS BOLUS GIVEN, sent to HOSPITAL FOR FURTHER EVALUATION. |
| 1156245 | 4/1/2021 | FL | 52 | F | 3/30/2021 | 3/30/2021 | Within 5-minutes of vaccination, the patient reported a syncopal event. EMS evaluated the patient on-site. The patient was hypotensive (72/46) with a FSBG of 142mg/dl. EMS administered 4mg Ondansetron and 1L of Normal Saline. EKG demonstrated NSR, rate 73bpm, no ST elevation. EMS transported the patient to Hospital Emergency Department. In the ED, the patient reported nausea and feeling lightheaded prior to EMS treatment. Patient stated history of vasovagal episodes in the past. Patient's hypotension improved to 103/82mmHg. After laboratory work-up, orthostatic BP tests, and EKG, the patient was discharged with diagnosis of Vasovagal syncope status post-COVID vaccine. |
| 1155993 | 4/1/2021 | MN | 48 | M | 4/1/2021 | 4/1/2021 | Patient in waiting room following COVID vaccine - syncope episode, temporary loss of consciousness 15-20 seconds - woke up and was given water - less than 5 minutes later second syncope episode, temporary loss of consciousness 15-20 seconds - 911 called - woke again - more water given - EMS providers then took over care |
| 1156183 | 4/1/2021 | WA | 56 | F | 3/30/2021 | 3/31/2021 | Fever about 24 hours after shot and extreme fatigue. About 37 hours after shot I woke up, was dizzy, tried to throw up then passed out. I already had covid 4 months ago. |
| 1156436 | 4/1/2021 | OH | 16 | F | 4/1/2021 | 4/1/2021 | Syncope |
| 1156168 | 4/1/2021 | AK | 46 | F | 3/31/2021 | 4/1/2021 | I woke up this morning and was disoriented, had a headache, went to get glass of water and fell down, fainting, was unconscious for 1 minute. |

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| 1156214 | 4/1/2021 | PA | 75 | F | 2/18/2021 | 2/19/2021 | Patient said the day after her shot, she woke up and was feeling very dizzy. In her kitchen, she turned and fainted, hitting her head on the counter and causing a concussion. |
| 1156110 | 4/1/2021 | OH | 64 | F | 3/30/2021 | 3/31/2021 | Passed out at the casino and transported to Hospital by Ambulance. I Was kept overnight. Feeling light headed , dizzy and hot. . 1 day after the second doze of the pfizer shot. Passed out approximately 15 minutes after filling the symptoms. |
| 1156081 | 4/1/2021 | CO | 23 | F | 3/31/2021 | 3/31/2021 | Patient received first dose of Moderna COVID19 vaccine at 1030 via IM injection in left deltoid. Prior to injection, patient reported being nervous about fainting. She reported no prior history of fainting due to vaccination or blood draws; she "passed out" two years prior to dehydration at a music festival. Approximately four minutes after injection, patient stated that she was going to "pass out" and had an episode of syncope. She exhibited pallor, dry heaving, and arm contractures. The nurse helped her to a supine position on the floor and called for assistance. The nurse team encouraged deep breathing and provided apple juice, pretzels, ammonia inhalent, and cool washcloths. EMS was called and arrived at 1045 for further assessment. Patient reported that she had not consumed any food or drink prior to vaccination and stated that her hands were "tingly". EMS took blood pressure and heart rate; both were within normal range. The patient was taken to the hospital by EMS at 1055, where providers determined that syncope was likely caused by anxiety. Patient returned home and reported feeling tired but stable when health department called to check in at 1400. |
| 1156049 | 4/1/2021 | IL | 22 | F | 4/1/2021 | 4/1/2021 | Blurred Vision. Hx of Fainting when she sees needles84/56 54 18 O2 sat 100% . Refused Transport |
| 1156048 | 4/1/2021 | FL | 32 | F | 3/4/2021 | 3/4/2021 | Vasovagal syncope 14 minutes after receiving vaccine. Hx of vasovagal syncope after IUD insertion |
| 1155970 | 4/1/2021 | IL | 46 | F | 4/1/2021 | 4/1/2021 | Sweating, thought she was going to vomit, close to fainting, was talking the whole time 15 minutes later she felt tightness in her throat Called 911 and paramedics came and took her to hospital |

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| 1155971 | 4/1/2021 | MN | 20 | F | 4/1/2021 | 4/1/2021 | Patient was given moderna vaccine. About 10 minutes after while she was waiting for her 15 minutes of observation to finish, she stood up and fainted. Pharmacist went over, had her lie down, and held up her legs. Patient said she felt okay but still dizzy. Emergency responders was called. Ambulance came about 10 minutes later to examine her. They took her vitals and blood sugar, found them to be within normal limits, and stated patient was okay to go home if she got a ride. She called a friend and her ride came about 30 minutes later. |
| 1157098 | 4/1/2021 | NE | 30 | F | 3/31/2021 | 3/31/2021 | I received the vaccine and approximately 5 minutes after the injection I began sweating profusely and passed out. While I have passed out in the past, I have never done so after receiving a vaccine or while sitting down (which I was). After I "came to" I felt an all over tingling sensation throughout my body. As noted, I have never had any reaction to a vaccine and my most recent previous vaccine was a tetanus booster in 2020. Not history of fainting or any adverse reactions to a vaccine. |
| 1156899 | 4/1/2021 | MS | 25 | F | 4/1/2021 | 4/1/2021 | Patient did not report any history of syncope with injections; stated she takes B-12 injection and injections for her migraine with no issues. She received the J&J vaccine at 3:41pm. Reported immediate arm soreness. While in the 15-min observation area at 3:45pm, patient fell out of chair onto the floor 2/2 LOC. I attended immediately to the patient (EMS was called at 3:47 due to LOC) When I arrived, patient was laying on her stomach and was awaking up. We turned her onto back and placed her feet in the air. Patient was immediately able to tell me her name and date of birth. She was given cold towels and she was cooled down. Initial vitals taken at 3:47p were 146/98, HR 66. EMS arrived at 4:02 and took vitals (BP=146/94, SPO2=99%). EMS stood the patient up and patient refused to go with EMS. Patient instructed to wait an additional 15 mins after EMS left. Patients left in care of boyfriend |
| 1157056 | 4/1/2021 | IL | 27 | F | 4/1/2021 | 4/1/2021 | patient said she felt light headed during the post administration wait time. I gave her an ice pack and checked in on her again. She has hx of fainting and getting light headed post administration. After 10 minutes she felt better. |

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| 1156169 | 4/1/2021 | PA | 24 | F | 3/31/2021 | 3/31/2021 | AFTER 15 MINUTES; PATIENT BEGIN TO FEEL SICK.. SHE GOT UP AND LOST HER BALANCE AND FAINTED |
| 1156576 | 4/1/2021 | TN | 20 | F | 4/1/2021 | 4/1/2021 | Patient passed out shortly after vaccination, nursing staff attended patient, used an alcohol swap, patient came to, pulse rate taken (86), patient was in chair during the duration of this. Patient was given juice, water, snack and was laid at an examination table. Was assessed by a nurse and after the patient was cleared she was walked /escorted to her vehicle out of the vaccination site by a security guard. |
| 1157009 | 4/1/2021 | OR | 54 | F | 3/27/2021 | 3/27/2021 | The patient presented with witnessed vasovagal syncope in her car after vaccination in the monitoring area. The patient had a weak radial pulse to palpation. EMS was summoned to the car. The patient was attached to monitor and 12 lead was performed. 12 lead showed no acute changes but sinus bradycardia initially at 33 bpm. BP was 120/95. The patient was supine in her car and given oral hydration. After serial evaluations, she improved with normalization in vitals and resolution of all symptoms. She was discharged home with her husband as a driver. |
| 1157006 | 4/1/2021 | NY | 46 | F | 3/24/2021 | 3/25/2021 | syncope |
| 1157048 | 4/1/2021 | CO | 25 | M | 4/1/2021 | 4/1/2021 | : Approximately 5 minutes after administration of first Moderna COVID vaccine, patient lost consciousness while sitting in chair for approximate 15 seconds. Fell onto floor, denies hitting head. Patient was placed prone on mat with feet flat. Given orange juice, wet cloth to head. Appears pale, cold, clammy skin initially. Improved quickly. Denies vomiting, nausea, difficulty breathing or headache. Girlfriend states he has passed out in the past, cause has frequently been due to anticipation of medical procedures, such as dental work or discussions of medical procedures. Witnesses included patients girlfriend and clinic staff. VAERS report to be submitted due to syncope with loss of consciousness |

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| 1156929 | 4/1/2021 | | 71 | M | 3/31/2021 | 3/31/2021 | Patient received his Moderna #2 around 9:40 AM. About 4 minutes later his wife signaled that he was in distress by honking her horn. Upon arrival to the patient, he was clutching at his throat, wheezing, and whispering he couldn't breathe. Dyspneic with respiratory rate 20-30, heart rate 60's. No hives/flushing or signs of syncope. Given significant respiratory distress, decision was made to give epinephrine IM right thigh. About 4-5 minutes after injection, patient's respiratory rate came down and he said he felt his throat open up. He was then sent to the ER, where he received Benadryl, Famotidine, Methylprednisone, and Albuterol/Atrovent nebulizer. Pt sent home at 1PM, after 3 hours of observation. Pt is still doing well via phone follow up 24 hours after event. |
| 1156795 | 4/1/2021 | SC | 38 | F | 3/22/2021 | 3/22/2021 | I passed out about 10 min after receiving the vaccine. The nurses said my BP dropped and kept me an hour after receiving the vaccine. Within 3 hours of receiving the vaccine I felt nauseous and had arm pain around the injection site. Two days after the injection the arm pain was gone but the nausea remained and I began having severe stomach cramps w/gas and feeling light headed. The nausea, body aches, stomach cramps and gas remain on day 9 and the night of day 9 I woke up shivering and drenched in sweat while having a nightmare. It is day 10 and I have nausea, stomach cramps, fatigue and mild body aches. |
| 1156794 | 4/1/2021 | PR | 46 | M | 3/30/2021 | 3/30/2021 | LIKE A SYNCOPE, EXCESSIVE SWEATING, PALE, FAINTED,LOW PRESSURE, NUMB FINGERS HANDS, VOMITS |

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| 1156778 | 4/1/2021 | FL | 24 | M | 4/1/2021 | 4/1/2021 | patient's vaccine was administered at 3:40pm, he disclosed that he had passed out after a vaccine previously so I advised that he could wait 15 minutes in the post-vaccination area but not to drive for 30 minutes. At 3:44pm the patient was waving at me indicating that he felt dizzy so I ran out there and he asked for ice and said he was feeling lightheaded and seeing black spots. I asked him to lay on the floor with his feet elevated in a chair. He stayed that way for a few minutes and said he was feeling better, and we were able to get him a cool pack. He sat up on the floor and put the cool pack on his neck. After a few minutes he was feeling better so I allowed him to remain seated in the chair until 4:10pm. Store management came to get a statement from him and he ended up staying in the pharmacy area for approximately 1 hour post-vaccination. He waved and thanked us when he left. |
| 1156759 | 4/1/2021 | NE | | U | | | Fever, almost fainted, really dizzy, my vision went black, got very weak, heart very accelerated |
| 1156673 | 4/1/2021 | AZ | 75 | F | 4/1/2021 | 4/1/2021 | Client was in observation for 30 minutes after vaccination. At 29 minutes client had near syncope event with shortness of breath. On-site EMS evaluated and called for transport and client was transferred to nearest emergency room. |
| 1156659 | 4/1/2021 | | 22 | M | 3/26/2021 | 3/26/2021 | Syncope Forehand abrasion/laceration BP from 152/81 to 132/94 HR 88 to 97 History of Guillen barre syndrome |
| 1156610 | 4/1/2021 | IL | 57 | M | 3/30/2021 | 3/30/2021 | syncope 2 hours after his vaccination. he felt nauseous and fainted. LOC lasted 30 seconds. no palpitations, dizziness, diaphoresis, chest pain. no seizure activity noted, but states he had urinary and fecal incontinence. |
| 1156596 | 4/1/2021 | FL | 53 | F | 3/30/2021 | 3/31/2021 | Eight hours after injection I had normal injection arm pain. 29 hours after injection I fainted but did not lose consciousness. I am prone to fainting so I didn't think anything of it, however my husband also fainted (he was at home, I was not) at roughly the same time and he has never fainted in his life. The day after fainting I ran a low-grade fever of 99 and was foggy all day, enough to make me not drive and conversations were a little slow in the thinking process. |

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| 1156932 | 4/1/2021 | VT | 35 | F | 1/19/2021 | 1/20/2021 | 1/19 vaccination 1/20 At about 3pm, I had symptoms of having my period. I started having really bad pain on lower back, I could not stand. I could not pick my baby up. I called my husband to come home. The pain was extremely bad, I could not walk. I took Ibuprofen, called clinic and they said you should call CDC or wait. I went to bed and around 6am I felt like I had to go to the bathroom. Walking back, I went to sit on edge of bed, I was in so much pain. I started feeling so bad, I fainted. When I woke up, my husband was asking me questions. We called 911, took vitals, transferred to ER. Gave Ibuprofen and did ultra sound. They discharged between 11-12. They said to follow up with PCM. It was so scary. Symptoms lasted for 4-6 days after. It became better each day. *still have not had second vaccine |
| 1151545 | 3/31/2021 | CT | 33 | F | 3/31/2021 | 3/31/2021 | Patient reported burning sensation on injection into left deltoid and localized painful reaction. Within approximately 10 minutes following injection, patient reported dizziness, weakness, and nausea. Patient tried to stand and reported that she experienced syncope, fell, and struck her head. Patient called out pharmacist's name. Pharmacist arrived to find patient lying on the floor. Patient had visible mark and bump on her forehead. Pharmacist elevated patient's feet. Patient elevated herself under her own power to a seated position. Patient was given water and blood pressure was taken. Blood pressure was 128/86 with a heart rate of 76. Patient requested pharmacist not contact 911. All events occurred within 15 minutes following vaccination. Patient reported she would visit urgent care following departure from pharmacy but unknown if patient will follow-up. Patient left under her own power and was driven home by husband. |
| 1150726 | 3/31/2021 | NY | 31 | M | 3/31/2021 | 3/31/2021 | Fainting, dizziness, blurred vision, sweating, feeling clammy, blood pressure dropping and sugar dropping. |

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| 1151494 | 3/31/2021 | MO | 22 | M | 3/31/2021 | 3/31/2021 | 1124 End of 15 minute observation period. Per witness, attempted to stand and fell forward onto floor. Seizure noted for one minute, responded to name and answered questions appropriately. Stated he "felt dizzy". Vital signs 118/60, 99%, 54. Blood glucose 97. Physician Assistant, present. Questions answered. 1131 Attempted to stand patient up again with assistance/supported X2. Stated he "felt dizzy again and blurry vision". Fainted while supported X2. Positioned on left side and immediately responded. Positioned supine. 1133 Vital signs 110/60, 96%, 72. 1142 Sitting up awaiting EMS, answers questions appropriately.. EMS present 1145 Vital signs 128/76, 100%, 72. |
| 1151455 | 3/31/2021 | FL | 60 | F | 3/12/2021 | 3/13/2021 | fainted; This is a spontaneous report from a contactable consumer (patient) reported that a 60-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 12Mar2021 11:30 as a single dose (at the age of 60-years-old) for covid-19 immunisation. The patient medical history was reported as none. The patient was not pregnant at the time of vaccination. Concomitant medications included glipizide and lisinopril both were taken for an unspecified indication, start and stop date were not reported. On 13Mar2021 14:30, the patient fainted and was rushed to the hospital and admitted with outcome of recovered on Mar2021. The reported event resulted in emergency room/department or urgent care, and hospitalization for 1 day on an unspecified date. The patient received treatment for the reported event as Catscan (as reported). The patient underwent lab tests and procedures which included sars-cov-2 test (nasal swab): negative on 13Mar2021. Information on Lot/batch number has been requested. |

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| 1151440 | 3/31/2021 | CA | 30 | F | 3/2/2021 | 3/2/2021 | cardiac arrhythmia; dizziness/lightheadedness; nausea; muscle weakness; extreme fatigue; lost consciousness/She is in and out of consciousness; extreme weakness; extremely low blood pressure; tachycardia when resting/heart rate is high/HR gets up to 135; One foot and leg became very cold and turned blue; One foot and leg became very cold and turned blue; other foot warm and hot; This is a spontaneous report from a contactable consumer (patient's sister). A 30-year-old non-pregnant female patient received the second dose of bnt162b2 (BNT162B2 reported as PFIZER COVID 19 VACCINE; lot number: EN/ EW 6198; expiration date: unknown), at vaccination age of 30-year-old via an unspecified route of administration in the left arm on 02Mar2021 as a single dose for covid-19 immunisation. The patient medical history was not reported. The patient was not diagnosed with covid prior to vaccination. The patient received the first dose of bnt162b2 (BNT162B2 reported as PFIZER COVID 19 VACCINE; lot number: EN6198), at vaccination age of 30-year-old via an unspecified route of administration in the left arm on 09Feb2021 as a single dose for covid-19 immunisation but had weakness, fainted, lost consciousness and concussion. There were no concomitant medications. The patient did not receive other vaccine in four weeks. The reporter mentioned that on the next day after vaccination (03Mar2021), the patient's one foot and leg became very cold and turned blue other foot warm and hot started cardiac arrhythmia, dizziness, lightheadedness, nausea, muscle weakness, extreme fatigue, extremely low blood pressure and tachycardia when resting. The reporter stated that since 02Mar2021, she hasn't been able to get out of bed due to extreme weakness. The reporter also mentioned that her heart rate (HR) gets up to 135 [unit unspecified]. The reporter also stated that the patient was wearing a heart monitor and was waiting for data. They went to the emergency room (ER) on 12Mar2021 due to concerns of blood clot, ruled out blood clot. The doctors can't explain what is happening to her. She was extremely healthy and fit, no previous cardiac or energy issues. No blood pressure issues or family HX. She says she "feels like she's dying". The adverse events resulted in doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care, |

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| | | | | | | | hospitalization, and life-threatening illness (immediate risk of death from the event). The hospitalization was reported as 1 day. It was unknown if the events received treatment. The patient was not tested post vaccination. It was further reported that her sister had the second Covid shot 02Mar2021 and a few hours later she lost consciousness. She has been in the hospital ever since. She was in and out of consciousness, her blood pressure is low, and her heart rate is high. One of her legs is blue and cold, the other is hot. She cannot get out of the bed. The doctors don't know what is wrong. It was mentioned that the patient was healthy and not taking any medication. The outcome of the events was not recovered. |
| 1151248 | 3/31/2021 | NC | 52 | M | 3/31/2021 | 3/31/2021 | patient fainted and fell to floor from chair during the waiting period of 15 minutes |
| 1151205 | 3/31/2021 | OH | 45 | M | 3/27/2021 | 3/27/2021 | I fainted about 5 minutes after the injection. When I awoke, my fingers tingled, I was hot, and my breathing was labored. |
| 1151161 | 3/31/2021 | CT | 30 | F | 3/25/2021 | 3/26/2021 | Fever nausea diarrhea fainting headaches bodyaches for a week |
| 1151114 | 3/31/2021 | NY | 44 | F | 3/29/2021 | 3/29/2021 | While waiting in the observation area and approximately 10 minutes after receiving the injection, I felt a strange wave come over me and I became very lightheaded and felt weird all through my body. I can't really explain the sensation. I passed out and when I came to, I was very weak. The staff at the facility gave me oxygen and took my blood pressure. They called the paramedics. The paramedics did an EKG which was normal and they took me to the ER for some other routine testing, which was all normal and then I was released. Since then, I have felt a bit nauseous and tired. |
| 1151099 | 3/31/2021 | NY | 27 | F | 3/27/2021 | 3/28/2021 | Syncope, Orthostatic Hypotension, tired |

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| 1150959 | 3/31/2021 | NC | 68 | F | 2/16/2021 | 2/24/2021 | sepsis; gallbladder attack; passed out from the gallbladder attack; Gets dizzy; Weakness; she was trying to gain her strength from being sick; her head hurt from the fall; her head hurt from the fall; she had to walk slower because she got dizzy; This is a spontaneous report from Pfizer. A 68-year-old female contactable consumer reporting for herself received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot EN6200, expiry date Jun2021) on 16Feb2021 at 14:45, in left arm, for COVID-19 immunisation. The patient received the COVID-19 vaccine for age and several comorbidities. No other vaccines were administered within 4 weeks. Medical history included ongoing high blood pressure diagnosed 25 years ago, ongoing hypothyroidism diagnosed 25 years ago, liver resection in 2007 for a benign tumor (she had not been sick and it was found accidentally), liver bile duct stopped up from 2017 and ongoing (due to scar tissue from the liver resection surgery; she had an emergency stent placed in her bile duct), chronic Crohn's disease, ongoing thyroid disorder. The patient previously received flu vaccines on unspecified dates for immunization experiencing unspecified side effects some years ago, but this past year she didn't have a reaction. The patient previously received pneumonia shots on unspecified dates since few years. Family history included gallbladder problems in her sisters and mother. Concomitant medications included oral amlodipine (manufacturer: Lupin, expiry date: 23Feb2022) from an unspecified date (a few years ago) and ongoing, 5 mg at night, for blood pressure, oral telmisartan (MICARDIS; manufacturer: Alembic, expiry date: 02Mar2022) from an unspecified date (few years ago) and ongoing, 80 mg at night, for blood pressure, oral metoprolol (manufacturer: Mylan, expiry date: 09Feb2022), from an unspecified date (few years ago) and ongoing, 25 mg twice daily, morning and night, for blood pressure, oral levothyroxine sodium (SYNTHROID) from an unspecified date (20 years ago or more), 75 ug daily in morning, with water, hour before any eating or other medications, for thyroid disorder. The patient experienced sepsis on 25Feb2021 with outcome of recovered on 03Mar2021, gallbladder attack on 24Feb2021 with outcome of recovering, passed out from the gallbladder attack on an unspecified date in 2021 with outcome of unknown, got dizzy on an |

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unspecified date in 2021 with outcome of not recovered, weakness from being hospitalized on an unspecified date in 2021 with outcome of not recovered, she was trying to gain her strength from being sick on an unspecified date in 2021 with outcome of unknown, her head hurt from the fall on an unspecified date with outcome of unknown. The patient was hospitalized for sepsis due to a gallbladder attack from 25Feb2021 to 03Mar2021. The events gallbladder attack and sepsis required also an ER visit. They did not require a physician office visit. Additional clinical course of the events included the following details. Gallbladder attack turned into infection/sepsis quickly. She previously had an emergency stent placed in her bile duct and now there was a stone in the bile duct and she was unsure if it was related; they will either remove her gallbladder or place a permanent stent. They removed stones and "goop" and placed a stent. Her gallbladder still needed to be operated on, but she was not sick with sepsis anymore. Regarding gallbladder attack the patient reported that it was controlled until further tests and surgery were performed. They couldn't do the surgery due to the infection which had cleared up but she did not want the surgery right now. A stent was placed in the duct until something was done and the stone will be crushed eventually. The patient passed out from the gallbladder attack. She never passed out, she had only ever passed out one other time in her 20's where she stood up too fast. The patient reported that she had to walk slower because she got dizzy and she was trying to adjust to getting home. She walked to the bathroom, used it, and her husband heard a thump while he was using the other bathroom. She was looking at the thermostat and fell in the den and she was surprised she didn't hit anything. Her head hurt from the fall. Sepsis: caller reported that as soon as she went to the ER, she was diagnosed with sepsis. Sepsis resolved the day she was discharged from hospital and when she was dismissed all tests were negative for sepsis. She went home on antibiotics for security for another week after discharge from hospital. Dizzy: it was just trying to get her strength up. She'll just be doing nothing and getting up too fast, it happened to any old person with blood pressure medicines. Dizziness began before she went into the hospital. She was experiencing weakness from being hospitalized and she was trying to gain her

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strength from being sick. Weakness began during her hospital admission and it was ongoing. On 03Mar2021 the patient underwent lab tests and procedures which included haematocrit: 30.4 %, haemoglobin: 10.4 g/dl (not in normal range yet), CMP: within normal limits (all results were within normal limits, including sodium and potassium), platelet count: 159, RBC count: 3.33 (supposed to be 3.9 or more but could have gotten better by now), WBC: 6.1 x10⁹/L, blood cultures: the results were not yet listed but sepsis was gone according to discharge blood work. She went to the doctor regularly. Her doctor knew how sensitive that was with her, but that her side effects were probably no more than anyone that experienced that. In some years she did not experience adverse events, specifically she did not with her flu vaccine in 2020. She has had side effects that had made her feel ill for 2-3 days and her niece was a nurse and thought she was making it up. The patient was advised to wait for the 2nd dose, she was unable to get it as scheduled on 08Mar2021. In meantime between receiving her first dose and her appointment for her second dose on 08Mar2021, she was hospitalized. The patient was just coming out of the hospital before 08Mar2021 and she still did not feel well so she cancelled the appointment. The hospital doctors, as well as the doctors approaching more tests with her gallbladder, recommended to not get the second dose as scheduled on 08Mar2021, but they could not recommend how or when to get it.

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| 1150954 | 3/31/2021 | CA | 30 | F | 2/9/2021 | 2/28/2021 | fainted; lost consciousness; weakness; concussion; This is a spontaneous report from a contactable consumer. A 30-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EN6198) on 09Feb2021 in left arm at single dose for COVID-19 immunisation. Medical history was none, unknown if known allergies. No covid prior vaccination. Concomitant medications were none (no other medications in two weeks). No other vaccine in four weeks. The patient was not pregnant, was not pregnant at time of vaccination. No covid tested post vaccination. The patient received first dose on 09Feb2021, on 28Feb2021 05:00 PM, experienced weakness fainted, lost consciousness, diagnosed with concussion. The events resulted in doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care, hospitalization, life threatening illness (immediate risk of death from the event). The patient was hospitalized for one day. Unknown if treatment for the events. Outcome of the event was not recovered. |
| 1150767 | 3/31/2021 | VA | 53 | F | 3/27/2021 | 3/28/2021 | had dose two in the morning - felt fine all day - went to sleep that night - woke up with headache, got up, took Advil, which promptly made me nauseous - went into bathroom, fainted, collapsed on floor - my husband came in and took care of me, then diarrhea, then back to sleep and I was pretty much fine the next day, although I rested all day |
| 1150688 | 3/31/2021 | NY | 36 | F | 3/25/2021 | 3/28/2021 | Syncope episode after getting up from toilet. Hit head as a result of falling. Found face down, turning purple, jerky movements. Nausea and vomiting after regaining consciousness. Had not eaten anything yet that day. Have a history of vasovagal syncope episodes, but usually can feel them coming on and lie down. This episode struck suddenly without warning. The previous night was very fatigued presumably from vaccine. No headache, no neck pain, no vision issues, no weakness, no chest pain, no shortness of breath. Menstrating. |

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| 1150917 | 3/31/2021 | OH | 52 | F | 3/8/2021 | 3/1/2021 | high level of shortness of breath; Diarrhea; spinal column hurt the worst (the spine from the top of her neck to her butt); butt muscles hurt really bad; caller's spinal column hurt the worst, the front of her calves and hip joints; spinal column hurt the worst, the very edges of her back, the side of her back was excruciating; Dizziness; Vomiting; not feeling well enough; shaking; shivering/ chills; pulse ox and it dropped down to 93; Excruciating body pain; Headache; sore arm / front of her calves, front of her thighs, left arm, 3 left fingers; Exhaustion; no appetite at all; This is a spontaneous report from a contactable consumer, the patient. A 52-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: unknown), via an unspecified route of administration in the left arm on 08Mar2021 at 10:15 (at the age of 52-years-old) as a single dose for COVID-19 immunization. Medical history included ongoing epilepsy since Oct2015 (officially diagnosed in Oct2015, but the doctors believed it was in her early 20s but she was misdiagnosed for decades), post-traumatic stress disorder (PTSD) from 2020 (diagnosed a year ago), sleep apnea since 2016 (patient thought she was diagnosed in 2016), COVID-19 in Nov2020 from which the patient almost died, memory loss (left over COVID symptom) for which the patient was in speech therapy, intermittent body pain (aftereffects of COVID-19), relapse in seizures due to COVID-19, her eyesight was terrible, epilepsy migraines. Concomitant medications included unspecified epilepsy medications. There was no other vaccine given on the same day, or 4 weeks prior to the vaccination. The patient previously received a flu shot and fainted, on an unspecified date. On 08Mar2021 at 11:15, the patient experienced sore arm (pain 2/10). On 08Mar2021 at 22:00, the patient had headache which got progressively worse, then it got so bad she wanted to pop her head off at midnight. On 09Mar2021 at 00:00, the patient had shaking and shivering where it looked like she was convulsing (she had history of epilepsy and knew what a seizure felt like, her husband may have thought she was having a seizure). The patient had chills to the point where she had multiple blankets and could not stop shaking, took her pulse ox and it dropped down to 93. The caller's baseline temperature was 97.1 and her daughter took her temperature and it was 98.9, most people wouldn't |

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consider that a temperature, but it was a temperature for her. The caller kept shaking like that for hours. On 09Mar2021 between 21:00-23:00, the patient had chills again. On 09Mar2021, the patient experienced excruciating body pain (pain 9/10) in very specific parts of her body. On 09Mar2021 by 12:00, the caller's spinal column hurt the worst, the front of her calves and hip joints, the very edges of her back, the spine from the top of her neck to her butt and then next to it was not so bad but the side of her back was excruciating, the butt muscles hurt really bad, the front of her thighs, left arm, 3 left fingers, but not the other 2 fingers. Oddly enough, she was considered a long hauler, it was the places that her occupational therapist and physical therapists were working on. On 09Mar2021 at 00:00, the patient experienced dizziness (that was on and off all day until bedtime last night on 09Mar2021) and vomiting (she couldn't hold down water). On 09Mar2021, the patient was not feeling well enough. On 10Mar2021 at 08:00, the patient experienced diarrhea (she's only gone to the bathroom twice). On Mar2021, the patient experienced exhaustion and no appetite at all. On an unspecified date, the patient experienced a high level of shortness of breath (patient was unsure if this was due to COVID-19). The patient underwent laboratory tests and procedures which included an echocardiogram on an unspecified date: her left atrium was enlarged and her cardiac numbers were high, they were going to monitor her heart and the doctors didn't know if it was because she had COVID-19 or if it was that the doctors got lucky and found it, they had nothing to compare it to because she only had this one echocardiogram. The patient had history of epilepsy migraines (can pinpoint the spot where it hurts), she thought she would try sumatriptan succinate (IMITREX) for this headache (her whole head hurt), as it didn't interact with her other medications. The patient also took acetaminophen/diphenhydramine (TYLENOL PM; Lot: GF6062, Expiry: Jun2022), ibuprofen (patient thinks the Lot is QWE2546A, but is unsure) for the headache. The patient took ondansetron (ZOFTRAN) which she had from a previous prescription and that made the vomiting stop. The events did not require an emergency room or physician office visit. The patient did not think that the reactions were due to her epilepsy medication. The clinical outcome of excruciating body

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| | | | | | | | | | pain was resolved on 09Mar2021 (it's hard for the caller to say if she has recovered because she had COVID-19 aftereffects and had body pains that come back intermittently), sore arm / front of her calves, front of her thighs, left arm, 3 left fingers, shaking, shivering/chills, pulse ox and it dropped down to 93, spinal column hurt the worst (the spine from the top of her neck to her butt), butt muscles hurt really bad, caller's spinal column hurt the worst, the front of her calves and hip joints, spinal column hurt the worst, the very edges of her back, the side of her back was excruciating, dizziness, vomiting, not feeling well enough, no appetite at all was resolved on 09Mar2021; headache was not resolved (unless the caller was asleep, she felt the headache); exhaustion was not resolved; diarrhea and high level of shortness of breath was unknown. Information on the lot/batch number has been requested. |
| 1151683 | 3/31/2021 | TX | 41 | M | 3/30/2021 | 3/30/2021 | | | Patient said he got woozy, light headed, felt like fainting. Gave him some water and observed him for 15 more minutes He called back and said it happened two more times. Today he is feeling fine. |
| 1152202 | 3/31/2021 | OK | 51 | F | 3/30/2021 | 3/31/2021 | | | Arm is extremely sore and my whole body is very achy and sore. Almost passed out and had tingling all over and almost threw up. Significant headache. |
| 1149834 | 3/31/2021 | | 54 | M | 3/25/2021 | 3/25/2021 | | | pt. reports feeling like his heart rate is elevated. radial pulse in 70s. pt. reports a hx of valovagal syncope. Medics present. Symptom beginning to resolve with comfort / calming measures. Will cont. to monitor for an additional 15 mins. pt. denies any difficulty swallowing / breathing &/or other S/S. |
| 1152192 | 3/31/2021 | MO | 65 | F | 3/22/2021 | 3/23/2021 | | | Passed out and had to go to emergency. My glucose level went high and my phrospherose and potassium level was very low |

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| 1150678 | 3/31/2021 | GA | 52 | F | 3/31/2021 | 3/31/2021 | Pt C/O syncope in the observation area while sitting in a chair. She struck her forehead and bridge of nose resulting in abrasions on forehead and bridge of nose. Fall was witnessed by other vaccine recipients in the observation area. Nurses assisted the pt within 1 minute. Pt was A&O X 4 after < or = to 2 minutes of the fall. Medical HX: Pt stated she returned from out of the country 2 days prior to her vaccination. Pt stated allergy to PNC. Pt stated that she had passed out on other occasion r/t to low BG. Interventions: Ice pack applied to forehead. C-Spine support was maintained by nurses until EMS arrived and transported the pt. Home Medications: Pt stated no routine prescribed medications. OTC dietary supplements only: Vitamins C and D and multivitamin only. Vital Signs: 1100; B/P 122/92; SPO2: 96% on room air; HR: 100 BPM; Respiratory Rate: 16 per minute. |
| 1152127 | 3/31/2021 | MN | 15 | F | 3/26/2021 | 3/26/2021 | Pre-syncope. Chest tightness/short of breath. Sternal Chest pain. Symptoms started 30 minutes after vaccination. Serial vitals and exam x 2 were normal. Symptoms resolved after another 60 minutes of observation. |
| 1152071 | 3/31/2021 | OH | 43 | M | 3/31/2021 | 3/31/2021 | Patient developed syncope approx. 10 min after receiving the vaccine and felt like he could vomit. EMS was called and he refused to go to hospital. |
| 1152139 | 3/31/2021 | CA | 55 | F | 2/28/2021 | 3/29/2021 | Extreme fever and chills all night after 2nd dose. No sleep. Body aches, head ache. Next day Queezy stomach , tiredness. I fainted after feeling queezy then seeing stars the day after jab at 3:30 PM. Still very tired and no appetite on day 2. Had fever /chills second night as well. |

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| 1151887 | 3/31/2021 | MD | 80 | F | 3/11/2021 | 3/11/2021 | Moderna COVID-19 Vaccine EUA Mod. severe muscle pain, esp across back/shoulders, incr. weakness, headache, pain at injection site, fatigue, nausea and dizziness. Retired early and got up during night with GI distress. Before getting back to bed passed out hitting my head and lower back on a metal door frame. I did not recall this but found myself back in bed partially dressed. Husband found a hallway Persian rug (heavy) displaced in AM. Slept until 3PM following day and awoke with lg. bump on head and pain in sacral area. Self treated with ice to painful areas plus Tylenol 500 mg. After 6 days with no relief saw orthopedist who took x-rays and diagnosed bruise to sacrum and post-concussive syndrome. Offered visit to neurologist which was declined as cognitive ability seemed intact. Treated with ice to sacrum 20 min. x 5 daily, Tylenol 1000 mg. and Aleve 1 q 12h x 5 days. Sx continued for 8 days requiring Tylenol, Aleve, iceand/or heat. Feeling less pain by Day 20 post vaccine. |
| 1151558 | 3/31/2021 | MI | 63 | F | 3/24/2021 | 3/24/2021 | Patient felt syncope/fainting. Onsite EMS was called vitals BP 104/66 BG 104 96% O2 HR 64. Patient treated and released against medical advise. |
| 1151671 | 3/31/2021 | IN | 50 | F | 3/29/2021 | 3/30/2021 | Almost passed out driving on the way to work the next morning. Started sweating profusely, terrible body aches, headache, and then nausea for 1/2 hour. I hurt so bad I couldn't go to sleep. Ended up taking Tylenol PM and sleeping for a couple hours. Symptoms lasted all day until 9:00PM. I continued to take ibuprofen and Tylenol to ease pain. |
| 1151666 | 3/31/2021 | TX | 21 | M | 3/29/2021 | 3/29/2021 | DIAPHORETIC, HYPOTENSIVE 95/45, BRADYCARDIC 45, PRESYNCOPE LAYED ON STRETCHER, DRANK WATER, SYMPTOMS RESOLVED. OPTED TO GO HOME ONCE SYMPTOMS RESOLVED |
| 1151655 | 3/31/2021 | NJ | 56 | F | 3/23/2021 | 3/25/2021 | Systemic: Fainting / Unresponsive-Mild |
| 1151646 | 3/31/2021 | NY | 37 | M | 3/30/2021 | 3/31/2021 | Systemic: Fainting / Unresponsive-Mild |
| 1151608 | 3/31/2021 | SC | 58 | F | 3/31/2021 | 3/31/2021 | PATIENT FAINTED ABOUT 5 MINUTES AFTER VACCINE |

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| 1151571 | 3/31/2021 | AK | 23 | M | 3/31/2021 | 3/31/2021 | brief episode of vasovagal syncope - onset approximately 5 minutes after vaccine administration, lasted approximately 1 minute, resolved without intervention |
| 1152053 | 3/31/2021 | OH | 19 | F | 3/31/2021 | 3/31/2021 | Patient felt like she was going to pass out, did not want to lie on the ground as instructed. Patient passed out in her chair, provider was next to patient and lowered patient to the ground. Patient was unconscious and not alert for a few seconds. When patient came to, she was alert and oriented, answered questions appropriately. Patient's BP was 118/82, HR 80, BG 63 (after a large lunch 2 hours prior). EMS was called, patient felt fine. Decided not to go to the hospital. Patient waited at vaccine clinic, BG 110 after an apple juice. |
| 1149398 | 3/31/2021 | CA | 33 | M | 3/29/2021 | 3/29/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Pt fainted losing consciousness for about a minute. Ambulance called, pt lay on floor. BP taken by pharmacist and then by emergency team. BP ok, pt recovered. pt stayed in shop. |
| 1149675 | 3/31/2021 | OH | 20 | M | 3/29/2021 | 3/29/2021 | Patient received first Moderna vaccine in sequence and about 10 minutes after passed out or lost consciousness for a few seconds. |
| 1149669 | 3/31/2021 | OK | 23 | F | 3/30/2021 | 3/30/2021 | Client passed out of chair face first on ground while sitting in observation right after receiving injection. Client convulsed for 15 seconds. Vital signs taken - BP 70/50, pulse ox 98% on room air, pulse 60. Client then became alert and oriented. EMS called and arrived on scene. Client refused EMS transport. Vital signs stable. Mom and boyfriend called via client phone. Boyfriend took client in his car. ER follow-up recommended by APRN on scene. Client has history of 1 other seizure. No other pertinent medical history. No injury from fall. |
| 1149520 | 3/31/2021 | MA | 45 | F | 3/10/2021 | 3/15/2021 | Pt received Moderna Dose 1 on 2/10/21 and Dose 2 on 3/10/21. On approximately 3/15 she began to develop intermittent fever, chills, diffuse myalgias, headache, followed by onset of sore throat and intermittent rash, leading to hospitalization on 3/21 after presenting with syncope. She is now undergoing evaluation for MIS-A vs. adult onset Still's. |

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| 1149435 | 3/31/2021 | SC | 40 | M | 3/30/2021 | 3/30/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: Pale, aware of surroundings-Medium, Systemic: Nausea-Mild, Systemic: Weakness-Medium, Additional Details: Pt was sitting with wife about 10 minutes after vaccine became unresponsive. Wife got my attention. Had weak pulse, cold to touch, but was responsive to me. Knew his surroundings but said didnt feel 100%. Had NP from minute clinic look at him and called EMS for extra evaluation. Pt was transported to hospital |
| 1149427 | 3/31/2021 | MA | 19 | F | 3/30/2021 | 3/30/2021 | Systemic: Confusion-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Blue lips, white face, blurry vision-Severe, Systemic: Hypotension-Severe |
| 1149425 | 3/31/2021 | CA | 25 | F | 3/29/2021 | 3/29/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Additional Details: .closed eyes when dissy about 6 to 7min after injection. leaned on wall while sitting then went to floor. does not remember getting to floor. nurses and pharmacist came to comfort as she came too. pt was passed out for just a brief couple seconds from when she got to floor. blood pressure was checked was high. then as she recovered pressure started to return to normal. also used ice pack on neck and head to feel better.** pt has history of passing out from needle. got ears pierced at age 14. |

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| 1149907 | 3/31/2021 | NY | | M | 3/16/2021 | 3/17/2021 | his body is fainted; weakness; his eyes are burning; swollen arm; accelerated heart; nose congestion; fatigue; his body feels hot; chills; A spontaneous report was received from a consumer (reporting on self), concerning male patient (age unspecified) who received Moderna's COVID-19 Vaccine (mRNA-1273) and fainted along with chills, fatigue, hot, burning eyes, weakness, swollen arm, accelerated heart and nose congestion. The patient's medical history was not provided. Concomitant medications included metoprolol and acetylsalicylic acid. On 16 Mar 2021, prior to the onset of the event, the patient received their first of two planned doses of mRNA-1273 (Lot unknown) intramuscularly for prophylaxis of COVID-19 infection. On 17 Mar 2021, the patient developed chills, fatigue, hot, burning eyes, weakness, swollen arm, accelerated heart and nose congestion and eventually fainted, details were not provided. Treatment included Tylenol (paracetamol). The adverse event of his body is fainted was assessed as medically significant. Action taken with mRNA-1273 in response to the events was not reported. Outcome of the events was unknown.; Reporter's Comments: Very limited information regarding this event/s has been provided at this time. Further information has been requested. |
| 1149403 | 3/31/2021 | MA | 35 | M | 3/30/2021 | 3/30/2021 | Systemic: Confusion-Mild, Systemic: Fainting / Unresponsive-Medium, Additional Details: Patient received covid vaccine - while in waiting area, fainted suddenly and hit his head (rug burn on forehead). Got up and felt fine. Called EMS who then took patient away. Patient was alert when taken away. Previously has fainted when he's gotten blood drawn. |

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| 1149838 | 3/31/2021 | | 40 | F | 3/2/2021 | 3/2/2021 | Anaphylaxis 40 y.o. female with multiple environmental allergies, migraines, asthma, mild OSA, and anxiety presents to the emergency department from the vaccine clinic with syncope and allergic reaction. She says shortly after getting her COVID-19 vaccine, she felt lightheaded, had near syncope. Per bystanders at the clinic, she had a brief episode of unresponsiveness and then spontaneously returned. She was conversant with multiple members of the code and rapid response team at the bedside. Did initially have some labored breathing but significantly improved. She had no vomiting but had mild nausea also significant improvement. In the field, IV was established and 125 mg of Solu-Medrol was administered. She was also given 1 IM dose of epinephrine. Her symptoms resolved she is at her baseline. Medically stable for discharge. Discharge home with short course of steroid, H2 blocker and Benadryl as needed. Advised patient to follow-up with PCP post discharge. Resume other home medicationS as listed. Of note, the patient had a similar reaction with influenza vaccine. |
| 1149391 | 3/31/2021 | TX | 20 | F | 3/30/2021 | 3/30/2021 | Systemic: Allergic: Difficulty Breathing-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Exhaustion / Lethargy-Mild, Systemic: WAS CLOSE TO FAINTING BUT DID NOT.-Mild, Systemic: Hypotension-Severe, Systemic: Shakiness-Severe, Additional Details: COMPLAINED OF DIZZINESS, VISION DISTURBANCES. STORE CALLED EMS BUT BY THE TIME THEY GOT TO STORE THE PATIENT WAS ALERT AND RESPONSIVE. PATIENT ALSO COMPLAINED OF THURST AND WE GAVE HER WATER TO DRINK. THEY DID A FULL WORKUP ON HER BUT DID NOT TRANSPORT HER TO HOSPITAL. SHE LEFT WITH HER MOTHER , EVENT LASTED ABOUT 45 MINUTES . |

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| 1149283 | 3/31/2021 | CA | 48 | M | 3/30/2021 | 3/30/2021 | After receiving the Pfizer vaccine in the Left arm, patient bled from the site after the syringe was pulled out. About 20 seconds later, patient said he was nervous and started sliding down in the chair. Patient was guided to the ground by vaccinating nurse. Patient was unresponsive for about 5 seconds, pulse present, face and lips blue for about 3 seconds and then transitioned to pale. Patient did not fall and did not hit his head. Vitals assessed, BP 152/93, Pulse 78, Temp 98.1, RR 17, SaO2 98%. Patient able to respond shortly after fainting, answered questions correctly. Patient stated he has a phobia of needles and has fainted in the past when getting blood drawn. 911 called by another vaccinating nurse during this time. Paramedics arrived at 1304. Patient safety and comfort maintained. Patient treated by paramedics. Vitals stable, EKG showed no abnormalities. Patient refused to be taken to the hospital after incident. Patient stayed moved from the vaccination area to observation without incident. Patient tolerated water and sitting up-right in chair. Patient monitored by RN and LVN. Vitals at 1328 BP 143/88, SaO2 98%, Pulse 98, Temp 98.1, RR 18. Patient tolerated waiting 15 minutes in observation and requested to ?get some fresh air.? Patient tolerated standing outside with two nurses observing him at that time. Patient was stable to leave site. Last vitals @ 1345 BP 148/94, Pulse 83, Temp 97.1, SaO2 97%. Patient left site without further incident. |

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| 1148727 | 3/31/2021 | TN | 65 | F | 2/21/2021 | 3/18/2021 | passed out on the floor; heaving all day; really cold; headache; fever; chills; A spontaneous report was received from a consumer concerning a 65-years-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced passed out on the floor, really cold, heaving all day, headache, fever and chills. The patient's medical history was not provided. No relevant concomitant medications were reported. On 21 Feb 2021, prior to the onset of the events the patient received first of two planned doses of mRNA-1273 (lot: 007M20A) intramuscularly in the left deltoid for prophylaxis of COVID-19 infection. On 21 Feb 2021, patient experienced sore arm and it recovered on 22 Feb 2021. On 18 Mar 2021, prior to the onset of the events the patient received second of two planned doses of mRNA-1273 (lot/batch:032M20A) through unknown route of administration in the left deltoid muscle for prophylaxis of COVID-19 infection. On 18 Mar 2021, the patient experienced really cold, headache, fever and chills. On 19 Mar 2021, the patient experienced passed out on the floor and heaving all day. The event passed out was medically significant. No laboratory data was provided. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable as it was second dose of vaccine. Th events really cold, fever and chills were recovered on 19 Mar 2021. On 19 Mar 2021 the outcome of cold, fever and chills. On 20 Mar 2021 the outcome of event(s), headache, passed out on the floor, heaving all day was resolved.; Reporter's Comments: This case concerns a 65 Y/O F with serious unexpected loss of consciousness and nonserious unexpected retching and nasopharyngitis, and expected pyrexia, chills, and headache. Event onset the same day as the second dose of mRNA-1273. Events resolved. Based on current available information and temporal association between use of the product and the start date of the event, a causal relationship cannot be excluded. |
| 1152212 | 3/31/2021 | MA | 22 | F | 3/31/2021 | 3/31/2021 | appx 5 minutes after vaccine patient fainted |

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| 1152453 | 3/31/2021 | WI | 27 | M | 3/31/2021 | 3/31/2021 | Client passed out around 10 minutes after vaccine was given. Came to without any injuries, with normal vital signs. Left building unassisted after around 20 minutes and refused transport. |
| 1148705 | 3/31/2021 | FL | 73 | M | 3/2/2021 | 3/2/2021 | passed out on the highway while driving; A spontaneous report was received from a consumer concerning himself, a 73 years old male patient, who received Moderna's COVID-19 vaccine and he passed out on the high way while driving/loss of consciousness. The patient's medical history was not provided. Concomitant product was not provided by the reporter. On 2-Mar-2021, prior to the onset of event, the patient received their first dose of mRNA-1273(batch number unknown) intramuscularly on his left arm for prophylaxis of COVID-19 infection. On2-Mar-2021, after vaccination he passed out on the high way while driving. The event passed out on the high way while driving was considered to be medically significant. Relevant laboratory investigation included blood pressure test which revealed as normal. Treatment information was not provided. Action taken with mRNA-1273 in response to the event was not reported. The outcome of the event which he passed out on the high was while driving was resolved.; Reporter's Comments: This case concerns a 65-year-old female with a serious unexpected event of loss of consciousness. Event onset occurred the same day as the first dose of mRNA-1273. Treatment not reported. Events resolved. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. |
| 1149407 | 3/31/2021 | MA | 35 | M | 3/30/2021 | 3/30/2021 | Systemic: Confusion-Mild, Systemic: Fainting / Unresponsive-Medium |
| 1150120 | 3/31/2021 | NY | 49 | F | 3/29/2021 | 3/29/2021 | 3/29 Rapid response team called for c/o dizziness, feeling of fainting and palpitations, near syncope, SOB, abdominal pain. 3/30 She reported that she felt like something was blocking her throat and 3/31 c/o headache |

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| 1150591 | 3/31/2021 | MI | 22 | M | 3/30/2021 | 3/30/2021 | Patient passed out after receiving vaccine. Patient experienced sweating. Onsite EMS was called vitals HR 57 BP 89/41 BG 63. He was given some water & chocolate. He recovered with BP 112/59 and passenger drove home. |
| 1150579 | 3/31/2021 | FL | 52 | F | 3/5/2021 | 3/6/2021 | I got very sick and fainted. I started feeling sick about 8 hours after and it lasted about 72 hours. I fainted about 18 hours after the vaccine. I did have covid back in November 2020 |
| 1150541 | 3/31/2021 | WI | 20 | F | 3/25/2021 | 3/25/2021 | Around 9pm I got very short of breath and got very sick. I was very nauseous and the next day I fainted. |
| 1150532 | 3/31/2021 | NY | 60 | F | 3/31/2021 | 3/31/2021 | dizziness, near syncope |

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| 1150517 | 3/31/2021 | MI | 79 | M | 1/28/2021 | 1/29/2021 | sore arm; injection site pain; extreme fatigue/Exhaustion; a little headache; chills; muscle pains which makes them a little achy overall; sleepy; feel like they have Covid all over again; feel achy; feel lousy; This is a spontaneous report from a contactable consumer. A 79-year-old male patient received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Lot Number: EL3248) via intramuscular in left arm on 28Jan2021 at single dose for COVID-19 vaccination. The patient medical history included Covid. Concomitant medications were not reported. On 29Jan2021 the patient was experiencing a sore arm, injection site pain, extreme fatigue, a little headache, chills, and muscle pains which makes them a little achy overall. It was reported that she and her husband both received the vaccine yesterday and stated that they feel like they have Covid all over again on 29Jan2021. She stated that they had Covid already and stated that they have chills and are achy 29Jan2021. Caller said that they are also having that Covid exhaustion. Their arms were quite sore too from the shot, but they did not expect to feel lousy on 29Jan2021. They have been sleepy all afternoon and stated that they sat down and just passed out, caller clarified that they went to sleep on 29Jan2021. Yesterday they were ok. The outcome of the events sore arm, injection site pain, a little headache was unknown, extreme fatigue/exhaustion, muscle pains which makes them a little achy overall, sleepy, feel like they have Covid all over again, feel achy, feel lousy was recovering, chills was resolved on 29Jan2021. No follow-up attempts are possible. No further information is expected. |

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| 1150393 | 3/31/2021 | UT | | M | 3/10/2021 | 3/10/2021 | I passed out, fell to floor and was unresponsive for multiple minutes; fell to floor; Momentary feeling of nausea and lightheadedness before passing out; Momentary feeling of nausea and lightheadedness before passing out; mild sore arm; This is a spontaneous report from a contactable consumer reporting for himself. A 52-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE) (lot number EN6198/expiration date: not provided), via an unspecified route of administration, on 10Mar2021 at 14:00 (as a single dose in the right arm for COVID-19 IMMUNIZATION. The patient had known allergies to statins and aspirin. The patient had no other medical history. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medication (other medications taken in two weeks) were none. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 10Mar2021, the patient experienced a mild sore arm. On 13Mar2021 at 17:30, the patient experienced nausea and lightheadedness before passing out. The clinical course was as follows: On 10Mar2021 afternoon, the patient received the first dose of COVID-19 vaccine. No overt signs of illness or other symptoms beyond mild sore arm. On 13Mar2021, in the afternoon, the patient passed out, fell to floor and was unresponsive for multiple minutes. Momentary feeling of nausea and lightheadedness before passing out. No other signs of illness at time. Paramedics and subsequent ER visit did not find any signs of physical symptoms that would have attributed to syncope. Lightheadedness lasted for awhile and was still occurring on and off during ER visit. The adverse events resulted in a doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care. The patient did not receive any treatment for these events. The outcome of the events mild sore arm, passed out, nausea and lightheadedness was recovered on an unspecified date in Mar2021. Since the vaccination, the patient had not been tested for COVID-19. |
| 1149687 | 3/31/2021 | AZ | 17 | F | 3/31/2021 | 3/31/2021 | Dizziness. Fainting. Low blood pressure |

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| 1150372 | 3/31/2021 | TN | 59 | F | 3/13/2021 | 3/14/2021 | When she passed out; feeling real dizzy; since her leg and knee feel bruised; right eye was swollen; felt unwell; weak; This is a spontaneous report from a contactable consumer (patient) reported that a 59-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 13Mar2021 as a single dose (at the age of 59-years-old) for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. It was reported that the patient got the Pfizer-BioNTech COVID-19 Vaccine first dose on Saturday, 13Mar2021, and was fine after the shot but had a reaction on Sunday, 14Mar2021. On 14Mar2021, she got up to make breakfast and started feeling real dizzy and the next thing she knew, she was on the floor; this happened twice. When she passed out, she must have hit something on her right side, since her leg and knee feel bruised and right eye was swollen. She felt unwell, dizzy and weak; no dizziness today (15Mar2021). She planned to discuss further with her physician. The outcome of the event dizziness was recovered on 15Mar2021 and unknown for the rest of the events. Information on the lot/batch number has been requested. |
| 1149756 | 3/31/2021 | NY | 35 | M | 3/30/2021 | 3/30/2021 | Patient fainted after receiving first Covid vaccine. Patient admitted to a history of fainting after vaccines. Patient given water and rested. Vitals signs were stable X3. He was able to stand with no issues and walked out of clinic after recovering. |
| 1150069 | 3/31/2021 | OH | 61 | F | 3/16/2021 | 3/17/2021 | I had my Pfizer vaccine on March 16, 2021. On March 17th I had a headache, body aches and fatigue which I expected since I had Covid in November 2020. Most of these symptoms only lasted 3 days. After the 3 days I had a continuing headache and started having jaw pain. On March 22nd I started having dizziness and a severe headache with jaw pain, fatigue and nausea. On March 23rd I got up abruptly and felt extremely dizzy and almost passed out. I am having continued sporadic headaches, nausea, dizziness behind my eyes with fatigue and a metal taste in my mouth especially when my mouth is dry. As of March 30th, only side effects lingering are dizziness behind my eyes and nausea |

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| 1150044 | 3/31/2021 | OH | 19 | F | 3/31/2021 | 3/31/2021 | I got my shot, sat down, and was reading through the information that the clinic provided me. A few minutes after, I noticed my right arm was getting warm, but I thought I was being paranoid (placebo effect). I began to feel nauseated. About another 5 minutes after feeling warm and nauseous, my ears began to ring and my vision went white. I was cold but sweating. I have passed out a handful of times before for various reasons, so I knew what was happening. I tried to signal to a volunteer from my seat that I needed help, but I ended up laying on the ground by my chair before someone came over. Once I laid down, the attention of the volunteers and nurses was on me. Three came over to assist me. They held my legs up, kept a hand on my wrist for a pulse, and fetched water. I talked myself through the dizziness and ringing in my ears. They put a cold rag on my forehead and had smelling salts on hand. Once I began to feel better, they helped me slowly sit up, and eventually helped me stand up and get into a chair. They kept a close eye on me for the next 30 minutes to make sure I didn't have any other reactions. |

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| 1149923 | 3/31/2021 | CA | 20 | F | 3/7/2021 | 3/11/2021 | fainted two times; felt very tired after the vaccine for several days; This is a spontaneous report from a contactable consumer (patient). A 20-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration, administered in left arm on 07Mar2021 11:45 (Lot Number: EN6206) as single dose for Covid-19 immunisation at age 20 years old. Medical history included allergies to penicillin. The patient is not pregnant. The patient had no covid prior to vaccination. There were no concomitant medications. The patient did not receive other vaccine in four weeks and no other medications in two weeks. The patient previously received amoxicillin and experienced allergies. The patient reported that she felt very tired after the vaccine for several days. Four days after she received the vaccine, she took a bath and when she got out of the bath, she fainted two times. She stated that she has never fainted before and she has taken several baths. Onset of the events was on 11Mar2021 21:00. No treatment given for the events. The patient had a covid test (saliva) post vaccination on 15Mar2021 with negative result. The patient recovered from the events. |

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| 1149914 | 3/31/2021 | NV | 69 | F | 3/12/2021 | 3/1/2021 | <p>blacked out/ didn't know what was going on; light headed; fever; A spontaneous report was received from a consumer concerning herself, a 69 year old female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced blacked out and didn't know what was going on/syncope, fever/pyrexia, light headed/dizziness. The patient's medical history was not provided. No relevant concomitant medications were reported. On 12 Mar 2021, prior to the onset of events the patient received first dose of their two planned doses of mRNA-1273 (Batch number: 040A21A) intramuscularly for prophylaxis of covid 19 infection. On an unspecified day in Mar 2021, the patient experienced blacked out and didn't know what was going on. She did not lose consciousness. The patient had developed fever and felt light headed. Patient was hospitalized on 13 Mar 2021 due to the events. Treatment information was not provided. Action taken with mRNA-1273 in response to the events was not provided. The outcome of the events, blacked out and didn't know what was going on/syncope, fever/pyrexia, light headed/dizziness were unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded.</p> |

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| 1149911 | 3/31/2021 | WI | 24 | F | 3/4/2021 | | <p>Passed out/passing out; Vertigo; Uncontrollable muscle twitching all over body; Dizziness/lightheadedness; Clammy hands/feet; Diarrhea; Gas; Rapid heart rate; Tingling in both feet/Tingling in bilateral feet; Liquid in both ears; Tiredness/fatigue; Nausea; Chills; A spontaneous report was received from a consumer, concerning a 24- year-old female who received Moderna's COVID vaccine and passed out and developed vertigo, dizziness, lightheadedness, uncontrollable muscle twitching, chills, clammy hands/feet/cold sweat, tingling in bilateral feet/paresthesia, fatigue ,nausea, liquid in the ears/ear discharge, diarrhea and gas/flatulence. The patient's past medical history was not provided. Products known to have been used by the patient, within two weeks prior to the event was reported as multivitamins (ascorbic acid, colecalciferaol, cyanocobalamin, pyridine hydrochloride, retinol palmitate, tocopherols mixed). On 04 March 2021 , prior to the onset of the event, the patient received first of two planned doses of mRNA-1273 (lot number:13A21A) intramuscularly for prophylaxis of COVID 19 infection. On an unknown date after receiving the first dose of the vaccine the patient passed out which was considered as serious event (medically significant). The patient also experienced vertigo, dizziness, lightheadedness, uncontrollable muscle twitching, chills, clammy hands/feet ,tingling in bilateral feet, fatigue ,nausea, liquid in the ears, diarrhea, gas and tiredness. The patient reported that she passed out 30 seconds later after getting injection and it was not due to vasovagal reaction. As per patient, tingling started when she woke up early in the morning but in feet only. Treatment medications include dimenhydrinate and paracetamol. The patient took water and electrolytes for hydration. Action taken with mRNA-1273 in response to events was considered as unknown. The outcome of the events passed out and developed vertigo, dizziness, lightheadedness, uncontrollable muscle twitching, chills, clammy hands/feet/cold sweat, tingling in bilateral feet/paresthesia, fatigue ,nausea, liquid in the ears/ear discharge, diarrhea and gas/flatulence was considered as unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded.</p> |

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| 1148719 | 3/31/2021 | TX | | F | 3/16/2021 | 3/16/2021 | light headed; fainted; cold hot sweats; dry mouth; felt thirsty; flu symptoms; unbearable body aches; A spontaneous report was received from a Consumer, concerning a female patient of 31 years-old-age, who received Modena's COVID-19 vaccine and she fainted and experienced cold hot sweats, dry mouth and felt thirsty. The patient's medical history was not provided. Advil was the Concomitant products that was provided by the reporter. On 16Mar2021 at 8am, the patient received their first of two planed doses of mRNA-1273 (Unknown lot number) intramuscularly in her right non-dominant arm for prophylaxis of COVID-19 infection. After getting the dose at 8am, she had a bad reaction where 5 min later she fainted and experienced cold hot sweats, dry mouth and felt thirsty. On Tuesday night (16Mar2021) she had flu like symptoms with unbearable body aches. She stated on 18Mar 2021 she is felling better but tired and felt like fainting, light headed and dizzy. The patient stated that she took Advil for flu like symptoms. Action taken with mRNA-1273 in response to the event was unknown. The outcome of the event, was recovering and resolving.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. No follow up is possible. |
| 1150664 | 3/31/2021 | MI | | 65 F | 3/30/2021 | 3/30/2021 | Patient was joking and laughing an able to communicate. Immediately after shot, patient heaved or turned away, eyes watering and then could only answer in single word answers. Massive change in "affect". Onsite EMS was called vitals BP 146/84 HR 98 Patient passed out 4 times with eyes rolling back. Ems took patient to the hospital. |

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| 1150378 | 3/31/2021 | CA | 64 | M | 3/12/2021 | 3/1/2021 | Fainted; Fainted; lightheadedness; drop in blood pressure; sweats; clamminess; major chills; shaking; nausea; vomiting; This is a spontaneous report from a contactable consumer reporting for himself. A 64-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot Number: EN6208) via an unspecified route of administration, administered in the left arm on 12Mar2021 15:45 (at the age of 64-years-old) as single dose for COVID-19 immunisation. Medical history included minor history of fainting (4x in 15 years). The patient had no known allergies. Concomitant medications included ibuprofen (ADVIL [IBUPROFEN]); omeprazole; fish oil, vitamins etc. The patient had no COVID prior to vaccination. The patient felt great initially. Fainted in response to lightheadedness (drop in blood pressure) 4 hours later on 12Mar2021 at 07:30 PM - on a hardwood floor. 7 stitches after an ambulance ride and multiple CT scans. Also had sweats/clamminess, major chills (shaking), and nausea and vomiting over the next 12 hours or so. Spent 2 nights in the hospital to rule out other causes for fainting. The received the following as treatment for the events: stitches, IV to rehydrate and anti-nausea meds. The events resulted to doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care and hospitalization. The patient was hospitalized for two days. The patient tested negative on a COVID-19 test via nasal swab on 12Mar2021. The patient was recovering from the events. |

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| 1153497 | 3/31/2021 | CT | 25 | F | 3/18/2021 | 3/18/2021 | Delirium; Fainting episode with convulsions; Fever with Chills; Nausea; Dizziness and disoriented; Dizziness and disoriented; This is a spontaneous report from a contactable consumer (patient). A 25-year-old female patient (not pregnant) received first dose of bnt162b2 (Batch/Lot Number: EN6207), via an unspecified route of administration, administered in left arm on 18Mar2021 08:30 as single dose for covid-19 immunization. Medical history included cystitis interstitial from an unknown date and unknown if ongoing. Concomitant medications included ethinylestradiol, ferrous fumarate, norethisterone acetate (LO LOESTRIN FE) taken for an unspecified indication, start and stop date were not reported. The patient experienced delirium, fainting episode with convulsions, fever with chills, nausea, dizziness and disoriented on 18Mar2021 09:00. No other vaccine in four weeks. The adverse event was not resulted in a visit to doctor or other healthcare professional office/clinic or Emergency room/department or urgent care. No treatment received. The outcome of events was resolving. No Covid prior vaccination. No Covid tested post vaccination. Not Known allergies. |
| 1154411 | 3/31/2021 | | 25 | F | 3/31/2021 | 3/31/2021 | fainted/seizure ? loss of bladder control. EMT called and assisted. Said all vital were normal and no signs of seizure. EMT recd pt see primary MD for follow up. |
| 1154407 | 3/31/2021 | MS | 42 | M | 3/31/2021 | 3/31/2021 | Felt a large amount of sensation in my injection arm 1-2 minutes after shot. Started to feel faint and light-headed 3-4 minutes after shot. Passed out about 5 minutes after shot. Felt sweaty, disoriented, spacey, and nauseated shortly after coming back to consciousness. Went to hospital in an ambulance and released a couple hours later. |
| 1154395 | 3/31/2021 | CA | 35 | M | 3/31/2021 | 3/31/2021 | Patient received the vaccine and was waiting in the waiting area. Approximately 5-6 minutes later he blacked out and fainted on the floor. He said he was stressed about the vaccine and also had not ate. We called 911 and the paramedics checked all the vitals and everything was okay. He left with his friend and was feeling better. |

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| 1154338 | 3/31/2021 | FL | 19 | M | 3/31/2021 | 3/31/2021 | PATIENT FAINTED APPROXIMATELY 5 MINUTES AFTER RECEIVING MODERNA COVID 19 VACCINE, BUT WOKE UP IMMEDIATELY. APPLIED COLD COMPRESS TO PATIENT AND GAVE COLD WATER. HE REFUSED EMERGENCY MEDICAL CARE. |
| 1154325 | 3/31/2021 | NY | 50 | F | 3/31/2021 | 3/31/2021 | Vaccine was administered in PM. Pt then was in observation area. At 5:14 PM, Pt felt dizzy and fainted for ~ 1 min. EMS was called. Vital signs were monitored - unremarkable: BP 127/87; Pulse -72 BPMs, T -97.9 degrees F; SO2 = 99%. After 1 minute, Pt felt better, was A&O x 3, not in acute distress. pt was evaluated by EMS; declined transferring to a hospital. EMS staff ruled out allergic reaction to vaccine - wrote "psychogenic reaction to injection". Pt was observed at office till 5:50 PM, and was transferred home by their daughter |

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| 1153164 | 3/31/2021 | | | F | 3/21/2021 | 3/21/2021 | <p>She's been nauseated, cannot drink or eat; She feels like sleeping a lot; Feeling weak; Her teeth were chattering for 2 hours; She was shaking compulsively for 2 hours; She had asthma very bad; Was sweating compulsively; She has passed out 3 times; She had bruises everywhere; She has had pain in the arm; A spontaneous report was received from a consumer concerning a female patient of an unknown age who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced events She has passed out 3 times/ Loss of consciousness, She had bruises everywhere/ Contusion, She was shaking compulsively for 2 hours/ Tremor, She had asthma very bad/ asthma, Was sweating compulsively/ hyperhidrosis, She feels like sleeping a lot/ sleepy, feeling weak/ Asthenia, She has had pain in the arm/ vaccination site pain, She's been nauseated, cannot eat or drink/ nausea, Her teeth were chattering for 2 hours/ Chills. The patient's current condition includes asthma and she's losing weight since February and this is ongoing. No relevant concomitant medications were reported. On 21 Mar 2021, prior to the onset of the events the patient received the first of two planned doses of mRNA-1273 (lot/batch: Unknown) intramuscularly for prophylaxis of COVID-19 infection. On 21Mar2021, she has had pain in the arm, she has passed out 3 times, she had bruises everywhere, and at 2AM of 22Mar2021 she was shaking compulsively for 2 hours, her teeth were chattering for 2 hours, went to hospital, she had asthma very bad, was sweating compulsively. On 23Mar2021 she feels like sleeping a lot and feeling weak. She's been nauseated, cannot drink or eat on an unknown date. The event Loss of consciousness was considered as medically significant. No treatment information was reported. Action taken with mRNA-1273 in response to the events was unknown. The outcome of events pain in the arm, passed out 3 times, bruises everywhere, shaking compulsively for two hours, teeth chattering for two hours, had asthma very bad and was sweating compulsively, she felt like sleeping a lot, weak, nauseated, cannot drink or eat, was unknown at the time of this report.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.</p> |

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| 1153505 | 3/31/2021 | OK | 67 | F | 2/4/2021 | 2/4/2021 | <p>passing out; she was 155 lbs before when she was in the hospital - and now 160 lbs; States that she was dehydrated in hospital and did not eat a thing; stayed dizzy; confused; She had felt disoriented; foggy; it was like the flu shot; sleeping a lot; her vision would get very narrow; thumb pink; erratic body temperature; horrible headache; bodyaches; dry heaves; slight fever/ body temperature 104.4; injection site sore; lymph nodes swollen; This is a spontaneous report from a contactable consumer (patient). The 67-years-old female patient received bnt162b2 (BNT162B2), dose 2 intramuscular, administered in Arm Right on 04Feb2021 (Batch/Lot Number: EN5318) as SINGLE DOSE for covid-19 immunisation. Medical history included breast cancer - stage 2 from Jan2008; 29Jan2008 surgery, breast cancer. First surgery for breast cancer removal and lymph node removal, then the cancer went around the first and second lymph nodes so they had to go back in because they had to take out a bunch more and she had to give them permission to take out more lymph nodes. Concomitant medication(s) included ongoing simvastatin for High cholesterol; ongoing bifidobacterium bifidum, bifidobacterium longum, lactobacillus gasseri (PHILLIPS COLON HEALTH) she has high pain tolerance, had stomach cramp did not know what it was and one a day vitamin. The patient previously took bnt162b2 (BNT162B2), dose 1 intramuscular administered in Arm Right on 14Jan2021 (Batch/Lot Number: EL8982) as SINGLE DOSE for covid-19 immunization and experienced Injection site sore. The patient experienced passing out on 28Feb2021, injection site sore, lymph nodes swollen on 04Feb2021, thumb pink on 26Feb2021, erratic body temperature, horrible headache, bodyaches, dry heaves on 05Feb2021, she was 155 lbs before when she was in the hospital - and now 160 lbs on an unspecified date. The patient was hospitalized for passing out from 01Mar2021 to 02Mar2021. The event passing out lead to emergency room visit. The patient lab tests and procedures which included cat scan/ cat scan groin area with contrast: normal; EKG: normal; blood workup: normal; Blood culture:normal, all on 01Mar2021; cat scan head and neck with contrast: normal and cat scan head and neck without contrast:normal on 02Mar2021. The outcome of the event thumb pink was recovering, erratic body temperature was not recovered,</p> |

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horrible headache, bodyaches, dry heaves recovered on 26Feb2021, and was unknown for the rest events. Reported as: Caller states that on 04Feb2021 she received her 2nd vaccine at around 3:30 pm, and then around 10 pm she had injection site soreness. The morning after the second injection around 4 am, she had site on her arm soreness, erratic body temperature with slight fever, horrible headache, bodyaches, and dry heaves. Her lymph nodes also swelled up again. Caller clarifies that this also happened after her first injection of the Pfizer Covid19 vaccine and on a similar timeline. Caller clarifies that 2 weeks later on 26Feb2021 she had ended up with horrible headache, dry heaves, headache, body temperature 104.4. She states that this lasted Friday night and Saturday night and Sunday she was feeling better. Clarifies that was the week of 26Feb2021. Caller states that her events were on a similar timeline and that her first vaccine was 14Jan2021 at 3:30 pm on Thursday. States that by 10 o'clock that night, injection site was sore. At 4 am, injection site was very sore. A couple of days later, her lymph nodes were swollen in her left leg, groin area, right arm under armpit. Adds that area under armpit was the size of her thumb. Also, on the left underneath her chest wall. She states that she has had breast cancer in that left breast. She states that the swelling went away completely, but that the groin area swelling took 2 weeks to go away. Unable to verbalize exact dates. Confirms that this was after the first vaccine and also occurred after the second vaccine. Caller then adds that she was feeling better Sunday, 28Feb2021 but that her husband then found her on the floor Sunday night at 8:45 pm. She states that she passed out. Monday she passed out again and was taken to the hospital where she stayed until 02MAR2021. Healthcare Provider also provides information that her son ran her to emergency room, and she is not familiar with the doctors there. Also, a doctor that she does not remember the third physician but it was a neurologist. Caller states that she was 155 lbs before when she was in the hospital - and now 160 lbs. States that she was dehydrated in hospital and did not eat a thing. Normally she runs around 160 lbs. States she had breast cancer so left arm cannot be used, so they used her right arm for both vaccines. caller adds that she had a cruise she was going to go on but refused to go on in 2020. States that

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she heard you will need to have a vaccination passport to travel in the future so she wanted to get vaccine. States she did not want to get covid. States that so many people have died. Caller clarifies that she was admitted to (Hospital Name) on 01Mar2021. Caller adds that she went to the hospital 2 weeks after the second dose. She states that is what makes them wonder if it is from the Covid vaccine. Adds that she is not saying that is what caused all of this, but that it is just a coincidence that it was exactly 2 weeks after the vaccine, exactly 2 weeks out when this happened. She states that she has been thinking if she should be wasting Pfizers time reporting this but it could be a coincidence or maybe a reaction. Caller adds maybe it is because she had 34 radiations, 8 chemo treatments, 1 year of Herceptine, and breast cancer. States that maybe she can save somebody else, or if a possibility, people can be prepared two weeks early. She adds that she is lucky she did not break an arm, leg, or bone. States that she doesn't know if maybe she can save some other person by sharing this information. Injection site sore: States that this was after both first and second vaccine. It stayed sore for about a week, and was just tender after that. If she touched it, she noticed, but it didn't hurt her from doing anything. With the first vaccine, injection site soreness started 14Jan2021 around 10 pm and completely resolved after about a week. She adds that with the second vaccine she also noticed injection site soreness that same day on 04Feb2021 around 10 pm also. She adds that it lasted about six days or seven days or so. It was the same way, tender the first day and then at 4 am was when it got really bad. That Friday 05Feb2021 was when it hurt worse. Adds that she went into hospital on 01Mar2021 on Monday. States she was feeling okay, stayed dizzy and confused and thought she was getting Alzheimer's or dementia but it cleared. At 11 pm on Sunday felt completely different, like the old her. States she was fine yesterday 15Mar2021. She had felt disoriented but is now feeling better and back to normal. Erratic Body Temperature: States that she started watching and recording her body temperature on 09Mar2021. She states that it was 104.5 on Friday, and Saturday and Sunday night she used a wet washcloth to her forehead. States that her body temperature initially was variable starting on 26Feb2021. She adds that it continued until

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Sunday 28Feb2021. On 26Feb2021, her body temperature was 104.5. She states that it was then low on Sunday 28Feb2021 and was 98 or 99. Adds that it had been erratic but that once the fever broke it has been between her normal which is 98.6 to 98.7. Adds that her and her husband know for sure that when she passed out the three times, her temperature was 94.4. States that her husband gave her aspirin for the temperature. Adds that her temperature has been between 97.9 to 94.9 and dropped to its lowest on Saturday 13Mar2021 at 10:35 am. She states that it is still doing this erratic behavior and that this morning it was 96 at 1 am and then 96.8 at 8 am. While on phone today, it is 97.1. Lymph nodes swollen: States noticed swelling at 4 AM 16Jan2021. States this occurred 4 am after both first and second injection. Occurred to groin area, right arm, and left arm. It was there for a couple of days and then it would just remind her it was there. The arm lymph node swelling went away after a few days, maybe before a week or so. The one in the groin was there for about two weeks. On a scale of 1 to 10, it was a 1.5 and was not something that people need to take an Advil or something for. Clarifies it was in the armpit except in the left side because they took those lymph nodes out during surgery in 2008. Also, she noticed lymph node swelling in the chest area. Lymph Nodes at second vaccine she also noticed them starting at about 4 am after the vaccine and it started hurting again. Caller reiterates both shots were given at 3:30 pm and then at 10 pm injection site gets sore. Then 4 am injection site gets more sore. She's been telling everybody to get the vaccine in the morning. Her symptoms lasted two weeks and then she was fine. Caller adds that her husband never felt a thing from receiving the vaccine. She states that the injection site was tender on her husband but gone the next day. Investigations: stated they looked at her in the hospital and said she was fine. The girl came back up and did more cultures and nothing grew. They were confused and so was she and she has been debating whether to call and waste time reporting but thinks that Pfizer needs to know what happened to her. Simvastatin: Adds that asked doctor if this caused her symptoms and he said no. Phillips colon: doctor 6 to 9 months later did scan, the next day was in emergency surgery and it was her appendix. It enlarged and had grown into the other

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organs. Doctor said it was a mess and it was ready to rupture as a precaution they wanted to remove it. Bayer product Code above expiration date states 0C09C and expiration is Mar2023. Thumb pink: thumb nail to finger print past where you bend it was where she noticed it was pink. States it is now 98% better. Friday 26Feb2021 afternoon at 1 pm, right thumb turned pink. She took a pen and marked where it was vertical and horizontally pink to scarlet in color. She put herself on antibiotics. She was not sure if maybe she cutting chicken and cut it, or closed finger in drawer. It swelled up twice the size, turned purple. Went all around the finger and it was hot. She thought it was going to pop off. She kept wondering what she was going to do to her thumb. She did jam it and cut herself 2 months ago. Clarifies it was right hand thumb. Treatment: took antibiotics, which she states they kept her on in the hospital in IV form. She started the antibiotics on Friday 26Feb2021. Took it Friday afternoon, Friday night, and Saturday and Sunday. She thought it was doing better Sunday night before she passed out. Clarifies Cephalexin, 500 mg daily (Keppra) three times a day and by mouth. Adds that she keeps this medication on her because she travels the world and it is good to have on hand since it is broad-spectrum. Passing out: 28Feb2021 Sunday night noticed the volume on television was driving her crazy and it was irritating. Around a quarter to 9 she got up to brush her teeth and go to the bathroom. She went pee and then fell off toilet. She got really really dizzy, and her husband was standing over her yelling asking what happened. She saw the wall and she did not know what happened. States she was out cold and he was calling her name but she did not hear him. She heard him asking what happened but it was in the distance. He got her to bed and about 20 minutes later (husband reports 30 minutes later) she was so dizzy and passed out again. She adds that this may have happened Saturday also because she was sleeping a lot and it was like she was seeing words repeat themselves over and over again and her vision would get very narrow. Her husband was not sure if she passed out on Saturday also, but said both times Sunday she was out cold. Monday 01Mar2021 she called her husband's office and woke up to the nurse on the other line screaming. She dropped the phone and heard her name being screamed over and over on the phone and

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when she picked it up the nurse said that she must have passed out even though she thought she was sleeping. The nurse got ahold of her husband in his office. She believes she passed out again Monday morning and was then in the hospital Monday and Tuesday.

Hospitalization: On 01Mar2021, her husband is a physician and suggested she go to the hospital. She was trying to get ahold of her son and daughter in law. She sent them a text and called and they did not answer. Her sons phone was charging and when he looked at it he was on his way to her. She states that when she came to all three times, she was extremely dizzy foggy and confused. Adds that the nurse at her husband's office alerted her husband and he told her to stay in bed and her son came to help her and then drove her to ER. States she was there Monday 01Mar2021, and discharged Tuesday night 02Mar2021 about 4:30 to 6 pm. Caller does not want to file a report for her husband regarding the injection site soreness. She states it was like the flu shot. She clarifies that it was not his arm, it was the injection side. She states that these people who are going on and on about their arm hurting, it is the injection site. She states it is the injection site and will not be the arm. States that it is like the flu shot. States she does not want to file a report regarding her husband because it was injection site soreness and went away. Provides no additional information. Adds that this is a new drug and new disease and we do not know what the future holds Caller adds that she keeps a diary and started a diary so that she has everything recorded in terms of medical history. States that it is important that everybody do so. Family Medical History Relevant to AE(s): callers dad passed out at age 85. He found out he was diabetic and had heart issues. Also had a stroke at age 87 and passed away. Adds that between ages 85 and 87 he passed out every few months, he would do one of his passing out things. Caller also had a brother who passed out sitting at table and went forward into table. She states at that time her brother didn't realize he had stage 4 lung cancer, and her brother passed away 1 and a half years later. Caller adds that he smoked from ages 15 to 64, and quit at age 63 because the doctor told him to. No follow-up attempts possible. No further information expected.

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| 1154553 | 3/31/2021 | MO | 64 | F | 3/31/2021 | 3/31/2021 | Patient was anxious before the shot was given. She was given orange juice and water to hydrate her just in case. After the shot she passed out and was disoriented and nauseated when she came out. Paramedics were called for evaluation and they took her to the hospital due to continued weakness and vomiting. |
| 1153422 | 3/31/2021 | OH | 21 | F | 3/30/2021 | 3/30/2021 | Three hours after the vaccine, the patient experienced nausea, vomiting and had syncope at home. She notice a petechial rash along her neck and chin. |

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1153417 3/31/2021 CA

81 F

passed out; dizzy spell; fell down; have gotten shorter/shrunk; This is a spontaneous report from a contactable consumer (patient). An 81-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN6203), via an unspecified route of administration on an unspecified date as a single dose for COVID-19 immunisation. Medical history included high blood pressure, diabetes, thyroid disorder, and bleeding. The patient stated "I am bleeder. My father had hemophilia and I have the female version which I never remember what it's called but I bleed easily but I didn't bleed at all for when I had the shot, it was fine." Concomitant medication included levothyroxine sodium (SYNTHROID). Patient stated, "Yes, I took my medication that morning. I take thyroid medication, blood pressure medication. I don't remember what I take for blood pressure." The patient reported "Well I am calling I felt just fine right now. I had my first shot by Pfizer on the 24th and I felt great and they watched me and I left and I was driving home and I had a dizzy spell while I was driving. I don't know if I passed out or not, I might have but if I did, it wasn't for very long, they were digging up the road I couldn't stop, couldn't park so I made it home okay and I was fine the rest of the day but then the next day, I had a lot of dizzy spells but I was at home so I didn't worry, I just sat down and I was okay and then the 3rd day I got up for breakfast and I bumped into everything, I dropped everything and then I started to get out of chair and the chair fell down and I fell down and that was just a mess. So, I went to bed and I felt at least if I fall, I fall on bed and that was the day I was dizzy but then it went away and I have been fine ever since. That began on 24th, the 24th was the first day and I did call my doctor and I have been trying to call here and I never think it through but finally today, sat to watch, hang on to the phone and what I am concerned about is getting my second vaccine. Is there anything I should watch for or tell anybody or, because my doctor said you shouldn't get dizzy but I did?" The patient confirmed the vaccine as Pfizer's Covid 19 vaccine. About the lot number, the patient stated, "It looks like EN, I am not sure if it's E and N 6203." The patient further reported, "No, I just went home and the first day I was over with it by the time I got home and I didn't had anymore. The next day I just sat

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| 1153389 | 3/31/2021 | | F | 1/28/2021 | | down and rested, I knew it will go away and it did and then 3rd day I went to bed and just thought I would fall and hurt myself and that's everything I did. Well I used to be 5 foot 2 and a quarter but I think I have gotten shorter, I don't know what I really am but little bit shorter than that now and my weight is 100 and lets see, I am going to say 170, I don't think that's exactly right but it's pretty close to that I think, I didn't really weighed myself lately. 5 foot 2 and a quarter that's what I was when I did last but now I shrunk and less than that but I don't remember what I am." The outcome of the events was unknown. |
| 1153327 | 3/31/2021 | | 46 M | 3/31/2021 | 3/31/2021 | she passed out; stroke; fever; diarrhea; This is a spontaneous report from a Pfizer Sponsored program. A contactable consumer reported for herself that a 71-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration on 28Jan2021 as single dose for covid-19 immunisation. Medical history included carotid artery is blocked. The patient's concomitant medications were not reported. The patient got her first dose last 28Jan2021. She experienced some side effects like fever and diarrhea. She mentioned that she has an unusual health situation (carotid artery is blocked) even before the first dose. She also mentioned that she passed out. She had stroke before. The outcome of events was unknown. Information on batch/lot number was requested. |
| | | | | | | Patient received dose of J&J COVID-19 vaccine at local vaccine clinic. Reportedly, a couple minutes later, patient experienced vasovagal syncope for which a Code Blue was called by clinic staff. 911 was also called. Patient was evaluated by ED physician on scene at the clinic, where patient had regained consciousness and responded to questions. Patient was then transported to ED next door by ED staff where patient was monitored and ultimately discharged home. |

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| 1153326 | 3/31/2021 | VA | 22 | M | 3/31/2021 | 3/31/2021 | PATIENT EXPERIENCED VASOVAGAL RESPONSE TO VACCINATION IMMEDIATELY AFTER ADMINISTRATION. PATIENT FAINTED FOR SEVERAL SECONDS, THEN EXPERIENCED DIZZINESS, LOW BLOOD PRESSURE, AND PROFUSE SWEATING. ALL SYMPTOMS RESOLVED WITHIN APPROXIMATELY 10 MINUTES. |
| 1153174 | 3/31/2021 | VA | 71 | F | 1/14/2021 | 1/15/2021 | Fainted; Vomited; Ringing in ears; Injection site was slightly sore; Sore throat; Hoarseness; Dry eyes; A spontaneous report was received from a consumer, concerning herself a 71 year old female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced events fainted/Syncope, Vomiting, Ringing in ears/, injection site was slightly sore/Vaccination site pain, Sore throat, Hoarseness, Dry eyes. The patient's medical history was not provided, concomitant medication was not provided by reporter. On 14Jan2021, prior to the onset of events patient received her first dose of two planned doses of mRNA-1273 (lot number: 028L20A) via unknown route on right arm for COVID-19 infection prophylaxis. On 15 Jan 2021 she experienced fainted, She was taken to the Emergency Room by ambulance. She was vomiting in route to the hospital. She also complained that she had ringing in her ears, & admits that she still had it. At the hospital, they performed a CAT scan & a MRI of her "stomach." They wanted to admit her, but she was fearful she would contract Covid during her hospital stay. The injection site was slightly sore. She admits she developed a sore throat & hoarseness that day, & has I've had it since then. On 01March 2021, her eye Dr diagnosed her with dry eyes. The seriousness for fainted, Vomiting, Ringing in ears, injection site was slightly sore, Sore throat, Hoarseness considered as hospitalization. Action taken with mRNA-1273 in response to the events was unknown. The outcome of the event, fainted, Vomiting, Ringing in ears, injection site was slightly sore, Sore throat, Hoarseness, Dry eyes was unknown at time of this report.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded. |

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| 1154321 | 3/31/2021 | NC | 39 | F | 3/31/2021 | 3/31/2021 | 30 minutes following injection the patient began experiencing tingling of the lips and sensation of swollen tongue. no shortness of breath, wheezing, chest tightness, lightheadedness or syncope. She was given 25 mg po Benadryl and monitored for 45 minutes. her symptoms resolved completely. |
| 1154672 | 3/31/2021 | CT | 21 | M | 3/31/2021 | 3/31/2021 | Patient fainted within 5 min of vaccine administration. Fell on the floor face down. Lost consciousness for a few seconds. He was saying he felt very dizzy and sweaty once he regained his consciousness, Pt was taken to the hospital by EMT |
| 1154825 | 3/31/2021 | OR | 39 | F | 3/31/2021 | 3/31/2021 | felt hot, flushed, lightheaded, tight feeling around jaw and chin within 2 minutes of giving vaccine; reported feeling very nervous before getting vaccine, due to prior anaphylaxis with different type of COVID vaccine, felt sx were more likely 2/2 anxiety. after discussion of risks/benefits, given pt's history of anaphylaxis and her understandable anxiety about current vaccine and post-injection symptoms, gave 50mg PO diphenhydramine and 125mg IM Solu-Medrol. at no point did she have sensation of face, tongue, or throat swelling; shortness of breath; nausea or vomiting; syncope or pre-syncope; chest pain; skin changes such as hives. HR 80s, SpO2 98-99% on room air, and BP 160s/90s throughout time pt was symptomatic. pt felt much better after 30 minutes of observation, ambulated comfortably without dizziness or pre-syncope. after 50 minutes of observation pt felt comfortable going home with family member driving. pt was unsure whether she had epi-pen in her car or purse, so she was sent with epi-pen and family member was instructed in administration of epi-pen with trainer device. pt was escorted out without incident. |
| 1154803 | 3/31/2021 | CA | 20 | M | 3/31/2021 | 3/31/2021 | Patient appeared to have a fainting episode 3 minutes after receiving his COVID vaccine. A nearby customer reported seeing a few jerking reactions and then he started to slide down in his chair. The store director was nearby and helped him sit back up. He appeared to be OK after this happened, but the paramedics were called to be sure. The patient stated that he has a fear of needles and didn't eat anything this morning. |

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| 1154793 | 3/31/2021 | PR | 36 | F | 3/27/2021 | 3/27/2021 | Immediately following the shot, I felt dizzy and had a vasovagal syncope. Hours after, chills, abdominal pain, muscle pain, fever, headache, nausea. This symptoms lasted four days. |
| 1154759 | 3/31/2021 | IN | 19 | F | 3/30/2021 | 3/31/2021 | The patient reported that beginning around 6 pm on the day of the vaccination (3/30/21) she began to feel achey, with body aches and headache that was a 4 on a 1-10 scale with chills, fever, and a temperature of 99.1. She stated that at 8 pm her symptoms worsened and she took Ibuprofen 600 mg without effect. She was able to sleep, however. This morning (3/31/21) @ approximately 8:30 AM she was standing in the bathroom and became lightheaded and thought she was going to pass out, sat down for a few minutes, felt better, began to walk into her bedroom holding onto the walls and then collapsed against the wall and "passed out". She recoved later on her own and sought help. She denied any head injury or tenderness of the scalp. Upon arrival at the clinic her vital signs: BP 80/46, P 88, R 16, O2sat 98%, T97.5 (she had just come in from outside where it was cold). Her vitals signs after 10 min: BP 80/50, P 104, R 16, O2sat 98%, T 99.1 She remained lightheaded for the remainder of her visit. She was instructed she would need to be evaluated in the local ED where she was then sent. |
| 1154753 | 3/31/2021 | CO | 27 | M | 3/31/2021 | 3/31/2021 | Patient was standing in pharmacy lobby after receiving Moderna vaccine during observation period. At about the 10 minute point, he fainted and fell to the floor. I attended him within about 45 seconds. he was conscious, but confused. Pharmacy staff called 911, and he was attended by myself and a physician assistant who was shopping. Paramedics arrived in less than 10 minutes. Patient was treated by paramedics for about 20 minutes and was determined to be unhurt from the fall, and had recovered from his episode of syncope. He was released into the care of his mother, who was in store with him. |

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| 1154750 | 3/31/2021 | OH | 37 | M | 3/31/2021 | 3/31/2021 | Fainted 10 minutes following administration of vaccine. Patient fell from chair, unconscious. I aroused him and he regained consciousness after about 1 to 2 minutes. Blood pressure check at that time was 89/43, pulse 59. Patient was able to speak, said he passed out, bumped his forehead and lip. I gave ice pack for head. EMS arrived after less than 10 minutes, check vital signs and forehead and lip condition. Blood pressure was too low, so EMS transported him to local hospital. Hospital gave 1 liter IV fluid, advised him to get second dose on time and discharged him same day. |
| 1154533 | 3/31/2021 | CA | 30 | M | 3/31/2021 | 3/31/2021 | patient was given the vaccine and then went to observation room. While there, he complained of dizziness and became diaphoretic and passed out for about 10 seconds. Vitals were taken and a rapid response was called for the team to come. He came back and felt thirsty and was pale. He was then transferred to Urgent Care to be observed before being discharged. |
| 1152440 | 3/31/2021 | | 34 | M | 3/30/2021 | 3/30/2021 | Patient became syncopal approximately 10 minutes after injection. Patient was sitting in a chair and rolled off and onto the floor. He was unresponsive for several seconds until sternal rub performed. Patient woke and did not know where he was. Patient states he has a hx of vasovagal syncope. |
| 1154541 | 3/31/2021 | PA | 48 | M | 3/31/2021 | 3/31/2021 | Patient passed out 5 minutes after receiving vaccine and hit his head and start bleeding |
| 1152220 | 3/31/2021 | KY | 54 | F | 3/30/2021 | 3/30/2021 | Patient presents to the ICC with complaints of chest tightness and heart racing that started a few minutes after getting her first dose of Pfizer Covid vaccine yesterday. Patient states she continues to have symptoms and is here to get checked. Patient denies a past history of cardiac disease, she has had a stress test in the past and was negative. Patient denies dizziness, headache, syncope or leg swelling. |

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| 1154611 | 3/31/2021 | PA | 36 | M | 3/18/2021 | 3/18/2021 | MODERNA COVID 19 Vaccine EUA Patient got the vaccine and was waiting the 15 minutes after during which he went to stand up and fainted. The pharmacy technician called the pharmacist immediately and when pharmacist arrived patient was alert and talking. He states that he always faints after he gets IVs placed or shots in his back. He states that this is normal and happens whenever he gets shots. EMT was called as a precaution because he hit his head as he fainted. Patient was okay and taken by the EMT to get evaluated. |
| 1154594 | 3/31/2021 | NY | 37 | F | 3/30/2021 | 3/30/2021 | After waiting 8 minutes, I had a minute episode where my heart started racing out of the blue unexpectedly and after a minute returned to normal. Within that minute, I was worried I could have physically passed out. Then it stopped. I didn't tell anyone because it happened quickly and I was worried it could be misconstrued as anxiety and I didn't fully understand what happened. The intensity and quickness of the episode felt very physically driven and I'm unsure if this is within the scope of normal reactions. I have never experienced anything like that getting a vaccine. |
| 1154592 | 3/31/2021 | WA | 64 | F | 3/29/2021 | 3/31/2021 | Fatigue and headache day after vaccination, next morning I passed out. Nausea, dizziness. |
| 1154557 | 3/31/2021 | KS | 66 | F | 3/30/2021 | 3/31/2021 | Pt called today, one day after getting her second moderna vaccine, stating that she was feeling nauseas and passed out. She states she has a history of passing out when feeling nauseas. She was concerned that the vaccine caused her to pass out. I explained to her that based on her history, that I did not think the vaccine caused her to pass out. Encouraged her to reach out to her health care provider if she was concerned. |
| 1154632 | 3/31/2021 | PA | 22 | M | 3/31/2021 | 3/31/2021 | Patient received vaccine was fine while sitting. When patient stood up and was walking to the door he passed out. BP was 117/74 prior to EMS arriving. When EMS arrived he was placed into a chair and BP was lower initially. After sitting for about 10 minutes his blood pressure returned back above 117/74. |

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| 1154729 | 3/31/2021 | WA | 25 | M | 3/26/2021 | 3/26/2021 | M pt. who presented with syncope after vaccination. EMS was called. Patient was lucid and responsive upon their arrival. Per safety officer account the patient was evaluated by EMS and was ultimately released to home. |
| 1152365 | 3/31/2021 | | 45 | M | 3/31/2021 | 3/31/2021 | Patient told the monitoring nurse he is going to pass out; monitoring nurse stayed with patient and called paramedics for help; while waiting for paramedics patient passed out in the nurse?s arms; patient did not hit the ground; patient woke up after 30 seconds; paramedics arrived in two minutes; patient was offered Gatorade; patient rested and was not transported. |
| 1152532 | 3/31/2021 | OH | 28 | M | 3/31/2021 | 3/31/2021 | Patient experiecnced syncope within seconds of vaccine administration. He regained consciousness in about 30 seconds |
| 1152499 | 3/31/2021 | CA | 46 | M | 3/31/2021 | 3/31/2021 | Client received 1st Pfizer dose and approx. 7 minutes later c/o being "light-headed", having "tunnel vision" and was observed to be diaphoretic and pallor. He was led to a zero gravity chair by EMT and experienced syncope for several seconds. When he regained consciousness, V/S were taken every 5 mins, all WNL. At 9:50am, he reported feeling a little better but a light headed. At 10am, he was observed to have normal skin tone, no diaphoresis, and walked away unassisted with a friend who came to pick him up. He reported "feeling better." Client reported to RN that he has a history of "passing out when giving blood." No medication was given. |
| 1152494 | 3/31/2021 | AZ | 41 | M | 3/31/2021 | 3/31/2021 | vasovagal syncope, fully recovered after 10-15 minutes |
| 1152469 | 3/31/2021 | IA | 39 | M | 3/30/2021 | 3/30/2021 | Pfizer COVID-19 Vaccine. Patient presents today 3/30/21 for medical observation of near syncope s/p COVID - 19 vaccine # 1. Past medical history is significant for SVT. Had not eaten anything prior to vaccination. Denies feeling of chest tightness, swelling of the face/lips/tongue and pruritus. Reports nausea. Patients vital signs were initially 117/70, 76, remained stable. Bilateral breath sounds CTAB, no swelling of the face/lips/tongue or rash. Alert and Oriented X 4, no gross neurological deficits. Patient was given ondansetron 4 mg ODT, juice, and crackers. Patient reports resolution of symptoms prior to being discharged. |

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| 1152449 | 3/31/2021 | VA | 47 | F | 3/19/2021 | 3/19/2021 | Felt faint, improved after rest. No syncope. 140/77, 123/73 |
| 1152570 | 3/31/2021 | FL | 33 | F | 3/31/2021 | 3/31/2021 | Fainting |
| 1152383 | 3/31/2021 | OH | 25 | F | 3/31/2021 | 3/31/2021 | after receiving the vaccine the patient was waiting in the observation area and i was alerted that the patient was not feeling good, upon checking her she said she was not feeling good and passed out for about a couple of seconds, 911 was immediately called by a associate, the paramedics came and assessed her and she said she was fine and did not want to go to the hospital. the patient was given water to drink and a a pop-tart to eat. |
| 1152275 | 3/31/2021 | IN | 59 | F | 1/1/2021 | 1/25/2021 | Had period of syncope after first dose. After second dose I again suffered from syncope that is still present. I get dizzy when I lay down that last for 5 to 10 seconds. After the second dose I also became ill and missed a week of work . Respiratory difficulties, coughing, HA, etc. Seen my my MD and tested for COVID which was negative. |
| 1152279 | 3/31/2021 | CA | 28 | F | 3/30/2021 | 3/30/2021 | Patient was sitting on chair for 15 minutes after vaccination to be observed for adverse reaction. Patient stood up from chair to pick her for phone on ground, and reported sudden dizziness. I asked patient to lay her back on ground. Patient reported she had fainted at blood exam before due to orthostatic hypotension. |
| 1152271 | 3/31/2021 | IN | 53 | M | 3/29/2021 | 3/29/2021 | dizziness, sweat passed out, seizures |
| 1152248 | 3/31/2021 | GA | 24 | F | 3/29/2021 | 3/29/2021 | few minutes after she was vaccinated, she fainted on the floor. she sat down on the chair for a little while, felt better, and went home. we offered to call ambulance, she refused. follow up calls were made, but no answer by patient. |

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| 1152241 | 3/31/2021 | GA | 40 | M | 3/31/2021 | 3/31/2021 | Client got lightheaded when changing position from sitting to standing. SN noted client kneeled on all fours and laid on floor. He become confused and verbally non responsive. His breathing was irregular on our assessment. On arousal patient started to respond after 30-40 seconds. His speech was garbled and delayed and patient was aware that he had fainted. He admits to a history of fainting in the past at work. He was able to walk to observation bay to lay down for approximately an hour. Paramedics were called at the beginning of episode. Bp 129/78, Pulse 78 Resp16, O2 sat 98% temp 32 C temporal He rested in bay about a hour and was transported home via car by wife after refusing transfer to hospital by paramedics |

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| 1153158 | 3/31/2021 | IA | 70 | F | 3/17/2021 | 3/17/2021 | Passed Out in Bathroom; Bloody Nose; Nausea; A spontaneous report was received from a consumer concerning for his wife, a 70-year-old, female patient who received Moderna (mRNA-1273) vaccine and experienced events Bloody Nose/Epistaxis, Nausea, and passed out in the bathroom/Loss of consciousness. The patient's medical history was not provided. No relevant concomitant medications were provided by the reporter. On an unknown date, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Batch number: unknown) via an unknown route for prophylaxis of COVID-19 infection. On 17 Mar 2021, prior to the onset of the events, the patient received their second of two planned doses of mRNA-1273 (Batch number: unknown) via an intramuscularly on Arm for prophylaxis of COVID-19 infection. On 17 Mar 2021, Bloody Nose, Nausea, and the consumer Passed Out in the Bathroom before being taken to the Emergency Room. Seriousness criteria for all events was considered as Hospitalisation. No Treatment information was provided. The patient received both scheduled doses of mRNA-1273 prior to the events therefore, action taken with the drug in response to the events was not applicable. The outcome of the events, Bloody Nose, Nausea, and passed out in the Bathroom was unknown at the time of this report.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded. |

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| 1154722 | 3/31/2021 | MN | 29 | M | 3/31/2021 | 3/31/2021 | syncope episode- 1:33 pm individual fell head-first off from chair in observation area and hit her head. I was called over by the observation person that someone needed attention right away. I ran over the individual was lying on the floor and her husband was sitting on a chair right next to her. He said she fainted and fell forward. The individual appeared to be unconscious when I arrived and was very diaphoretic. I loudly asked if she was okay and then tapped her chest. She looked up at me and said "oh snap.?" She was oriented to person and place and her pupils were equal, round, and reactive. She denied that she had any tingling in her arms or legs. She said she heard everyone talking to her, but thought she was dreaming. She said that she has a history of passing out with finger-pricks (she cannot donate blood anymore because of this), shots, and she passed out when she got a piercing in the past. She said she felt her HR slowly starting to climb, but she felt she would be okay. She said she then started feeling lightheaded and passed out. I took HR BP at 1:35 128/74, 62 and again 5 minutes later 128/80, 62. Individual was given an ice pack for her head. She had a bump on the upper right side of forehead. She said she had not eaten or drank much before her shot. She said her stomach was a little upset. She was given water and granola bars and sat up for a while before standing up. She asked if I thought she should get her head checked out. I said it is never a bad idea to get checked and since she did hit her head hard enough for a bump to happen right away. Individual was feeling better before she left, stating just her head hurt. We told her to ice and ibuprofen or Tylenol to treat discomfort. |
| 1152401 | 3/31/2021 | MN | 45 | M | 3/31/2021 | 3/31/2021 | Patient waiting his 15 minutes after receiving 1st dose. Became limp in chair, face pale. He responded to his name and other simple questions within 30 seconds of onset but continue to appear pale and reported feeling light headed. Stated that he has fainted before after giving blood, etc; His blood pressure then was 110/60 and pulse 68-72. @nd blood pressure a few minutes was 82/40. He continued to feel light headed with nausea. Decision was made to take him to the Emergency department as vaccine clinic was in hospital. Patient was admitted then to the Emergency room. |

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| 1153125 | 3/31/2021 | NV | 70 | F | 1/21/2021 | | Practically fainted; Shortness of breath; Tingling in right hand; Numbness; Brain fog; Feels weak; Soreness; Itchiness; Fatigued; A spontaneous report was received from a consumer concerning a 70-year-old, female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced numbness, tingling in right hand, fatigued, practically fainted/Syncope, feels weak, itchiness, soreness, shortness of breath, brain fog. The patient's medical history was not provided. Concomitant medications were not reported. On 21 Jan 2021, prior to the onset of the events, the patient received the first of two planned doses of mRNA-1273 (Lot number:028L20A) unknown route of administration in the left non-dominant arm for prophylaxis of COVID-19 infection. On 18 Feb 2021, prior to the onset of the events, the patient received the second of two planned doses of mRNA-1273 (Lot number:031L20A) unknown route of administration in the left non-dominant arm for prophylaxis of COVID-19 infection. On an unspecified date, the patient practically fainted, felt numbness, tingling in right hand, felt fatigued, feels weak, itchiness, soreness, shortness of breath and brain fog. Treatment for the events were not reported. The adverse event of practically fainted was assessed as medically significant. Action taken with mRNA-1273 in response to the events was not applicable. The outcome of events of numbness, tingling in right hand, fatigued, practically fainted, feels weak, itchiness, soreness, shortness of breath, brain fog was unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. |

| <i>VAERS_ID</i> | <i>RECVDATE</i> | <i>STATE</i> | <i>AGE_YRS</i> | <i>SEX</i> | <i>VAX_DATE</i> | <i>ONSET_DATE</i> | <i>SYMPTOM_TEXT</i> |
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| 1153150 | 3/31/2021 | TN | 80 | F | 2/22/2021 | 2/22/2021 | <p>Almost passed out; Vomiting; Heat on side of head; A spontaneous report was received from a consumer concerning a 80-years-old, female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced almost passed out/loss of consciousness, heat in head/feeling hot and vomiting. The patient's medical history was not provided. Concomitant medications included inhaler and statin. On 22 Feb 2021, approximately three hours prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Batch Number: 031L20A) for prophylaxis of COVID-19 infection. On 22 Feb 2021, three hours later, the patient experienced heat on side of head and almost passed out a medically significant event. On 26 Feb 2021, the patient had heat in head again and did pass out and vomited. The patient was hospitalized when passed out and did tests and everything was ok. Treatment details included anti-nausea medication. Action taken with mRNA-1273 in response to the events was not reported. The outcomes of the events almost passed out, heat in head and vomiting was resolved on 27 Feb 2021.; Reporter's Comments: This case concerns an 80-year-old female who had a serious unexpected event of loss of consciousness along with NS events of unexpected feeling hot and expected vomiting. Event onset the same day as the first dose of mRNA-1273. Treatment with anti-nausea medication. Events resolved. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.</p> |

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| 1153140 | 3/31/2021 | MD | 38 | F | 3/1/2021 | 3/1/2021 | passed out; doesn't remember much; fatigue; incontinence; tingling of toes; shaking; extreme weakness; unable to lift arms, legs or move. Could not turn over; achy; chills; 39 days between 1st and 2nd dose; A spontaneous report was received from a consumer concerning a 37 Years-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced achy, chills, shaking, passed out, incontinence, extreme weakness, tingling toes, fatigue and 39 days between 1st and 2nd dose. The patient's current medical history included several autoimmune disorders, Rheumatoid arthritis, Raynaud's, Ankylosing spondylitis. Patient has had bladder surgery and reports having difficulty with urinary incontinence No relevant concomitant medications were reported. On 01 March 2021, prior to the onset of the events, the patient received the second of two planned doses of mRNA-1273 (lot/batch:006m20a) unknown route and in left arm for prophylaxis of COVID-19 infection. On 01 March 2021, the patient experienced 39 days between 1st and 2nd dose, and at the same night after the vaccination the patient began to felt achy, chills. On 02 March 2021, the patient experienced the events shaking, passed out, incontinent, extreme weakness, unable to lift her arms, legs and could not move or turn over, tingling in her toes. Ambulance took patient to hospital meanwhile patient was in and out of consciousness. She came back to home and experienced weakness and fatigue. The event Passed out was a serious event. Laboratory details not included. Treatment details included as IV fluids was given in the hospital. Action taken with mRNA-1273 in response to the events was not applicable. On 01 March 2021, the outcome of the event 39 days between 1st and 2nd dose was Resolved.; Reporter's Comments: This report refers to a case of inappropriate schedule of vaccine for mRNA-1273, lot # 006M20A with associated AEs achy, chills, shaking, incontinence, extreme weakness, fatigue, loss of consciousness. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. |

| <i>VAERS_ID</i> | <i>RECVD</i> | <i>STATE</i> | <i>AGE_YRS</i> | <i>SEX</i> | <i>VAX_DATE</i> | <i>ONSET_DATE</i> | <i>SYMPTOM_TEXT</i> |
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| 1152265 | 3/31/2021 | MA | 22 | F | 3/31/2021 | 3/31/2021 | 22 yo female with near-syncope s/p receiving 1st Pfizer COVID vaccine on 03/31/21 ~1:35 pm. Pt immediately started feeling lightheaded/dizzy, weak, and nauseous. She was hypotensive at 1:45 pm with BP of 66/44 and HR of 91. She did not lose consciousness. She was transferred to a recliner, given water, and was feeling better by 2:08 pm - her vitals improved to BP: 100/66 and HR: 86. She was d/c'ed to her father at 2:15 pm. |
| 1152630 | 3/31/2021 | OH | 16 | F | 3/31/2021 | 3/31/2021 | Patient waited 15 minutes after her vaccine and when she stood up to leave she fainted. Her mom alerted me right away and when I got out to the patient she was up and sitting in her chair. She was feeling fine at that point. She waited another 15 minutes and she was all better. |

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| 1153136 | 3/31/2021 | NY | | F | 2/9/2021 | 3/8/2021 | lacerations on her head; Bleeding; had a weird feeling; dizziness; afraid to go upstairs; chills; nauseas; feels so weak; Might have had syncope; Minor pain at injection site; A spontaneous report was received from a 79-year-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and who have experienced syncope (might have had syncope), skin laceration (lacerations on her head), nausea (nauseas), vaccination site pain(minor pain at injection site), feeling abnormal (had a weird feeling), fear (afraid to go upstairs), dizziness (dizziness), chills (chills), and asthenia (feels so weak) and bleeding (was on the floor and saw blood on the floor). The patient's medical history include fluctuating blood pressure. The patient was allergic to mono sodium glutamate, NutraSweet, codeine and prednisone.No concomitant product use was reported. On 09 Feb 2021, the patient received their first of two planned doses of mRNA-1273 (Lot number: 012M20A) intramuscularly for prophylaxis of COVID-19 infection. It was known that the patient was scheduled to receive the second dose of vaccine on 09-Mar-2021. On 08 Mar 2021, the patient received their second of two planned doses of mRNA-1273 (Lot number: D77727310) intramuscularly for prophylaxis of COVID-19 infection. On 08-Mar-2021, the patient experienced minor pain at the injection site, and chills during the night time. On 09-Mar-2021, the patient reported "had a weird feeling", "was on the floor and saw blood on the floor". On the same day, an unspecified duration later, the patient "passed out again" on the bed and reported that the pillow was full of blood. On 09-Mar-2021, a neck brace was placed and the patient was taken to the hospital. It was known that the patient had experienced nauseas and was sick, "almost like a blur". During the patient's stay in the hospital, over a period of 3 days, the patient reported "everything spins", experienced lacerations on the head and dizziness. The patient had surgical staples placed on head and felt very weak. The patient was "afraid to go upstairs". According to the physician the patient could have had a fever leading to the drop in the blood pressure and might have experienced syncope. Treatment information was unknown. Action taken with mRNA-1273 was unknown. The outcome of the events, syncope (might have had syncope), skin laceration (lacerations on her head), nausea (nauseas), loss of |

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consciousness (she might have passed out again),
injection site pain (minor pain at injection site), illness (so
sick), feeling abnormal (had a weird feeling), fear (afraid
to go upstairs), dizziness (dizziness), chills (chills),
asthenia (feels so weak), was unknown.; Reporter's
Comments: Based on the current available information
and temporal association between the use of the product
and the start date of these events, a causal relationship
cannot be excluded.

| <u>VAERS_ID</u> | <u>RECVDATE</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1153084 | 3/31/2021 | FL | | F | | 3/11/2021 | VOMITING; SHAKY; CHILLS; HEADACHE; FEVER; NAUSEA; PAIN AT INJECTION SITE; FAINTING; LOW BLOOD PRESSURE; This spontaneous report received from a consumer concerned a female of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, administered on 11-MAR-2021 to left deltoid for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 11-MAR-2021, the subject experienced fainting. On 11-MAR-2021, the patient experienced low blood pressure and pain at injection site. On 12-MAR-2021, the patient experienced vomiting, shaky, chills, headache, fever and nausea. It was reported that, the patient had bad reaction within few minutes after receiving the vaccine low blood pressure and fainting. Later, the patient was taken into stretcher, monitored vitals onsite and 45 minutes later, she drove home. The patient felt ok last night. At the time of this report, the patient was shaky, had chills, fever, nausea, vomiting, headache and injection site pain. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from fainting, and low blood pressure on MAR-2021, was recovering from shaky, chills, nausea, and vomiting, had not recovered from headache, and pain at injection site, and the outcome of fever was not reported. This report was serious (Other Medically Important Condition). Version created to amend previously reported information on 12-MAR-2021. Upon review, the following information was amended: Vaccination site (left deltoid) was added into the narrative and causality statement was removed.; Sender's Comments: V1: Version created to amend vaccination site and remove causality statement in narrative. 20210325938-JANSSEN COVID-19 VACCINE-Fainting and Low blood pressure. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s). |

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| 1152808 | 3/31/2021 | CA | 25 | M | 3/30/2021 | 3/30/2021 | After receiving the Covid Vaccine, Pt was waiting in a chair as advised by our pharmacists to make sure he had no adverse reactions. About 5 minutes after receiving the vaccine, pt reports he felt dizzy and fainted from the chair falling on the floor. Pharmacist immediately called 911. Pt recovered after a few seconds but pharmacy staff advised him not to move. Paramedics came and took him out in a stretcher. |
| 1152802 | 3/31/2021 | OH | 19 | M | 3/31/2021 | 3/31/2021 | pt received vaccine, walked to the waiting area, sat down, then fainted shortly thereafter. after talking with mom and son afterwards, they both get anxious and faint from any type of injection |
| 1152741 | 3/31/2021 | TN | 25 | M | 3/29/2021 | 3/29/2021 | Patient received his shot during an immunization clinic at about 08:40am on 03/29/21 and while waiting at the observation area he passed out and fell off his seat. Another patient who observed him fall said he hit his head on the floor. By the time the pharmacist got to the patient he was alert and requested to lay on the floor as this would help him recover better. EMS was called to help the patient further patient . Patient informed the pharmacist that this was a common occurrence when he receives shots or gets blood drawn. |
| 1152784 | 3/31/2021 | GA | 52 | M | 3/31/2021 | 3/31/2021 | Patient fainted and fell off chair and hit head on floor. Patient was treated by paramedics. The patient recovered from faint and did not need go to the hospital. The time was 12:10 PM. |
| 1152778 | 3/31/2021 | IL | 73 | M | 3/1/2021 | 3/8/2021 | Syncope, weakness, lightheadedness, somnolense, confusion, hallucination, acute kidney injury, gross hematuria |

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| 1152759 | 3/31/2021 | NE | 48 | F | 3/17/2021 | 3/25/2021 | 7 AM 3/25/2021 - Patient called out to husband from the bathroom where she experienced a syncopal event, then passed out. An ambulance was called and she was revived for a short period of time. She was taken to Hospital where she coded 3 times. She was then life-flighted to second Hospital. According to the hospital records, tests conducted over the course of several days determined that she had no neurological activity. Initial reports in the records indicate pulmonary embolism, cardiac and respiratory arrest. She was on life support for the remainder of her time. Organ donation is being pursued at present and results of this are pending at time of this report submission. Date of death is unknown until organ retrieval is accomplished. Family will be contacted in the next few days to ask further questions about any other kinds of vaccine-related reactions that may have happened more immediately to days after the vaccination on 3/17/2021. A co-worker thought that she had shortness of breath for 3-4 days before this critical event occurred on 3/25/2021. |
| 1152636 | 3/31/2021 | FL | 36 | M | 3/28/2021 | 3/29/2021 | I woke the next morning after the 2nd shot at 5:30am to use the bathroom and I fainted. |
| 1152791 | 3/31/2021 | CA | 46 | M | 3/31/2021 | 3/31/2021 | drive-through vaccination POD. Patient was in truck In monitoring area feeling a little bit faint after vaccination; then he actually fainted. Nurses called code green for paramedics; patient laid down on a cot for evaluation by paramedics. Not transported |
| 1152715 | 3/31/2021 | IL | 85 | F | 3/30/2021 | 3/30/2021 | Patient sitting in chair passed out sternal rub performed lowered to floor sternal rub performed again responsive breathing shallow lost bowels pulse weak ammonia salts used and EMS called |
| 1152732 | 3/31/2021 | GA | 25 | F | 3/31/2021 | 3/31/2021 | Patient fainted briefly. Her face was flushed. time was 2:45 PM. |
| 1147170 | 3/30/2021 | TN | 44 | M | 3/26/2021 | 3/26/2021 | I passed out driving 60mph on the highway. I awoke stopped in the middle lane not really understanding what was going on. Sweat was gushing down my head. Luckily nobody was injured. I start to feel better around 4:30pm |

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| 1147093 | 3/30/2021 | TX | | F | 3/4/2021 | 3/1/2021 | Fainting; Vomiting; Shingles R Herpes infection; Rash on the back; A spontaneous report was received from a consumer concerning a 82- year old, female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced Fainting (Syncope), Shingles R Herpes infection (Herpes zoster), Rash on the back (Rash) and Vomiting (Vomiting). The patient's medical history included shingles but not had since 2006.. She received the old Shingles shot in 2006. Now receiving new Shingles shot a year before and later. The patient's current conditions included diabetes and heart disorders. Concomitant medications included,medications for heart conditions and diabetes. On 04-Mar-2021,prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot number-unknown) via unknown route on right arm for prophylaxis of COVID-19 infection. On 18-Mar-2021,the patient experienced, about to Pass out, fainting followed by vomiting-3 episodes. On an unknown date in Mar 2021, she had Shingles R Herpes infection which broke out now. On an unknown date in Mar 2021, she also felt rash on the back. The event about to Pass out and fainting was medically significant events. On 18 Mar 2021, the laboratory data included, blood pressure was 128/84 and pulse rate was 94/50 .Treatment information included pain relievers and calamine lotion for rash. Action taken with mRNA-1273 in response to the events was unknown. The outcome of the events, Fainting (Syncope), Shingles R Herpes infection (Herpes zoster) and Vomiting (Vomiting) was unknown at the time of the reporting. On an unknown date, the outcome of the event, Rash on the back (Rash) was recovering.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded. |
| 1147076 | 3/30/2021 | NJ | 22 | F | 3/26/2021 | 3/26/2021 | Adverse event occurred approximately 11-13 hours vaccination. Moderate chills, turned into approximately 100 degree fever (felt like the fever is breaking), sweating, became dizzy, vision was spotty, and then fainted. (Adverse event occurred after both doses. After receiving 1st dose (February 26) and 2nd dose (March 26). |

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| 1147070 | 3/30/2021 | TX | 40 | F | 3/25/2021 | 3/26/2021 | Husband reports that within 24 hours, patient was extremely weak and had fainted x2 in the home. She continued to feel weak for a total of 48 hours post vaccination. |
| 1146759 | 3/30/2021 | NJ | 32 | M | 3/29/2021 | 3/29/2021 | Site: Pain at Injection Site-Mild, Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Hypotension-Medium, Systemic: Nausea-Mild, Additional Details: Pt was sitting for observation, after 8min, pt suddenly fell to lateral side, pt denies head trauma. IM Rx and Technician responded immediately. |
| 1147039 | 3/30/2021 | CA | 31 | M | 3/28/2021 | 3/28/2021 | Pt felt lightheaded, passed out in chair, vasovagal. |
| 1147007 | 3/30/2021 | CO | 30 | F | 3/29/2021 | 3/30/2021 | I have experienced severe episodes of nausea with some vomiting and feelings of near syncope. The near syncope resolved when lying down but returns when standing up. The nausea seems to be intermittent and also improved when lying down. Earlier this morning at approximately 3 a.m. I woke with chills and nausea which lasted an hour. When the chills resolved I began to feel very warm as if I had a fever but I did not get up to check my temperature. |
| 1147181 | 3/30/2021 | WA | 32 | M | 3/26/2021 | 3/26/2021 | Medic on site working in the observation area witnessed patient in his car, slumped into the seat and not moving forward as expected per protocol of this drive through mass vaccination site. Upon assessment by medics, the patient had very pale skin color, eyes were closed, but he was responsive to questions. Patient was able to state that he had a history of syncope and that this is not an unusual response for him to needles. Patient was able to place his vehicle in park and wait in place for about 15 minutes and until he recovered. When fully recovered, patient traded seats with one of the other passengers in his vehicle and had one of the other passengers drive as they left the vaccination site. |

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| 1147505 | 3/30/2021 | WI | 79 | F | 3/26/2021 | 3/27/2021 | <p>Syncope. about twelve hour later she developed some chills and fever and dizziness which was not unexpected. Overnight into Saturday morning 3/27/2021 however she fell a few times and believes that she did pass out. She injured her face in the fall but no other injury and the injuries or not severe. By our appointment on 3/29/2021 She is feeling a little bit fatigued at this point but otherwise back to her normal self.</p> |
| 1146753 | 3/30/2021 | IA | 20 | M | 3/29/2021 | 3/29/2021 | <p>Patient fainted moments after vaccination. Staff helped move him from the chair to sit on the floor. He came to within a minute of fainting episode. He refused to lay down, but remained seated on the floor for a few minutes and was given a glass of water. Stated he felt fine and noted he had had a similar reaction years ago to a shot in his buttocks. Staff had him remain seated in the waiting area for 30 minutes to monitor for any other reaction.</p> |
| 1147041 | 3/30/2021 | | 40 | M | 3/25/2021 | 3/25/2021 | <p>Patient passed out after standing post vaccination. Patient responsive after around 30 seconds. Alert and oriented. States he has done this in the past after "shots". Patient provided snack and water. Patient helped to wheelchair and monitored for 30 minutes. Patient states he has returned to baseline.</p> |
| 1147183 | 3/30/2021 | IL | 31 | M | 3/24/2021 | 3/24/2021 | <p>4:58 pm -Patient in monitoring area, in vehicle, spoke to monitoring nurse, stated was doing fine. 5:03 pm patient honked horn, stated wasnt feeling well, felt like he was going to pass out. Patient was pale, cool and clammy to touch. While attempting to recline patient, he passed out. Reclined patient in seat of his car. Blood pressure not detectable. Lung sounds clear to auscultation. RR 10. Sternal rub, client came around, still not feeling well, cool moist cloth applied, client stated he had never had that happen before after getting shots. 5:07- B/P 110/72, P41, pulse ox- 97% on Room air. Less than 5 minutes later, client began feeling like he was going to pass out again, 911 called. Client oriented X3. Monitored client continuously. Paramedic from another section of clinic came to location to help with patient. Called client's wife to inform. 5:19 -Ambulance arrived. Care handed of to EMS.</p> |

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| 1147260 | 3/30/2021 | NC | 35 | F | 3/3/2021 | 3/3/2021 | 35 yo female with a history of heart failure (EF 35%) dx 2020, reports AE after Covid vaccine #1 (3 MAR 2021) at drivethrough event characterized by onset of dizziness and CP 6/10, feeling cold 10 minutes after vaccine receipt. She denies, pruritis, urticaria, oral/face/throat/tongue swelling, flushing, red/watery eyes, cough, wheeze. She was transferred to ER with neg eval and released. She states CP continued until that evening, but was consistent with CP she intermittently experiences baseline. She reports mild dizziness continued for two days. She had mild site pain. She had increased fatigue for a few days and resolved. She reports a history of presyncope after blood draws. She denies previous AE after vaccine. She was treated with IVF, ASA 325, torrodol 30 mgs and zofran 8 mgs. No repeat event with second dose receipt. |
| 1147291 | 3/30/2021 | AR | 34 | F | 3/30/2021 | 3/30/2021 | Is 17 weeks pregnant with her first child. I do not know her estimated date of delivery. She fainted approximately 5 minutes after receiving her vaccine and fell from a chair. She landed on her side face down, so we turned her face up so we could see her face. Her eyes were barely open, but she nodded her head the second time we asked if she could hear us. We took her blood pressure, and it was 107/71 with a heart rate of 85. EMS came, and she felt better, so she decided not to go with them. They asked her to stand up to sit back in the chair. When they left, she slowly progressed to walking around while talking on the phone with someone to come pick her up so she didn't have to drive herself. She told us this was the first time she had fainted in 3 years and the first time ever fainting due to a vaccine. |

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| 1147294 | 3/30/2021 | RI | 20 | F | 3/26/2021 | 3/26/2021 | Roughly 12 hours after I recieved my second dose of the vaccine (around 11:00 PM on 3/26) I started to develop a fever, headache, and chills. These symptoms lasted throughout the night into the morning. In the morning on Saturday (3/27), and for most of the day I felt fatigued and slightly nauseous. At 5:00 PM that night, I was walking in the hall of my residence when I experienced a syncopal episode, which has never happened to me before. I fainted several times and my roommate brought me to the ER. Other than low BP, my EKG and other vitals looked fine, and the doctor sent me home with the conclusion it was likley related to the vaccine. The next day, Sunday 3/28, I felt naseua and dizziness all day. |
| 1147333 | 3/30/2021 | TX | 64 | F | 3/26/2021 | 3/27/2021 | I passed out, vomited and a heavy sweating. |
| 1147400 | 3/30/2021 | IL | 33 | F | 3/30/2021 | 3/30/2021 | Passed out for 3 seconds after about 10 minutes of the shot then felt very nauseous sweating Patient did not eat at all called EMT AND they took her |
| 1147526 | 3/30/2021 | NY | 61 | F | 3/26/2021 | 3/27/2021 | 2nd day: Soreness of injection site 3rd day: Soreness of injection site with swelling at site 4th day: Soreness with sensitivity to touch throughout the upper part of the arm 5th day: Severe pain throughout the arm. Numbness in my fingers. light headiness, passed out for a few second. light tremors. |
| 1147562 | 3/30/2021 | AZ | 76 | F | 3/28/2021 | 3/29/2021 | The next morning, severe headache, vomiting, chills, sweating, passed out hit my head and now have a black eye and cheek bone swallon. extemely tired, light headed nausea . |

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| 1147630 | 3/30/2021 | KS | 66 | F | 3/9/2021 | 3/29/2021 | <p>Patient presents for pre-syncope and then subsequent development of chest pain. She was in therapy when she had to use the restroom. She was urinating and having a BM when she suddenly felt extremely lightheaded as though she were about to lose consciousness. She did not thankfully lose consciousness, but rather rapidly developed chest pain after this event. She was brought to ED for evaluation. COVID screen in ED is positive. She was infected with COVID in November, 2020. She has since had a negative COVID screen. She is now positive again >90 days after first positive test, thus this will be treated as a new COVID infection. Place in negative pressure room. I am inclined to begin. Remdesivir as patient is always at high risk for progression to severe disease. 11/11/2020 positive COVID-19 2/13/2021 negative COVID-19 3/29/2021 positive COVID</p> |

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| 1146732 | 3/30/2021 | CA | 42 | F | 3/4/2021 | 3/4/2021 | extreme pain in left side of neck with difficulty moving; fainted; dizziness; Extreme pain in left side of neck with difficulty moving; gout-like reaction in feet; arm pain; fatigue; weakness; body aches; left hand knuckles swelled turned red stiff and painful; left hand knuckles swelled turned red stiff and painful; left hand knuckles swelled turned red stiff and painful; headache; vision disturbances; shakiness; This is a spontaneous report from a contactable other health care professional (patient). A 42-year-old female patient (non-pregnant) received first dose BNT162B2 (Solution for injection, COVID 19, Pfizer, lot number: EN6198) via Intramuscular in Left arm on 04Mar2021 at 10: 45 at single dose for COVID-19 immunisation. Patient medical history included Gluten allergy. Concomitant medications included Phentermine, hydrochlorothiazide, ibuprofen. On 04Mar2021 at 16:00, patient had extreme pain in left side of neck with difficulty moving, gout-like reaction in feet, arm pain, fatigue, weakness, body aches, left hand knuckles swelled turned red stiff and painful, fainted, headache, vision disturbances, shakiness, dizziness. Adverse events was not resulted in Emergency room/department or urgent care. treatment was not given. No covid prior vaccination and no covid tested post vaccination. Outcome of events were not recovered.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the serious event, syncope cannot be completely ruled out. The impact of this report on benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. |

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| 1145738 | 3/30/2021 | CA | | F | | | This spontaneous report received from a consumer concerned a female of unspecified age. The patient's weight, height, and medical history were not reported. The patient received COVID-19 vaccine AD26.COVS (suspension for injection, intramuscular, batch number: Unknown, and batch number: UNKNOWN expiry: UNKNOWN) .5 ml, start therapy date was not reported for prophylactic vaccination. No concomitant medications were reported. On an unspecified date, the subject experienced fainted after getting vaccine, and flu like symptoms. The action taken with COVID-19 vaccine AD26.COVS was not applicable. The outcome of the flu like symptoms and fainted after getting vaccine was not reported. The reporter considered the causality between JNJ-78436735, and faint and flu like symptoms as possible. Company causality between JNJ-78436735, and faint and flu like symptoms was possible. The batch number was not reported and has been requested. This report was serious (Other Medically Important Condition). Additional information was received from consumer on 12-Mar-2021 following information was updated and incorporated into case narrative: Patient demographic details (patient initials and sex) and other identification numbers was added. |
| 1147365 | 3/30/2021 | NY | 47 | M | 3/30/2021 | 3/30/2021 | After 2-3 mins in observation area. I fainted. came too, hot, sweating. had to go to hospital. |
| 1146294 | 3/30/2021 | CA | 31 | F | 3/29/2021 | 3/29/2021 | Site: Bruising at Injection Site-Mild, Systemic: Confusion-Medium, Systemic: Diarrhea-Medium, Systemic: Dizziness / Lightheadness-Severe, Systemic: Exhaustion / Lethargy-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Fever-Mild, Systemic: Headache-Mild, Systemic: Hyperventilation-Medium, Systemic: Hypotension-Medium, Systemic: Weakness-Medium, Additional Details: patient completed vaccination form at 10:43am. Patient recieved vaccination at 10:45am and by 10:50am patient request informed others she felt light headed. Nurse rushed to the patient with the Epi pen. They observed patient head tilted backward and unresponsive. Nurse opened the Epi pen but did not remove the blue needle cover and was unable to inject patient. At this time the patient started to be responsive and was confused. called 911, patient refused to go with them |

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| 1149043 | 3/30/2021 | FL | 47 | M | 3/30/2021 | 3/30/2021 | Immediately following injection, patient complained new onset headache. Patient then fainted. Patient came to approximately 30 seconds after passing out. Patient was pale and sweating. Patient able to drink water and chewed a glucose tablet. Patient was also given an ice pack to cool down. Patient rested in pharmacy for 30 minutes then indicated he felt fine, just ?tired.? Patient left the pharmacy approximately 45 min after incident, stating he felt much better. Patient had spouse with him and she drove home. |
| 1147637 | 3/30/2021 | CT | 63 | F | 3/30/2021 | 3/30/2021 | Systemic: Confusion-Severe, Systemic: Dizziness / Lightheadness-Mild, Systemic: Exhaustion / Lethargy-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: clamy-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Hypotension-Severe, Systemic: Shakiness-Medium, Systemic: Weakness-Medium |

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| 1145728 | 3/30/2021 | FL | | F | 3/11/2021 | 3/11/2021 | <p> FAINTING (Fainting, Syncope) LOW BLOOD PRESSURE (Low blood pressure, Hypotension) VOMITING (Vomiting, Vomiting) SHAKY (Shaking, Tremor) CHILLS (Chills, Chills) HEADACHE (Headache, Headache) FEVER (Fever, Pyrexia) NAUSEA (Nausea, Nausea) PAIN AT INJECTION SITE (Injection site pain, Injection site pain) This spontaneous report received from a consumer concerned a female of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2 .s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, administered on 11-MAR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 11-MAR-2021, the subject experienced fainting. On 11-MAR-2021, the patient experienced low blood pressure and pain at injection site. On 12-MAR-2021, the patient experienced vomiting, shaky, chills, headache, fever and nausea. It was reported that, the patient had bad reaction within few minutes after receiving the vaccine low blood pressure and fainting. Later, the patient was taken into stretcher, monitored vitals onsite and 45 minutes later, she drove home. The patient felt ok last night. At the time of this report, the patient was shaky, had chills, fever, nausea, vomiting, headache and injection site pain. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from fainting, and low blood pressure on MAR-2021, was recovering from shaky, chills, nausea, and vomiting, had not recovered from headache, and pain at injection site, and the outcome of fever was not reported. The reporter considered the causality between covid-19 vaccine ad26.cov2.s and fainting, low blood pressure, shaky, has chills, fever, nausea, vomiting, headache, injection site pain as related. Company causality between covid-19 vaccine ad26.cov2.s and fainting, low blood pressure, shaky, has chills, fever, nausea, vomiting, headache, injection site pain was possible. This report was serious (Other Medically Important Condition). </p> |

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| 1145733 | 3/30/2021 | CA | 36 | U | 3/10/2021 | 3/11/2021 | <p>FAINTING (Fainting, Syncope) DIZZINESS (Dizziness, Dizziness) BODY ACHES (General body pain, Pain) NAUSEA (Nausea, Nausea) This spontaneous report received from a patient concerned a 36-year-old, unspecified sex. The patient's height, and weight were not reported. The patient had no known allergies. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1802072, expiry: UNKNOWN) dose was not reported, 1 total, administered on 10-MAR-2021 17:00 to left deltoid for prophylactic vaccination. No concomitant medications were reported. On 11-MAR-2021, since 0900 the patient began feeling dizzy and nauseous and fainted, patient also complained of body aches. The action taken with JNJ78436735 (Ad26.COV2.2) was not applicable. The patient recovered from fainting, nausea, and dizziness on 11-MAR-2021, and had not recovered from body aches. The reporter considered the causality between covid-19 vaccine ad26.cov2.s and fainting, nausea, dizziness and body aches as related. Company causality between covid-19 vaccine ad26.cov2.S and fainting, nausea, dizziness and body aches was possible. This report was serious (Other Medically Important Condition).</p> |
| 1145734 | 3/30/2021 | OH | | F | 3/10/2021 | | <p>PASSED OUT (Passed out, Loss of consciousness) VERTIGO (Vertigo, Vertigo) MASSIVE PROBLEMS (Adverse event NOS, Adverse event This spontaneous report received from a patient concerned a female of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26 .cov2 .s (suspension for injection, intramuscular, and batch number: 1802068 expiry: UNKNOWN) 0.5 ml, administered on 10-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On an unspecified date, patient experienced two days of massive problems, passed out, vertigo. The action taken with covid-19 vaccine ad26 .cov .s was not applicable. The outcome of passed out, vertigo and massive problems was not reported. The reporter and company causality between covid-19 vaccine ad26 .cov .s and passed out, vertigo and massive problems was possible. The report was serious (Other Medically Important Condition).</p> |

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| 1145737 | 3/30/2021 | FL | | F | 3/11/2021 | 3/12/2021 | PASSED OUT ONCE (Passed out, Loss of consciousness) COUGHING OUT (Coughing, Cough) CHILLS (Chills, Chills) NAUSEA (Nausea, Nausea) FEVER (Fever, Pyrexia) HEADACHE (Headache, Headache) This spontaneous report received from a patient concerned a female of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805025, expiry: UNKNOWN) dose was not reported, administered on 11-MAR-2021 14:00 for prophylactic vaccination. No concomitant medications were reported. On 11-MAR-2021, after getting the vaccine, the patient experienced achiness throughout the body, coughing out, chills, fever, headache and nausea. On 12-MAR-2021, the patient also passed out once. The action taken with covid-19 vaccine ad.26.cov2.s was not applicable. The patient recovered from passed out once, and fever on 12-MAR-2021, and chills on MAR-2011, had not recovered from headache, and achiness throughout the body, and the outcome of nausea and coughing out was not reported. The reporter causality between covid-19 vaccine ad26.cov.2.s and passed out once, coughing out, achiness throughout the body, chills, nausea, fever, headache was possible. The company causality between covid-19 vaccine ad26.cov2.s and passed out once, coughing out, achiness throughout the body, chills, nausea, fever, headache was possible. This report was serious (Other Medically Important Condition). |

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| 1146198 | 3/30/2021 | IL | 22 | M | 3/29/2021 | 3/29/2021 | <p>Pt received the first of the two-series COVID vaccination at 1512. Once in observation area, pt became unresponsive shortly after sitting down. This provider was called over by staff to pt, which was noted to have become unresponsive while sitting in the chair. Pt remained in the chair, did not fall or injure self. Upon arrival to patient, he was noted to have severe diaphoresis, prominent pallor, with shallow, slow breathing, no cyanosis noted. His head initially fell back and head was aligned/adjusted to maintain an open airway. This provider was speaking to the pt and performed a sternal rub to elicit a response, pt remained unresponsive and with eyes closed. Pt remained in this state for approximately 10 seconds. Pt noted to suddenly have some muscular rigidity to arms and torso and in order to prevent injury upon possible onset of seizure activity, pt was lowered to the floor by this provider and RN . Once on the ground the pt was relaxed and opened his eyes. Pt was immediately verbally responsive and asked if he passed out. Pt was able to sit up and was assisted into the wheelchair. Pt moved to treatment area where vitals and blood glucose were obtained. (@1525 BG- 104 mg/dL, VS BP 116/72, HR bradycardic @51 bpm, O2 sat 95%). Patient responses/speech was clear and pt was oriented to self, place, time and situation. Pt stated that he felt nauseated upon sitting in the observation area and admitted that he only had a coffee today, nothing to eat all day and attributed this as the cause of his reaction. Pt verbalized that he would not respond to the hospital with the paramedics and was encouraged to at least call someone to take him to the hospital. This provider spoke with the patient?s mother and explained the events. The patient?s mother stated that the patient had febrile seizures when approximately 4 years old, associated with asthma exacerbations; but pt was evaluated with a neurologist and there were no abnormal findings. Pt admitted that he has a similar syncopal episode after washing a laceration and seeing his finger bleeding. Pt states this was a few years ago and witnessed by his father that told the patient he initially fainted and then became momentarily rigid before responding appropriately (similar to today?s events). Ambulance - arrival @1536 report given and pt stated he was feeling better and declined further evaluation in truck and also declined transport to ED (departed at 1545).</p> |

VAERS_ID RECVD STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| | | | | | | | Pt?s overall condition, appearance, including color was much improved. Pt denied any allergies or medication history. Past medical hx of febrile seizures at approximately age three and four, childhood asthma and one syncopal episode as an adult. Pt girlfriend arrival and she agreed to drive patient from the vaccine clinic. Pt and girlfriend were both provided with an explanation of the many concerning causes of syncope and the necessity for further evaluation in the Emergency department to rule out any underlying conditions. Both patient and girlfriend verbalized understanding and although they still declined to respond to ED directly from the clinic, both did agree to respond to ED if any changes in mental status occurred. Pt lives alone, but agreed to stay with parents and family in order to have others watch him for any changes. Pt was advised to followup with PCP and made aware that an provider would contact him tomorrow to check on his status, understanding verbalized and agreed with plan of care. Pt in no acute distress, awake, alert and oriented. Color within normal limits for and departed facility with girlfriend at 15:56, steady gait noted. Patient?s appointment for second dose was cancelled and will need to obtain clearance prior to second vaccine dose. |
| 1146270 | 3/30/2021 | MA | 28 | M | 3/29/2021 | 3/29/2021 | Systemic: Fainting / Unresponsive-Severe, Systemic: Seizure-Severe, Additional Details: Patient fell out of chair. Regain conciousness, fluttering eyes. Heart rate 35 , O2 was 98. Heart rate went up to 51 once paramedics arrived. O2 remained 95-98. Patient was brought to hospital by EMS. |
| 1146276 | 3/30/2021 | CA | 31 | F | 3/29/2021 | 3/29/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Mild, Additional Details: After patient recieved their shot they passed out. Pt states that this has happened before after vaccination. Paramedics were called and patient declined to go to the hospital. |
| 1146213 | 3/30/2021 | CA | 53 | F | 3/15/2021 | 3/20/2021 | Vertigo and almost fainted |

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| 1146286 | 3/30/2021 | MA | 25 | F | 3/28/2021 | 3/28/2021 | Systemic: Allergic: Rash (specify: facial area, extremities)-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Hives on chest-Medium, Systemic: Flushed / Sweating-Severe, Systemic: Shakiness-Medium |
| 1146729 | 3/30/2021 | IL | 54 | M | 3/26/2021 | 3/26/2021 | Client received vaccination and then became dizzy and lightheaded. Passed out was sent to ER via EMS |
| 1146329 | 3/30/2021 | PA | 43 | M | 3/29/2021 | 3/29/2021 | Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Medium, Systemic: Syncope-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Shakiness-Mild, Additional Details: Bradycardia |
| 1146332 | 3/30/2021 | TX | 29 | F | 3/29/2021 | 3/29/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: PATIENT IS AFRAID OF NEEDLES AND AFTER GETTING THE VACCINE SHE FAINTED. SHE WAS RESPONSIVE THE WHOLE TIME. WE PUT A COLD TOWEL ON HER FOREHEAD AND GAVE HER SOME WATER. AFTER 20 MINUTES SHE FELT FINE AND SHE LEFT. WE CALLED LATER IN THE DAY AND PATIENT IS FEELING FINE |
| 1146335 | 3/30/2021 | CA | 21 | F | 3/29/2021 | 3/29/2021 | Systemic: Chest Tightness / Heaviness / Pain-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Shakiness-Mild |
| 1146345 | 3/30/2021 | CA | 16 | M | 3/29/2021 | 3/29/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Seizure-Medium |

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| 1146357 | 3/30/2021 | FL | 86 | F | 2/2/2021 | 2/3/2021 | 02/03/2021 EXPERIENCING CHEST PAINS. 911 CALLED. TRANSPORTED TO HOSPITAL . ALL HEART TESTS (ECHO, BLOOD TEST) CAME BACK NORMAL. CHEST XRAY SHOWED CONGESTIVE HEART FAILURE AND ADMITTED TO HOSPITAL TO REDUCE SWELLING IN LEGS 02/03/2021 EVENING. HOSPITAL DR'S STARTED 80MG LASIX BY IV. DISCHARGED 02/05/2021 @ 12:00PM. TOOK HOME - PASSED OUT X4 BEFORE CALLING 911 AGAIN. TRANSPORTED BACK TO SAME HOSPITAL. ER DR. ASKED IF POSSIBLE FOR HER TO LOOSE 21.6 LBS IN LESS THAN 48 HRS. RE-ADMITTED INTO HOSPITAL 02/05/2021 @ APPROX 9:30PM FOR RE-HYDRATION ORALLY. DISCHARGED 02/10/2021 |
| 1146370 | 3/30/2021 | FL | 61 | F | 3/26/2021 | 3/26/2021 | Date and time adverse event started: 3/26/21, 0800 Adverse events experienced and are they still occurring now: syncope, headache What happened as a result of the adverse event? (doctor visit, ED or urgent care visit, hospitalization, life threatening illness, disability/permanent damage, death, none of these): Recommended Tylenol or ibuprofen for headache and to stay hydrated as well as continuing to rest. In addition, if symptoms worsen, advised to see primary provider. |
| 1146388 | 3/30/2021 | FL | 72 | F | 3/25/2021 | 3/26/2021 | Date and time adverse event started: 3/26/21 0345 Patient had syncopal episode on toilet; has hx of vasovagal syncope per husband; patient also developed headache on 3/28/21 7pm. Took tylenol with good relief What happened as a result of the adverse event? (doctor visit, ED or urgent care visit, hospitalization, life threatening illness, disability/permanent damage, death, none of these): Spoke with Cardiologist re: syncopal episode and elevated HR at rest |
| 1146401 | 3/30/2021 | VA | 54 | F | 3/29/2021 | 3/30/2021 | 12:30 AM - minor headache, body aches, trouble sleeping, pain at injection site 2:30 AM - freezing cold hands, cold feet and body, minor headache, body aches, trouble sleeping, pain at injection site 6:30 AM - minor headache, body aches, trouble sleeping, fainting, pain at injection site |

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| 1146722 | 3/30/2021 | MA | 22 | M | 3/28/2021 | 3/28/2021 | Site: Pain at Injection Site-Mild, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Headache-Medium, Systemic: Hypotension-Medium, Systemic: Nausea-Medium, Additional Details: Pt was sitting for observation and suddenly fell to lateral side. Staff RN and technician responded immediately. |
| 1146277 | 3/30/2021 | IN | 43 | M | 3/29/2021 | 3/29/2021 | I received a shot around 9:20. About 9:25 I fainted while in the 15 minute waiting period. I was "out" long enough for 911 to be called. I "woke" up a little later, in enough time to cancel the 911 call, and regained my composure. I waited another 10 minutes and felt much better. I have had no other side effects since. I want to add that I was not nervous about the vaccination. I did not have any fear or anxiety about the shot. |
| 1148906 | 3/30/2021 | TX | 34 | F | 3/27/2021 | 3/27/2021 | Patient presented to the ER with dizziness, near syncope and anxiety |
| 1148461 | 3/30/2021 | IL | | M | 3/19/2021 | 3/19/2021 | PT FELT LIGHTHEADED AFTER RECEIVING HIS COVID-19 VACCINE. HE WARNED THE NURSE HE FELT LIGHT HEADED AND PASSED OUT. PATIENT LOWERED TO THE GROUND, ONCE PATIENT AWAKE JUICE PROVIDED AND TRANSFERRED TO PRIVACY RECOVERY ROOM. PATIENT PICKED-UP BY EMS |
| 1148493 | 3/30/2021 | MN | 66 | F | 3/26/2021 | 3/27/2021 | Rash, dizziness, syncope, fever/chills, nausea, hives, fatigue. Went to ER received Benadryl, and epinephrine, methyl prednisone inj, pepcid inj. rested and continued Benadryl and prednisone for 5 days. Now feeling good. |

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| 1148528 | 3/30/2021 | UT | 60 | F | 3/19/2021 | 3/19/2021 | Sensitivity started within four hours of dose. Autistic sensitivities to maximum. Scrambling of all senses including proprioception to the point of not being able to move from standing or sitting. By hour seven, all sensory inputs were too overwhelming to do anything but shut down and sleep. 911 was not an option because they don't let you sleep, and ERs are overwhelming already, before maximizing all inputs. 7.5 mg hydrocodone for overwhelming pain and sensitivity, allowed sleep. On waking, sensitivity was lessened, but the pain started, 18 hours after the vaccination. Emotional lability for three days. Average aching of arm and injection site were not above expected levels. "Brain fog" and lack of ability to articulate (another autism symptom) started within that first seven hours, and diminished over next ten days. Not yet gone as of today Dry mouth; overproduction of thick 'chunky' mucus that wouldn't cough out, treated with guaifenesin, lasted three days. Shortness of breath and cough associated with that mucus also diminished after three days. Not completely gone ten days later. Excessive thirst, onset two hours after vaccine, lasted two days. Hyperalert (can't sleep without drugs), hyperactive despite weakness, and hypervigilant (extreme startle reflexes) lasted three days as well. Sleep was achieved with hydrocodone and THC. All over body pain, feelings of immune mobilization (coming down with) for two days were not above expected levels. No fainting or other collapse at time of injection, or later. Knowing that severe over-stimulation is exacerbated in a medical setting, it was decided not to seek medical support for three days of systemic symptoms that would have easily merited hospitalization. |

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| 1148544 | 3/30/2021 | AZ | 24 | M | 3/28/2021 | 3/29/2021 | got up about 5:15AM to use the restroom, parents heard a huge crash and we came running - he had collapsed and fainted in the bathroom, against the toilet, (with shelves and glass crashing down him - he grabbed the shelves and had a few cuts and bruises), was unresponsive, no color in his face, could not stand or move, could barely speak - slumped against the toilet. Parents called 911 and tried to get him to respond, he was listless but opened his eyes - we lifted him and moved him to recliner in living room. Fire Dept./EMT's arrived within a few minutes, blood pressure was 87/43, glucose was normal. EMT's determined it was a reaction to the vaccine and asked if he wanted an ambulance or if parents should drive him for further care - he opted for us to drive him (his Mom called the Dr. on staff first - Dr. said it was a reaction to the vaccine and he should not get a 2nd dose). Patient's Dad took him to Urgent Care - they ran an EKG (normal), and stayed there until his blood pressure showed (although still low) normal/acceptable again. I looked at the CDC website for covid anaphylaxis and it appears it was an allergic reaction (cardiovascular), on the site, he had these symptoms: "Cardiovascular: fainting; hypotension (abnormally low blood pressure); pallor. ... Symptoms of anaphylaxis often occur within 15-30 minutes of vaccination, though it can sometimes take several hours for symptoms to appear.~~ |
| 1148551 | 3/30/2021 | CA | 25 | F | 3/30/2021 | 3/30/2021 | Patient felt dizzy after 5 minutes of sitting in wheelchair with her legs elevated (she said she had a history of fainting at the sight of needles. Took her vitals and B/P was 82/42, removed her mask to focus on breathing. O2 sats were 97% on RA, HR was 53. Ice pack placed to her neck and O2 per N/C placed at 3 L. At 10:47 she briefly lost consciousness for a few seconds and ammonia whiffs were given. Stat team called and she was taken to clinic treatment area for further observation. Patient's mother reported that patient had taken Ativan PO at 0945, same day. |
| 1148571 | 3/30/2021 | WA | 54 | F | 3/30/2021 | 3/30/2021 | fainted a couple of mins, regained consciousness but feeling light headed, nauseated reported a cold sweat. had diarrhea. was not still feeling well so 911 called and was taken to a hospital |

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| 1148575 | 3/30/2021 | MO | 30 | M | 3/30/2021 | 3/30/2021 | Dizziness occurring 10 minutes after vaccine given Fainting occurring 10 minutes after vaccine given Headache occurring 30 minutes after vaccine given Nausea occurring 30 minutes after vaccine given Vomiting occurring 1 hour after vaccine given |
| 1148855 | 3/30/2021 | WA | 30 | M | 3/30/2021 | 3/30/2021 | syncope |
| 1148401 | 3/30/2021 | GA | 20 | M | 3/30/2021 | 3/30/2021 | Patient reports routinely having spells of syncope with injections and still insisted on receiving COVID-19 vaccination. Gave injection into left deltoid. Had patient scoot up to table in immunization room with both legs fully under the table just in case there was an issue. I set the timer for 15 minutes and left him in the immunization room with his girlfriend, who also received a vaccine. A few moments later the girlfriend asked for our help stating he was feeling like he was going to pass out. I went into the IMZ room and checked with him. At the time, he was sweaty with a rapid heartbeat. I instructed him to take some deep breaths and went to get a cold paper towel to apply to his head. When I returned he had passed out, not responsive but still breathing, in his chair and his girlfriend was holding his head in her hand. We gently lowered his head to rest on the table while another associate called 911 per girlfriend's request. He began moaning a few moments later and was able to talk to us. He was very hot and sweaty, light headed and breathing rapidly. We applied a cooling pack to his forehead as he continued to lie his head on the table. He then said he might feel more comfortable lying on the floor. We assisted him to the floor, elevated his feet on a chair and placed his head on a roll of paper towels. At that time the paramedics showed up and said his blood pressure was fine and he was just having some hyperventilation. The paramedics got him back up in the chair and his girlfriend got him some apply juice. After about 30 minutes he was talking fine, shaking had stopped and his breathing a temp went back to normal |
| 1148891 | 3/30/2021 | TN | 44 | F | 3/30/2021 | 3/30/2021 | dizziness, syncope |

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| 1148960 | 3/30/2021 | TN | 31 | F | 3/30/2021 | 3/30/2021 | The patient selected on our consent form that she will faint with vaccines sometimes, gave the patient the vaccine, she said she felt fine so she went to sit in our waiting area. I came out to give the next patient a vaccine, I checked on the patient and she was fine. Once I was completing the other patient's vaccine I noticed that she looked slightly pale so I went over to the patient to see if she was okay. She sat down on the floor, as we got her to the floor she passed out in my arms, she regained consciousness about a minute later. The patient waited around for another 20-30 minutes then left once she felt better. We gave her a cold glass of water while she waited as well. |
| 1148908 | 3/30/2021 | NH | 48 | M | 3/30/2021 | 3/30/2021 | PT was administered vaccine at 1025 and shortly there after started to shake, felt sweaty and just felt weird. Then passed out. PT was quickly assisted by vaccination staff at car side and then medical staff was notified. Upon arrival PT was very pale and lacked color, but was awake and stated that he has never had that happen before. Denies any history of having adverse effects to medications. NKDA. Ambulance was called. 1045 Vitals BP: 80/60 Pul: 68 SpO2: 97 1045 Ambulance arrived 1050 BP: 92/58 PT was taken to local ER for further observation. |
| 1148934 | 3/30/2021 | CA | 22 | F | 1/21/2021 | 1/21/2021 | Received shot, 5 minutes after felt extremely nauseous , unbearable headache and dizziness. Left okay after 30 minutes, walked back to office which is 30 second walk from clinic office, walked into office and vomited for 15 minutes, went to sit in chair, was completely dizzy and faint, after 5-10 minutes felt worse and worse. Got up to go to clinic and fainted, was found by security guard and rushed down to emergency room. |
| 1149270 | 3/30/2021 | TN | 17 | F | 3/30/2021 | 3/30/2021 | The patient received her COVID-vaccine and then told the immunizer she felt dizzy seconds afterward. She passed out for a few minutes and we were unable to wake her. We called 911 and she came back to consciousness after what felt to be several minutes. |
| 1147659 | 3/30/2021 | | 76 | M | 2/25/2021 | 2/26/2021 | the day after injection, he had vasovagal syncope episode with acute vertigo |

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| 1149052 | 3/30/2021 | TN | 23 | M | 3/30/2021 | 3/30/2021 | Patient became light headed and fainted after immunization. EMS evaluated the patient and he no further complaints. He did not experience any other episodes of syncope and reported no other side effects at the time and at 3 hour follow up. |
| 1149066 | 3/30/2021 | NC | 31 | M | 3/30/2021 | 3/30/2021 | Cold sweats, dizziness, nausea, almost fainted (hearing got muffled, vision was fuzzy) All in the first 5 min then about 15 min later another bout of cold sweats and nausea. |
| 1149094 | 3/30/2021 | FL | 34 | M | 3/30/2021 | 3/30/2021 | Patient was waiting in a chair in front of pharmacy for the required 15 minutes. Told his wife he needed some water. Then passed out hitting his head on the floor. Ran out to him and he was already coming out of it. Ambulance came and cleared him to go. He said he was dehydrated. |
| 1149268 | 3/30/2021 | AZ | 37 | F | 3/30/2021 | 3/30/2021 | Passed out |
| 1148964 | 3/30/2021 | PA | 28 | F | 3/27/2021 | 3/27/2021 | Patient received vaccine. Approximately 15 minutes later she experienced syncope. |
| 1148863 | 3/30/2021 | PA | 25 | F | 3/30/2021 | 3/30/2021 | FAINTING |
| 1147859 | 3/30/2021 | GA | 54 | F | 3/8/2021 | 3/9/2021 | SYNCOPE DAY AFTER VACCINE |
| 1148984 | 3/30/2021 | FL | 35 | M | 3/30/2021 | 3/30/2021 | Fainted |

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| 1148376 | 3/30/2021 | MA | 67 | F | 3/19/2021 | 3/19/2021 | By late afternoon my left arm and armpit felt a little sore. I went to bed around 8 p.m. and awoke at 11 p.m. ~12 hours after receiving my second vaccination, with chills, arthralgias, myalgias, headache, a slightly stiff neck. I got up to take some Acetaminophen and Ibuprofen. My hands shook badly and I had trouble opening the bottles and getting out a couple of pills (APAP 500 mg, Ibuprofen 400 mg). I returned to bed and eventually the symptoms subsided and I fell asleep. In the morning I had extreme lethargy, felt dizzy after standing a few minutes to the point of pre-syncope as I made it back into bed. I slept on and off most of the day (Saturday). By Sunday, I was much improved but still had little energy and took it easy. My left axilla still felt a little full but I could not detect any lymph nodes. By Monday, I was pretty much back to normal including my left arm and axilla. |

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| 1147678 | 3/30/2021 | WI | 68 | F | 2/26/2021 | 2/27/2021 | <p>Passed out at one time; Having COVID symptoms; Massive headache; A spontaneous report was received from a consumer concerning a 68-year-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced massive headache, passed out at one time/syncope and having COVID symptoms. The patient's medical history was not reported. No relevant concomitant medications were not reported. On 26 Feb 2021, approximately two days prior to onset of the events, the patient received their dose of mRNA-1273 (batch number: 023M20A) intramuscularly for prophylaxis of COVID-19 infection. On 27 Feb 2021, the patient had a massive headache. On an unknown date, the patient passed out at one time (medically significant event) and overall just having COVID symptoms. No treatment information was reported. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events massive headache, passed out at one time and having COVID symptoms was not reported.; Reporter's Comments: This case concerns a 68-year-old female who experienced serious unexpected events of syncope along with nonserious events of unexpected COVID-19 and expected headache. Event onset occurred on Day 2 after the first dose of mRNA-1273. Treatment not reported. Event outcomes unknown. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.</p> |

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| 1147683 | 3/30/2021 | MI | | F | 3/11/2021 | 3/11/2021 | Passed out; felt dizzy; she experiencing shaking; Massive pain in my head; really achy; Didn't feel good; A spontaneous report was received from a consumer concerning an 70 year old, female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced achy, did not felt good, Massive pain in head, Dizzy, passed out, Shaking. The patient's medical history and concomitant medications were not reported. On 11 Mar 2021, the patient received their second of two planned doses of mRNA-1273 (lot number 030A21A) via unknown route for prophylaxis of COVID-19 infection. On 11 Mar 2021, during evening time patient did not feel good and achy, on12 Mar 2021 patient woke up and went to walk after some time she got a massive pain, felt dizzy, and passed out and shaking. Treatment information provided was Tylenol. Action taken with mRNA-1273 in response to the events was not applicable as. The outcome for Ache was recovering and for other events recovered .; Reporter's Comments: This case concerns a 70 Y/O F with a serious unexpected event of loss of consciousness and NS unexpected pain, feeling abnormal, dizziness, tremor and expected headache. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |
| 1147734 | 3/30/2021 | IL | | M | 3/30/2021 | 3/30/2021 | Patient had Vasovagal and fainted 3 minutes after receiving the the vaccine |
| 1147791 | 3/30/2021 | NM | 41 | M | 3/30/2021 | 3/30/2021 | Syncope, hypotension |
| 1147937 | 3/30/2021 | NJ | 36 | M | 3/30/2021 | 3/30/2021 | Patient fainted, syncopal event during the post-vaccination monitoring period. Patient states they did not eat today. The patient was caught by EMS before reaching the floor. Did not hit head. Vitals, sinus bradycardic, HR 38, BP 120-70, 18 RR, blood glucose 103. Pt says his HR usually runs in the 50's. After the patient's observation period ended, HR was 60, BP 136/81, RR 16. Patient refused further treatment and refused transportation to the ER. Patient denies dizziness and pain/discomfort. Patient signed refusal to treat form. |

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| 1147960 | 3/30/2021 | OH | 16 | F | 3/30/2021 | 3/30/2021 | Felt dizzy about a minute after vaccine administration, patient described blurry vision and then she fainted and fell to the floor. Patient described no prior history of reactions to prior vaccinations. After about a minute she regained consciousness and was able to walk, talk, and function normally. Mom did intend to follow up with primary care doctor regarding the fainting episode. |
| 1147983 | 3/30/2021 | NC | 31 | M | 3/30/2021 | 3/30/2021 | Syncope, vomiting, abdominal pain Patient spouse indicated this is normal when patient sees blood |
| 1148014 | 3/30/2021 | OH | 30 | F | 3/26/2021 | 3/26/2021 | Pt was seen falling forward out of chair to the floor with hands shaking . Patient did not remember what happened but stated that she has a history of seizures and fainting after injections. Patient received an ice pack for her lip and no other treatments. EMS was called and patient was taken to hospital. |
| 1148129 | 3/30/2021 | NV | 58 | M | 3/10/2021 | 3/11/2021 | Syncope, sent to ER for workup and was monitored obs over night. |

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| 1148371 | 3/30/2021 | CA | 50 | F | 1/19/2021 | 1/20/2021 | She got her vaccine, told them that she had a lot of reactions to many foods. The shot area was a little swollen, kept messaging it so that it wouldn't be painful the following day. She told them that she was feeling a little wheezy but that she would get a reaction within 24 hours. She did have some dizziness but nothing to complain about. She went to bed and at 12:35 AM she work up with a high fever, body aches, extreme chills to the point of toes being frozen, extreme headache, excruciating abdominal pain. Her muscles were sore and swollen. The chills went away within 24 hours. Where she received her shot it was about the size of a baseball. She could not move, she did make it to the restroom and her temp was 104 degrees. She was able to put water on her body and got it down to 103, which took about 45 minutes and then she passed out. She thought she was going to die. She focused on her breathing, lives alone. She lost her equilibrium, and was not able to get up to get anything to eat or drink anything. She woke up around 4-5 hours later and she was tired, still in pain muscle wise, abdominal area was very painful and that's when she started calling us. She took Tylenol for these symptoms. She did call her doctor and he advised her to call 9-1-1 if her breathing got worse and advised her not to get the 2nd vaccine. On the 5th day she was okay and back to her baseline. |
| 1148313 | 3/30/2021 | MA | 53 | F | 3/18/2021 | 3/18/2021 | dizziness, lightheadedness, flushing to chest and face, pre-syncope, BP 190/100 |
| 1147748 | 3/30/2021 | MN | 37 | F | 3/26/2021 | 3/26/2021 | A few hours after receiving my second dose, I fainted while walking down the stairs in my house. I lost feeling in my body from my neck down as I was taking a step down a stair. I then felt intense pain in my feet as I fainted and fell to the bottom of the stairs. I landed flat on my face at the bottom. I immediately went to the ER where X-rays showed I displaced my fifth metatarsal in my right foot. |
| 1148042 | 3/30/2021 | NC | 30 | F | 3/29/2021 | 3/29/2021 | Janssen COVID-19 Vaccine EUA Patient verbalized fainting after prior vaccines. Patient fainted almost immediately post-vaccination. Assessed and attended at vaccination clinic site. Vital signs within normal limits. Monitored on site for 45 minutes; released with her friend. Vaccine Clinic at a community site. |

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| 1148167 | 3/30/2021 | CO | 35 | M | 3/29/2021 | 3/29/2021 | Incident occurred at Health Department mobile clinic hosted by County Public Health at County Fairgrounds. The clinic was staffed by Health Department staff, County Public Health volunteers, County Fire Department Paramedics and contract temp staff. Client received his first dose of Pfizer vaccine (lot #: EP6955 exp: 6/30/21) and was advised to wait in the waiting area for 15 minutes for recovery. During the recovery period, about 10 minutes post-vaccine, client was seated and reported to the monitoring paramedic that he felt "dizzy and might faint" and moved onto his knees. The paramedic immediately attended to the client and caught him as he fainted. The paramedic slowly brought the client to the ground in a supine position. A second paramedic called for an ambulance and Health Department RN also responded at 4:45pm. The client immediately regained consciousness. The client was alert and oriented. The client reported that he has never before fainted or had problems with vaccine administration. The client was returned to a seated position and provided juice and water. EMS arrived with ambulance at 4:55pm, they conducted their assessment and were concerned about 'abnormal heart rhythms' found via EKG. Client reported no cardiac hx. They offered to transport the client to Hospital for further evaluation. The client accepted the transport. The client left County Fairgrounds via ambulance at 5:16pm. |
| 1148131 | 3/30/2021 | PA | 31 | F | 3/29/2021 | 3/29/2021 | patient complaint of dizzy, light-headed, vertigo. patient was lowered to the floor. feet were elevated. Negative findings: SOB, wheeze, stridor, angioedema, nausea or vomiting, syncope. vital signs: bp 100/80, heart rate 78, oxygen saturation 98%. 15:40 bp 122/72 good color. Assessment mild vasovagal reaction. Plan to d/c to home in care of husband with instructions to push fluids and follow up with pcp if further symptoms. |

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| 1148192 | 3/30/2021 | MO | 35 | M | 3/30/2021 | 3/30/2021 | Pt. has history of having reactions when given shots. Pt. walked to a chair outside about 20 feet outside of the injection room after receiving his shot. He sat down in the chair and within 1-2 minutes the patient fell face down on the floor. A customer yelled for help and pharmacy staff and the nurse practitioner responded to help. Pt. was passed out but breathing heavily. We rolled patient to his back and he came to and tried to get up. We told him to stay flat and assured him he was being taken care of. The nurse practitioner stated it was a vagal nerve response. The patient sat up and talked with us and stated this has happened before. The ambulance response was called and checked patient out and he was released about 30 minutes later. His blood pressure was normal and patient stated he felt fine. |
| 1148118 | 3/30/2021 | CA | 23 | F | 3/28/2021 | 3/28/2021 | pt was shaking up and fainted after vaccination and ambulance was called. Pt was taken away by ambulance |
| 1148111 | 3/30/2021 | NC | 27 | F | 3/22/2021 | 3/30/2021 | Day after receiving vaccine, my entire body was extremely sore. I also felt dizzy and almost passed out. I am now 1 week post vaccine and have developed COVID arm. I have a rash near my injection site. I have also noticed little red itchy spots on parts of my body as well. No treatment had been done. Hoping it will resolve on its own. |
| 1148088 | 3/30/2021 | MA | 22 | F | 3/29/2021 | 3/29/2021 | FAINTED 20 MINUTES AFTER RECEIVING COVID19 VACCINE, SWEATING, UNRESPONSIVE. CALLED 911, EMTs ARRIVED IN LESS ABOUT 6 MINUTES. SHE COMPLETELY REVIVED ON HER OWN, EMT CHECKED HER VITALS, RELEASED HER, SHE WALKED OUT ON HER OWN POWER ALONG WITH HER TWO FRIENDS. CALLED HER AN HOUR LATER AND SHE WAS REPORTED TO BE DOING WELL. |
| 1148054 | 3/30/2021 | CA | 46 | F | 3/30/2021 | 3/30/2021 | It hurt my arm muscle REALLY badly right as it was being administered. I passed out within 2 minutes due to the pain. (The first shot barely hurt a month earlier at the same vaccine distribution center.) EMT checked heart rate which dropped to 50 and blood pressure was up and down, but was "dangerously low.~~ |

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| 1143767 | 3/29/2021 | AZ | 31 | F | 3/27/2021 | 3/28/2021 | I passed out and had convulsions while sitting in a chair at a nail salon. During this event I peed myself. Prior to the event I had some minor body aches, but no fever. Following the event I returned home and began running a fever of 100.5. |
| 1143731 | 3/29/2021 | | 48 | M | 3/29/2021 | 3/29/2021 | After receiving the 1st dose of Pfizer COVID-19 vaccine, the patient moved to the observation area. After 5 min, patient reported feeling light-headed and tried to stand up. The patient sat down on the floor and leaned against the wall. Patient was able to stand and walk to the provider room for closer observation. Patient felt hot and looked pale. The provider placed a blood pressure cuff on the patient, at which point the patient slumped forward and stopped breathing. A carotid pulse was not able to be appreciated. The patient was pulled to the floor, positioned airway open and was given oxygen. BP was 96/40. Blood sugar was checked (104) and the AED pads were placed. EMS was called. AED advised no shock, patient had a pulse and was breathing. Patient gradually became alert, though reported not feeling well. Patient was disoriented and was not aware of passing out nor the current event. Repeat BP 115/50. Patient began vomiting (~300-400 mL). Patient left with EMS to be evaluated at local Emergency Department. Of note, patient reports history of vasovagal syncope events 2/2 to various situations. |
| 1143867 | 3/29/2021 | TX | 37 | M | 3/26/2021 | 3/26/2021 | Vasovagal syncope post injection lasting a few seconds, no injuries helped to floor, complete recovery. |
| 1143713 | 3/29/2021 | FL | 78 | F | 3/4/2021 | 3/5/2021 | 1st dose: Syncope 2nd dose: rash (Chest and injection site, lip edema) |
| 1143820 | 3/29/2021 | FL | 58 | F | 3/24/2021 | 3/24/2021 | Patient is spanish speaker only, 10 minutes post vaccination, lower lip became numb, eyelid and cheeks were swollen, syncope, dysphagia occurred. As of today, only has numbness in lower lip. Recommended for her to see provider right away. Patient says she does not have insurance. Recommended some income based clinics but call was disconnected, called back but no answer. |

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| 1143823 | 3/29/2021 | NY | 57 | M | 3/29/2021 | 3/29/2021 | Patient had Moderna Vaccine Dose #1. He started to feel light headed. He fell from chair to floor. He was unconscious when first found approx 950 am. Nurse administered Chest compressions. Patient regained consciousness. EMS was called 9:52 am by clinical staff. At same time vitals were stable 129/62, oxygen sat at 95%, pulse 77. No supplemental oxygen or medications were administered. Vitals at 10:02am 130/74 pulse 78 oxygen sat 95%. Vitals at 10:07 were 113/76 oxygen sat 98% pulse 79. EMS was on scene at 10:08am. Patient stated he has a history of vasovagal syncope. He denies any current medications, medical history, or allergies. He refused EMS services to be transported to hospital stating he was "fine" and he "usually has these reactions". He denied any difficulty breathing, shortness or breath, chest pain, palpitations, or any symptoms pertaining to an anaphylaxis reaction. |

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| 1143809 | 3/29/2021 | NY | 65 | F | 3/8/2021 | 3/8/2021 | feeling sick to my stomach ended up fainting onto bathroom floor; feeling sick to my stomach; arm felt mildly painful as injection went in; severe chills; fever; fatigue; restless sleep; This is a spontaneous report from a contactable consumer (patient). A 65-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), second dose at the age of 65-years-old via an unspecified route of administration on 08Mar2021 08:15 (lot number: EN6203) as single dose for covid-19 immunisation. Medical history included covid-19 (covid prior vaccination: yes) from 10Jan2021 to an unknown date. There were no known allergies. Concomitant medication included acetaminophen taken for an unspecified indication, start and stop date were not reported. The patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), first dose at the age of 65-years-old, administered on the left arm on 15Feb2021 08:15 (lot number: EL9264) for covid-19 immunisation and experienced very painful injection site, chills, fever and fatigue. The patient reported that when she had her second vaccine on 08Mar2021, her arm felt mildly painful as injection went in, as though never healed from previous shot. This time, within 3 hours of vaccine, she began to feel fatigue, then began to experience chills and fever. She drank plenty of fluids, and took acetaminophen about 6 hrs after injection. In the evening her temp was up to 101.2 (her normal 97.2) and she took Acetaminophen at bedtime. Had very restless sleep, and at 5 AM on 09Mar2021, she got up feeling sick to her stomach ended up fainting onto bathroom floor. Luckily uninjured, and felt better upon "coming to". She was very fatigued rest of day, then normal next day. The patient underwent lab tests and procedures which included body temperature: 101.2 on 08Mar2021. No treatment was received for the events. The patient recovered from the events on an unspecified date.; Sender's Comments: Linked Report(s) : Same reporter,patient,product/ 2nd dose;US-PFIZER INC-2021269674 Same reporter,patient,product/ 2nd dose |
| 1143884 | 3/29/2021 | | 25 | M | 3/26/2021 | 3/26/2021 | Patient was feeling dizzy and then fainted. The patient was unconscious for a few seconds and then regained consciousness. We kept the patient hydrated and he felt much better. |

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| 1144110 | 3/29/2021 | OR | 80 | F | 1/27/2021 | 1/30/2021 | 3 days after receiving 1st shot, I woke up as usual & after putting on coffee I returned to dressing room to put in my eye drops...a morning ritual, and as doing so I completely 'blacked out' & fell against the dressing room counter and floor. I have fainted before and this was nothing like that. I don't think I was 'out' long nut when I cam to I was on the floor afraid I had had a stroke or heart attack..ruling that out I slowly got up and after sitting for a minute, called my neighbor and then she called 91. I was taken to the emergency at Hospital where they ran all kinds of test |
| 1144317 | 3/29/2021 | MT | 47 | M | 3/24/2021 | 3/24/2021 | Patient called into clinic to report about two hours after receiving vaccine he passed out and the person that was with him said he had a seizure. Patient reported feeling fine after about an hour, but was very tired and had a headache. |
| 1143649 | 3/29/2021 | MD | 53 | F | 3/19/2021 | 3/19/2021 | severe migraine sore throat swollen glands loss of appetite diarrhea nauseous light-headed fainted earaches cough tired and no energy I went to Hospital |
| 1142739 | 3/29/2021 | CA | 25 | M | 2/27/2021 | 2/28/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: vasovagal reacion-Mild |
| 1144418 | 3/29/2021 | FL | 29 | M | 3/29/2021 | 3/29/2021 | Patient fainted after vaccination. He regained consciousness very quickly, but was pale. I gave him an ice pack and checked his blood pressure at 12:18PM (104/57 pulse 48). Patient stated he has not fainted for a vaccination before, but has fainted for bloodwork in the past. Blood pressure rechecked at 12:40pm (112/69, pulse 53), Patient no longer pale and he said he felt back to normal. He did not want any additional assistance. |

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| 1144446 | 3/29/2021 | WA | 79 | F | 1/26/2021 | 1/28/2021 | Received vaccine on 01/26/2021 and unknowingly experienced event. Early morning of 01/28/2021 had fainting spell and thought it was caused by low blood pressure. Felt fine for remainder of day. On evening of 01/29/2021 I started having strange symptoms. Could not concentrate, vision impaired and couldn't figure out what evening meds I needed to take. Decided to go? to hospital on 01/30/2021. Getting ready, I passed out and husband called emergency services. Husband learned later in the day that I had a stroke. Doctors i;nfo?rmed that had blood clots in heart and lungs. Doctors advi;se not to get second vaccine shot. |
| 1144215 | 3/29/2021 | MO | 61 | M | 3/26/2021 | 3/27/2021 | UNKNOWN VACCINATION LOCATION. ADMITTED TO CENTER THE DAY AFTER HIS 2ND SHOT FOR CONFUSION, MENTAL STATUS CHANGES, SYNCOPE VS SEIZURE ACTIVITY, LOSS OF CONSCIOUSNESS. NEURO CONSULTED AND THOUGHT POSSIBLE ADVERSE REACTION TO COVID VACCINE #2 AS NO OTHER REASON HAS BEEN FOUND WITH LABS, IMAGING, ETC. NEURO CALLING IT A 2 HOUR FUGUE EVENT. |

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| 1142926 | 3/29/2021 | CA | 46 | F | 3/4/2021 | 3/1/2021 | The second day after injection temperature dropped to 93.7; I was very cold; I was dizzy almost passed out; tired; nausea; headache; almost passed out; Hypertension/BP 155/103; This is a spontaneous report from a contactable consumer (patient). A 46-years-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Solution for injection, Lot Number: EN6203, expiry date not reported) via an unspecified route of administration, administered in left arm on 04Mar2021 at a single dose for COVID-19 immunisation. Medical history included interstitial cystitis and endometriosis, known allergies to milk and sulfa, have had a complete hysterectomy, and patient was getting hormone injections. The patient was not pregnant at the time of the report and vaccination. The patient had no covid prior to vaccination. Concomitant medications were unspecified; it was reported that patient had other medications in two weeks. The patient previously took ibuprofen and experienced known allergies; and had first dose of bnt162b2 for covid-19 immunisation on an unknown date. The patient had no other vaccine in four weeks. The second day after injection (06Mar2021), temperature dropped to 93.7, BP 155/103, and patient was very cold. Patient was dizzy, almost passed out (Mar2021). Patient temp ran from 97 to 98 and was able to get temp up to 95 (2021) but it's been there and dropping to 94.9 since 06Mar2021. Patient did have hypertension BP but take meds for it (Mar2021). Patient was also very tired, nausea and headache on and off (Mar2021). But all those have been reported. It's not normal for the patient to be cold because patient have had a complete hysterectomy and was getting hormone injections. Therapeutic measures were taken as a result of the event hypertension. No treatment received for the other events reported. The patient was not tested for covid post vaccination. The outcome of the events was not recovered. |

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| 1145199 | 3/29/2021 | UT | 38 | M | 3/25/2021 | 3/26/2021 | Started with the regular symptoms shaking (like with a fever) nausea. Was on a road trip in a snow storm don?t know if it just was a combination of the nausea and the dizziness of the snow flying towards the windshield. But started to feel like throwing up. Pulled over and passed out, my wife says I was shaking. Came back to and throw up a few times. After that I was just not feeling well and had nausea. Started feeling better later that day. |
| 1144464 | 3/29/2021 | FL | 29 | M | 3/29/2021 | 3/29/2021 | patient fainted after vaccine while sitting outside pharmacy in post-vaccine waiting area. He regained consciousness quickly and was pale. He was given cold pack and blood pressure checked 12:18pm (104/59, pulse 48). Patient said he has not fainted from vaccination before, but has fainted after bloodwork. Blood pressure rechecked 12:40pm (112/69, pulse 53), he said he felt normal again, did not want any additional assistance, and left. |
| 1142670 | 3/29/2021 | UT | 35 | F | 3/25/2021 | 3/25/2021 | About 9 hours after receiving my vaccine and feeling fine until that point, I became suddenly dizzy, nauseated, pale and clammy, and felt pressure in my head, my vision became tunnel-like, and I nearly fainted in the span of 1 minute. My spouse prevented my fall, helped me sit down and got me water. After about half an hour later I had recovered from almost fainting, but experienced moderate headache, nausea, muscle aches and fatigue for the following 48 hours. |
| 1142738 | 3/29/2021 | NJ | 31 | F | 3/28/2021 | 3/28/2021 | Systemic: Confusion-Mild, Systemic: Fainting / Unresponsive-Medium, Systemic: Shakiness-Mild, Additional Details: PATIENT DID NOT DISCLOSE SHE HAS A BLOOD/NEEDLE PHOBIA AND USUALLY PASSES OUT AFTER A SHOT. BOYFRIEND WAS ALSO AWARE OF THIS CONDITION AND DID NOT DISCLOSE TO RPH OR TECHNICIAN |
| 1142761 | 3/29/2021 | MN | 45 | M | 3/28/2021 | 3/28/2021 | Systemic: Allergic: Anaphylaxis-Medium, Systemic: Allergic: Difficulty Breathing-Medium, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Medium, Systemic: Fainting / Unresponsive-Medium |
| 1142773 | 3/29/2021 | FL | 31 | F | 3/28/2021 | 3/28/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium |

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| 1142917 | 3/29/2021 | CO | 68 | M | 2/12/2021 | 2/12/2021 | feeling faint; internal sensation jolt; increase blood pressure; pulse declined; face flush; fatigue; A spontaneous report was received from a consumer, concerning a 68-year old, male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced internal sensation body jolt, feeling faint, increase blood pressure, pulse declined, face flush, fatigue. The patient's medical history includes allergic to codine drug. Concomitant product use was not provided by the reporter. On 12-Feb-2021, prior to the onset of events, the patient received their first of two planned doses of mRNA-1273 (lot number 029L20A) via intramuscularly for prophylaxis of COVID-19 infection. On 12-feb-2021,he experienced internal sensation body jolt, feeling faint, increase blood pressure, pulse declined, face flush, fatigue. After 45 minutes following injection his blood pressure are as follows 145/90 mmhg,172/92 mmhg, Late 1 hr of injection blood pressure was decreased . No HCP consulted, advised him to consult HCP before receiving second vaccine. Action taken with mRNA-1273 in response to the event was unknown. The outcome of the events were unknown; Reporter's Comments: This case concerns a 68-year-old female who had a serious unexpected event of syncope along with nonserious unexpected myoclonus, blood pressure increased, heart rate decreased, flushing, and fatigue. Event onset occurred the same day as the first dose of mRNA-1273. Treatment not reported. Event outcomes unknown. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. |
| 1143572 | 3/29/2021 | MI | 40 | M | 3/25/2021 | 3/25/2021 | Patient stated he might of passed out for a few seconds. He also stated he felt dizzy and nauseated . Onsite EMS was called vitals HR 56 BP 105/68. Patient was released to go home. |
| 1142980 | 3/29/2021 | | 19 | F | 3/25/2021 | 3/25/2021 | Patient has syncope/nausea after vaccination and was transported to ED for further eval. Patient states that she typically faints/has syncope when giving blood. Patient received one dose of Zofran PO in ER and was discharged. |

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| 1143244 | 3/29/2021 | IA | 31 | M | 3/25/2021 | 3/25/2021 | Approx 15 mins post injection, right arm heaviness and pain. Then extreme fatigue, vagal stimulus when stood up, vasovagal near syncope, diaphoretic. Approx 18-20 mins after injection throat and tongue tingling and swelling. PO liquid diphenhydramine 50mg given at that time. Then taken to ER for further observation. In the ER, right arm did lock up. No further treatment given. |
| 1143384 | 3/29/2021 | MN | 34 | F | 3/24/2021 | 3/24/2021 | Patient s a 34 y.o. female with PMH of seizure, general anxiety disorder, spells undifferentiated presents to the emergency department chief complaint syncope. Patient reports she received her 1st COVID vaccine shot approximately 1000 hours this morning. Shortly after she started feeling nauseous, reports waking up and seeing EMS and staff standing above her. At the time of ED arrival she reports feeling anxious is requesting her husband and support dog be allowed in the room with her. |

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| 1143464 | 3/29/2021 | OH | 55 | F | 3/11/2021 | 3/11/2021 | <p>Passed out; Had three staples put in for a crack on her head; Extremely weak/Could hardly get up; Arms and legs were tingling; Lips were tingling; Doctors thought it might be anxiety;Sense of dread/ felt like something was wrong; Blood pressure was really low; Could not breath well; Felt a little sore; vomited; Nauseous; A spontaneous report was received from a consumer concerning a 55-year-old, female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced passed out/loss of consciousness, had three staples put in for a crack on her head/skin laceration, extremely weak-could hardly get up/asthenia, arms and legs were tingling/paraesthesia, lips were tingling/paraesthesia oral, doctors thought it might be anxiety; sense of dread/ felt like something was wrong/anxiety, blood pressure was really low/hypotension, could not breath well/dyspnea, felt a little sore/myalgia, nausea and vomiting. The patient's medical history we not reported. No relevant concomitant medications were reported. On 11 Mar 2021, prior to the onset of the events, the patient received the first of two planned doses of mRNA-1273 (Lot number: 030A21A) intramuscularly in the right arm for prophylaxis of COVID-19 infection. On 11 Mar 2021, within 10 minutes of receiving the vaccine, she passed out which is considered medically significant. Paramedics came and she went to ER (emergency room) where she had three staples put in for a crack on her head. She states she was extremely weak and could hardly get up. She was nauseous, had not eaten for hours and vomited. She states her lips, arms and legs were tingly and that it came in waves for a few hours. The doctors thought it might have been anxiety. She stated that she had a sense of dread after getting the vaccine like something was wrong. She states that her blood pressure was really low. She also felt a little sore and could not breath well after the vaccine. Treatment for the events were none. Only had three staples put in for a crack on her head. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events, loss of consciousness, skin laceration, asthenia, paraesthesia, paraesthesia oral, anxiety, hypotension, dyspnea, myalgia, nausea and vomiting were unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship</p> |

| <i>VAERS_ID</i> | <i>RECVDATE</i> | <i>STATE</i> | <i>AGE_YRS</i> | <i>SEX</i> | <i>VAX_DATE</i> | <i>ONSET_DATE</i> | <i>SYMPTOM_TEXT</i> |
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| 1143481 | 3/29/2021 | IN | 73 | F | 2/2/2021 | 2/25/2021 | cannot be excluded. Had one fainting episode; Very tired; low energy (it has been almost 3 weeks); problems with high blood pressure; This is a spontaneous report from a contactable consumer (patient). A 73-year-old non-pregnant female patient received her second dose of bnt162b2 (BNT162B2 reported as PFIZER COVID-19 VACCINE; lot number: EL9262), at vaccination age of 73-year-old via an unspecified route of administration in the left arm on 02Feb2021 16:00 as a single dose for covid-19 immunisation. Medical history included hypertension and PCN allergies (penicillin allergy). The patient was not diagnosed with COVID-19 prior to vaccination. The patient did not receive other vaccine in four weeks. Concomitant medication included unspecified medication. The patient received the first dose of bnt162b2 (BNT162B2 reported as PFIZER COVID-19 VACCINE; unknown lot number and expiration date), at vaccination age of 73-year-old via an unspecified route of administration in the left arm on Jan2021 15:15 as a single dose for covid-19 immunization. On 25Feb2021 06:00 PM, the patient was very tired, low energy (it has been almost 3 weeks), had one fainting episode though the patient doesn't know if it was related, and problems with high blood pressure. The fainting episode is reported, the other problems have been ongoing since second shot. The events required emergency room/department or urgent care visit. The patient underwent lab tests and procedures which included blood pressure was high on 25Feb2021 and nasal swab (sars-cov-2 test) was negative on 22Feb2021. The outcome of the events was recovering. Information on the lot/batch number for first dose has been requested. |

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| 1143489 | 3/29/2021 | | | F | 3/1/2021 | 3/1/2021 | she felt her body slide off the seat and her head rocked to the right and hit her shoulder/she nearly passed out; dizzy; she could feel something going on with her heart/heart started racing; felt like she was stoned; had a hard time forming sentences and talking; Headache; tired; she was jolted back by the pain in her neck; felt flush; This is a spontaneous report from a contactable consumer. A female patient (age: 60 with no unit provided) received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration on Mar2021 (Batch/Lot number was not reported) as single dose for covid-19 immunization. The patient was pretty reactive to most drugs. The patient had anaphylactic reaction to a spider bite. She has a history of having gotten stung by a scorpion and having an anaphylactic reaction. She was also one of those people who end up having to throw away a lot of medicines because she was allergic to them. She has had seven spine surgeries and gets a lot of shots so she was not scared of needles. The patient had the first shot on Friday in Mar2021. The patient had a not so pleasant reaction to it immediately. The patient heart started racing right after they injected and then she felt dizzy in Mar2021. The heart racing went away pretty quickly but the dizziness did not. For the first 15 minutes the patient had a hard time forming sentences and talking. It felt like when someone wakes you from a dead sleep. Like wanting to tell people to go away, go away. Then she felt head drop to right shoulder and slide off of feet. That caused pain because she have had multiple neck surgeries in the past and jolted her out of whatever was happening. Then that passed. At 4:30 she told them she need to go before rush hour. She felt like she was driving stoned. Very carefully like she was under the influence of something. The dizziness gradually faded, and she went to bed. The next day she had a headache, felt flush, and tired. And then eventually everything went away. She took a Benadryl an hour and a half before getting the vaccine because that's why provider told her to do. She did take Benadryl before the vaccine just in case, she was unsure if she took it after or not, she thought about it. As soon as she got the injection of the first dose of the Pfizer COVID 19 vaccine she could feel something going on with her heart. Then she got really dizzy. While waiting in the parking lot, there were two paramedics that |

VAERS_ID RECVD STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1142780 | 3/29/2021 | CA | 19 | F | 3/28/2021 | 3/28/2021 | stood there and spoke with her because she had mentioned that she thought she was high risk. The first thing she noticed was that she was wondering why they wouldn't go away, she was dizzy, and then she felt her body slide off the seat and her head rocked to the right and hit her shoulder and she realized she nearly passed out and she was jolted back by the pain in her neck. On the way home she was still dizzy and as she was driving she felt like she was stoned. She was very careful getting home and went to bed at about 1830 and just watched TV. The dizziness went away overnight. The next day she had a headache and was tired and then by Sunday she was okay. She was concerned that her doctor will tell her it was an allergic reaction and she just need a straight answer as to whether the second shot was recommended for her. Outcome of the events was recovered in Mar2021. Information about lot/batch number has been requested. |
| | | | | | | | Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient received first dose of Pfizer COVID vaccine. Several minutes later, patient felt faint, got up to inform family to inform pharmacist, and fell to the ground |

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| 1145940 | 3/29/2021 | MN | 26 | M | 3/29/2021 | 3/29/2021 | Patient reported to immunizing technician before administration of vaccine that he had a history of fainting post-vaccination due to anxiety and nerve about needles. Pt stated that previously he had fainted immediately post-vaccination. After discussing patient's medical history the supervising pharmacist advised pt to stay in vaccination seat for direct observation for 10-15min. After about 10 minutes post-vaccination in observation period the pt alerted immunizing tech, "oh, its happening." The tech brought a wet paper towel and placed it on the back of patient's neck and pt replied, "oh, that feels good", then patient's head immediately dropped and he went out of consciousness. Pharmacist witnessed event and rushed over to support patient from falling off chair. Pharmacist was rubbing and patting patients back and chest, yelling his name to arouse him. Pharmacist directed tech to call code white and alert store manager. In total, the patient was approximately in and out of consciousness about 20 seconds. Pt responded to stimulus and recovered without other effects or injury. Patient was fully responsive and aware of event went he became conscious again. We offered him a cold water bottle and encouraged him to remove mask if it helped him to breath better. Pt was able to communicate with pharmacist about the sensations he had leading to the event where he described first tingling in his feet, than dissociation from body, where he felt like he was having a dream but could hear someone yelling at him. EMS arrived at the scene and performed vital check. Based on patient abnormal hypertension at scene and higher BMI, EMS offered to transport patient to the ED for further tests and observation but patient declined. Patient was accompanied by his emergency contact, his father (who also witnessed the events unfold). |
| 1145390 | 3/29/2021 | CA | 42 | M | 3/23/2021 | 3/23/2021 | Chills, body aches, migraine headache, nausea. Nausea has continued to be a big issue from the night of injection until today, which is Monday, 3/29/2021. On Saturday night (3/27) I experienced overwhelming stomach pain and nearly passed out on my toilet multiple times during a bout of diarrhea. |
| 1145465 | 3/29/2021 | OH | 24 | F | 3/29/2021 | 3/29/2021 | Syncope Dizziness |

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| 1145499 | 3/29/2021 | CA | 28 | M | 3/29/2021 | 3/29/2021 | Patient is a 28 year old male who has completed a 45-minute observation period with the following signs and symptoms of an adverse reaction: other - syncopal episode. COVID-19 vaccine # 1 in series administered. Patient complaints of syncopal episode witnessed by other patients after received 1st dose of Covid vaccine. Patient states that he developed clammy skin, lightheadedness 10 minutes after he received his Covid vaccine, patient tried to get out of chair when he had a syncope episode and fell on the floor face down witnessed by other patient in the Covid vaccine lobby area. Denies any head or facial injury. Patient states that he has needle phobia and he forgot to tell the nurse about his needle phobia. Treatment provided/action Taken: Vital sign @ 1325: blood pressure 114/44, heart rate: 71. SPO2: 98%, respiration : 16; Vital sign @ 1335: blood pressure 104/62, heart rate: 82. SPO2: 95%, respiration : 16; Vital sign @ 1352: blood pressure 102/68, heart rate: 90. SPO2: 99%, respiration : 16; Patient states that he didn't eat breakfast or lunch today, able to tolerated fluid and intake well, eating chocolates. Action taken: Transferred to higher level of care (urgent care); Patient advised to discuss second dose considerations with a clinician. |
| 1145532 | 3/29/2021 | | 64 | F | 3/25/2021 | 3/26/2021 | Fever, major headache and nausea, mild cough, shortness of breath, syncope episodes |
| 1145778 | 3/29/2021 | PA | 50 | F | 3/23/2021 | 3/24/2021 | Syncope at work. |
| 1145387 | 3/29/2021 | WA | 34 | M | 3/29/2021 | 3/29/2021 | Patient fainted and hit his head. We called 911, elevated his feet, and have him an icepack for his head. The EMTs assessed him, and determined him to be okay, and had a friend come get him to drive him home. |
| 1144488 | 3/29/2021 | IL | 45 | M | 3/21/2021 | 3/21/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Exhaustion / Lethargy-Medium, Systemic: Fainting / Unresponsive-Medium |
| 1145921 | 3/29/2021 | GA | 28 | F | 3/29/2021 | 3/29/2021 | Patient fainted after receiving her vaccine. EMTs came and found very low blood pressure, and took her to the hospital. |
| 1144947 | 3/29/2021 | OH | 30 | M | 3/29/2021 | 3/29/2021 | Arm soreness Nausea Anxious feelings Ear ringing Syncope |

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| 1145974 | 3/29/2021 | NY | 20 | F | 3/28/2021 | 3/29/2021 | woke up at 7am and fainted upon standing up (vaso-vagal event) --NO HX OF VASO VEGAL EVENTS IN PAST , headaches, nausea , body aches |
| 1145980 | 3/29/2021 | FL | 21 | F | 3/28/2021 | 3/28/2021 | Low blood pressure, fainting, dizziness, headache, and numbness of the entire injected arm on day of the vaccination. Fatigue, muscle aches, headache, fever, injection sight soreness, and feeling unwell the entire day after the vaccination. |
| 1146061 | 3/29/2021 | PR | 42 | F | 3/28/2021 | 3/28/2021 | itching in the arm, high blood pressure (114/99 mmHg) 107 , headache, pulse 107, panic attack, fainting |
| 1146065 | 3/29/2021 | AZ | 25 | M | 3/29/2021 | 3/29/2021 | Patient had just finished receiving his covid-19 vaccination from vaccinator. At the time of patients fainting I was mixing up covid-19 vaccinations when the technicians said we need you to come out here because a patient is having a seizure, When arriving on the scene I found patient unconscious on the floor face down, while assessing the scene I noticed some blood on floor. I tried to look for any trauma, patient was breathing and I tried to awaken him. I told someone to call 911 and contact a store manager. Then all of a sudden he popped up and sat up like nothing happened. I then noticed the bruising on his nose and asked for an ice pack and a bottle of water. Patient knew his name, was coherent, and seemed to be fine. I stayed with patient until paramedics arrived. Paramedics did a thorough examination and everything checked out. Patient waited for parents to arrive instead of going with paramedics. Vaccinator stayed with patient till his parents arrived. |
| 1146068 | 3/29/2021 | FL | 52 | F | 3/27/2021 | 3/27/2021 | Vasovagal Syncope... per husband patient had a history of previous events after vaccines (apparently had shot anxiety)... No other reaction presented. no need for Epi-pen... We had call emergency services, to assist the patient as well. |
| 1145793 | 3/29/2021 | MA | 17 | F | 3/28/2021 | 3/28/2021 | Patient fell on her face and fainted for a couple of minutes. |

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| 1144651 | 3/29/2021 | NY | 72 | F | 3/20/2021 | 3/27/2021 | Presented to the ED with difficulty closing the R eye with notable R-sided facial droop that began on Saturday, March 27th. On physical exam, cranial nerves 2-12 intact, but notable R-sided facial droop and 7th nerve lesion in the peripheral distribution. VFF, PERRLA, 4/4 strength in the biceps/triceps/hand grip/hamstrings/quads/plantar/dorsiflexion. SILT UE/LE. No pronator drift. Normal finger-nose-finger. Normal rapid alternating movements. Reflexes 2+ in the patella bilaterally. Normal gait. BP on the presentation was 226/111, pulse was 78, respiratory rate was 20, oral temperature was 36.8 degrees Celsius, and SpO2 was 99%. Denied COVID-19 symptoms, activity change, chills, fever, congestion or dental problems, discharge or itching of the eye, chest tightness, shortness of breath, stridor, chest pain, leg swelling, abdominal distention or pain, dysuria, frequency, arthralgias, joint swelling, color change or rash, dizziness, syncope, back or neck pain, weakness, N/V, HA, vision changes, confusion, bowel changes, behavioral problems or confusion. Has been taking medications as prescribed, no prior history of CVA. PMH of DM and HTN. |
| 1145942 | 3/29/2021 | | 37 | F | 3/29/2021 | 3/29/2021 | Patient with syncope post vaccination. Placed on 3L O2 NC. Appeared to be in respiratory distress. BP initially 98/72. Recovered to 145/86. MD at bedside and discontinued O2 since patient alert and O2 ok. After a few minutes patient began to desat occasionally and appeared in respiratory distress. Placed on NRB 15L. IV placed and given Zofran 4mg IVP. EMT's at bedside and did EKG. Patient said "my heart hurts." Transferred via ambulance to ED. |
| 1145252 | 3/29/2021 | FL | 52 | M | 3/29/2021 | 3/29/2021 | Patient fainted while sitting at the post-vaccination waiting area about 10 minutes after vaccination. Immediately reached out to the patient. Positioned him properly. Other Pharmacist called 911. less than a minute, patient responded. He sat down and meantime the paramedics came in. They took him to the E.R. Called patient after 5 hours, he is still in the ER under observation. but he feels fine |

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| 1144490 | 3/29/2021 | TX | 21 | M | 3/18/2021 | 3/18/2021 | Patient complained of dizzy spells, and fainted. He bit his tongue while experiencing a possible seizure. No prior history of seizure disorder. Parent was called right after the student experienced adverse reaction. Vital signs taken B/P 128/88, Pulse - 80, Pulse oximetry - 99 %, temperature was 97.4. Patient had not prior history of COVID-19, not taking any medications, no hypertension. Patient became alert 30 seconds afterwards. |
| 1144558 | 3/29/2021 | TX | | U | | | Fainted in the shower; A spontaneous report was received from a consumer concerning a friend who is a patient of unknown age and race that received Moderna's COVID-19 Vaccine (mRNA-1273) and fainted in the shower (Syncope). The patient's medical history was not provided. Concomitant product use was not provided by the reporter. On an unknown date, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (batch number: unknown) intramuscularly for prophylaxis of COVID-19 infection. On an unknown date, the patient fainted in the shower. No treatment information was provided by the reporter. Action taken with mRNA-1273 in response to the events was unknown. The outcome of event, fainted in the shower was considered as unknown.; Reporter's Comments: Very limited information regarding this event/s has been provided at this time. Further information has been requested.; Sender's Comments: MOD-2021-031707:patient's case |

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| 1144565 | 3/29/2021 | FL | 21 | F | 3/11/2021 | 3/11/2021 | fainted when I sat down; stood up and started to feel dizzy; I felt throat pain like strep throat pain; started feeling very intensive cramps in my lower abdomen like very intense period cramps for about 10 minutes.; felt very weak with no energy to get out of bed; This is a spontaneous report from a contactable consumer (patient). A 21-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot number: EL3302) via an unspecified route of administration, administered on the right arm on 11Mar2021 16:00 at a single dose for COVID-19 immunisation. Medical history included low thyroid. There were no concomitant medications. After receiving the shot of the vaccine on 11Mar2021 16:00, the patient stood up and started to feel dizzy. She was able to find a nearby chair and fainted when she sat down. When she woke up seconds later of fainting, she felt throat pain like strep throat pain and then she started feeling very intensive cramps in her lower abdomen like very intense period cramps for about 10 minutes. The patient stated that nobody in the (Pharmacy name) was prepared to react to these symptoms and the rescue took too long to come in, when they came in she was feeling better and did not see the need of going to the hospital. But it was an immediate reaction that affected 3 different parts of her body that was very painful. During the day and the day after she felt very weak with no energy to get out of bed. "I am wondering if I can still receive the second dose after this reaction to the first dose?" No treatment was received for the events. Prior to vaccination, the patient was not diagnosed with COVID-19. Post vaccination, the patient has not been tested for COVID-19. Patient was not pregnant. No known allergies. The facility where the vaccine was administered was in a pharmacy drug store. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Outcome of the events was recovering. |

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| 1144677 | 3/29/2021 | AZ | 38 | M | 3/29/2021 | 3/29/2021 | Patient became lightheaded and dizzy. Patient was placed in seated position on floor and passed out. Mild muscle spasm/seizure like activity and pharyngeal gurgling. Patient was unresponsive for approximately 2 minutes and regained consciousness without intervention. EMS was called and attended to patient. Sinus rhythm normal, blood pressure 140/82. Patient placed into an upright seated position, blood pressure remain unchanged. Patient declined transport to hospital, was observed for several minutes and released on his own volition. |
| 1144685 | 3/29/2021 | FL | 26 | M | 3/29/2021 | 3/29/2021 | I received the shot and was told to sit in a chair and wait for 15 minutes. After about 5-10 minutes I began to feel faint/lightheaded/clammy. I do have a history of these from shots I have had in the past. I got the pharmacists attention and told her I was feeling faint and asked for some water. Once she left, breathing in my throat felt significantly constricted. I had a reaction to clear my throat a few times but that didn't not affect anything. The pharmacist came back with water and an ice pack that she held against my neck. During this episode I was able to drink water still. The severity of the breathing issue leveled off and eventually I was able to breathe normally again. The whole thing lasted 1-2 minutes. It felt longer thinking back on it but I don't think it lasted as long as my impression of the episode. After that I felt tingling followed by shakiness in my extremities which was more typical of the fainting side effects ive had in the past. I've never experienced breathing issues with other shots I've received in the past. The pharmacist kept me there to monitor me for 30-45 minutes. No additional medication was administered |
| 1144691 | 3/29/2021 | OH | 16 | F | 3/29/2021 | 3/29/2021 | Approximately 15 minutes following vaccination, the patient complained of headache, dizziness, chest pain and throat burning. I asked that she wait an additional 15 minutes so that we could monitor her. Approximately 30 minutes after vaccination, patient appeared to experience syncope or absence seizure (prev. history). we called 911 and paramedics transported her to hospital |

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| 1144797 | 3/29/2021 | CA | 79 | F | | | Severe vomiting, blood pressure spiked at 172/157 pulse rate 148, then severe hot flushing sensation ending in being soaking wet and clammy feeling, dizziness and feeling like I was passing out. Sat down on toilet, called my daughter and all I could say was help, I think I'm passing out. She found me passed out on the toilet, got me to wake up but not coherent. She called 911 and I was checked and taken to emergency room with diagnosis of dehydration caused by the vomiting. |
| 1144815 | 3/29/2021 | NY | 54 | F | 3/24/2021 | 3/25/2021 | Pfizer-BioNTech Covid-19 Vaccine EUA I felt fine the day of the injection at 2PM (3/24/21). I slept poorly and woke up feeling exhausted (3/25/21). Developed a fever of over 101 degrees Fahrenheit and was resting in bed. At around 2:45PM I used an oximeter and noticed how my pulse was steadily increasing within a few minutes - from 80's to over 135 and then I fainted. I was in bed and didn't fall. After I came back after maybe 1/2 minute I was still dizzy but started feeling better shortly. As my husband happened to observe me passing out we went to the ER. At around 3:45PM my blood pressure, when checked in the ER, was 102 over 58 and my temperature had gone back down to 98.4 degrees. I started feeling better quickly after that. I was tested for a heart attack which was negative and released later that evening. |
| 1144845 | 3/29/2021 | MO | 61 | F | 3/22/2021 | 3/29/2021 | passed out at home, diarrhea and nausea, and blood in stool this all |
| 1145117 | 3/29/2021 | IN | 46 | F | 3/27/2021 | 3/28/2021 | Severe headache, muscle aches, fever, chills, dizziness, sore arm. Body chills started around 1am, by 7:00 a.m., I had headache and dizziness, with extreme fatigue. I almost passed out after breaking out in cold sweat by 8:30 a.m. Started running a fever around 9:30 a.m. Took Tylenol for headache and body pain. Slept until 1:30p.m. Woke with a fever of 101.4 and severe headache. Took more Tylenol and laid back down. By 4:30p.m. I was able to lift my head off a pillow and walk without dizziness. Chills and low-grade fever returned around 6:30pm. Went to sleep. Woke at 7:30 am. No headache, slight fatigue, sore arm. No fever, no dizziness. |

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| 1144560 | 3/29/2021 | MO | 68 | F | 3/8/2021 | 3/10/2021 | <p>passed out on way to bathroom; Maybe it was a seizure; Feeling weak; Fever of 103,Lowest the fever could get is 101; Diverticulitis attack; A spontaneous report was received from a consumer concerning a female patient of 68 years old, who received Moderna's COVID-19 vaccine(mRNA-1273) and experienced Diverticulitis attack, felt weak, passed out, seizure and Fever of 103. The patients medical history included sensitivity to medicines. No relevant Concomitant medications were reported. On 08 Mar 2021,prior to the onset of events, the patient received the first of two planned doses of mRNA-1273(Lot number: 011A21A) vaccine through unknown route for prophylaxis of COVID-19 infection. On 10 Mar 2021, at 1am, she woke up with a fever of 103. The highest was 103 and the lowest she could get it down to was 101. The patient passing out on way to bathroom at one point also and does not know how long she was out for. She believes she could have had a seizure. She also had a diverticulitis attack in this time period which she states being the worse attack and she felt pretty weak . Treatment for the event included Tylenol and used icepacks and was on a liquid diet. Action taken with the mRNA-1273 in response to the event was not provided. The fever resolved on 12 Mar 2021 while the diverticulitis attack and weakness resolved on 16 Mar 2021. The outcome were unknown for other events.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p> |

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1140659 | 3/28/2021 | TX | 70 | F | 3/12/2021 | 3/12/2021 | sweating; Pain in arm; Fever; Chest pain (left side); No bowel movement-watery; Labored breathing; Over sleeping; Passed out; Chills; Dizziness; Headache; A spontaneous report was received from a consumer concerning a 70-years-old female patient who received Moderna COVID 19 vaccine and experienced pain in arm, dizziness, major chest pain (left side), pain in shoulder, neck, headache, no bowel movement-watery, chills, labored breathing, passed out, over sleeping, no urine, sweating, fever and sore throat. The patient's medical history included congestive heart failure, high blood pressure and gout and had 3 heart attacks in lifetime. No relevant concomitant medications were reported. On 12 Mar 2021, prior to the onset of the event, the patient received their first of two planned doses of mRNA-1273 (lot/batch number: 031A21A) intramuscularly for COVID-19 prophylaxis. On 12 Mar 2021, the patient experienced headache and dizziness. On 13 Mar 2021, the patient experienced pain in arm, major chest pain (left side), pain in shoulder, neck, no bowel movement-watery, chills, labored breathing, passed out, over sleeping, no urine, sweating, fever and sore throat. Treatment for the event included nitroglycerin and paracetamol. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the event dizziness was resolved on 12 Mar 2021. The outcome of the events chills, fever and headache was resolved on 14 Mar 2021. The outcome of the events pain in arm, major chest pain (left side), pain in shoulder, neck, no bowel movement-watery, labored breathing, passed out, over sleeping, no urine, sweating and sore throat was resolved on 15 Mar 2021.; Reporter's Comments: This case concerns a 70 Y/O F with a serious unexpected loss of consciousness and NS unexpected dizziness, chest pain, dyspnea, gastrointestinal motility disorder, hypersomnia, hyperhidrosis, and expected pain in extremity, pyrexia, chills, headache. Event onset Day 1 after first dose mRNA-1273. Events resolved. Based on current available information and temporal association between use of the product and the start date of the event, a causal relationship cannot be excluded. |

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1141305 | 3/28/2021 | KY | 34 | F | 3/26/2021 | 3/27/2021 | 9 hours after receiving my 2nd Moderna shot, I woke up with diarrhea. 12 hours after receiving the shot, I got up to use the bathroom, and began to feel dizzy. When I sat down, my blood pressure dropped and the room started spinning and I could feel that I was going to lose consciousness. My husband came to help and watched as I passed out cold on the toilet for over a minute. 15 hours after receiving the shot, I passed out again on the toilet with the same symptoms before losing consciousness. I was unable to get up without passing out for over 16 hours after receiving the shot. I had continued dizziness and muscle weakness for over 24 hours, along with flu-like symptoms as expected. |
| 1141565 | 3/28/2021 | CO | 59 | F | 3/24/2021 | 3/24/2021 | Approx. 5 hours after shot broke out in a profuse sweat, got dizzy and passed out while standing in my kitchen. Felt unstable for about an hour after then symptoms subsided. No other reactions after that |
| 1141557 | 3/28/2021 | ID | 80 | F | 3/9/2021 | 3/10/2021 | The morning after the 2nd dose, I got up to make coffee. I had just started and felt a bit light-headed. I was going to go sit down, but I passed out and fell onto the kitchen floor for a few seconds. I have never passed out before or felt such light-headedness. I went to lay down. I vomited a bit of liquid. I lay down and several hours later my husband drove me to the emergency room. After many tests they said I had suffered a Syncope and had a slight concussion. |
| 1141583 | 3/28/2021 | PA | 42 | F | 3/27/2021 | 3/27/2021 | Shortly after exiting the vaccination room, the patient felt lightheaded and dizzy and experienced an episode of near-syncope. She immediately lay down on the floor. She was sweating profusely. She remained on the floor for approximately 5 minutes with her legs raised and she started to feel better. She was given a bottle of orange juice to drink and was taken to the waiting area where she was observed for another 25 minutes. Patient stated that she felt fine and left the pharmacy. |
| 1141394 | 3/28/2021 | PA | 60 | F | 3/25/2021 | 3/26/2021 | Fever and chills began around 3 am following vaccination at 6:45 PM. Upon arising around 7 am, fainted in bathroom and was dizzy when upright for about thirty minutes. Bruised ribs secondary to falling. |

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| 1141380 | 3/28/2021 | CA | 62 | F | 3/27/2021 | 3/27/2021 | Patient received first does of Moderna on left arm at 0900 on 03/27/21 in her vehicle. Soon after she felt dizziness, nausea, upset stomach and felty syncope coming on. Patient received medical attention and all vital signs were within normal range. Patient refused to go to hospital. Patient was with her daughter who assumed driving responsibility and would drive the patient home. Patient advised to stay additional time to monitor her. |
| 1141320 | 3/28/2021 | | 23 | F | 3/28/2021 | 3/28/2021 | Patient was observed post Covid-19 immunization for 15 minutes . During the observation period, she experienced an adverse reaction with the following symptoms: syncope. Sitting in chair, fell to right hitting head on floor, patient became alert within seconds, transported via w/c to stretcher to be assessed by EMS, vitals taken, within normal limits, CBG 94, pt being sent home on concussion protocol, Fiance driving patient home and staying with her for 24 hours. Patient refused transport to hospital. Alert oriented at discharge. Assessment : Time of assessment 0943. Alert and oriented. Paramedic on site, vitals taken Actions taken: Vitals sign taken VAERS form completed Medications administered: No medication administered. Disposition: Reports no further symptoms of adverse reaction after observation for 30 minutes. Discharged home. Instructed to follow up with PCP for evaluation for second dose. Instructed to call 911 for trouble breathing, rapid heart rate, dizziness, swelling of tongue or throat. |
| 1141314 | 3/28/2021 | IN | 52 | F | 3/26/2021 | 3/26/2021 | Johnson and Johnson single dose. Sore arm, numbness in hand and forearm within 2 hours of shot. Numbness disappointed within 24 hours, soreness continues. Nausea, headache, tiredness, fever, body aches started approx 6 hours after shot. Approx 7am day after woke up with severe nausea. Fainted approx 7:15am. Fever and lethargy continued until approx 4pm on 3/27. 3/28 woke with no symptoms other than sore arm (feels like pins and needles). Feel normal other than the arm. |
| 1141295 | 3/28/2021 | OH | 38 | M | 3/28/2021 | 3/28/2021 | Syncope Sweating Shaking Tunnel vision |
| 1141260 | 3/28/2021 | SC | 43 | F | 3/23/2021 | 3/23/2021 | Started 15 min post vaccine injection. Dizzy, fainting, low blood pressure. Numbness in hands/feet. Took an hour to recover. |

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| 1141146 | 3/28/2021 | FL | 60 | F | 3/27/2021 | 3/27/2021 | Site: Pain at Injection Site-Medium, Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: vomiting-Severe, Systemic: Nausea-Severe, Systemic: Shakiness-Medium, Systemic: Vomiting-Severe, Systemic: Weakness-Severe |
| 1141139 | 3/28/2021 | CA | 33 | F | 3/26/2021 | 3/26/2021 | Systemic: Allergic: Anaphylaxis-Medium, Systemic: Fainting / Unresponsive-Medium, Additional Details: Pt fainted 2-3 minutes after getting vaccinated with the first dose of moderna covid vaccine. She recovered immediately but had her front teeth bent from falling forward. Pt was talking as usual after regaining consciousness and her bp was within normal range. |
| 1141135 | 3/28/2021 | FL | 26 | F | 3/27/2021 | 3/27/2021 | Patient was administered vaccine and told to wait the 15 minute monitoring period. After about 4 minutes, I heard her say "I'm not feeling right." I went to where she was sitting and asked "are you ok?" and had her take some slow, deep breaths. I then saw her eyes roll back and she lost consciousness. Thankfully, I was there and grabbed her as she toppled from the chair. I told the staff to call 911 and supported her neck and body in the chair. I could tell she was breathing and she was sweating profusely. I held her and spoke to her, and after about 15 seconds, she began to come out of it. After about a minute she was alert and orientated again. I had her slowly sip a little water. The EMTs arrived in about 5 minutes and the assessed her vitals. She indicated that this was the first time anything like this had happened to her. They advised that since she had fainted, she should go to the hospital for observation, but she declined, stated that she felt fine at that point. Since she was driving, I insisted that she remain another one-half hour before leaving. During that time she drank more water and alternately sat and walked around the pharmacy. She did indicate that she had drank a protein shake that morning, but not eaten. I advised her to in the future, tell her doctor and/or any immunizer about the event. She left, stating that she was feeling fine, and I called her several hours later to make sure that she had indeed gotten home ok. She again said that she felt fine. |

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| 1141133 | 3/28/2021 | VA | 33 | M | 3/27/2021 | 3/27/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Exhaustion / Lethargy-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Passed out for less than a minute-Severe, Systemic: Flushed / Sweating-Mild, Systemic: Hyperventilation-Medium, Systemic: Nausea-Mild, Systemic: Numbness (specify: facial area, extremities)-Medium, Systemic: Tingling (specify: facial area, extremities)-Medium, Systemic: Weakness-Mild, Additional Details: Patient passed out less than 10 minutes after receiving Moderna vaccine. stated he felt fine after initially receiving his vaccine but felt dizzy while using the rest room. While having a seat in the immunization area, the patient passed out for less than a minute. 911 was called right away. was monitored by his immunizer, & myself and remained conscious as we awaited the arrival of the EMT's. Patient was able to walk out but is unknown if with Emts |

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| 1140685 | 3/28/2021 | CT | 69 | F | 3/8/2021 | 3/9/2021 | mild nausea; Syncope (2x) w/mild seizure; Syncope (2x) w/mild seizure; Flu-like symptoms; chills; joint/muscle pain; joint/muscle pain; injection site pain; headache; labored breathing; dry-heaving after second syncope; This is a spontaneous report from a contactable consumer (patient herself). A 69-year-old female patient, not pregnant, received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: LOT 6205 (as reported)), via an unspecified route of administration in the right arm, on 08Mar2021, at a single dose, for covid-19 immunization. The patient has no medical history and has no known allergies. Concomitant medications included sertraline; docusate sodium, ferrous fumarate (FERRO-SEQUELS); and multivitamin - all taken for unspecified indications, start and stop dates were not reported. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EN6201) on 15Feb2021 17:00 in the right arm for covid-19 immunization at 69-years-old. The patient did not have covid prior vaccination. The patient did not receive any other vaccines in four weeks. The vaccine was given at the public health clinic. The following day on 09Mar2021 15:30 after a short walk, the patient experienced flu-like symptoms, chills, joint/muscle pain, injection site pain, headache, syncope (2x) with mild seizure, labored breathing, and dry-heaving after second syncope. The patient was then taken by ambulance to the ER (resulted in an emergency room visit) and was given saline fluids via IV. The vitals and EKG were "ok" on 09Mar2021. The patient recovered relatively quickly and was released. The only symptoms remaining on 11Mar2021 were mild headache and mild nausea. The patient had not recovered from headache and nausea at the time of the report; while recovered outcomes on Mar2021 for all the other remaining adverse events. The patient was not covid-tested post-vaccination. |
| 1141601 | 3/28/2021 | NY | 65 | F | 3/27/2021 | 3/28/2021 | Fainted. Felt faint, sat in chair, fainted, woke up on floor with chair tipped over. Nauseated, dizzy, & stiff muscles for several hours. |
| 1142184 | 3/28/2021 | | 19 | F | 3/28/2021 | 3/28/2021 | Patient had a seizure, followed by syncope |

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| 1141053 | 3/28/2021 | CA | 42 | M | 3/27/2021 | 3/27/2021 | Pt. passed out for about 2 minutes. Skin and lips were very pale. pt hunched over to the right while in chair. eyes fluttering and very diaphoretic. Pt was helped to lay down on the floor in supine with legs elevated. clothes loosened, applied cold icepacks and deep breaths were encouraged. Pt . gained consciousness and was able to retell what had happened. |
| 1142268 | 3/28/2021 | IL | 42 | M | 3/28/2021 | 3/28/2021 | syncope , lightheaded, dizzy history of H.S.P- AUTO IMMUNE RESP 104/70,70,16, BS 122 124/68,90,16 |
| 1142127 | 3/28/2021 | NJ | 58 | F | 3/26/2021 | 3/26/2021 | Passed out 20 minutes after vaccination; ringing in ears, tingling feeling spreading from injected left arm to chest, black spots in front of eyes prior. Feeling of blacking out occurred several times after initial feeling/fainting. Extreme pallor. Was given place to lie down, given ice pack; given oxygen when I reported my chest felt tight; didn't feel like I was getting air. Slowly (30 minutes) felt better. Paramedic said he had seen fainting before with first Moderna. Declined to go to hospital and symptom did not return. Severe side effects the following day and day after (fever, chills, muscle aches, nausea); pallor is gone. |
| 1142564 | 3/28/2021 | NY | 68 | M | 3/26/2021 | 3/26/2021 | Immediate whole body severe sweating, eye pupils extremely dilated, skin color and lips became very pale, dizziness, disorientation, tremor in the hands, thirst, a bit of nausea, fainting . No treatment received except for ice pack. Neither doctor or nurse was present on the site. |
| 1142418 | 3/28/2021 | IN | 65 | F | 3/23/2021 | 3/24/2021 | Had vaccine. Went Home; was okay until that evening. Had slight headache, tired achy so took 1 tylenol pm and went to bed. Woke up to go bathroom and felt nauseous and light headed. Went to bathroom was washing hands and room was spinning. Called for my husband and he came to help hold me but a passed out, slipped out of his arms and landed on floor. I came to, he took my oxygen which was 77; fever of 100. He put my oxygen on and got me to bed. Woke up next morning, nauseous all day, headache, and have a black eye from fall. Felt tired but felt better the following day. |

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| 1141633 | 3/28/2021 | CA | 83 | M | 3/27/2021 | 3/27/2021 | Pt sts to nurse that he "feels weak" 20 minutes after receiving vaccine. Radial pulse 67 and slightly irregular. Day was very warm and patient sitting in very warm vehicle. EMS called. Patient transported to hospital.. Remained awake and alert. No syncope, shortness of breath or chest pain. |
| 1142283 | 3/28/2021 | | | U | | | Fainted approximately 5.5 hours (12:00am) after vaccine followed by diarrhea 30 minutes afterwards. I am still experiencing chills and fatigue. |
| 1142254 | 3/28/2021 | | 26 | M | 3/28/2021 | 3/28/2021 | Patient vaccinated and within a few minutes after vaccination, patient with syncope. Able to stabilize patient in chair and bring to first aid. Patient recovered quickly. MD at bedside. Discharged without difficulty. |
| 1142240 | 3/28/2021 | CA | 45 | F | 3/25/2021 | 3/26/2021 | I woke up at approximately 2:30 AM feeling very sore, achy, clammy, and feverish. I felt like I needed to get out of bed because laying there felt very uncomfortable. I got up to go to the bathroom. On my way to the bathroom, I fainted in the hallway and landed flat on my face. My front left tooth was knocked completely out of my mouth, and the two adjacent teeth were knocked loose. I found my tooth on the floor, placed it on a shelf in my bathroom, and then took a shower as I was in shock and felt very sweaty and out of sorts. At 2:41, after the shower, I called 911, but declined an ambulance ride and hung up. I then googled what to do when your tooth is knocked out, and learned that I should put the tooth back in its socket immediately. I put the tooth back in and then at 2:57, I called an emergency dentist dispatch line. The dispatcher told me about a dentist who could make an urgent appointment for me when their office opened at 7 AM. I felt like I needed to be under medical supervision right away, so at 3:37 AM, I took a Lyft to the ER at , where I was observed and given an IV. I was discharged at 6:45 AM, and caught a Lyft home at 6:51 AM. My husband returned from work at 8:15 AM. He took me to my emergency dental appointment at 10 AM, where the dentist gave me multiple novocaine shots, straightened my two loose teeth and wired all my front teeth together to stabilize the front tooth that had been knocked out. It is unclear at this time whether my natural tooth will be able to be saved. |

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| 1142200 | 3/28/2021 | KS | 35 | M | 3/26/2021 | 3/27/2021 | Vaccination at 11:15am. Onset of soreness / flu-like symptoms around 9pm. Patient awoke around 3am to use the bathroom and fainted (lost consciousness and collapsed) on the floor. Patient's wife tried to help patient back into bed, once patient was standing patient lost all muscle control and experienced muscular spasms in legs (possibly arms). Patient's wife laid patient flat on floor; patient's eyes rolled into back of head. Patient was unresponsive for approx 1 minute, by the time wife retrieved phone to call for help, patient was again responsive and displayed extreme flu-like symptoms (severe shaking, sweating, and thirst). Patient remained laying on ground for 10 minutes before being able to sit and return to bed. |
| 1141778 | 3/28/2021 | CA | 32 | M | 3/28/2021 | 3/28/2021 | Soon after vaccination patient felt very light headed. No Syncope. States always feels like this with needles. |
| 1141688 | 3/28/2021 | CA | 69 | F | 2/25/2021 | 3/5/2021 | I initially had 2 days or so of feeling very ill. Then ok for 5 days. Then second round of reaction started. Intense pain and swelling of right side of neck for 3 days. Also left wrist unable to use. Pale, ill. Vital signs ok. Then on 3/8, pain switched to left side of neck and upper back. 3/10, right neck again with swollen lymph nodes bilateral. 3/11 back of neck and upper back hurts. Intense. Could not sleep. 3/12 pain in upper quads and hips, mid pack. Feeling freezing cold. Temp ok. Called my Dr. Right side of neck continued to hurts even now (3/28/2021) but at least I can function now. I no longer feel sick, brain fog, cold. So greatly improved but not normal. Reaction has lasted a month. Vaccine number one resulted in 2 days feeling ill with upper back pain, chills but only a few days. First night vomited, passed out. First vaccine reaction was frightening but was short lived. I am a retired RN. |
| 1142574 | 3/28/2021 | IN | 43 | F | 3/26/2021 | 3/27/2021 | Headache, hot flashes, passed out several times, very thirsty |
| 1142114 | 3/28/2021 | WY | 57 | F | 3/27/2021 | 3/27/2021 | Syncope of unknown cause in the evening after receiving Moderna vaccine in the morning . Event resulted in endotracheal intubation and hospitalization. Patient also has co-morbidity of COPD. |

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| 1142113 | 3/28/2021 | MI | 20 | F | 3/28/2021 | 3/28/2021 | immediately felt dizziness and syncope, observed for 30 minutes and recovered, no issues |
| 1141985 | 3/28/2021 | CA | 42 | M | 3/28/2021 | 3/28/2021 | Patient received the vaccination and after he got up from the chair, he passed out and fell to the floor. The intern notified the pharmacist. When I went to see that patient, he was laying on the floor with his eyes rolled in the back of his head and was unresponsive. He was not alert. He started having a mild seizure and I rolled him over on his left side. While I was bracing the patient, pharmacist came in and administered an Epi-pen to his left thigh. Patient stopped seizing so I rolled him back on his back. He became alert and was able to provide me his name, DOB and what he was at the pharmacy for. I rested my hand under his head and monitored his pulse until the paramedics arrived |
| 1141858 | 3/28/2021 | IL | 73 | F | 3/4/2021 | 3/4/2021 | Moderna COVID-19 Vaccine EUA - after receiving the second dose of the moderna covid-19 vaccine, pt developed a red and warm to the touch face while being observed in the waiting area. Also, while being observed and these symptoms were noticed, pt fainted in the waiting area. She regained consciousness seconds later and we continued to monitor her for an additional 30 minutes. No other adverse events were noted, she declined additional assistance. |
| 1141820 | 3/28/2021 | MA | 40 | F | 3/26/2021 | 3/27/2021 | 12 hours after receiving the first dose, I woke in the night with extreme dizziness and subsequently fainted. I was unconscious for about 10 seconds. When I regained consciousness, I was violently ill with vomiting and diarrhea. I had chills and sweating, and extreme dizziness that felt like a hallucination. We called 911 and I was taken to the hospital in an ambulance and admitted to the hospital for treatment. |
| 1142163 | 3/28/2021 | NJ | 22 | F | 3/27/2021 | 3/27/2021 | Onset of symptoms occurred within a minute of having the vaccine administered. Symptoms included heart racing/palpitations, profuse sweating, sudden lack of vision and hearing, on the verge of fainting. |
| 1142287 | 3/28/2021 | AR | 63 | M | 3/28/2021 | 3/28/2021 | patient had syncope |

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| 1139620 | 3/27/2021 | IA | 73 | F | 2/24/2021 | 2/27/2021 | <p>Pfizer COVID-19 EUA Vaccine Pt received first COVID vaccine 2/25/21. Tested positive for COVID late February. Reported to ED 3/5/21 with near syncope. Patient was seen emergency department laying in bed. The patient had a noticeable scalp laceration to posterior parietal area. After being symptomatic with COVID-19 for a few days, the patient reports getting up at 5:00 a.m. to use the bathroom, feeling lightheaded, then ended up on the floor, she reports sitting on the floor and then hit her head at some point, but was not entirely sure of this timeline. She states she ended up moving to the living room when she noticed that her head was bleeding a lot and her fiance called 911. She reports a history of syncopal episode in 2001 when she had influenza and apparently the story was much the same as this time, but she actually lost consciousness in 2001. Admitted to observation. 3/7: 73-year-old female recent COVID-19 infection admitted on 03/05/2021 for an episode of syncope probably secondary to bradycardia versus volume depletion. Paramedic on arrival at home reported bradycardia with heart rate in the 30s but has been normal since admission. The CT angiogram of the chest done at the emergency room showed bilateral infiltrates compatible with recent COVID-19 infection. No PE. However patient has no respiratory symptoms and O2 saturation is perfectly normal. Urinalysis was suggestive of infection and subsequent culture was positive for E coli and it is pansensitive. She was admitted to hospital for overnight observation. She was commenced on IV Rocephin and azithromycin. The EP cardiologist was consulted and she recommended echocardiogram and it revealed mild global hypokinesis with LVEF of 45-50% but patient denied any prior history of cardiac problem. On re-evaluation this morning the vital signs remains normal. Patient has not had any episode of bradycardia since she presented to the emergency room. She will be discharged home follow up with the EP cardiologist for further evaluation. Patient does not need outpatient oral antibiotics as IV Rocephin for 3 days should be adequate for uncomplicated UTI.</p> |

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| 1139724 | 3/27/2021 | CO | 59 | F | 3/20/2021 | 3/20/2021 | Within 10 minutes of the vaccine patient experienced a "near syncope" episode and was noted to have some twitching when EMS arrived to the car. Patient states she felt dizzy, denies shortness of breath, denies chest pain, no rash, no swekking |
| 1139779 | 3/27/2021 | FL | | U | | | Acute diastolic congestive heart failure, Accelerated hypertension, Acute injury to kidney, Hypomagnesemia, Hyperkalemia, Syncope and collapse |
| 1139845 | 3/27/2021 | NJ | | M | 3/8/1989 | 3/8/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient fainted forward after receiving vaccine from seated position. patient recovered within 30 seconds but did chip front teeth, had patient sit for additional 30 minutes for observation. got an emergency visit to dentist for repair. Follow up call indicated patient felt fine though tired at home |
| 1139904 | 3/27/2021 | IL | 19 | F | 3/24/2021 | 3/24/2021 | Pt reports of syncope (fainting) twice immediately after receiving the vaccine. First one occurred within a minute of receiving and second one occurred five minutes later according to patient and mother of patient who accompanied the patient. Patient reports that the facility called for paramedics whom found the patient to be in stable condition. Patient reports that paramedics informed that her BP and blood glucose levels were in normal range. Patient expressed of having anxiety about the vaccination and having nauseous feeling just before administration and "imagining the needing going into the muscle" as she was receiving the vaccine. Patient was assessed in the office roughly 2 hours post vaccine. Patient's history is clear of any diagnosis and patient was not on any medication. Patient stated that she feel well. Pt. is diagnosed of having vasovagal syncope and was educated to monitor and report any other symptoms. Need for blood work or lab assessment was discussed. |
| 1139934 | 3/27/2021 | SD | 22 | F | 3/27/2021 | 3/27/2021 | Patient has hx of syncope. Patient was lightheaded and dizzy HR 42. Epi given. Vasovagal likely. Called EMS however patient refused. |

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| 1139937 | 3/27/2021 | CO | 18 | F | 3/25/2021 | 3/25/2021 | About two hours after getting vaccinated, Patient had her first ever migraine and the pain was so intense she passed out. Paramedics transported her to ED where she had altered consciousness for about another 4 hours. |
| 1139968 | 3/27/2021 | TN | 24 | F | 3/27/2021 | 3/27/2021 | PATIENT CAME IN ALERT AND ORIENTED. STATED HAD A REACTION IN PAST TO VACCINES AND HAS FAINTED. PREVIOUS VACCINE FOR GOING OUT OF COUNTRY. PATIENT AGREED ALONG WITH MOTHER TO GET VACCINE TODAY. PATIENT RECEIVED VACCINE WITH NO INCIDENT. WE HAD HER SIT THERE AND SHE STARTED FEELING FAINT. SECOND VACCINATOR ALSO NEXT TO PATIENT. PATIENT DID FAINT AND SEEMS TO HAVE A SMALL SEIZURE AS HAD INVOLUNTARY ARM MOVEMENT AND HAD LOST CONSCIOUSNESS. PATIENT BECAME ALERT IN ORIENTED WITHIN 30 SECONDS. PATIENT STATED FELT BETTER BUT CALLED 911 FOR THEM TO COME ACCESS HER. MOM CALLED INTO ROOM AND STATED THIS INCIDENT HAD OCCURRED BEFORE. FIRE DEPARTMENT (EMS) IN STORE AND RESPONDED ALMOST IMMEDIATELY. PATIENT WAS ON FLOOR AT THIS TIME BY DIRECTIONS OF PHARMACY STAFF WITH FEET ELEVATED. BREATHING NORMAL, ALERT AND ORIENTED BUT APPEARS PALE (MOM STATES NORMAL SKIN COLOR). PATIENT ASSESSED BY EMS AND BLOOD PRESSURE LOW. PATIENT AGREED TO GO GET CHECKED OUT BY HOSPITAL DUE TO LOW BLOOD PRESSURE, PALE. LEFT WITH EMS STAFF. |

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| 1139211 | 3/27/2021 | CA | 31 | F | 3/26/2021 | 3/26/2021 | On Friday, March 26, 2021 client 31 years old female received her second dose of Pfizer COVID vaccine (LOT # ER 8732, EXP 7/2021) at approximately 2:38pm by vaccinator. After vaccine was administered, client complaint of dizziness and brief seizure seating at the vaccination chair in an upright position. Vaccinator lead registered nurse clinician lead, came to assist vaccinator with client's care. (EMT) assumed care of client. Per EMT prior to onset of syncope and brief seizure, patient was alert and oriented to person, time, place, and situation with Glasgow Coma Scale score of 15 (responsive) with all airway, breathing and circulation intact. Client told EMTshe has no prior medical history or reported allergies and had no issues with first Pfizer vaccination on 3.3.21 with Lot #:EN6199.. EMT placed patient on the ground into a recovery position and assessed vitals first time at 2:43 PM: BP 86/60, P 70, R 18. Patient's vitals assessed the second time at 2:48 PM until paramedics arrived: BP 80/66, P 71, R 18. Client remained stable and paramedics arrived at 2:49 PM and they placed client in a supine position on a gurney before transported client to the hospital. No further interventions indicated. |
| 1139988 | 3/27/2021 | CA | 34 | F | 3/27/2021 | 3/27/2021 | dizziness after 2 minutes, then passed out < 1 minute, then regained consciousness and stability. |
| 1139950 | 3/27/2021 | MO | 21 | M | 3/27/2021 | 3/27/2021 | Patient reported feeling dizzy. Patient was sitting in chair and fainted approximately 5 minutes after receiving the vaccine. Patient was unresponsive for about 30 seconds. Patient was not injured from fainting (This writer was able to catch him and guide him to the ground). Patient remained in pharmacy for about 45 minutes. Patient was given water, a cold compress, and candy (Patient felt that his blood sugar was low and requested candy). Patient left feeling well. |
| 1139414 | 3/27/2021 | MI | 66 | F | 3/17/2021 | 3/18/2021 | Had expected body aches and chills during the night. Very lightheaded when I got up and some nausea. Thought to ?sit down before you fall down? then ?came to? next to toilet. Head resting on toilet seat. Had some bruising on cheek but don?t remember going to floor. Rest of day was okay with just the most common side effects. Never fainted before but not uncommon for me to be lightheaded with nausea. Most embarrassing...passed some stool. |

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| 1139317 | 3/27/2021 | OR | 42 | F | 3/26/2021 | 3/26/2021 | Site: Pain at Injection Site-Medium, Systemic: Allergic: Difficulty Breathing-Mild, Systemic: Dizziness / Lightheadness-Severe, Systemic: Exhaustion / Lethargy-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Nausea-Medium, Systemic: Shakiness-Mild, Additional Details: Patient had a few seconds of syncope after patient came back to consciousness she experienced difficulty breathing that was alleviated by taking off her mask. She was lighted head ed and nauseous while 911 came |
| 1139293 | 3/27/2021 | OR | 30 | M | 3/26/2021 | 3/26/2021 | Systemic: Fainting / Unresponsive-Mild |
| 1139291 | 3/27/2021 | MI | 43 | F | 3/26/2021 | 3/26/2021 | Systemic: Exhaustion / Lethargy-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Hypotension-Severe, Systemic: Weakness-Medium, Additional Details: Patient became unresponsive. We gave cold compress to help with this. Blood pressure was 76/46. This happened at 10:57 am. We ask if patient was a diabetic she said no. Follow up phone call was completed around 4:30pm but no response. VM was left for patient to call back with update. |
| 1139290 | 3/27/2021 | NC | 36 | F | 3/25/2021 | 3/25/2021 | Systemic: Chills-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Visual Changes/Disturbances-Mild, Systemic: Weakness-Mild |
| 1139274 | 3/27/2021 | MA | 20 | M | 3/26/2021 | 3/26/2021 | Systemic: Fainting / Unresponsive-Mild |
| 1140000 | 3/27/2021 | PA | 17 | F | 3/27/2021 | 3/27/2021 | Anxious with injections, felt lightheaded, then near syncope, placed to floor by staff with recovery, BP 80/50 in OBS- felt better, BP 84/54 at time of discharge and normal condition |
| 1139226 | 3/27/2021 | UT | 64 | F | 3/25/2021 | 3/26/2021 | Fainted approximately 22 hours after vaccination, head knocked a dent into wall, no treatment sought |
| 1139494 | 3/27/2021 | GA | 38 | F | 3/26/2021 | 3/26/2021 | Dizziness and syncope 10 hours following vaccination |

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| 1139203 | 3/27/2021 | NY | 68 | M | 3/23/2021 | 3/23/2021 | Upon my return home, I felt very dizzy, weak, nearly fainted, where a sensation ran through the left side of the body. I then was assisted to the bed, where my left arm and left leg felt numb. I rested assuming this would fade away, being I has some numbness from the 1st vaccine. On 3/24/21, as I attempted to get up from the bed, I could not maintain my balance and gait. The numbness was still in my entire left arm and entire left leg, yet I was able to raise move and wiggle my limbs, toes, fingers to a degree. |
| 1139183 | 3/27/2021 | CA | 16 | F | 3/25/2021 | 3/25/2021 | Syncope, dizziness. BPs 92/54 (pulse 75), 105/60 (pulse 82). O2 sat 100%. |
| 1139273 | 3/27/2021 | CA | 25 | M | 3/25/2021 | 3/25/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Seizure-Mild, Systemic: Shakiness-Mild, Additional Details: pt came in for his first covid shot. checked pt health status pt was fine. while pt was at the observation seat his head went back and he started to have minor sshakiness/seizure like/faintness for about 5 sec. paramedic came and pt refused the pramedic he was checkout by paramedic and was responsive. pt then told us he had been fasting for 2 days and had marijuana on his injection day. pt went home and called his primary dr. and is doing well. |
| 1140912 | 3/27/2021 | | 29 | M | 3/27/2021 | 3/27/2021 | lightheaded, near syncope, sweating, HR = 45, BP 80s/50s, pt laid down, BP improved EKG showed sinus rhythm, symptoms improved with , pt declined juice/rest, ED recommended |
| 1139333 | 3/27/2021 | GA | 32 | M | 2/1/2021 | 2/1/2021 | syncope leading to head trauma and concussion followed by post-concussive syndrome |
| 1140003 | 3/27/2021 | TX | 35 | F | 3/24/2021 | 3/25/2021 | Woke up in middle of the night. Got up to take medicine. Became nauseous and fainted |
| 1140922 | 3/27/2021 | | 44 | M | 3/27/2021 | 3/27/2021 | lightheaded with fainting episode from seated position hitting head on ground, unconscious about 10 seconds, evaluated by EMS, recommended transport but refused |

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| 1140901 | 3/27/2021 | NV | 42 | M | 3/26/2021 | 3/27/2021 | Started was a very cramped stomach and then the rest followed. Whole body turned red including eyes. Upset stomach with vomiting and diarrhea. Body was shaking and didn't have a fever. Skin felt like it was burning whole body felt swollen. Started around 2:30am with the cramping. It woke me up. Once I got up everything came so fast. Was rushed to hospital where I was admitted very quickly. I was blacking out on the drive there and blacked out while in their care. This was from one dose of Pfizer vaccine for Covid. I was put on a GI, Allergy, and steroid medications. I was hooked up to an IV and 3 drugs were injected. I passed out numerous times but was discharged at 5am. |
| 1140767 | 3/27/2021 | NY | 28 | F | 3/27/2021 | 3/27/2021 | Pt was being obs starting 5:25pm, post J7J vax. After 15 min obs, at 5:40pm, she fell out of her chair and onto floor. Pt's eyes were closed, not responsive, not breathing, and stiff. Immediately 911 initiated, VS initiated, Pt was turned to Right side-lying position. Stimuli initiated (sternal rub, verbal communication). Pt opened eyes after 10 secs and started breathing. at 5:41pm/ Pt was able to answer all questions Alert & Oriented x4. Pt supine, ice packs applied to neck and chest. 5:42pm: 1st VS = BP 110/60, HR 58, RR 18, O2SAT 98%. 5:44pm: Pt vomited into trashcan, yellow emesis. Pt said that last time she ate was 3:30pm. 5:47pm: 2nd set VS = BP 115/60, HR 75, RR 18,, O2SAT 99% 5:50pm: Pt sitting upright position on floor. Pt said she "feels warm" 5:53pm: Fire dept arrived 5:55pm: EMS arrived. 3rd Set VS = BP 118/60, HR 88, RR 18, O2SAT 99%. Pt disclosed that she has "fainted once when I was little at a concert". 5:58p: Pt left ambulatory with EMS & her friend. |
| 1140712 | 3/27/2021 | IL | 52 | F | 3/25/2021 | 3/25/2021 | After 30 minutes of observation, patient started to leave and didn't feel good. Her face complexion turned white and said her chest started to get tight. Staff couldn't get a BP reading. Patient was lowered to the ground as she passed out. An Epi Pen was administered at 11:02am and she woke up immediately. Patient was slowly transferred her to a stretcher and monitored her vitals until EMS arrived at 11:20am. Patient refused to go to hospital after being observed by EMS and her husband came to pick her up. |

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| 1140706 | 3/27/2021 | TX | 22 | F | 3/27/2021 | 3/27/2021 | At 5:38;client had an episode of syncope, upon arrival she was pale,oriented. snacks and water was given,client claim she has not eaten since 10am this morning. Client was hypotension when vital sign was done. but after eaten color she started feeling better,vs stable. At 5:55pm. client was stable, was wheel out via wheelchair with ems to her car. |
| 1140473 | 3/27/2021 | OH | 39 | M | 3/27/2021 | 3/27/2021 | Two minutes after receiving his vaccination, he reported feeling lightheaded. He had a brief episode of syncope for proximately 20 seconds. He was taken to a private section of the arena in monitoring. His initial vitals showed |
| 1140454 | 3/27/2021 | HI | 71 | F | 3/16/2021 | 3/21/2021 | Moderna Lot #001B21A. Given 3/16/2021 Pain & bruising at site Within 5 days felt weird, low blood sugar, Headache Unwell, joint aches, pain, muscle pain, weak, Wednesday 24th during the night nauseated, vomited several times came in waves hot sweaty fainted for a few seconds x 2 March 27th still feel weak, joint pains fuzzy in the head, gradually getting better but not well yet. Yellow fading bruise at site. I emailed Dr to notify him just in case it was related to the vaccine |
| 1140423 | 3/27/2021 | | 28 | F | 3/27/2021 | 3/27/2021 | After adminstaration of vaccine, patient has fainted after 5 minute after administration. Paramedic came and took vitals signs and ekg. Patient symptoms subsided and she spoke to a behavioral health. As her smptoms dissipate she was release by the nurse. |
| 1140402 | 3/27/2021 | AZ | 26 | F | 3/27/2021 | 3/27/2021 | Patient fainted about 2 minutes after receiving the vaccine. Lost consciousness for approximately 30 to 60 seconds. Paramedics were called, they recommended she see a doctor due to hypotension. She walked out of the store with the paramedics under he own power. Prior to administration patient had reported a history of fainting after vaccines. |
| 1140255 | 3/27/2021 | MI | 22 | F | 3/27/2021 | 3/27/2021 | Patient had vasovagal syncope |

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| 1140090 | 3/27/2021 | OH | 19 | M | 3/27/2021 | 3/27/2021 | Seven minutes after getting his vaccination coming he felt lightheaded. He had a brief episode of syncope lasting less than one minute. He was taken to a private area and monitored. Initial but pressure was 80s/50s with HR in the 50s. 20 minutes monitoring showed that his blood pressure and heart rate normalized. CN II-XII intact and Neuro exam normal. |
| 1140401 | 3/27/2021 | MD | 24 | M | 3/27/2021 | 3/27/2021 | after 5-7 minutes after the administration of the vaccine, patient approached the counter to report that he had fainted between the isles. in doing so, he fainted for and fell down. regained consciousness immediately. but patient was very warm and clammy to the touch.. patient complained that his skin felt burning and his right knee was hurting. Patient was tended until 911 personnel arrived. |
| 1140226 | 3/27/2021 | NJ | 50 | M | 3/27/2021 | 3/27/2021 | Patient has a phobia of getting any kind of shots.. he passed out but still had a pulse.. we woke him up by yelling his name and his eyes fluttered and he was then able to talk and wanted water.. EMT came but patient denied services |
| 1140186 | 3/27/2021 | GA | 35 | M | 3/27/2021 | 3/27/2021 | Patient fainted after getting vaccination, bumped the car in front of him. Did not remember hitting the car. He was diaphoretic, clammy, palor in color, VSS but low, patient stated that he vagals with all shots. He was removed from his car and taken to the emergency tent. laid on a cot with his legs elevated. His vital signs were: 80/40, 49, 98%, 88/60, 56, 99%; 100/64, 78, 96%; 110/68, 64 98% Patient stated that he was feeling better, he runs a low blood pressure and frequently gets orthostatic hypotension. |
| 1140273 | 3/27/2021 | OH | 35 | F | 3/27/2021 | 3/27/2021 | Within a minute after receiving her vaccination, she initially felt lightheaded and had a brief episode of syncope the last approximately 30 seconds. She slumped in her chair, was caught and had no head trauma. She was taken to a private section of the arena and monitored. Her blood pressure and heart rate were within normal limits. |

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| 1140288 | 3/27/2021 | WI | 29 | F | 3/27/2021 | 3/27/2021 | AFTER 15 MINUTE OBSERVATION, PT WAS UNABLE TO WALK MORE THAN 10-15 FT BEFORE NEEDING TO SIT BACK DOWN AT WHICH TIME SHE SLOWLY SLID OFF THE CHAIR AND ONTO THE FLOOR (GUIDED BY HER FRIEND WHO ACCOMPANIED HER). SHE REMAINED LYING ON THE FLOOR UNTIL MEDICAL PERSONNEL ARRIVED. SHE APPEARED TO HAVE PASSED OUT, HAD VERY BRIEF CONVULSIONS/TREMORS BEFORE COMING TO, AT WHICH TIME SHE WAS ABLE TO RESPOND TO QUESTIONS AND ANSWER THEM. HER PULSE RATE SEEMED WITHIN NORMAL WITH SLIGHTLY ELEVATED RESPIRATORY RATE. MEDICAL PERSONNEL ASSISTED HER FROM THE FLOOR TO THE GURNEY. SHE WAS TAKEN TO THE AMBULANCE IN THE PARKING LOT FOR FURTHER EVALUATION. NO UPDATE ON HER STATUS WAS GIVEN TO US. |
| 1140363 | 3/27/2021 | NV | 24 | F | 3/26/2021 | 3/27/2021 | Convulsive syncope upon standing from supine position 22 hours post-dose, lasting 30 seconds. No loss of consciousness. |
| 1140364 | 3/27/2021 | CA | 19 | M | | 3/18/2021 | Felt light headed then passed out hit his head on cement floor. |
| 1140391 | 3/27/2021 | FL | 25 | F | 3/27/2021 | 3/27/2021 | 25 YO FEMALE WITH A SYNCOPE EPISODE A FEW SECONDS AFTER ADMINISTERING VACCINE PATIENT WAS ALERT AT ALL TIME WHILE I WAS TALKING TO HER AFTER EPISODE SHE VOMITING |

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1140394 | 3/27/2021 | AZ | 69 | F | 2/25/2021 | 3/24/2021 | <p>This is a 70 year old female with paroxysmal atrial fibrillation (anticoagulated on Eliquis), obstructive sleep apnea (uses CPAP), mitral valve regurgitation, remote tobacco use, hypertension and dyslipidemia who presents to the ED for worsening dyspnea, cough, subjective fever, chills and body aches that have been ongoing for the past several days. The patient indicates that her dyspnea is exacerbated with exertion but she denies chest pain, pleuritic chest pain, leg swelling or calf pain. She mentions that she has received both of her COVID-19 vaccines (Pfizer); the first immunization was on 02/25 followed by her second immunization which took place eight days ago on 03/18. She is not confident that she has had any contact with a known sick or definitive COVID-positive individual recently. Of note, the last documented incidence of testing for COVID-19 was performed on 10/31/2020 after the patient was seen at a Clinic after a exposure for a COVID-positive individual. Testing at that time had resulted negative. To her knowledge, she states that she had, in fact, tested positive for COVID-19 in late fall of 2020, but she was not hospitalized. Yesterday (3/26/2021), she was evaluated at a Pharmacy where she was testing for COVID-19 which has since resulted positive. The patient denies any other acute symptoms of illness. In the ED, the patient was found to have acute respiratory failure with hypoxemia and pneumonia due to SARS-CoV-2 infection. Review of Systems Constitutional: Positive for chills, fatigue and fever. Negative for activity change. Respiratory: Positive for cough and shortness of breath. Cardiovascular: Negative for chest pain and leg swelling. Gastrointestinal: Negative for abdominal pain, diarrhea, nausea and vomiting. Genitourinary: Negative for dysuria. Musculoskeletal: Positive for arthralgias and myalgias. Negative for gait problem. Neurological: Negative for syncope. All other systems reviewed and are negative. Vitals Blood pressure 159/79, pulse 65, temperature 36.4 °C (97.5 °F), temperature source Oral, resp. rate 18, height 1.6 m (5' 3"), weight 107 kg, SpO2 98 %. Physical Exam Vitals reviewed. Constitutional: General: She is awake. She is not in acute distress. Appearance: Normal appearance. She is well-developed. She is morbidly obese. She is ill-appearing. She is not toxic-appearing. Interventions: Nasal cannula in place. HENT: Head: Normocephalic</p> |

VAERS_ID RECVD STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| | | | | | | | and atraumatic. Nose: Congestion present. Mouth/Throat: Mouth: Mucous membranes are dry. Pharynx: Oropharynx is clear. Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Pulses: Normal pulses. Heart sounds: Normal heart sounds. Pulmonary: Effort: Pulmonary effort is normal. Breath sounds: Decreased breath sounds present. Comments: Diminished breath sounds in all lung fields. Occasional cough. Abdominal: General: Bowel sounds are normal. There is no distension. Palpations: Abdomen is soft. Tenderness: There is no abdominal tenderness. Musculoskeletal: General: Normal range of motion. Cervical back: Normal range of motion and neck supple. Skin: General: Skin is warm and dry. Neurological: General: No focal deficit present. Mental Status: She is alert and oriented to person, place, and time. Psychiatric: Behavior: Behavior is cooperative. |
| 1140111 | 3/27/2021 | OH | 35 | F | 3/27/2021 | 3/27/2021 | had syncope approx. 15 mins after injection - after pt aroused she was noted to right have facial droop, slurred speech, dysarthria, 2/5 strength to RLE, 4/5 strength to RUE. |
| 1137295 | 3/26/2021 | NY | 42 | M | 3/26/2021 | 3/26/2021 | Pt states he has a history of fainting after I.M. Injections. Pt states he is feeling faint and wants to lay down. Pt was moved to exam area. Pts vitals are stable. Pt states he?s feeling better and would like to leave. Pt didn?t require transport to hospital. |
| 1137238 | 3/26/2021 | TX | 37 | F | 3/25/2021 | 3/26/2021 | Severe arm pain, fever chills headache. Dizziness and fainting. |

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| 1137215 | 3/26/2021 | CA | | F | 1/12/2021 | 1/12/2021 | <p>passed out about 7 to 8 times; Pain on the right side of body; Dizziness; Felt like golf ball in right chest; Couldn't breathe; Nausea; Fever; Injection site redness; Outer part of the skin is bumpy; A spontaneous report was received from a consumer, a 46-year-old female patient, who was administered Moderna's COVID-19 vaccine (mRNA-1273) and experienced passed out about 7 to 8 times/loss of consciousness, pain on the right side of body/pain, dizziness, felt like golf ball in right chest/chest discomfort, couldn't breathe/dyspnea, nausea, fever/pyrexia, injection site redness/injection site erythema and outer part of the skin is bumpy/injection site reaction. The patient's medical history included was migraine. Product known to have been used by the patient, within two weeks prior to the event, included was ibuprofen for migraine. On 12 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (Lot number: 011J20A) intramuscularly in her left arm for prophylaxis of COVID-19 infection. On 12 Jan 2021, the patient experienced feeling a lot of pain on the right side of her body and the shot was given on her left arm. Fever, nauseous, supper dizzy, passed out about 7 to 8 times, felt like she got a golf ball in her right chest, red on the injection site, the outer part of the skin is all bumpy, couldn't breathe. Treatment for the events included were ibuprofen and diclofenac injection. The Action taken with the second dose of mRNA-1273 in response to the event was not reported. The outcome of the events, passed out about 7 to 8 times/loss of consciousness, pain on the right side of body/pain, dizziness, felt like golf ball in right chest/chest discomfort, couldn't breathe/dyspnea, nausea, fever/pyrexia, injection site redness/injection site erythema and outer part of the skin is bumpy/injection site reaction were considered as unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested.</p> |

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| 1137083 | 3/26/2021 | | 69 | F | 3/23/2021 | 3/23/2021 | within 30 seconds of injection the following symptoms were experienced: flushing, headache (still experiencing), nausea, weakness, chills, tightness of throat--felt like it was closing, feelings of fainting, weakness, loss of appetite, diarrhea after 32 hours, joint pain |
| 1137034 | 3/26/2021 | IN | 41 | F | 3/23/2021 | 3/23/2021 | Chills, flue like symptoms, lightheadedness fainting/ passing out |
| 1137019 | 3/26/2021 | NY | 22 | M | 3/26/2021 | 3/26/2021 | Patient passed out and began seizing within 5 minutes of vaccine administration sitting down on chair. Tonic, clonic motions for 5 seconds. No foaming at the mouth. Patient was taken off chair, held on the ground until seizure ended. Patient gained consciousness after a minute. Given water, snacks, air and EMS was called. EMS assessed situation, and allowed patient's girlfriend to pick him up from site and drive back home. |
| 1136933 | 3/26/2021 | MI | 69 | M | 3/19/2021 | 3/19/2021 | Patient received the second dose of Moderna COVID vaccine, within a few minutes of receiving, patient passed out for approximately 90 seconds. Patient then stated that he has had this happen in the past as a vasovagal response, which he did not explain prior to receiving the vaccine. He states he has a history of syncopal episodes associated with needles since he was a teenager. |
| 1137648 | 3/26/2021 | OH | 29 | F | 3/26/2021 | 3/26/2021 | Syncope Nausea Sweating |
| 1137826 | 3/26/2021 | OH | 22 | M | 3/26/2021 | 3/26/2021 | Patient fainted and fell to the ground from a sitting position. Pharmacist instructed family member to call 911 as patient's eyes were open at time of lost consciousness. After about 10 seconds patient regained full consciousness and was able to sit up and drink water. EMS arrived to assess patient's vital signs and reported no issues except patient had somewhat low blood sugar. EMS instructed patient to stay hydrated, rest, and eat. |

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| 1135699 | 3/26/2021 | NY | 45 | M | 1/14/2021 | 1/15/2021 | A spontaneous report was received from a Consumer concerning himself, a 45-years-old male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced uncontrollable extreme abdominal pain/abdominal pain, cold sweats/cold sweat and passed out/loss of consciousness. The patient's medical history was not provided. No relevant concomitant medications were reported. On 14 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot batch: 013L20A) in his left upper arm for prophylaxis of COVID-19 infection. On 15 Jan 2021, the patient experienced uncontrollable extreme abdominal pain, and passed out. He also had cold sweats. Lab data was not provided. No treatment was taken, just rehydrated. Action taken with mRNA-1273 in response to the events was unknown. The outcome of events -uncontrollable extreme abdominal pain, cold sweat and passed out so badly was considered resolved within 24 hours on 16 Jan 2021.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the onset date of the reported events, a causal relationship cannot be excluded. |
| 1137354 | 3/26/2021 | FL | 68 | M | 3/3/2021 | 3/3/2021 | 3 minute span, 7 minutes into 15 minute post vaccine wait... BP dropped to 68/57.. pale, dry, blue lips... visual disturbance... nausea, dry heaves, dizzy, close to fainting... left side of body has more color than right side.... BP returned to 100/71 within 2 minutes... coherent throughout |

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| 1137390 | 3/26/2021 | MO | 20 | F | 3/26/2021 | 3/26/2021 | Pt received COVID-19 vaccine at 9:57am. Pt went to waiting area in front of pharmacy and sat down. Pt was on her phone when she said she felt like she started dreaming. Her friend said her eyes rolled back and she threw her phone on the floor at 10:02am. When I got to the patient a customer (nurse) was already assisting the patient. EMS and Code White were called at 10:03am. Pt was awake and aware of what was going on. She said she had no history of fainting or seizures. She did say that she normally had a lower blood pressure. Pt was sitting up but laid back down at 10:05am saying that she was having vision issues and feeling dizzy. BP was 112/70 and HR 75 at 10:10am. EMS arrived at 10:12am and took over. BP was still low at that time. Pt denied going to the hospital and EMS left at 10:20am. Pt stayed with friends until 10:40am. Pt left the store with 3 friends who had also received vaccine. |
| 1137397 | 3/26/2021 | NH | 32 | F | 3/25/2021 | 3/25/2021 | Vasovagal within 2 minutes. Sweats blurred vision almost syncope. Numbness and tingling in arms lasting 10 minutes. |
| 1137813 | 3/26/2021 | CA | 21 | M | 3/26/2021 | 3/26/2021 | pt experienced syncope post injection, reported that he could not hear or speak for a moment. Benadryl and EpiPen were present, but pharmacist on site performed blood pressure reading, and did not believe it was anaphylaxis. Paramedics arrived and patient tried to refuse medical care, but paramedics convinced patient to go with them to the ambulance so that they can monitor blood pressure, heart, and blood glucose. |
| 1137517 | 3/26/2021 | IL | 32 | F | 3/26/2021 | 3/26/2021 | syncope after 1st dose COVID-19 vaccine laid pt down 1108: BP88/56, HR64, SpO2 97% 1109: BP94/62, HR72, SpO2 98% 1111: HR78, SpO2 97% 1112: BP90/74, HR68, SpO2 97% 1116: BP102/78, HR80, SpO2 96% 1120: BP104/76, HR74, SpO2 96% |
| 1137650 | 3/26/2021 | NC | 34 | M | 3/25/2021 | 3/25/2021 | Patient was given vaccine: about 3-5 minutes later patient came to pharmacist stating he felt lightheaded . within seconds patients fell to ground (passed out) . Pharmacist/ Technician ran to patient, called EMS . Patient left with EMS |

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| 1137755 | 3/26/2021 | TX | 28 | M | 3/26/2021 | 3/26/2021 | 1257 as patient drove off from vaccine bay, mom reports he?s started fainting and she pulled over so he would not crash. As we arrived to the vehicleA patient was Faint and lethargic but responsive. Patient mom reports patient always faints whenever he gets a shot. 1:01 911 called 1:02 Dr. arrived, blood pressure 121 systolic 1:06 fire Dept. arrived blood pressure 126/78 , 99% on room air 12 lead normal sinus rhythm. Patient and his parents feel going to the hospital will cause more anxiety. 1:28 patient went home wiener his parents. Mom driving his car 1:26 |
| 1137784 | 3/26/2021 | CO | 74 | F | 2/2/2021 | 2/4/2021 | Patient is a lovely 74-year-old female with a long history of PACs and hypertension. Her blood pressure has been getting a little bit worse over the past years. She was admitted through the ER with 1st known episode of atrial fibrillation and hypertension. She reports that on 02/02 she received her 2nd COVID vaccine. She had joint achiness and a low-grade temperature. She rested the following day but then on 02/04 went for her usual hour long runs/hike. She did not feel very well during exercise and started have a headache and some increasing palpitations. Later that evening she was watching TV and started to have significant tachycardia that was irregular. Symptoms persisted and she presented to the ER which sound to be in AFib with rapid ventricular response with a blood pressure of 215/158. She was started on a diltiazem drip and has converted to sinus rhythm with PACs. Blood pressure has improved significantly. Troponin negative x2. Her last evaluation at a Heart facility was in 2017. She had an echocardiogram in 2014 with normal EF, mild MR and mild TR with normal estimated PA systolic pressure. She denies chest pain or dyspnea. No history of syncope. Sometimes with palpitation she does get lightheaded. She gets occasional lower extremity edema that seems dependent in nature. She is still having palpitations but recognizes that she is no longer in atrial fibrillation as that was more severe in terms of symptoms of tachycardia. |
| 1136889 | 3/26/2021 | | 61 | F | 3/25/2021 | 3/25/2021 | syncope, n/v |
| 1136408 | 3/26/2021 | TX | 39 | M | 3/25/2021 | 3/25/2021 | Systemic: Fainting / Unresponsive-Mild |

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| 1137458 | 3/26/2021 | CA | 23 | F | 3/25/2021 | 3/25/2021 | At approximately 0943 patient reported feeling faint, starting to lose vision, and nausea. Lead nurse was notified and patient was assisted into anti-gravity chair. Patient assessed. Pallor noted and patient reported feeling hot and stated "I'm going to throw up". Patient given emesis bag at approx. 0944. Patient reported feeling better. Patient given water. patient denied rashes, hives, and throat irritation. Patient reported feeling scared of needles and no history of fainting after prior vaccinations. Vitals assessed at 0946: BP 90/75 mmHg, SpO2 99% RA, PR 75 bpm. Pt advised to stay for 30 mins for further observation. Vitals reassessed at 1004: BP 100/80 mmHg, SpO2 99% RA, PR 56 BPM. Vitals reassessed at 1020: BP 80/50 mmHg, SpO2 99% RA, PR 60 BPM. Pt advised to wait 20 mins due to drop in BP. Vitals reassessed at 1040: BP 100/80mmHg, SpO2 99%, PR 65 BPM. Patient denied throat irritation and stated she was feeling better. Patient advised to sign up on CDC- V-safe. Pt left facility at approx. 1045 with steady gait and unlabored breathing. |
| 1136429 | 3/26/2021 | TX | 52 | M | 3/25/2021 | 3/25/2021 | Systemic: Chills-Mild, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: profuse sweating, lose of sight left eye, dizziness, nausea-Severe, Systemic: Nausea-Mild, Systemic: Shakiness-Medium, Systemic: Visual Changes/Disturbances-Severe, Additional Details: Patient began to feel better about 5 minutes after epinephrine was administered. EMS was called but did not transport. |
| 1136963 | 3/26/2021 | MA | 20 | F | 3/24/2021 | 3/24/2021 | Patient received the vaccine and was walked to the observation area. She was on the phone with her mother when she said she was feeling faint and proceeded to faint. Woke almost immediately, no injuries. Said had a history of fainting once awake. EMS onsite took glucose which as 110. |

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| 1135715 | 3/26/2021 | FL | 80 | M | 2/5/2021 | 3/11/2021 | <p>passed out; Golf ball sized knot from hitting head somehow, believes he passed out; Nauseous and sick; Dry heaves for 10-15 minutes; Nauseous and sick; A spontaneous report was received from a consumer concerning a 80-years-old male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced events of loss of consciousness, head injury, malaise, nauseous and retching, believes he passed out, dry heaves for 10-15 minutes, golf ball sized knot from hitting head. The patient's medical history was not provided. Concomitant medications reported were blood pressure meds for drug use for an unknown indication. On 5 Feb 2021, prior to the onset of the events the patient received first of two planned doses of mRNA-1273 (lot number: 031L20A) via unknown route for prophylaxis of COVID-19 infection. On 10 Mar 2021, prior to the onset of the events the patient received their second of two planned doses of mRNA-1273 (lot number: 011A21A) via unknown route for prophylaxis of COVID-19 infection. On 11 Mar 2021, the patient experienced the event(s) loss of consciousness, head injury, malaise, nauseous and retching, believes he passed out, dry heaves for 10-15 minutes, golf ball sized knot from hitting head. Treatment information was unknown. Action taken with mRNA-1273 in response to the events was not applicable. On 12 Mar 2021 the outcome of event(s), nauseous and sick, believes he passed out, dry heaves for 10-15 minutes, golf ball sized knot from hitting head was considered as recovered/resolved..; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p> |

| <u>VAERS_ID</u> | <u>RECVDATE</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1135722 | 3/26/2021 | NC | 73 | F | 2/26/2021 | 2/27/2021 | Dehydrated; Itchy; Long 4-inch rash, it was itchy; Fainted; sick, like she had a high fever; A spontaneous report was received from a consumer , who was a 73-year old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced fainting (syncope), sick like had a high fever (illness), long 4-inch rash (rash), itchy (pruritis), and dehydrated (dehydration). The patient's medical history was not provided. Concomitant product use was not provided by the reporter. On 29 Jan 2021, the patient received her first of the two planned vaccine doses of mRNA-1273 (Batch number: 012M20A) intramuscularly in the left deltoid for prophylaxis of COVID-19 infection. On 26 Feb 202, the patient received her second of the two planned vaccine doses of mRNA-1273 (Batch number: 014M20A), intramuscularly in the left deltoid for prophylaxis of COVID-19 infection. On 27 Feb 2021 the patient was sick, like she had a high fever.. Reportedly, her temperature was not taken. She was unable to eat or drink and she fainted. It was reported that she was not aware that she fainted until the next day when her husband told her. The following Monday, she was informed by the doctor that she was dehydrated. On 28 Feb 2021, the patient developed a long 4-inch rash, that was itchy, but resolved in a week. It was reported that this reoccurs every now and then and feels itchy. Treatment information was not provided. The patient received both scheduled doses of mRNA-1273; therefore, action taken with the drug in response to the events is not applicable. The outcome of the events, fainting, sick like had a high fever, long 4-inch rash, itchy, and dehydrated, were not reported.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |

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| 1135726 | 3/26/2021 | CA | 49 | F | 3/11/2021 | 3/11/2021 | fainted and collapsed for few seconds; husband mentions she was wide awake as ghost and unconscious at the same time; dizzy; fainted and collapsed for few seconds; disoriented; weak; intense chills; felt overwhelmingly nauseous; went to bed with throbbing injection site pain; stiff and sore arm; A spontaneous report was received from a consumer concerning a 49-year-old, female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced stiff and sore arm (musculoskeletal stiffness), went to bed with throbbing injection site pain (vaccination site pain), nauseous (nausea), disoriented, dizzy and weak (asthenia), then fainted (loss of consciousness) and collapsed (fall)for few seconds, and having intense chills (chills). The patient's medical history, was not provided. No Concomitant medications were reported . On 11 Mar 2021 prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: 003A21A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 11 Mar 2021, the patient felt stiff and sore arm, went to bed with throbbing injection site pain,. On 12 mar 2021, she had awakened around 1 AM and experienced overwhelmingly nauseous, disoriented, dizzy and weak. She then fainted, collapsed for few seconds, during that that time her husband mentioned that she was wide awake as ghost and unconscious at the same time. The patient also mentioned that she had intense chills. She also reported that she had no history of fainting and or reactions from any vaccine in the past. Treatment for the events included Ibuprofen.Action taken with mRNA-1273 in response to the events was not reported. The outcome for the events, experienced stiff and sore arm (musculoskeletal stiffness), went to bed with throbbing injection site pain (vaccination site pain), nauseous (nausea), disoriented, dizzy and weak (asthenia), then fainted (loss of consciousness) and collapsed (fall)for few seconds, and having intense chills (chills). were reported as unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded. |

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| 1135727 | 3/26/2021 | OH | 73 | M | 3/16/2021 | 3/16/2021 | Almost fainted; A spontaneous report was received from a Consumer concerning a 73-year-old, male patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced almost fainted. The patient's medical history, was not provided by the reporter. Concomitant use of the Products was not Provided by the reporter. On 16-Mar-2021 at 10:10 am, approximately eight hours prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 16-Mar-2021, after first dose of vaccine. At 6:00 pm, the patient almost fainted while having shower and was referred to HCP. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the event, almost fainted was unknown. The Causality between the event and the m-RNA-1273 Vaccine was not provided.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded. |
| 1136294 | 3/26/2021 | UT | 34 | M | 3/22/2021 | 3/24/2021 | Severe tremor and chills; near fainting; blood in urine and stool. |
| 1136399 | 3/26/2021 | MD | 38 | M | 3/25/2021 | 3/25/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Hypotension-Mild |
| 1136400 | 3/26/2021 | CA | 42 | M | 3/23/2021 | 3/23/2021 | Systemic: Fainting / Unresponsive-Medium, Additional Details: Patient indicated a severe phobia of needles, has had history of fainting when exposed to needles. RN on staff monitored bp, (was wnl) gave water, cool towels, and apple juice and was monitored for extra time before being taken home by family member |
| 1136411 | 3/26/2021 | TX | 41 | F | 3/25/2021 | 3/25/2021 | Site: Pain at Injection Site-Mild, Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Seizure-Mild |

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| 1136409 | 3/26/2021 | CA | 51 | M | 3/25/2021 | 3/25/2021 | Systemic: Fainting / Unresponsive-Medium, Additional Details: vax by RN, during pts 15 min wait, fainted to the floor, pt attended to, 911 was called, pt was responsive immediately after fainting, pt reported fainting post other vaccines or blood draws. paramedics evaluated pt, pt vitals were normal, pt decided not to go to hospital, followed up with patient at home and indicated he is doing well. |
| 1136880 | 3/26/2021 | | 23 | M | 3/25/2021 | 3/25/2021 | Syncope episode and hypotension. |
| 1136432 | 3/26/2021 | CT | 50 | F | 3/25/2021 | 3/25/2021 | Systemic: Vomiting-Medium, Additional Details: patient fainted while in triage...woke up and vomited. 911 called, emt's responded. unknown if patient was brought to hospital.. |
| 1136435 | 3/26/2021 | MN | 29 | M | 3/25/2021 | 3/25/2021 | Systemic: Fainting / Unresponsive-Medium, Additional Details: patient fainted after 10 minutes after the vaccination. He HAS ALWAYS fainted after ANY shots. Patient confirmed it himself. The nurse look after him for 5 minutes after the shot but the patient fainted after he walk for 2 minute to the staff member and fainted. We checked his blood pressure 5 times with blood pressure elevation 3 times. We checked his blood pressure until the blood pressure was normalize back to safety level. patient left the pharmacy after being counseled about dangerous sympt |
| 1136448 | 3/26/2021 | PA | 25 | M | 3/24/2021 | 3/24/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium |
| 1136460 | 3/26/2021 | MI | 46 | F | 3/24/2021 | 3/24/2021 | Sore arm, fever for 24 hours, reached 103. Passed out, nausea, head ache, loss of appetite |
| 1136470 | 3/26/2021 | | 91 | F | 12/30/2020 | 1/12/2021 | SYNCOPE, fall, head contusion FATIGUE DIARRHEA Pneumonia due to SARS-associated coronavirus Diverticulitis Hyponatremia Hypoxia Sepsis, due to unspecified organism, unspecified whether acute organ dysfunction present (CMS/HCC) |

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| 1136598 | 3/26/2021 | MO | 34 | M | 3/13/2021 | 3/13/2021 | started to faint & passed out; I was sweating; had the chills; A spontaneous report was received from a consumer concerning a 34-year-old, male patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced faint, passed out ,sweating,and chills.. The patient's medical history, was not provided. Concomitant medications was not reported. On 13 Mar 2021 prior to the onset of the events, the patient received his first of two planned doses of mRNA-1273 (Lot number: 040A21A) in the left arm for prophylaxis of COVID-19 infection. On 13 Mar 2021, prior to receiving mRNA-1273, the patient felt faint, passed out ,sweating,and chills.Treatment for the events was unknown. Action taken with mRNA-1273 in response to the events was not reported. The outcome of events, faint, passed out ,sweating,and chills, were considered resolved on 13 Mar 2021.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events,a causal relationship cannot be excluded. |
| 1136701 | 3/26/2021 | IN | 69 | F | 3/18/2021 | 3/20/2021 | Saturday Night, I felt nauseated and tried to eat a cracker. I was dizzy and almost passed out. Sunday and Monday, had no appetite, weak, No energy. Tuesday, felt fine. |
| 1136793 | 3/26/2021 | TX | 23 | F | 3/25/2021 | 3/25/2021 | Dizziness starting around 8:30 PM, fever from 10 PM to sometime after 3 AM, syncope x2 around 8:30 AM |
| 1136402 | 3/26/2021 | VA | 34 | F | 3/15/2021 | 3/16/2021 | Site: Itching at Injection Site-Medium, Site: Pain at Injection Site-Severe, Site: Redness at Injection Site-Severe, Site: Swelling at Injection Site-Severe, Systemic: Abdominal Pain-Medium, Systemic: Body Aches Generalized-Medium, Systemic: Chills-Medium, Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Severe, Systemic: Exhaustion / Lethargy-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Headache-Severe, Systemic: Lymph Node Swelling-Medium, Systemic: Nausea-Medium, Systemic: Unable to Sleep-Medium, Systemic: Visual Changes/Disturbances-Medium, Systemic: Vomiting-Medium, Systemic: Weakness-Medium |

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| 1138876 | 3/26/2021 | MA | 27 | F | 3/8/2021 | 3/8/2021 | While in waiting area after being given vaccine, felt tingly in head and over body within 3 minutes. Dizzy. Started getting black spots in vision/tunnel vision. Heart pounding and sweating. On verge of fainting. Drank some water and symptoms disappeared within 10 minutes. Did not lose conciousness |
| 1138535 | 3/26/2021 | CO | 54 | M | 3/26/2021 | 3/26/2021 | Light headed and dizzy, sweating, passed out briefly. 15 seconds. This was 45 minutes after getting injection. I did not have trouble breathing or swallowing. Very similar to what has happened to me sometimes getting blood drawn but happens at time of appointment not after. Reclined, deep breaths and started to feel better within 10 minutes. An hour later feeling much better. |
| 1138545 | 3/26/2021 | CA | 33 | F | 3/25/2021 | 3/25/2021 | One hour after vaccination my chest tightened and I started losing vision. I was driving and pulled to the side of the road, felt I needed to pay down and opened the car door and passed out on the pavement. After regaining consciousness I got in the car and felt a second wave coming , called 911 |
| 1138556 | 3/26/2021 | VA | 73 | F | 3/26/2021 | 3/26/2021 | Patient fainted, coming in and out of consciousness, complained that she feels cold |
| 1138645 | 3/26/2021 | KY | 55 | M | 3/26/2021 | 3/26/2021 | PATIENT HAD VASO SYNCOPE. HE HAD TINKLE IN LEFT HAND. HE WAS ASKED TO SIT FOR 30 MINUTES VS. 15 MINUTES FOR EXTRA OBSERVATION. HE SAID HE WAS FEELING LIGHT HEADED AND SWEATING. AS I WAS WALKING OVER FOR THE 3RD TIME TO CHECK ON HIM I WAS GOING TO ASK HIM TO PUT HIS HEAD IN BETWEEN HIS LEGS HE STARTED TO SLIDE OUT OF CHAIR. WE CALLED 911. WHEN HE CAME TO HE SAID HE PASSES OUT EVERY TIME BLOOD IS TAKEN, AND HE THINKS IT WAS DUE TO THIS ANXIETY. |
| 1138694 | 3/26/2021 | TX | 67 | M | 3/4/2021 | 3/5/2021 | 24 hrs after vaccine, oxygen level went down in the 80 and passed out. Recouperated and was fine afterwards. Weakness lasted approx 30 mins. No medical attention needed. |
| 1138705 | 3/26/2021 | FL | 20 | F | 3/26/2021 | 3/26/2021 | nausea, blurred vision, dizzy, almost fainted. paramedics were called and pt was diagnosed as dehydrated and low blood sugar |

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| 1138710 | 3/26/2021 | NM | 27 | M | 3/25/2021 | 3/25/2021 | Low blood pressure, syncope |
| 1138713 | 3/26/2021 | TX | 38 | M | 3/26/2021 | 3/26/2021 | lightheadness and passed out for seconds |
| 1138515 | 3/26/2021 | | 45 | M | 3/26/2021 | 3/26/2021 | After vaccine vaccination, patient has vasovagal syncope. Patient states swelling of tongue, blurry vision, nauseous hands tingling, dizzy and lightheaded. Called code green, paramedics arrived. Laid patient down flat down on cot. Patient is stable. BP 106/67 98% o2sat HR 65 RR 16 |
| 1136905 | 3/26/2021 | VA | 23 | F | 3/26/2021 | 3/26/2021 | Patient reported no to having prior history of fainting or dizziness after receiving vaccine. Vaccine was administered at approximately 9:04 am and patient's boyfriend was administered at approximately 9:08. Upon return to his seat beside her at approximately 9:10 am, he noticed she was losing color and going limp. He called for help, and I assisted. The pharmacy team sent a Code White on the radio and several members of management responded to check on the scene. We moved the patient to the floor and applied ice packs to the neck and chest and removed her face mask for better circulation. The patient was wearing a thick sweatshirt so we attempted to increase air flow around her head and neck to cool her down as she was visibly sweating. The patient never lost consciousness or breathing and her pulse was always palpable. By 9:20 am, we had moved the patient from the floor to a sitting position then to a chair and provided her with a cold bottle of water and continued one ice pack on her neck. She stayed seated until 9:40 (34 minutes after her injection). She denied the need for an ambulance transport as she had her boyfriend here who could drive her. |
| 1138783 | 3/26/2021 | AZ | 32 | M | 3/26/2021 | 3/26/2021 | Pt had syncope episode while waiting in observation area. Pt fell out of his chair and hit face on outer corner of right eye causing a skin abrasion. Suffered a small abrasion to outer aspect of his right wrist. |
| 1138908 | 3/26/2021 | TN | 35 | F | 3/25/2021 | 3/26/2021 | Severe dizziness leading to almost fainting, nausea, diarrhea, feeling like ice was flowing through veins while severely sweating, rushing noise in ears, difficulty standing without feeling faint. Lasted for about 30 minutes before being able to fall back asleep. |

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| 1138970 | 3/26/2021 | SC | 19 | F | 3/26/2021 | 3/26/2021 | Medical staff administered the vaccination and turned to put the needle in the sharps container, then patient passed out from a seated position to her knees then flat on the floor. Medical staff came to get the pharmacist on duty. We straightened her out and checked to make sure she was still breathing - she was still breathing. I went to call 911 and came back in the room with the phone while I was directed to do a breathing test by the operator. Patient was moaning off and on during the time she was passed out. She was not responding to verbal commands. She came to as the paramedics arrived. They took her to the hospital. |
| 1138972 | 3/26/2021 | GA | 57 | F | 3/19/2021 | 3/19/2021 | Blood pressure and heart rate increased to 163/100 and heart rate was 105. I almost passed out and was very dizzy and disoriented. Fatigue for 7 days and heart rate is still elevated. Also experienced green bulging veins in hands and feet. |
| 1139008 | 3/26/2021 | MN | 65 | F | 3/25/2021 | 3/26/2021 | Chills, fatigue, fainting. Cut head during fainting episode on 3/26 which required urgent care to close the wound with staples. |
| 1139032 | 3/26/2021 | IL | 42 | F | 3/25/2021 | 3/26/2021 | Fainted after getting up to use the restroom in the middle of the night. Fainting resulted in injury to my chin and head. Had to get 7 stitches in chin from falling into dresser. I have no memory of falling. Only remember using restroom and be woken up from the floor by my husband. |
| 1139052 | 3/26/2021 | GA | 64 | M | 3/26/2021 | 3/26/2021 | patient was anxious before the vaccination. after vaccination, he wanted walk around then sit. he sat on the floor and was stating that he had a phobia to needles/shots. he passed out briefly and came to shortly afterwards. 911 called, very low bp. patient and wife were moved to ambulance where patient eventually felt better and was able to walk. patient and wife did not want to go to hospital. we called him later to check on patient, he said he was feeling much better. |

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| 1139117 | 3/26/2021 | OK | 29 | M | 3/16/2021 | 3/18/2021 | I felt soreness and pressure build up in my arm starting a few hours after the receiving the dose. The soreness and pressure got progressively worse over the course of two days. It wasn't unbearable, just uncomfortable. The second day after the vaccine I had stretched my arm pretty good for minute, when I released the stretch I felt a rush of something for from my arm into my torso. I got really dizzy and passed out, my wife was in the room at the time and said I never closed my eyes; but I had completely blacked out. My wife had woken me up and I wasn't sure what had happened, it took me about 30 seconds to realize I had passed out after stretching that arm. My arm had felt better after waking up from passing out, and soreness had passed a couple days later. I didn't get checked out, after I woke up I started feeling fine. I'm honestly not sure if it's directly related to the vaccine or not, I just thought I should let someone know just in case. |
| 1139143 | 3/26/2021 | CA | 42 | F | 3/21/2021 | 3/22/2021 | I am 5 days out from the 2nd dose. I had to make an urgent care visit because of shortness of breath, blurred vision, light headedness, brain fog, nausea, fatigue, feeling of fainting and tightness in throat. These symptoms have been present and overwhelming for over 3 days presented themselves after day 2 of vaccine. The original symptoms of headache, body aches and chills subsided by day 3. |
| 1137871 | 3/26/2021 | IN | 67 | M | 3/24/2021 | 3/25/2021 | Extreme Flu-like symptoms. Massive headache, nausea, muscle aches. Coincidentally, happened to have a previously scheduled blood draw for the next day at my doctor, listed previously. I got extremely nauseous, began sweating profusely and passed out right after the draw (have never had a blood draw reaction). 56 hrs since my shot and I still feel poorly, but better. |

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| 1138745 | 3/26/2021 | AZ | 64 | F | 3/24/2021 | 3/24/2021 | Pain/pressure at injection. Within 2 min. Passed out for 5 to 10 seconds then tingling of arms/hands and legs. Sweating head and neck. Cramping of both hands, unable to move fingers lasting 2 to 4 minutes. Burped almost throwing up twice. Possible rapid heartbeat causing rapid breathing. Was asked to and did stay 30 to 45 minutes. Was better within 10 minutes of injection. At home experienced being very cold some mild soreness of arm. Temperature of 96 at 3:15 pm. Temp back to normal next day. |
| 1138074 | 3/26/2021 | MD | 24 | M | 3/26/2021 | 3/26/2021 | customer passed out and or had seizure and EMS was called. customer is alert and fine now. |
| 1137878 | 3/26/2021 | TX | 56 | M | 3/26/2021 | 3/26/2021 | Syncope lasting 2 minutes |
| 1138901 | 3/26/2021 | OH | 32 | M | 3/26/2021 | 3/26/2021 | A few minutes after the vaccine was administered the patient felt hot, lightheaded, dizzy and had to sit down. While sitting down his eye rolled back and he passed out. His spouse said his body was shaking. She lowered him to the floor and he awoke. Paramedics were called and determined his blood pressure was very low. They tried to stand the patient up to take another blood pressure reading, but the patient had to sit down as he became dizzy and lightheaded again. The paramedics took him to the ER where the doctor said he was fine and discharged him. |
| 1138508 | 3/26/2021 | CA | 32 | M | 3/26/2021 | 3/26/2021 | Patient received the first covid19 Pfizer biontech immunization and 15 minutes later reported to the pharmacist that they felt nauseous and dizzy. Pharmacist instructed patient to sit down on the ground and as they crouched down to do so, he passed out and his wife caught him and eased him to the ground. Patient then regained consciousness in less than 30 seconds and remained on the ground for 15 minutes with legs propped up. 911 was contacted and fire dept came to check patient's vitals. Patient reported feeling a lot better after the wait period and vital signs were reported normal. Consultation was provided and patient instructed to follow up with primary MD, and patient went home. |

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| 1137887 | 3/26/2021 | | | F | | 2/1/2021 | <p>Passed out for around one minute and did not remember anything for that one minute; Her arm was very itchy; Passed out for around one minute and did not remember anything for that one minute; Feeling tired after vaccination; A spontaneous report was received from a consumer on 22 Feb 2021, with additional information received on 15 Mar 2021, concerning about a female patient of an unknown age, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced an adverse reaction including passed out for around one minute and did not remember anything for that one minute, Her arm was very itchy, and Feeling tired after vaccination. The patient's medical history was reported as the patient have allergy towards nuts, cats, dogs, dust and trees. Concomitant medications were not reported. On an unknown date in Feb 2021, prior to the onset of the events, the patient received their planned doses of mRNA-1273 (Batch number: unknown) via unknown route for the prophylaxis of COVID-19 infection. The patient experienced an adverse reaction including passed out for around one minute and did not remember anything for that one minute, Her arm was very itchy, and Feeling tired after vaccination. Treatment information was not provided. Action taken with mRNA-1273 in response to the events were not provided. The outcomes of the reported events remain unknown.; Reporter's Comments: Very limited information regarding the events has been provided at this time. Further information has been requested.</p> |
| 1137900 | 3/26/2021 | MA | 18 | F | 3/26/2021 | 3/26/2021 | <p>Pt was waiting in observation area after receiving her covid vaccine. PT began feeling dizzy and lightheaded. Pt fainted briefly and EMS responded immediately. Fire/Rescue immediately responded shortly after. Pt regained consciousness and was evaluated by EMS and Fire/Rescue. Pt stated she has this kind of medical episode every so often. Last episode was 3 months ago. Pt and EMS do not believe this was directly related to the Covid vaccine. Pts vital were stable and exited premises on her own. Pt had family waiting for her in the the parking lot.</p> |

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| 1137917 | 3/26/2021 | CT | 83 | F | 3/1/2021 | 3/1/2021 | felt groggy; sick to the stomach; passed out; felt very weak; cold sweat; shaky; A spontaneous report was received from a consumer who was also an 83-year old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and passed out/loss of consciousness, felt very weak/asthenia, sick to the stomach/ nausea, cold sweat, shaky/ tremor, could not see straight/ blurred vision and felt groggy/ somnolence. The patient's medical history was not provided. Products known to have been used by the patient, within two weeks prior to the event, included levothyroxine sodium, calcium, tramadol and vitamin B complex. The patient received their first of two planned doses of mRNA-1273 (Batch number:02AL20A) on 29 Jan 2021. On 01 Mar 2021, prior to the onset of the symptoms, the patient received their second of two planned doses of mRNA-1273 (Batch number: 003A21A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 01 Mar 2021, 10 hours after getting the 2nd dose, the patient felt very weak, sick to the stomach, cold sweat, shaky, could not see straight and she passed out. On 02 Mar 2021, the patient felt groggy. The patient stated that she did not take any medications for her symptoms. The patient received both scheduled doses of mRNA-1273 prior to the events; therefore, action taken with the drug in response to the events is not applicable. The events, passed out, felt very weak, sick to the stomach, cold sweat, shaky and could not see straight, were considered resolved on 02 Mar 2021. The event felt groggy was considered resolved on 03 Mar 2021.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Further information has been requested. |

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| 1137960 | 3/26/2021 | NY | | F | 2/11/2021 | 3/12/2021 | Fainted; Feeling dizzy; Weak; Exhausted; A spontaneous report was received from a consumer concerning a 66 years old female patient who received Moderna's COVID-19 (mRNA-1273) and experienced fainted/syncope, feeling dizzy/dizziness, weakness/asthenia, and exhaustion/fatigue. The patient's medical history was not provided. Concomitant product use was not provided by the reporter. The patient received their first of two planned doses of mRNA-1273 (Batch number: 039K20A) on 11 Feb 2021. The patient received their second of two planned doses of mRNA-1273 (Batch number: 036A21A) on 11 Mar 2021 intramuscularly for prophylaxis of COVID-19 infection. On 12 Mar 2021, the patient felt so weak and exhausted, she didn't have the strength to brush her teeth. She remembered feeling dizzy while standing in the bathroom. She fainted shortly after. She felt like couldn't stand up because she was so weak and was very scared. Treatment of the event was not provided. The patient received both scheduled doses of mRNA-1273 prior to the events; therefore, action taken with the drug in response to the events is not applicable. The events fainted, feeling dizzy, weakness, and fatigue were considered resolved on 13 Mar 2021.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |
| 1138091 | 3/26/2021 | MI | 33 | M | 3/18/2021 | 3/18/2021 | Became very dizzy and nearly fainted within 5 minutes of receiving the vaccine. Needier assistance walking. Felt discomfort in leg for for 2 days. |
| 1138097 | 3/26/2021 | AZ | 84 | M | 3/22/2021 | 3/23/2021 | Patient apparently was in the bathroom, shaving. Patient's wife was in the kitchen. He does not recall exactly what happened other than he fell backwards. His wife heard a "thud." She went into the bathroom and the patient was not responding. Eyes were open but he was not focusing. He did have generalized shaking of his extremities. Nine-one-one was called at this time. Patient does complain of some mild back pain. He denies any significant headache. There has been no nausea or vomiting. He was diagnosed with syncope event and new onset bells palsy. |

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| 1138104 | 3/26/2021 | MI | 62 | M | 3/23/2021 | 3/26/2021 | Cold sweats 64.5 hours later, causing fainting, followed by vomiting 6 times and diarrhea once. Recovered after 1 hour. |
| 1138491 | 3/26/2021 | VA | 73 | F | 3/26/2021 | 3/26/2021 | Patient fainted, was losing consciousness, she complained she was cold |
| 1138500 | 3/26/2021 | CA | 60 | M | 3/26/2021 | 3/26/2021 | Patient experienced syncope within 10 minutes after administration of vaccine |
| 1137939 | 3/26/2021 | MI | | F | 1/22/2021 | 1/23/2021 | Weird chills; These symptoms include fainting / passed out on the floor, eyes rolled back; Chills were like shakes in my hand; Elevated heart rate (117); Weakness; Sweating profusely; Dizziness; Nausea; A spontaneous report was received from a 73-year-old female consumer who received Moderna's COVID-19 vaccine (mRNA-1273) and developed events, fainting / passed out/syncope, eyes rolled back/syncope, chills were weird/chills, chills were like shakes in my hand/tremor, heart rate was up/heart rate increased, nausea, weakness/asthenia, dizziness and sweating profusely/hyperhidrosis. The patient's medical history included positive COVID-19 test on 11 Dec 2020. No relevant concomitant medications were reported. On 22 Jan 2021, prior to the onset of the events, the patient received the first of two planned doses of mRNA-1273 (Batch number: 029L20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 23 Jan 2021, around 2:00 clock in the morning, the patient experienced the symptoms including fainting, eyes rolling back, weird chills like shakes in her hand, sweating profusely, elevated heart rate (117), and other symptoms that occurred when she had COVID such as nausea, weakness, dizziness. Treatment information was not provided. Action taken with mRNA-1273 in response to the event was unknown. The outcome of the events fainting / passed out/syncope, eyes rolled back/syncope, chills were weird/chills, chills were like shakes in my hand/tremor, heart rate was up/heart rate increased, nausea, weakness/asthenia, dizziness and sweating profusely/hyperhidrosis was considered as resolved on 25 Jan 2021.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. |

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| 1138492 | 3/26/2021 | OH | 33 | M | 3/26/2021 | 3/26/2021 | Passed out 10 minutes after receiving shot |
| 1138194 | 3/26/2021 | NY | 33 | M | 3/24/2021 | 3/24/2021 | patient felt dizzy a few minutes after the receiving the vaccine. He was sitting and fainted and fell off the chair and onto the floor. Pt was shaken and got up immediately. Patient hit his head during the fall but did not fall unconscious. Patient had gatorade and felt better within minutes. Pt was asked if there was anyone should be called and he said no. He called his significant other on cellphone to inform her what happened. Pt stayed at the pharmacy for 30minutes to make sure he felt okay. Patient was called on 3/26 by witnessing pharmacist and informed her that he was okay and felt fine throughout the rest of the day. |
| 1138485 | 3/26/2021 | VT | 63 | F | 3/11/2021 | 3/16/2021 | I had a vaso-vagal syncope and a very severe drop in Blood pressure. |
| 1138368 | 3/26/2021 | IA | 84 | M | 3/21/2021 | 3/21/2021 | Injection SUNDAY. within 2 hrs of the 2nd injection, he was amazed to no longer feeling the chronic pain throughout his shoulder. MONDAY: The following evening (after supper) he experienced severe light-headedness, followed by violent, prolonged projectile vomiting, during which, his eyes rolled back and he passed out while continuing to vomit. Low BP. transported to hospital; CT scan showed perforated esophagus, air in chest lining. 2nd CT: air and fluid spread to neck area, bowel obstruction/infection. TUESDAY: 5am: Transferred to hospice ward, unresponsive. Tuesday, 2:20pm: died. |
| 1138344 | 3/26/2021 | NJ | 29 | M | 3/26/2021 | 3/26/2021 | After receiving COVID 19 vaccine the patient instructed to sit for 15 minutes. During his 15 minute window the patient stated he got anxious and went to the bathroom to splash water on his face. Patient stated he felt tingling and passed out. Patient fell forward hitting left side of face on the toilet. |
| 1138310 | 3/26/2021 | MO | 36 | F | 3/24/2021 | 3/24/2021 | Altered mental status, severe abdominal pain, fatigue, syncope |

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| 1138290 | 3/26/2021 | CA | 29 | F | 3/26/2021 | 3/26/2021 | Patient collapsed onto floor 10min s/p Pfizer vaccination patient stated feeling dizzy and not realizing she fell. Patient has history of fainting after shots but did not advise anyone. Patient got quarter of an in laceration on forehead. Vital signs stable, cleaned and wrapped laceration and sent with paramedics to ER. |
| 1138210 | 3/26/2021 | | 31 | M | 3/26/2021 | 3/26/2021 | After the vaccine observation period, the patient stood up and passed out. This has happened before when he has had blood work completed in the past. |
| 1133295 | 3/25/2021 | TN | 62 | F | 3/23/2021 | 3/23/2021 | Felt the vaccine immediately in arm, Got a funny taste in my mouth, Started feeling dizzy before I stood up, Moved to a different chair from injection chair location. Passed out. Never vomited but become very nauseated. These symptoms all occurred within five minutes of the injection. Ran low grade fever all day on March 24 (day after). |
| 1134258 | 3/25/2021 | GA | 59 | M | 3/21/2021 | 3/23/2021 | Very sore arm. Cold sweets. Elevated temp for 2 days reaching 101.5 degrees. Sick stomach. Nearly passed out one evening when I got up out of bed. Nearly didn't make it back to bed. Body aches. Used cold compresses and took extra strength Tylnol and Aspirin. Lots of water and Ensure. Dressed in layers to stay warm. My wife and I are sick at the same time from vaccine injection. Missed 2 days of work. Also had skjn hypersensitivity in my upper back. Had fatuque, but not as bad as my wife. |
| 1132754 | 3/25/2021 | TX | 26 | M | 3/24/2021 | 3/24/2021 | 3/24/2021 9:59 AM VACCINE AT 9:30 AM - SYNCOPE-COLD CLAMY, VASOVAGAL RESPONSE CAME TO WITH REPOSE. BP TAKEN NO MEDICAL PROBLEMS. |
| 1132723 | 3/25/2021 | NC | 50 | F | 3/24/2021 | 3/25/2021 | Woke up to strong and painful diarrhea - almost passed out while sitting on the toilet. Had an odd white noise in my ears - not "ringing" but buzzing kind of sound. Lasted for about 3-5 minutes and I ended up lying on the floor for about 15 minutes before I could get back up. Felt like I may blackout. It's three hours later and I'm ok now. |

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| 1133014 | 3/25/2021 | MS | 20 | M | 3/8/2021 | 3/8/2021 | fainting spells; Metallic taste in the mouth; weakness; nausea; vomiting; This is a spontaneous report from a contactable consumer. A 20-year-old male patient received the 1st dose of bnt162b2 (BNT162B2), via an unspecified route of administration, as single dose in in left arm on 08Mar2021 12:30 AM for COVID-19 immunisation, administered at drive thru site. Medical history included hypertension, COVID-19 prior vaccination, no known allergies. Concomitant medications in two weeks included lisinopril (manufacturer unknown); methylphenidate (manufacturer unknown), both taken for an unspecified indication, start and stop date were not reported. No other vaccine in four weeks. On 08Mar2021 13:00 the patient experienced fainting spells, metallic taste in the mouth, weakness, nausea, vomiting. No treatment received. COVID-19 was not tested post vaccination. The outcome of events was unknown. Information about lot/batch number has been requested. |

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| 1133030 | 3/25/2021 | FL | 74 | F | 3/2/2021 | 3/1/2021 | she had low pressure; she passed out at one point; She is very pale in her face.; lightheaded/Dizzy; She felt very bad the second day; She had an allergic reaction; This is a spontaneous report from a contactable consumer. A 74-year-old female patient received second dose of BNT162B2 (BNT162B2), via an unspecified route of administration, administered in Arm Left on 02Mar2021 09:45 (Batch/Lot Number: EL9262) as single dose for covid-19 immunization. Medical history included seizure (she had convulsions as a child). There were no concomitant medications. The patient experienced she passed out at one point on 03Mar2021, she had low pressure on 03Mar2021 at 08:00. The patient also experienced she is very pale in her face, lightheaded/dizzy, she felt very bad the second day and she had an allergic reaction on Mar2021. Reporter states She had an allergic reaction. The first day she felt fine, the second day she had low pressure and she passed out at one point and the rest of the day she had low blood pressure. She felt very bad the second day and Monday was the same and she is still feeling light headed and dizzy today. She says the first dose was given on the 05Feb2021 and her second dose she just had that on 02Mar2021 and that is the dose she is reporting about today. She says it was 03 Mar when she started having low blood pressure and passed out. She says she is still light headed and dizzy today, that is ongoing. She has not checked her blood pressure today but she feels like it is still low. She is very pale in her face. The patient underwent lab tests and procedures which included blood pressure measurement: low pressure on an unspecified date (she had low pressure). Outcome of she had low pressure and lightheaded/Dizzy was not recovered. Outcome of all the other events was unknown. |

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| 1133033 | 3/25/2021 | OH | 66 | M | 3/6/2021 | 3/6/2021 | I have never passed out prior; 1 in. laceration above the right eye along; food is less flavorful and does not excite me; Feeling queasy; bruising to my upper arm, leg and back; don't feel right; About 10 hours after the second injection began to have chills and a low grade fever.; About 10 hours after the second injection began to have chills and a low grade fever.; This is a spontaneous report from a contactable consumer (patient). A 66 -year-old male patient received his second dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, lot number: EN6203), via an unspecified route of administration (on left arm) on 06Mar2021 12:00 (at the age of 66 -years-old), single dose for COVID-19 immunisation. Medical history included Diabetes Type 2 (Doctor stated that I really do not fit either profile. Concomitant medications included pioglitazone, metformin, lisinopril, ascorbic acid, tocopheryl acetate, xantofyl, zeaxanthin, zinc (AREDS). Patient stays away from all Opioids they make him very nauseous. Patient typically gets a low grade fever (100-101) and chills 4 hours after a Flu Vaccine that last almost exactly 24 hours. The patient had the first dose of covid vaccine on 11Feb2021 for covid-19 immunisation and experienced only minor soreness at the injection site with the first dose. Experience only minor soreness at the injection site with the first dose. About 10 hours after the second injection began to have chills and a low grade fever. Sunday morning 07Mar2021 started feeling queasy. Patient thought that if I took a shower that I might feel better. As Patient was getting toward the end of his shower Patient just thought, Patient don't feel right. The next thing Patient remember Patient was picking himself of the floor of the shower. Patient have never passed out prior to this episode. Patient received a 1 in. laceration above the right eye along with bruising to his upper arm, leg and back. Patient basically ate nothing the remainder of Sunday nor Monday. It is as if the food is different. Even though he is a Diabetic and keep his blood sugar under control. Patient knows that this may sound weird, but it is as if the food is less flavorful and does not excite him. As 09Mar2021, he still does not feel together. The outcome of the events was not recovered. No treatment for any adverse event. No Covid prior vaccination, not Covid tested post vaccination. |

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| 1133043 | 3/25/2021 | AZ | 43 | F | 12/23/2020 | 12/23/2020 | Guillain Barre Syndrome; POTS; Syncope; This is a spontaneous report from a contactable other hcp. A 43-years-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), via an unspecified route of administration, administered in Arm Left on 23Dec2020 07:30 (Batch/Lot Number: EH9899) as SINGLE DOSE for covid-19 immunisation. Medical history included Known allergies as wine. Concomitant medication included loratadine (CLARITIN [LORATADINE]) 10 mg, as needed, daily for unspecified indication. On 23Dec2020 07:45 patient experienced Paresthesia tip of RIGHT little finger within 10 minutes of vaccine. Tachy arrhythmia, loss of function in RIGHT little finger/hand, and syncope 45 minutes after vaccine while driving. Tachycardia, hypertension, generalized weakness, and severe fatigue walking upstairs (persistent and worsened over several days). Loss of function/sensation RIGHT arm and RIGHT leg 8 days after vaccination. Symptoms persisted and worsened. Diagnosed with Guillain Barre Syndrome and POTS at follow up on 19Jan2021. She still have persistent weakness/paresthesias/neuropathy. The patient underwent lab tests and procedures which included sars-cov-2 test: negative on 31Dec2020. Seriousness criteria for all events was hospitalization. The events Guillan Barre syndrome and syncope were medically significant. Outcome of the event Guillain Barre Syndrome was recovering. Outcome of the other events was unknown. |
| 1133188 | 3/25/2021 | CA | 30 | M | 3/25/2021 | 3/25/2021 | Patient received 1st dose of vaccine and sat in the post-vaccination area. Pt lost consciousness and slumped to floor off chair. RN and RN responded to patient. Pt was conscious and responsive to verbal stimuli. Pt reports he became sweaty and dizzy and then passed out. Pt denies any pain or urgent medical issues. After incident pt reports to passing out once before due to getting blood drawn. Pt stable and responsive after post vaccination area clearance. Patient denies blood thinners. No deformities noted upon physical exam. |

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| 1133286 | 3/25/2021 | GA | 68 | M | 1/18/2021 | 1/18/2021 | 1/18 vaccination Within 4 minutes, my husband started with tremors in his hand. Feeling funny. Felt like something was wrong. He was trying to hold hands still but then other extremities started to shake. He passed out. Honked for help. It took both ambulances to tx my husband and onto the stretcher and strapped in. Grand Mal Seizure. It started to fade when he got into but then had another one after he was in the ambulance, worse then the first one. He continued to have seizures for 4 more days. Every couple hours, give him the kepra and topomax to help. 1/20 orthopedist 1/25 PCM 1/26 Neurologist 1/28 home health nurse 2/8 PCM, mental health 2/10 orthopedist 2/12 home health nurse 2/17 home health nurse *Dr Neurologist *Dr. PCM *Dr. **stated he cannot have 2nd vaccine. 'if he has another grand mal seizure it will kill him' |
| 1132727 | 3/25/2021 | TX | 30 | F | 3/3/2021 | 3/4/2021 | 3/4/2021: -Woke up with headache (best compared to a dehydration headache but had frequent urination that day) and sore arm -Body aches and fever started 24 hours after first dose of vaccine. Fever climbed to 102. By 18:30, fever had broken and all that was left was the headache -Noticed my heart rate was elevated. Smart watch said it was 86bpm resting 3/5/2021: -Woke up with headache and sore arm again -Had a doctor's appointment at 11:45 unrelated to vaccine and resting heart rate was 98bpm -Around midnight, I decided to take a shower to relax because my heart rate was making it difficult to fall asleep. **After the shower, I had a sharp pain in my chest and passed out.*** |
| 1133338 | 3/25/2021 | FL | 62 | F | 3/23/2021 | 3/23/2021 | Within 15-minutes of vaccination, the patient reported dizziness. EMS evaluated the patient on-site. The patient was hypertensive (175/97) with a FSBG of 152 mg/dl. EKG demonstrated NSR, rate 86bpm, no ST elevation. EMS transported the patient to Emergency Department for further evaluation. In the ED, the patient reported dizziness, lightheadedness, near-syncope, aching headache, generalized fatigue, and weakness. Physician administered 25mg PO Meclizine. Upon reevaluation, the patient reported improvement and was discharged with diagnoses of Vaccine reaction and Dizziness. |

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| 1133391 | 3/25/2021 | TX | 74 | F | 3/13/2021 | 3/14/2021 | 03/14/2021 Horrible head ache, nausea, dizzy, exhaustion, brain fog, confused, chills, heart pounding, fainted. Went to ER by ambulance. The patient still has bouts of a pounding rapid heart beat & brain fog. She states that her head feels full with these bouts. |
| 1133492 | 3/25/2021 | FL | 72 | M | 2/5/2021 | 2/5/2021 | Passed out; cardiac event; This is a spontaneous report from a contactable consumer from a Pfizer-sponsored program COVAX Support. A 72-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 2 via an unspecified route of administration, administered in left arm on 05Feb2021 15:30 (Batch/Lot Number: EL9269) as a single dose for COVID-19 immunisation. Medical history included defibrillator insertion from 2014 to an unknown date (has never had it go off), blood pressure abnormal, heart disorder, blood cholesterol increased (Lipitor indication: to lower cholesterol), and eye disorder. The patient previously received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Batch/lot number: EL3246), on 15Jan2021, at 15:30 PM in the left arm, for COVID-19 immunization. Concomitant medications included acetylsalicylic acid (ASPIRIN) taken for heart from 2010 and ongoing; carvedilol taken for heart from 2014 and ongoing; ubidecarenone (CO Q 10) helps with the statin for his heart from 2014 and ongoing; atorvastatin (LIPITOR) taken to lower cholesterol from 2014 and ongoing; lisinopril taken for blood pressure from 2014 and ongoing; xantofyl (LUTEIN) taken for eye from an unspecified start date and ongoing; and warfarin taken as blood thinner from 2010 and ongoing. The patient reported that 2 hours and 15 minutes after the second dose on 05Feb2021, he passed out and his defibrillator kicked in and he had a cardiac event but was not sure what kind of cardiac event. He stated it was probably unrelated, but the doctor said to call Pfizer to notify. He said he has had the defibrillator since 2014 and has never had it go off. He is having a stress test to check it all out. He added he felt great by about two hours after the defibrillator kicked in and went golfing. The outcome of the events was recovered on 05Feb2021. |

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| 1133493 | 3/25/2021 | NJ | | F | 2/1/2021 | 2/1/2021 | passed out; felt dizzy all day long; concussion in her head; felt very nauseous; diarrhea; headache; This is a spontaneous report from a contactable consumer (patient). This 60-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot number was not reported), via an unspecified route of administration at single dose in Feb2021 for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. In Feb2021, the patient experienced passed out (medically significant), felt dizzy all day long, concussion in her head, felt very nauseous, diarrhea, headache, all with outcome of unknown. Clinical course was described as follows: Patient received the first dose of the Pfizer-BioNtech Covid-19 vaccine approximately 3 weeks ago, she's scheduled for her second dose on Saturday. When she received the first dose of the vaccine she felt dizzy all day long and when she went to the bathroom she passed out and had a concussion in her head, she also felt very nauseous, had diarrhea and a headache. Her doctor told her that she passed out from the injection and then her headache was from the concussion, he recommended her that for her second dose there's someone with her because she lives alone. Patient would like to know if this dosage of the vaccine could have caused her the reaction. Information on lot number/batch number has been requested. |
| 1133577 | 3/25/2021 | OR | 60 | F | 3/7/2021 | 3/7/2021 | Day 1 muscle stiffness lower back and slight fever, tired. Day 2 bone, muscle pain moved to right hip, sore to touch, tired. Day 3 bone, muscle pain moved upper back, tired. Took aspirin. Day 4 bone, muscle pain more extreme, tired. Took aspirin. Day 5 extreme pain in hip and ribs, sore to touch hard to breath, fainted, tired. Took tylenol. Pain went away |
| 1133632 | 3/25/2021 | SC | 40 | M | 3/25/2021 | 3/25/2021 | Pt was leaving after 15 minute waiting period and passed out at the check out. Pt reported feeling fine and did not remember passing out. Pt BP 113/71 hr 61. Pt BP dropped to 89/56 after 20 minutes. 1 liter of IV fluid given. Pt monitored an additional 30 minutes. Final BP 118/73 HR 69. Pt discharged home with sister. |
| 1133670 | 3/25/2021 | | | F | 2/4/2021 | 2/4/2021 | Vasovagal syncope: pt states was fasting at time of inoculation, tx with 1L NS bolus |

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| 1133685 | 3/25/2021 | PA | 42 | F | 3/17/2021 | 3/17/2021 | patient fainted from seated position in recovery waiting room. she was attended by Dr. for supportive care. paramedics were summoned and transported patient to medical center for further treatment. Symptoms were not anaphylaxis; most likely vasovagal response. |
| 1133731 | 3/25/2021 | MO | 33 | F | 3/25/2021 | 3/25/2021 | Systemic: Fainting / Unresponsive-Medium, Additional Details: patient fainted post administration briefly. patient stated that this is a normal reaction to vaccines. declined further care. patient was brought to sitting position, given water and left shortly after. |
| 1134173 | 3/25/2021 | | 34 | F | 3/20/2021 | 3/20/2021 | Patient experienced anxiety, reported they passed out after first dose. Patient was able to be comforted, and felt no reactions after 15 min. Patient's vitals taken before and after vaccination, vitals within normal limits. |
| 1132705 | 3/25/2021 | NJ | 69 | M | 3/9/2021 | 3/10/2021 | pt had fever and fainted X 2 hitting head resulting in severe concussion |
| 1133986 | 3/25/2021 | OK | 72 | F | 3/2/2021 | 3/3/2021 | Headache Trouble staying awake Fever Passed Out (once) |
| 1131948 | 3/25/2021 | FL | 39 | M | 3/18/2021 | 3/18/2021 | Client passed out-Syncopal episode. Going to Hospital. BS-96, BP 80/40, HR 58, O2 97%. |
| 1131186 | 3/25/2021 | IL | | F | 3/10/2021 | 3/11/2021 | she passed out for 2-3 min; A spontaneous report was received from a consumer, concerning that his wife who is of age 48 years, was received Moderna's COVID-19 vaccine and experienced passed out for 2-3minutes/ loss of consciousness. The patient's medical history was not provided. Concomitant product use was not provided by the reporter. On 10 MAR 2021, prior to the onset of events, the patient received their first of two planned doses of mRNA-1273 (002A21A) via unknown route for COVID-19 infection prophylaxis. On 11 MAR 2021, the patient experienced the events of passed out for 2-3min/loss of consciousness. No treatment information was provided. The outcome of the event, passed out for 2-3minutes/ loss of consciousness, is considered unknown.; Reporter's Comments: Very limited information regarding the events has been provided at this time. Further information has been requested. |

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| 1131211 | 3/25/2021 | CA | 23 | M | 3/8/2021 | 3/8/2021 | <p>Passed out /Lost all awareness; Light-headed; Hyperventilating; He caught his breath; Elevated heart rate; Tingling sensation; He was unable to form cohesive sentences; Muscles movements were impeded; This is a spontaneous report from a contactable consumer (patient). A 23-year-old male patient received the first dose of BNT162B2 (Pfizer-Biontech Covid-19 Vaccine, Lot. EN6206) single dose, in the left arm, on 08Mar2021, at 11:45 AM, for COVID-19 immunisation. The patient had not received any other vaccines within 4 weeks prior to the BNT162B2 vaccine. The patient had not received any other medications within 2 weeks. Relevant medical history and concomitant medications were unknown. No known allergies were reported. The patient had not experienced COVID-19 prior vaccination. On 08Mar2021, at 12:00 PM, 5 minutes after vaccination, the patient became very light-headed. In a few seconds his vision went dark and he passed out. After an unknown amount of time, he became semiconscious and was hyperventilating. While hyperventilating, his eyes were open, but he could not see anything. Once he caught his breath, after about 15 seconds, his vision came back and he lost all awareness of where he was. After about 30 seconds, the patient realized he was in the observation area for the facility and alerted the medical professionals near his vehicle he was sitting in. Medical professionals checked his vitals, which were fine other than an elevated heart rate, and he had a tingling sensation over his body for the next two minutes. In this time, he was unable to form cohesive sentences, and his muscles movements were impeded. It took another 40 minutes to return to a relatively normal state. No treatment was received. The patient recovered from the adverse events. Post the vaccination, the patient has not been tested for COVID-19. No follow up attempts are possible. No further information is expected.</p> |

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| 1131187 | 3/25/2021 | NY | 58 | F | 12/31/2020 | 12/31/2020 | <p>Has not gotten second dose; Got really sick; Violent bed shaking chills; Pain at injection site all the way up the right and left side of neck; Was white; Minor chills; Tunnel vision; Going to pass out; Sweaty; Increased heart rate; Blood sugar dropped; Dizzy; Pain at injection site all the way up the right and left side of neck; A spontaneous report was received from a consumer concerning a 58-years-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced tunnel vision, felt like going to pass out/ presyncope, was white/ pallor and sweaty/ hyperhidrosis, increased heart rate/ heart rate increased, blood sugar dropped/ blood glucose decreased, minor chills/ chills, dizzy/ dizziness, pain at injection site/ vaccination site pain all the way up the right and left side of neck/ neck pain, got really sick/ illness, had violent bed shaking chills/ chills and has not gotten second dose/ product dose omission issue. The patient's medical history was not provided. No relevant concomitant medications were reported. On 31 Dec 2020, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Batch Number: 039K20A) for prophylaxis of COVID-19 infection. On 31 Dec 2020, immediately after receiving vaccine, the patient felt like she was going to pass out, tunnel vision a medically significant event, was white and sweaty, increased heart rate, blood sugar dropped, minor chills, dizzy, pain at injection site all the way up the right and left side of neck. The patient was monitored at a doctor's office for about 3 hours before she felt good enough to drive home and felt better. Pain injections lasted a week and other symptoms ended on an unspecified date. On 26 Feb 2021, the patient got really sick and had violent bed shaking chills (ended on an unknown date). The patient has not gotten her second dose but did test negative for COVID. Laboratory details included increased heart rate, blood sugar dropped and test negative for COVID. No treatment information was reported. Action taken with mRNA-1273 in response to the events was not reported. The outcome of events, tunnel vision, presyncope, pallor, hyperhidrosis, heart rate increased, blood glucose decreased, chills, dizziness and neck pain, was resolved on 31 Dec 2020. The outcome of events, vaccination site pain, illness and chills, was resolved on an unspecified date.; Reporter's Comments: Based on</p> |

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| | | | | | | | the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |
| 1134282 | 3/25/2021 | FL | 36 | M | 3/20/2021 | 3/20/2021 | Client had a syncope episode after receiving the vaccine. Client states he has a history of syncope after vaccination. 97.9 degrees, HR 68, BP 127/72. 1:30 pm asst. to BR, gait steady, no c/o dizziness, continued to wait in observation area. Allowed to leave at 2pm. |
| 1131743 | 3/25/2021 | MN | 52 | F | 3/4/2021 | 3/4/2021 | Patient received her 2nd dose of Moderna COVID-19 vaccine at 16:14 and felt faint, dizzy and diaphoretic at 16:20. She reported that she had none of these symptoms after her first dose of COVID vaccine 4 weeks prior. PHN took VS at 16:24 BP- 73/41, P-56, R-18, O2- 96%; 16:27 BP-78/42, P-59, R-18, O2- 96%; at this point EMS/911 was notified and PHN had epinephrine auto-injector at the ready but did not administer. Patient was able to talk to nurse while symptomatic and did not report any tightness in her chest or throat, but did report a history of fainting after blood draws. 16:29 BP- 105/68, P-76, R-20, O2- 93%; 16:32 BP- 125/69, P-90, R-16, O2- 94% at this point EMS arrived and took report from clinic nurse; completed 2 set of VS and patient felt symptoms improved and refused medical transport, denied need for further medical attention. She was driven home by her husband and left clinic at 16:50 |
| 1131781 | 3/25/2021 | NV | 26 | F | 3/24/2021 | 3/24/2021 | Patient was vaccinated, moments later she had lost consciousness. Administering technician notified pharmacist immediately. When patient was approached she was regaining consciousness. Boyfriend said she was out for about 30 seconds. She vomited and moments later was feeling better. She was monitored until 9pm. Patients blood pressure was taken sporadically for about 1.5 hours with numbers ranging from 76/57, to 190/146. Last BP reading was 101/76. She said she was well enough to go. Gave patient card and told her to call for any other AE or questions/comments. Patient stated she has a history of syncope, especially when in medical atmosphere. |

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| 1131842 | 3/25/2021 | FL | 65 | F | 3/24/2021 | 3/24/2021 | Systemic: Allergic: Difficulty Breathing-Mild, Systemic: Fainting / Unresponsive-Medium, Systemic: Hyperventilation-Severe, Systemic: Seizure-Severe, Systemic: Shakiness-Medium |
| 1131843 | 3/25/2021 | TX | 38 | M | 3/23/2021 | 3/23/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Hypotension-Mild, Systemic: Nausea-Medium, Systemic: Vomiting-Medium, Additional Details: EMS was called. However patient recovered prior to EMS arrival. Contacted patient at 8pm on 03/23/21. Patient stated he was doing fine and did not need to seek additional medical attention as of the time we spoke. |
| 1131848 | 3/25/2021 | OH | 43 | M | 3/24/2021 | 3/24/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Additional Details: Patient experienced syncope briefly he thinks due to sudden drop in blood pressure but recovered within minutes. |

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| 1131209 | 3/25/2021 | MA | 68 | M | 2/27/2021 | 2/27/2021 | Felt like fainting; Weakness; Sudden drop of blood pressure; I had trouble sleeping at night; Headache; My arm was sore; A spontaneous report was received from consumer concerning himself, a 68-year-old male patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced weakness (asthenia), felt like fainting (dizziness), sudden drop of blood pressure (blood pressure decreased), arm was sore (pain in extremity), had trouble sleeping at night (insomnia) and headache. The patient's medical history was not provided. No relevant concomitant medications were reported. On 27 Feb 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Batch Number: 012A21A) in the left arm for prophylaxis of COVID-19 infection. On 27 Feb 2021, 10 minutes after the vaccination, the patient experienced weakness and felt like fainting. The patient had low blood pressure and was hospitalized. On 28 Jan 2021, the patient's arm was sore. The patient also experienced trouble for sleeping at night and had headache. Treatment information included IV. Laboratory data included low blood pressure measurement, stress test (results unknown), chest x-ray (results unknown), covid test negative and blood test (normal). Action taken with mRNA-1273 in response to the events was unknown. The outcome of the events, weakness, felt like fainting, sudden drop of blood pressure, arm was sore, had trouble sleeping at night and headache, was considered as unknown.; Reporter's Comments: This case concerns a 68-year-old male who was hospitalized for serious unexpected events of blood pressure decreased, dizziness, asthenia, along with NS unexpected insomnia, and NS expected pain in extremity, headache. Event onset occurred 10 minutes after the first dose of mRNA-1273. Treatment unknown. Event outcomes unknown. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. |

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| 1131854 | 3/25/2021 | NC | 41 | F | 3/24/2021 | 3/24/2021 | Systemic: Allergic: Difficulty Breathing-Medium, Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Severe, Systemic: Exhaustion / Lethargy-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Numbness (specify: facial area, extremities)-Medium |
| 1132670 | 3/25/2021 | MN | 29 | F | 3/24/2021 | 3/24/2021 | Patient became dizzy and fainted approximately 15 minutes following vaccination. Fell and hit forehead on tile floor in hallway outside clinic room. Brief loss of consciousness. Patient continued to have periods of dizziness, spotted vision and weakness as well as developed nausea. Ambulance was called and patient was transported to the hospital for further evaluation. Patient was given water and a snack, but continued to have symptoms. Later determined patient had not eaten breakfast prior to vaccination. |
| 1131987 | 3/25/2021 | PA | 19 | F | 3/25/2021 | 3/25/2021 | pt was having fainting spelling |
| 1132049 | 3/25/2021 | GA | 62 | M | 3/24/2021 | 3/24/2021 | Patient experienced perspiration, dizziness, and fainting with no loss of consciousness. Patient was talking and answering questions appropriately. B/P 120/80, FSBS 131 @ 1:52PM. EMS was notified and Patient was transported to local hospital. I spoke with the patient today and he states he was discharged from hospital and everything was fine. He states he is doing good today. |
| 1132089 | 3/25/2021 | KY | 31 | M | 3/19/2021 | 3/19/2021 | Patient passed out 5 minutes after vaccine was administered. EpiPen was administered and 911 called. Patient was conscious before the arrival of EMS. Per patient's mum , the patient has a history of passing out with needle stick. She sees it as a normal reaction. |
| 1132306 | 3/25/2021 | NY | 56 | F | 3/23/2021 | 3/23/2021 | A few hours after the shot I started experiencing chills, tiredness, then in the evening my left arm started to develop a large red hot bump that hurts and very itchy. During the night, fever of 101.1, chills, could not get warm, my whole body ached from head to toe. Headaches. Symptoms continued through the whole next day. Fever broke in the evening, Today, arm is still swollen, red, raised injection site, hot to touch. I had dizzy a dizzy spell when I got up this morning, almost passed out in the shower. Dizziness passed after a half hour. Still very tired and achy today. |

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| 1132345 | 3/25/2021 | MI | 53 | F | 3/21/2021 | 3/21/2021 | Anxiety, syncope, abnormal feeling in her throat |
| 1132353 | 3/25/2021 | FL | 63 | F | 2/4/2021 | 2/4/2021 | I rec'd my 2nd vaccination on 02/04/2021 @ approx. 5:15, within a few hours I started to have normal and expected reaction. Approximately 9am the next morning I passed out without any type of warning (dizziness etc) I passed out another 2 times during Friday morning. I stayed in bed the remainder of Friday, felt sluggish on Saturday and back to normal on Sunday |
| 1132481 | 3/25/2021 | NY | | M | 2/2/2021 | 2/1/2021 | went to the hospital because he passed out from low blood pressure; went to the hospital because he passed out from low blood pressure; pneumonia; was dehydrated; This is a spontaneous report from Pfizer-sponsored program. A contactable 73-year-old male consumer received the first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE) on 02Feb2021 via an unspecified route of administration, at single dose for COVID-19 immunisation. Relevant medical history and concomitant medications were not reported. The patient went to the hospital because he passed out from low blood pressure. He was scheduled for his second dose on 17Feb2021, but he never made it to his second appointment because he was in the hospital. He was in rehab now. It was almost 6 weeks. The patient felt ok after getting the shot, but that night his son found him on the floor and took him to the hospital. It turned out he had pneumonia, low blood pressure and was dehydrated. The outcome of the events was unknown at the time of report. Information on lot/batch number has been requested. |

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| 1132488 | 3/25/2021 | KY | 37 | M | 3/12/2021 | 3/12/2021 | struggling to catch my breath; swinging from 120+ BPM to 50 BPM in an instant; pass out; racing heart; big rush of the room spinning; I could feel the medicine in my body, almost to my toes; This is a spontaneous report from a contactable consumer. A 37-year-old male patient received the first dose of BNT162B2 (Pfizer-BIONTECH COVID-19 Vaccine; lot number: EL9267) on 26Feb2021 and the second dose of BNT162B2 (Pfizer-BIONTECH COVID-19 Vaccine; lot number: EN6202) on 12Mar2021, via an unspecified route of administration on Left Arm at single dose for COVID-19 immunisation. The administration of first dose of BNT162B2 resulted in Palpitations, dizziness, hyperhidrosis and Syncope the same day of administration. Relevant medical history included allergy to penicillin. Relevant concomitant medications included testosterone cypionate (TESTOSTERONE CYPIONATE). During second dose of vaccine the patient stated that he feels the medicine in his body, almost to his toes. The patient was fine for a minute or two but then he reported a big rush of the room spinning, struggling to catch my breath, racing heart. EMS personnel was called over and they monitored my heart rate. It was swinging from 120+ BPM to 50 BPM in an instant and during the low BPM was when he passed out. The patient was treated with Epinephrine due a potential reaction and transported to hospital. The reported events were feeling abnormal, vertigo, dyspnoea, palpitations, heart rate irregular and loss of consciousness. All events were serious as hospitalization and Life-threatening illness (immediate risk of death from the event). |
| 1132636 | 3/25/2021 | MI | 44 | M | 3/23/2021 | 3/23/2021 | Patient experienced very low blood pressure and fainted. He came to quickly, but was transported to hospital by ambulance as a precaution |
| 1132653 | 3/25/2021 | PA | 40 | F | 3/25/2021 | 3/25/2021 | Classic vasovagal reaction without syncope Warmth, clamminess, dizziness, partial tunnel vision Self resolving symptoms with BP, pulse, O2 sat all within acceptable ranges with 60 minute observation No orthostasis and comfortable ambulation at discharge from observation unit |

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| 1131851 | 3/25/2021 | OH | 16 | M | 3/24/2021 | 3/24/2021 | Systemic: Confusion-Mild, Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient and his mother presented about 30 minutes after receiveing vaccine stating he passed out in the car for about 15 seconds and fell on his way back into the store. He lied down for a while and said he was fine. Mother said do not call an ambulance, she would take him to the emergency department. |
| 1135999 | 3/25/2021 | | 74 | M | 3/23/2021 | 3/23/2021 | vaccine side effect. Patient reports slurred speech, difficulty forming sentences, SOB, R arm tingling x 3 hours. Patient reports symptoms have improved but not resolved. J&J vaccine today at 1045. Denies chest pain, N/V/D, HA, vision changes. Patient is a 74 year old male who presents to ED following a 10 second episode of right arm tingling followed by a 90 minute episode of difficulty finding words. This happened tonight at 8:30pm after dinner when he was with his wife. His symptoms resolved upon arrival at the ED at 10pm. He denies any weakness, no syncope, no chest pain or shortness of breath, no new visual symptoms. He does have a history of CHF, MI in 2013 s/p stend placement, he takes Plavix. He takes a beta blocker for PVC's. He reports he had a J&J COVID shot this morning at 11am and is wondering if his symptoms are a reaction to the vaccine. He is followed closely at Ajou hospital for all his medical care. |
| 1135536 | 3/25/2021 | NY | 70 | F | 3/17/2021 | 3/18/2021 | 3/17/21 Chills from 12:30 am until 7:30 am. 7:30 am felt very very ill. had temp of 101.7. All of a sudden I had Urinary incontinence. I started peeing in my bed. Asked my husband to help me to bathroom because I felt so sick. I fainted in his arms Got back into bed and had a horrible migraine. had to have my eyes covered and dark room I felt as though I was going to throw up for hours. Did not eat anything until 8 pm. some toast and tea. 3/18/21 Still sick but not as bad. Stayed in bed for 1/2 day. it was a slow go. 3/19/21 Still not myself. 3/20/21. Felt more myself. |

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| 1135549 | 3/25/2021 | NJ | 24 | F | 3/11/2021 | 3/11/2021 | left arm is very sore, painful to touch and difficult to move; left arm is very sore, painful to touch and difficult to move; fainted /vasovagal syncope episode; might have convulsed on the floor; out of breath; nausea; dizziness; This is a spontaneous report from a non-contactable consumer (reported for herself). A 24-year-old female patient (not pregnant at the time of vaccination) received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), dose 1 intramuscular, administered in Arm Left on 11Mar2021 15:00 (Lot Number: EN6199) at the age of 24 years old as single dose for covid-19 immunisation. The patient's medical history was not reported. Concomitant medication received within 2 weeks of vaccination included levonorgestrel, ethinyl estradiol (reported as "Levonor-E Estrad"). Facility where the most recent COVID-19 vaccine was administered in Pharmacy or Drug Store. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 11Mar2021 15:15, Few minutes after vaccination patient fainted and might have convulsed on the floor. Patient became conscious after a couple min. Patient had spouts of nausea and dizziness. 2 hr after dose (11Mar2021) patient was out of breath and went to a hospital. Doctors suppose that the incident was a vasovagal syncope episode. After 18 hr (12Mar2021) patient's left arm was very sore, painful to touch and difficult to move. The events resulted in Emergency room/department or urgent care. No treatment received for the adverse events. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient hadn't been tested for COVID-19. No covid prior vaccination. No covid tested post vaccination. The outcome of the events was recovering. No follow-up attempts are possible. No further information is expected. |

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| 1135558 | 3/25/2021 | NC | 70 | F | 2/20/2021 | 2/21/2021 | Bruising of foot; foot was all messed up/it was all bruised and swollen, but it was not broken. She says this was her right foot; Fatigue; had a low blood sugar episode she supposed; passed out/Unconsciousness; had muscle spasms almost to seizure amount of shaking/full body muscle spasms; had muscle spasms almost to seizure amount of shaking/full body muscle spasms; crashed unconscious to the floor/fell/fell backwards/caught her foot under the vanity; This is a spontaneous report from a contactable consumer (patient) reporting for herself A 70-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), dose 2 via an unspecified route of administration, administered in the left arm on 20Feb2021 11:00 (Lot Number: EN6201) as a SINGLE DOSE (at the age of 70 years old) for covid-19 immunisation. Medical history included breast cancer from 1988 to an unknown date , ovarian cancer from 2015 to an unknown date , she has had lymph nodes removed from her right arm "30 years ago" from 1988 to an unknown date, pass out from unknown date to unknown date. Concomitant medication included olaparib (LYNPARZA) taken for ovarian cancer from Feb2020 at 150mg, 2 tablets in the morning and 1-2 tablets at night by mouth.She says she is a little person and couldn't tolerate the side effects of that, so she varies how many she takes based on her side effects. She says she is supposed to take 300mg in the morning and 300mg at night. She says how she takes it is, she takes 150mg or one pill in the morning, then one or two at night depending on how she is doing. Historical vaccine information included BNT162B2 dose 1, lot no: EL9264, route left arm for Covid-19 immunisation. Past drug history included on days of intravenous (IV) chemo when she was being highly treated in the past sometimes she would pass out. The patient reported approximately 15 hours after the shot, on 21Feb2021 she had muscle spasms almost to seizure amount of shaking, full body muscle spasms. She clarifies that her side effects didn't kick in until 02:30AM on 21Feb2021. She says at 07:00AM on 21Feb2021 she got up and went into the bathroom and passed out, and had a low blood sugar episode she supposed. She crashed unconscious to the floor. She said that could be from the shot, but she is also a high risk patient, a cancer patient, and is on a maintenance chemo drug. She says on days of |

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intravenous (IV) chemo when she was being highly treated in the past sometimes she would pass out, so she doesn't know if that was related to the COVID shot or not. No testing had been done on high risk patients, so she thought maybe this could be a good heads up for something someone else may experience. Her side effects were on and off for several hours, the shaking and spasms would subside and then start again. She says that they went away, and then she got up and passed out, and her foot was all messed up, she doesn't know what she did when she fell, but she had it checked and it was not broken, it was all bruised and swollen, but it was not broken. She says this was her right foot. She says she thinks she fell backwards, and she thinks she caught her foot under the vanity. On unknown date, she experienced bruising of foot, fatigue, foot was all messed up/it was all bruised and swollen, but it was not broken. She says this was her right foot. Outcome of the events was unknown. Information on the lot/batch number has been requested.

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| 1135566 | 3/25/2021 | OK | 54 | F | 3/5/2021 | 3/6/2021 | delirious as if I was hungover; delirious as if I was hungover; felt on the brink of fainting; chills; joint pain; pain at the injection site; lethargic; dry cough; severely nauseous; could not eat; serious fogginess; General malaise; fatigued; a debilitating headache; did not feel comfortable driving; weak; hurt in my chest; slept the whole day; This is a spontaneous report from a contactable consumer. A 54-year-old non-pregnant female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration, administered in the left arm on 05Mar2021 at 13:30 (Batch/Lot Number: EN6202) at 54-years-old as a single dose for COVID-19 immunization; administered in a hospital. The patient did not receive any other vaccine within four weeks of the suspect vaccine. Medical history included hypertension, and acne from an unknown date and unknown if ongoing. The patient did not have COVID prior to the vaccination. Concomitant medications included hydrochlorothiazide, olmesartan medoxomil (MANUFACTURER UNKNOWN) taken for an unspecified indication, start and stop date were not reported; isotretinoin (MANUFACTURER UNKNOWN) taken for an unspecified indication, start and stop date were not reported. The patient previously took (ceftriaxone sodium) ANCEF, start and stop date were not reported, and experienced drug allergy. On 06Mar2021 at 04:00 (as reported), the patient experienced: delirious as if i was hungover (medically significant), felt on the brink of fainting (non-serious), chills (non-serious), joint pain (non-serious), pain at the injection site (non-serious), lethargic (non-serious), dry cough (non-serious), severely nauseous (non-serious), could not eat (non-serious), serious fogginess (non-serious), general malaise (non-serious), fatigued (non-serious), a debilitating headache (non-serious), did not feel comfortable driving (non-serious), weak (non-serious), hurt in my chest (non-serious), slept the whole day (non-serious); with no treatment received. The clinical course was reported as follows: The patient reported that on the first night (as reported) she had chills, joint pain and pain at the injection site. The next day (as reported) she was lethargic and was severely nauseous to the extent she could not eat. The patient also experienced serious fogginess, felt delirious as if she was hungover. The patient felt general malaise and a |

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| 1135831 | 3/25/2021 | | 64 | F | 3/24/2021 | 3/25/2021 | debilitating headache all day. The patient was fatigued to the extent she did not feel comfortable driving. The patient was so weak, that she felt on the brink of fainting. That evening, the patient slept the whole night through, except when she would awake with a dry cough that hurt in her chest. This cough was not as persistent and intense but was lasting even now. The patient slept the whole day and was just now beginning to feel as if she had recuperated from the vaccine four days later. The clinical outcome of the events was recovered with sequelae on an unspecified date (also reported as "recovered with lasting effects"). The patient was not tested for COVID post vaccination. |
| 1135839 | 3/25/2021 | | 19 | M | 3/25/2021 | 3/25/2021 | syncope, fever |
| 1135858 | 3/25/2021 | MI | 34 | M | 3/25/2021 | 3/25/2021 | Patient felt dizzy, lightheaded and passed out. Cleared by EMS |
| | | | | | | | GAVE HIM THE COVID 19 SHOT AT 12.40 PM AND ASKED THE PATIENT TO WAIT FOR 15 MINUTES AT THE DESIGNATED WAITING AREA. PT WAS WITH HIS SPOUSE AFTER FEW MINUTES THE SPOUSE SPOUTED AT ME THAT THE PT IS PASSING OUT. I IMMEDIATELY RAN OUT AND PATIENT WAS ON THE FLOOR AND HE SAID HE IS NOT DOING WELL FEELING TINGLING AND HE WAS SWEATING. HE WAS ABLE TO BREATHE AND TALK . WE CALLED 911 AND I GAVE HIM EPIPEN 0.3MG ONE SHOT AT 12.45 PM. I WAS STILL MONITORING THE PT AND AT 12.50 PM EMS PERSONAL CAME AND TOOK OVER FROM ME. EMS PERSONAL CHECKED HIS VITALS AND THEY SATISFIED THAT HE WAS DOING GOOD AND LET HIM GO HOME. I CALLED THE PATIENT AROUND 2.30 PM TO ENQUIRE ABOUT HIS HEALTH AND THE PT SAID HE IS DOING FINE AND HE SAID THAT HE PASSED OUT IN THE PAST MANY TIMES AFTER A BLOOD DRAWN OR SHOT. AS A PHARMACIST I FEEL HE DID NOT HAVE ALLERGIC REACTION FROM THE VACCINE ITSELF. ANXIETY IS THE CAUSE OF ENTIRE SITUATION |

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| 1135872 | 3/25/2021 | CA | 17 | M | 3/25/2021 | 3/25/2021 | 17 year old male had syncope episode with fall from seated position to floor with spontaneous regain of consciousness. 911 was called. Normal vital signs. Legs were elevated. Patient assessed by paramedics, PA and NP. Patient declined transport to hospital for further medical evaluation and was encouraged to seek medical care if symptoms worsened. Yes |
| 1135877 | 3/25/2021 | GA | 31 | F | 3/25/2021 | 3/25/2021 | lightheaded without syncope, burning/itching to right arm then tingling/itchy lips and roof of mouth, tachy sent to ED after Benadryl 25mg po and watched for 45min wasn't improving. In ed given Solumedrol 125mg, Pepcid 20mg, Zofran without improvement and then began dry heaves, Phenergan given and epi 0.3mg IM with improvement of symptoms, No hives but red rash to right arm/neck. |
| 1135886 | 3/25/2021 | CA | 32 | M | 3/18/2021 | 3/18/2021 | 5 minutes after receiving 1st dose of Moderna vaccine, patient slumped over in waiting area, patient aroused with contact, appeared pale, stated anxious, nausea, "not feeling right," A&O x 4, denied SOB, chest pain, swelling, itching, no redness, swelling, hives noted. B/P: 98/60, HR: 58, BG: 98, SPO2: 99%. Per DO, MA applied 4L face mask. Patient laid supine: feet up, given water, removed O2. After 15 minutes: B/P 105/66, HR: 59 supine, SPO2 99%RA. After 30 minutes: B/P 97/67, HR 59 sitting, SPO2 100%RA. Patient stated "feeling better" another 30 minutes later. B/P: 110/67 HR: 58. Patient stated all symptoms resolved, had been anxious about vaccine, has had syncope prior at dental appts. Patient denied SOB, chest pain, swelling, itching. Patient advised to call EMS if develops any above symptoms. Patient monitored for 1 hour total. |
| 1135420 | 3/25/2021 | KY | 27 | M | 3/25/2021 | 3/25/2021 | Pt received Pfizer COVID-19 vaccine on 3/25/21 at around 11:15 am and immediately lost consciousness. Nurse administered epinephrine and called 911. Pt regained consciousness shortly after receiving epinephrine. Pt did report history of syncope with injections before receiving the vaccination. |

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| 1135942 | 3/25/2021 | | 28 | M | 3/5/2021 | 3/5/2021 | Patient experienced an episode of syncope within 45 seconds of administering vaccine. Patient lost consciousness for approximately 20 seconds. Patient did not hit head or sustain any other injuries. Medical alert response was activated and patient vital signs were monitored until WNL. Patient was taken in wheelchair to curbside for discharge. Patient stated prior to vaccine that he had a history of anxiety and fainting. |
| 1136238 | 3/25/2021 | AL | 17 | M | 3/25/2021 | 3/25/2021 | Pt was nervous about the shot, but seemed ok immediately after it was administered. He went to the chair to wait his 15 minutes with his mom. A minute later, his mom was calling that he was having a reaction. A technician called 911 while I went to check. He passed out for just a moment and came to quickly. His mom said he was ok but paramedics arrived within minutes and were checking him out. His blood pressure was super low and they monitored him and took over. They were gone within probably 10 minutes. |
| 1136024 | 3/25/2021 | MN | 36 | F | 3/25/2021 | 3/25/2021 | Drop in blood pressure and fainting episodes. Blood pressure still not stabilized after 10 hours. Dropped 25-30 points below my average. |
| 1136032 | 3/25/2021 | LA | 22 | F | 3/23/2021 | 3/23/2021 | Moderna COVID-19 Vaccine EUA, headache was first followed by body aches, weakness, then uncontrollable chills, and fever. I could not sleep due to the chills and body aches. I fainted from weakness. I did not feel better until the night of March 24th. |
| 1136071 | 3/25/2021 | IA | 83 | M | 3/11/2021 | 3/13/2021 | Passed out. |
| 1136094 | 3/25/2021 | OH | 21 | F | 3/25/2021 | 3/25/2021 | Patient fainted multiple times after receiving injection. |
| 1136109 | 3/25/2021 | TX | 64 | F | 3/25/2021 | 3/25/2021 | Pt passed out briefly about 7 minutes after vaccine was administered. I followed company's protocol and she was okay after about 2 to 5 minutes. Paramedics came but she refused going to ER with them because she was already feeling better by the time they arrived |
| 1136123 | 3/25/2021 | AZ | 24 | M | 3/25/2021 | 3/25/2021 | Patient was given the 1st dose of the Pfizer- BioNtech vaccine and was told to wait in observation and few minutes later the patient fainted and had what appeared to be a seizure. Pharmacists onsite responded immediately and EMS was called. |

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| 1136213 | 3/25/2021 | IL | 31 | F | 3/25/2021 | 3/25/2021 | after 5 mins patient receiving the shot, she fainted on the chair at the pharmacy waiting area. Immunizing pharmacist injected patient epipen shot and she woke up afterward. Paramedic was called. |
| 1136271 | 3/25/2021 | AK | 25 | F | 3/25/2021 | 3/25/2021 | Patient experienced syncope after Moderna Covid-19 immunization. She never lost consciousness but was lowered from her chair to lie down on the floor by administering pharmacist and technician. Store management brought her cushioned chair to be seated more comfortably. Eventually was able to walk and was driven home by roommate. |
| 1134347 | 3/25/2021 | TX | 43 | M | 3/25/2021 | 3/25/2021 | Fainted. Denies SOB, chest pain. refused to ER. states he feels much better after 5min. History of same symptom in the past with needle stick. Seen and cleared by EMS |

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| 1131207 | 3/25/2021 | FL | 32 | F | 3/15/2021 | 3/15/2021 | ~~Faint for 5 minutes 6 hs after the shot"; "Some dizzy and light headed"; Arm Sore; A spontaneous report was received from a consumer concerning a 32-year-old female patient who received Moderna (mRNA-1273) vaccine and Fainted/Syncope and was dizzy and light headed/dizziness, and experienced Arm sore/ Vaccination site pain. The patient's medical history was not provided. No Relevant concomitant medications were reported. On 15 Mar 2021, prior to the onset of symptoms, the patient received their first of two planned doses of mRNA-1273 (Lot number: 002B21A) for prophylaxis of COVID-19 infection. On 15 Mar 2021, the patient fainted for 5 minutes, about 6 to 8 hours post vaccine administration. The patient was dizzy and lightheaded and experienced arm soreness. The event, fainted for 5 minutes, about 6 to 8 hours post vaccine administration was considered medically significant. No Treatment information were provided. Action taken with mRNA-1273 in response to the event(s) was unknown. On 15 Mar 2021, the outcome of the event, fainted for 5 minutes, about 6 to 8 hours post vaccine administration was considered resolved The outcome of the events, was dizzy and lightheaded, and experienced Arm sore were considered unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |
| 1135890 | 3/25/2021 | OH | 22 | M | 3/25/2021 | 3/25/2021 | Gave patient Shot. Patient stated it burned, and stated that he wasn't feeling well. Head started to slump, and patient passed out. Called 911. Patient passed out 4 times including once while EMS was present. |
| 1134521 | 3/25/2021 | NC | 26 | F | 3/25/2021 | 3/25/2021 | She fainted, employee stated she saw her seize, EMS called and she was transfered. Intial reaction 15:37 pm. |
| 1135411 | 3/25/2021 | NY | 62 | M | 3/25/2021 | 3/25/2021 | Patient fainted about 5-10 minutes after receiving vaccine. EMS evaluated, patient left and drove home. |

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| 1134502 | 3/25/2021 | CO | 31 | F | 3/22/2021 | 3/24/2021 | Woke up feeling nauseous/diarrhea at 1 am on Wednesday (approx. 60 hours after injection). Side note- on Tuesday (day after injection), I donated blood. Not sure if this is relevant. After waking up nauseous, I experience extreme shortness of breath and full body chills for roughly 30 seconds to 1 minute. I walked about 10 steps to wake up my partner and fainted instead. I woke up to him calling my name, and almost immediately threw up. Afterwards, I felt okay, only tired and a little weak. I was able to go back to sleep and woke the next day with no lingering side effects. I would say the entire episode lasted roughly 5 minutes. |
| 1134368 | 3/25/2021 | NJ | 28 | F | 1/20/2021 | 1/20/2021 | Upon standing post inoculation, reports feeling lightheaded. Syncope episode while sitting in observation area. Epinephrine 0.3mg IM administered & transferred to ED for observation. No medications administered in ED. Dx: vasovagal syncope - stable |
| 1134548 | 3/25/2021 | NE | 25 | F | 3/25/2021 | 3/25/2021 | Patient fainted after receiving vaccine, she required a fan and needed to sit for an hour after dose. She could breath fine, but felt light headed. She had this reaction within 5 minutes of the immunization. |
| 1134552 | 3/25/2021 | NC | 34 | M | 3/25/2021 | 3/25/2021 | Patient fainted after receiving vaccination. |
| 1134556 | 3/25/2021 | NC | 18 | F | 3/25/2021 | 3/25/2021 | She had recieved her dose, she fainted while she was seated, vitals were normal incident occured at around 8:37 am. |

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| 1134585 | 3/25/2021 | WA | 18 | F | 3/25/2021 | 3/25/2021 | Hx of anxiety with imms but no hx of syncope, has never had any jerking or an anxiety attack before, 15 seconds after imm pt pale and asks if she can sit here for a few minutes, RN asks if feeling lightheaded-no response, then lowers her head and draws up bil arms and begins rythmic jerking of bil arms and torso, RN calls code blue and second RN responds right away, pt safely lowered to the ground by two RN's-feet elevated, 911 called and VS obtained 110/60 98 16 98% on RA, after 20 seconds jerking self resolves, pt opens her eyes and immediately asks what happened, pupils remain dilated, she remember events up to asking if she can sit here for a minute, denies any tightness to chest or throat, denies difficulty breathing, no wheezing or rash noted by RN, pt laid on ground for about 10 minutes and was then escorted with 2 person assist to the lobby to wait for EMS to arrive, pt remained pale and clammy and light headed, 1305- pt father notified of incident 1320-RN gives report to EMS in lobby, pt still laying on ground with feet elevated but laughing and talking to her friends, BP now 114/64 and color is improved, RN advised her to follow up with her PCP 1330-pt sitting up in chair and BP 110/60 |
| 1134615 | 3/25/2021 | SC | 70 | F | 3/23/2021 | 3/23/2021 | After patient received vaccine and waited 15 minutes she asked if she could wait longer because she didn't feel well. Paramedic was called and took patient to the EMS tent - per EMS pt was diaphoretic with hypotension and near syncope -after laying down BP normalized and pt resumed normal status. Pt requested to go to the ED. Pt is currently being treated with chemotherapy and had her last dose 5 days prior. She was brought in by EMS after appearing cool, diaphoretic, nauseous, and unwell after vaccine administration. Patient states that she was feeling nauseous, dizzy, and weak 1 hour after administration. She likely had a vasovagal-like response to vaccine administration. Did not lose consciousness. |
| 1134625 | 3/25/2021 | IL | 32 | F | 3/25/2021 | 3/25/2021 | Light headed, dizzy, near syncope episode. Patient laid dodwn, elevated legs, felt better |

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| 1134685 | 3/25/2021 | CA | 63 | F | 3/25/2021 | 3/25/2021 | Pt presented today for 1st Pfizer mRNA COVID vaccine. She received the vaccine at 11:06am and proceeded to the check out area and scheduled her second appointment and checked out at 11:10am. She was sitting in the secondary seating area, she looked scared, then she indicated to the APP she felt dizzy, eyes fluttered back, and slumped back into the chair and into APP's arms. With the assistance of another RN, we laid her down on the ground and lifted her legs. She was arousable to sternal rub and complained of dizziness. She was able to report her name and that her husband was outside in the car waiting for her, however, she was slow to answer questions and still appeared distressed. We made several attempts to obtain a BP, however, it would not register on machine, O2 sat 100%, HR 42, manual HR 50 at pericordium. Her bilateral upper extremities were cool to touch and appeared mottled. We attempted to give her apple juice just she was only able to take a few sips. We placed her on 100% non-rebreather. Given low HR, unable to obtain BP, and semi-conscious state, we elected to call 911 at 11:30am. Her husband was retrieved and at patient side when EMS responded. He reported that she has fainted in the past with blood draws and has a past medical history of "leaky valve, low platelets" and later it discovered via her medical records that she has a history of seizures and was on vimpat and lisinoril. EMS arrived, assessed the patient, and moved her to stretcher and transported patient at 11:39am. |
| 1134727 | 3/25/2021 | CA | 62 | M | 3/23/2021 | 3/25/2021 | Syncopal episode while at store. Patient brought to emergency department via ambulance. |

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| 1135287 | 3/25/2021 | AL | | F | 1/19/2021 | 1/19/2021 | Light energy; Fever; Arm hurt pretty bad; Chills; Body aches; Fatigue; Passed out twice; Felt like ran over by truck; A spontaneous report was received from a consume who is a female patient who passed out twice/ loss of consciousness, felt like she was run over by truck/ feeling abnormal, fatigue, chills, body aches/ myalgia, fever/ pyrexia, arm hurt pretty bad/ pain in extremity and light energy/ asthenia. The patient's medical history was not reported. Patient's concomitant reported included Lexapro and Spironolactone. On 19 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (Lot number: 041120A) intramuscularly for prophylaxis of COVID-19 infection. On 19 Jan 2021, same day of receiving vaccine, the patient passed out twice and felt like she was run over by truck. She also experienced fatigue, chills, body aches, fever and arm hurt pretty bad. On 21 Jan 2021, 2 days later, she had light energy. No treatment information was reported. Action taken with mrna-1273 in response to the events was not reported. The outcome of events was not reported.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events (pyrexia, pain in extremity, chills, myalgia, asthenia, fatigue, feeling abnormal) a causal relationship cannot be excluded. Very limited information regarding the event (LOC) has been provided at this time. Further information has been requested. |
| 1135388 | 3/25/2021 | TX | 33 | F | 3/24/2021 | 3/24/2021 | Rash covering arms and legs, extreme fatigue, fainting occurred approx 6.5-7hrs after shot. Unconscious for under 2 mins. Dizzy and light-headed. |
| 1135395 | 3/25/2021 | TN | 39 | M | 3/24/2021 | 3/24/2021 | Pt fainted after receiving vaccine. Low BP, sweating. Monitored in safe area until recovered |
| 1134749 | 3/25/2021 | OH | 19 | F | 3/25/2021 | 3/25/2021 | syncope after injection, VSS, no emergency transport needed |

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| 1135295 | 3/25/2021 | FL | | M | 3/8/2021 | 3/9/2021 | Stomach is crampy; Muscle joints hurt; Bad headache; Chills; Threw up; Bad fever; Passed out; Loose bowels; Sweating; A spontaneous report was received from a consumer concerning a 53 years old male patient who developed passed out/loss of consciousness, diabetic/diabetes mellitus, loose bowels/diarrhoea, bad fever/pyrexia, sweating/hyperhidrosis, muscle joints hurt/myalgia, stomach is crampy/abdominal pain, bad headache/headache, threw up/vomiting and chills. The patient's medical history included diabetes and sinus infection. Products known to have been used by the patient, within two weeks prior to the event, included Metformin and sinus medication. The patient received their first of two planned doses of mRNA-1273 (Batch number: 036A21A) on 8 Mar 2021 in the left arm for prophylaxis of COVID-19 infection. On 9 Mar 2021 around 10 AM the patient started feeling bad. Patient threw up, had loose bowels, bad fever, couldn't get warm for 3 hours, was sweating, and passed out. On 10 Mar 2021 patient stated that all his muscle joints hurt, and his stomach is crampy, and has a bad headache and chills. The medically significant event is loss of consciousness. Treatment information was not provided. Action taken with mRNA-1273 in response to the event(s) was not provided. The outcome of the event(s) passed out, diabetic, loose bowels, bad fever, sweating, muscle joints hurt, stomach is crampy, bad headache, threw up and chills was not reported.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded. |

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| 1135304 | 3/25/2021 | NY | 53 | F | 3/2/2021 | 3/2/2021 | <p>Passed out; she lost control of bladder; Blood pressure low; A spontaneous report was received from a consumer concerning a 53-years-old, female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and passed out (loss of consciousness) and lost control of bladder (urinary incontinence) and blood pressure low(hypotension). Patient's past medical history included, low blood pressure. It was normally on the lower end. She had fainted 10-15 times in her life. The patient was going through menopause and had been having hot flashes. Products known to have been used by patient with in past two weeks included bupropion hydrochloride and vitamins nos. On 02-Mar-2021, 5-7 minutes before the onset of events, the patient received their first of two planned doses of mRNA-1273 (Lot number: 010A21A or 010AZ1A illegible), intramuscularly in left arm for prophylaxis of COVID-19 infection. On 02-Mar-2021, the patient passed out. She lost control of bladder. They took her into room, her blood pressure went low and passed out, they got her blood pressure back up she came around in a couple minutes. They called 911 but no ambulance came. When the patient felt good enough to leave, then they sent them home. She felt effects for rest of day, but felt normal the next day. No treatment information was provided. Action taken with mRNA-1273 in response to the events was unknown. The events of passed out (loss of consciousness) and lost control of bladder (urinary incontinence), blood pressure low(hypotension) resolved on 03-Mar-2021.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p> |

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| 1134845 | 3/25/2021 | TN | 30 | F | 3/25/2021 | 3/25/2021 | Patient received vaccine while seated and had no problems. She stood up and walked several feet to the observation seating area and had a seat. A few minutes later she fainted and fell out of the chair onto the floor. We helped her up to a sitting position and gave her a bottle of water and an ice pack. The right side of her forehead appeared red from apparent hit on the floor when she fainted. We had her wait on the floor for about 30 minutes to ensure she remained conscious. Patient reported an ache on her forehead at site of hit. She was also sweating and reported feeling hot. Patient had a partner with her who agreed to escort her to an urgent care clinic in the same building as the pharmacy. Store manager in charge took the patient to the urgent care clinic by wheelchair to be examined. |
| 1134832 | 3/25/2021 | TN | 23 | M | 3/25/2021 | 3/25/2021 | patient fainted after receiving vaccine. patient was transported to hospital and has recovered |

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| 1134827 | 3/25/2021 | MN | 39 | F | 3/25/2021 | 3/25/2021 | Patient received her 1st Pfizer vaccination dose at 12:37PM. Patient was seated in the vaccination waiting area for her 15 minutes observation window. About 5 minutes after vaccination the patient fainted and fell out of her chair on to the ground. She hit her head on the wall behind her, and ground when falling. Pharmacy staff immediately went to check on patient. She was found to be breathing, but unresponsive for about 20 seconds. 911 was called immediately by another employee. She was positioned lying on the ground with her feet up and came to consciousness quickly. Once awake patient was alert, verbal, and seemed to have a normal mental status. She reported no respiratory issues, no throat or lip symptoms, and no itching or hives. She states that she felt fine other than her head hurting from the fall. She reported no symptoms prior to waking up on the ground. She was speaking in full sentences, responsive, and had a strong, steady pulse at 98 bpm and a normal respiratory rate. No hives, swelling were observed. Patient reported she was a type 1 diabetic and her blood sugar was found to be normal (approx. 145) after she was able to sit. No medications were administered on site as she did not report any additional symptoms indicative of anaphylaxis. The ambulance and local PD arrived quickly. She was walked outside for observation and appeared to be taken away in the ambulance. The patient was not reached for a follow-up call to check in on her later the same afternoon. |
| 1134800 | 3/25/2021 | MD | 74 | F | 3/23/2021 | 3/24/2021 | I fainted, along with having fever, chills, headaches, nausea and swollen sore arm. I hadn't read of people fainting, so I wanted to let you know. I only fainted once and I was recovered by March 25. |
| 1134797 | 3/25/2021 | CA | 24 | M | 3/25/2021 | 3/25/2021 | Pt experienced fainting sensation shortly after receiving vaccine. Pt was sweating and reported temporary loss of vision after getting up after the vaccine. Pt informed pharmacist of 2 previous incidents of vasovagal syncope and was instructed to receive the vaccine while sitting on a cot. Pt was instructed to lie down flat on the cot for 30 minutes to be observed by pharmacists. Blood pressure and pulse monitored (normal range 126/66mmHg and 76BPM). Pt fully recovered after 5 minutes. Pt was instructed to seek emergency help if any new symptoms develop or worsen. |

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| 1134771 | 3/25/2021 | CA | 27 | F | 3/25/2021 | 3/25/2021 | History of fainting with blood draws. RN helped pt to lie down on cot, pt C/O tunnel vision felt like going to pass out. Code Green called paramedics assessed BP132/88, HR 95, RR 18. Pt felt much better, kept in observation for an additional 30 minutes. |
| 1129670 | 3/24/2021 | FL | 83 | M | 3/4/2021 | 3/5/2021 | fainted; A spontaneous report was received from a consumer who was an 83-year-old, male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and fainted. The patient's medical history was not provided. No relevant concomitant medications were reported. On 4 Mar 2021, prior to the onset of the event, the patient received their second of two planned doses of mRNA-1273 (lot/batch: 030421a) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 5 Mar 2021, the patient reported that he fainted and had to be taken to the hospital by a family member. He reported that he had been hooked up to multiple machines for testing. He believed that the syncopal event was related to his heart rate. No treatment information was provided. Patient received both scheduled doses of mRNA-1273, therefore, action taken with the drug in response to the event was not applicable. The outcome of event, fainted the day after 2nd dose, was considered unknown.; Reporter's Comments: Very limited information regarding this event has been provided at this time. Further information has been requested. |

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| 1129662 | 3/24/2021 | TX | 51 | F | 3/6/2021 | 3/6/2021 | <p>Feeling sleepy yesterday; Itching around the neck and arm but no rash; Chills; Headache; Nausea; Fever; Body ache; Felt tired; Vomiting; Tired muscle; Passed out in kitchen; Heavy chest which did not affect her breathing but it felt like adrenalin rush; A spontaneous report was received from a 51 year-old female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced chills, headache, nausea (nausea), vomiting (vomiting), fever (pyrexia), itching around the neck and arm but no rash (pruritus), body ache (pain) with tired muscle (muscle fatigue), felt tired (fatigue), passed out in the kitchen (loss of consciousness), heavy chest which did not affect the breathing but it felt like adrenalin rush (chest discomfort) and felt sleepy (somnia). The patient's medical history was not provided. No relevant concomitant medications were reported. On 06 Mar 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Batch Number: 012A21A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 06 Mar 2021, 5 to 6 hours after the vaccination, the patient experienced chills, headache, nausea and vomiting, fever, itching around the neck and arm but no rash, body ache, felt tired and passed out in the kitchen. The patient also had heavy chest which did not affect the breathing, but it felt like adrenalin rush. On 07 Mar 2021, the patient felt sleepy and had muscle tiredness. Treatment included paracetamol and ibuprofen every 4 hours to treat the symptoms.. Action taken with mRNA-1273 in response to the events was not applicable. The outcomes of the events, chills, headache, nausea and vomiting, fever, itching around the neck and arm but no rash, body ache with tired muscle felt tired and passed out in the kitchen, heavy chest which did not affect the breathing but it felt like adrenalin rush and felt sleepy, were unknown.;</p> <p>Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p> |

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| 1129661 | 3/24/2021 | CA | 63 | F | 3/3/2021 | 2/6/2021 | Fell after urinating and hit her head; Semi delirious and confused; Cramps were intermittent for 1-2 hours; Tremulous; Low blood pressure; Dizzy; Cold, clammy; Very sweaty; Severe diarrhea; Lost consciousness; Borderline in shock or in shock; Head injury; abdominal discomfort; A spontaneous report was received from a physician concerning a 63-year-old, female patient who developed severe diarrhea, abdominal discomfort, lost consciousness, fell after urinating and hit her head, cold and clammy, very sweaty, low blood pressure, semi delirious, confused, tremulous, cramps, in shock and dizzy. The patient's medical history was not provided. Concomitant product use was not provided by the reporter. On 03 Mar 2021, approximately four days prior to the onset of the symptoms, the patient received her first of two planned doses of mRNA-1273 (Batch number: 041L20A) intramuscularly for prophylaxis of COVID-19 infection. On 06 Mar 2021, the patient experienced severe diarrhoea and abdominal discomfort. At 4 AM she had lost consciousness and fell after urinating and hit her head on the curb of the shower. Her husband found her and when he saw her, she was cold, clammy and very sweaty. Her husband reported that the patient had low blood pressure that caused syncope and caused her to fall. The patient was in a semi-delirious state and was confused, tremulous. The cramps were intermittent for 1-2 hours. The patient was in a borderline shock or in shock as she was very dizzy when she stood up. The events were resolved after four hours. On the next day her temperature was at 98.8 degrees Fahrenheit. Treatment information was not provided. Action taken with mRNA-1273 in response to the events was not provided. The outcome of the events, diarrhea, abdominal discomfort, loss of consciousness, fall, cold sweats, hyperhidrosis, hypotension, syncope, confusional state, tremors, muscle spasms, shock and dizziness were recovered.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |

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| 1129683 | 3/24/2021 | TX | 52 | F | 2/25/2021 | 2/25/2021 | <p>short of breath; felt like she was fainting; dizziness; loss of straight; fatigue; muscle pain/body aches; headaches; joint pain; A spontaneous report was received from a consumer concerning a female patient of 52 year old, who experienced events loss of straight, headaches, muscle pain, body aches, fatigue, dizziness, joint pain,short of breath and syncope. The patients medical history,as provided by the reporter, included she had covid-19 three months ago and prediabetes. Concomitant medications were reported included 2 unknown medications for prediabetes On 25 Feb 2021,prior to the onset of events, the Patient received their first of two planned dose of mRNA-1273(Lot number: 012a21a) vaccine intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 25 Feb 2021, The first day of vaccination patient experienced loss of straight, headaches, muscle pain, body aches, fatigue, dizziness and joint pain for 3 days. On an unknown date, patient experienced short of breath and syncope. The event syncope was also considered to be medically significant. Treatment for the event included Ibuprofen 800mg. Action taken with the second dose of mRNA-1273 in response to the event was not reported. The event loss of straight, headaches, muscle pain, body aches, fatigue, dizziness and joint pain were considered resolved on 28 Feb 2021. The outcome of the event short of breath and syncope was unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p> |

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| 1129658 | 3/24/2021 | TX | | M | 2/24/2021 | 2/24/2021 | Fainted in shower; while having dinner fainted, dizziness, and light headed; Body ache; Extreme high fever; A spontaneous report was received from a consumer, concerning a male patient of unspecified age, who received Moderna's COVID-19 vaccine and experienced fever, body ache, fainting, dizziness and lightheadedness. The patient's medical history was not provided. Concomitant product use was not provided by the reporter. On an unknown date, the patient received their first of two planned doses of mRNA-1273 (lot number unknown) via unknown route for COVID-19 infection prophylaxis. On 24-FEB-2021, prior to the onset of events, the patient received their second of two planned doses of mRNA-1273 (lot number unknown) intramuscularly on left upper arm for COVID-19 infection prophylaxis. On 24-FEB-2021, after second dose of vaccine, the patient experienced extreme high fever and body ache. Treatment medication included Tylenol for the event extreme high fever. On 26-FEB 2021, patient was feeling better and was able to walk for an hour. At night, he went to the restaurant for dinner and while having dinner, patient fainted, experienced dizziness and felt light headed. He had ongoing symptoms of dizziness while standing and sitting. The patient received both scheduled doses of mRNA-1273 prior to the events; therefore, action taken with the drug in response to the events is not applicable. The outcome of the event, fainting was unknown at the time of this report. The outcome of the events extreme high fever and body ache was resolved on 26-Feb-2021. The outcome of the event dizziness is not resolved/not recovered.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |

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| 1129656 | 3/24/2021 | | 73 | M | 2/11/2021 | | He almost passed out and felt like the life was going out of him; Feeling very weak; Little out of breath; Little lightheaded; Little depressed; Nausea; Vomiting; A spontaneous report was received from a Consumer concerning a 73 Years-old male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and the patient experienced nausea, almost passed out and felt like the life was going out of him, very weak, vomiting, little out of breath, little lightheaded, depressed. The patient did not take any medication. No relevant concomitant medications were reported. On 11-02-2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 for prophylaxis of COVID-19 infection. On an unknown date, the patient experienced nausea, almost passed out and felt like the life was going out of him which was assessed as medically significant based on IME list, very weak, vomiting, little out of breath, little lightheaded, depressed. Laboratory details are not provided. The patient had not received any medication. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events, nausea, almost passed out and felt like the life was going out of him, very weak, vomiting, little out of breath, little lightheaded, depressed were unknown.; Reporter's Comments: Very limited information regarding the events has been provided at this time. Further information has been requested. |
| 1129484 | 3/24/2021 | MD | 48 | M | 3/24/2021 | 3/24/2021 | Patient sweated and almost passed out after received the shot. He recovered after 10 minutes and BP resumed normal. |

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| 1129747 | 3/24/2021 | NY | 61 | F | 3/5/2021 | 3/5/2021 | <p>Right hand feels tingly with numbness; Moderate chest pains; Passed out in chair; Super dizzy; Suffocation in chest; Sick to their stomach; Heart racing immediately after vaccine administration; Fever; Had allergic reaction at the vaccine site; A spontaneous report was received from a consumer concerning a 61-years-old male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced events suffocation in chest, super dizzy, moderate chest pains, sick to their stomach, heart racing immediately after vaccine administration, passed out in chair, fever, right hand feels tingly with numbness. The patient's medical history included COPD (chronic obstructive pulmonary disease), staph infection, CAD (coronary artery disease), depression, anxiety, shortness of breath and suffocation on chest. Concomitant medications reported were amoxicillin, gliclazide, acetylsalicylic acid, amlodipin, atorvastatin, clonazepam, hydroxyzine, multi vitamin, inhaler, albuterol as needed and nebulizer, all were used for an unknown indication. On 05 Mar 2021, prior to the onset of the events the patient received first of two planned doses of mRNA-1273 (lot/batch: 036A21A) Intramuscularly for prophylaxis of COVID-19 infection. On 05 Mar 2021, the patient had allergic reaction at the vaccine site, felt sick to their stomach, dizzy, heart racing immediately after inoculation with the vaccine. Pharmacist thought they were having a panic attack, but patient says no. That evening developed a fever. On 06 Mar 2021, the patient felt suffocation in chest that was tolerable. On 07 Mar 2021, the patient experienced bad suffocation in chest, super dizzy and passed out in chair. Stated that they were knocked out for 35 minutes. Suffocation decreased. On 14 Mar 2021, suffocation comes on with major chest pains. On 15 Mar 2021, the patient experienced the events moderate chest pains and right hand feels tingly with numbness. Treatment details included none. Action taken with mRNA-1273 in response to the events was not reported. The outcome of event, sick to their stomach and heart racing immediately after vaccine administration was resolved on 05 Mar 2021. The outcome of events, suffocation in chest and passed out in chair was resolved on 07 Mar 2021. The outcome of events, super dizzy, moderate chest pains, fever and right hand feels tingly with numbness was unknown.; Reporter's Comments: Based on the current available information and temporal</p> |

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1129468 | 3/24/2021 | KY | 66 | F | 3/23/2021 | 3/23/2021 | association between the use of the product and the start date of the events (suffocation feeling, abdominal discomfort, pyrexia, tachycardia, and vaccination site reaction) a causal relationship cannot be excluded. Very limited information regarding the events (LOC, hypoaesthesia) has been provided at this time. Further information has been requested. |
| 1129587 | 3/24/2021 | MD | 34 | M | 3/5/2021 | 3/6/2021 | Started overnight (after 9:30pm on 3/23/21: Injection site pain, Tiredness,- The following occurred around 8am on 3/24/21: Headache, Muscle pain, Chills, Joint pain, Fever, Nausea, Feeling unwell, Dizziness, Fainting |
| | | | | | | | fainted; severe headache; Chills; body aches; arm pain; This is a spontaneous report received from a contactable consumer (patient). A 34-year-old male patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 05Mar2021 at 14:00 (Lot Number: EN6198) (at 34-year-old) at single dose in arm left for COVID-19 immunization. The patient's medical history was not reported. No allergy to medications, food, or other products. The patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. Concomitant medications within 2 weeks of vaccination included testosterone cypionate, chorionic gonadotrophin (HCG), rosuvastatin, and tadalafil (CIALIS), all taken for an unspecified indication, start and stop date were not reported. The patient previously received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 12Feb2021 at 14:00 (Lot Number: EN6201) at single dose in arm left for COVID-19 immunization. He woke up in the middle of the night (4:00 am on 06Mar2021) after getting his second vaccine with severe headache, chills, body aches and arm pain. After getting up and using the bathroom, he went to take his temperature and fainted. The events were reported as non-serious, while resulted in emergency room/department or urgent care, treatment included intravenous (IV) fluids, paracetamol (TYLENOL). The outcomes of the events were resolved on an unspecified date in Mar2021. Information on the expiration date of vaccine has been requested. |

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| 1129684 | 3/24/2021 | NJ | 70 | F | 3/10/2021 | 3/10/2021 | passed out; hurt her knee and ankle; tired; headache; chills; flu-like symptoms; A spontaneous report (United States) was received from a 70-years-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced passing out, tired, headache, chills flu-like symptoms and hurt her knee and ankle. The patient's medical history was not provided. No relevant concomitant medications were reported. On 10-MAR-2021, prior to the onset of the events the patient received their second of two planned doses of mRNA-1273 (lot/batch: 030M20A) intramuscularly for prophylaxis of COVID-19 infection. On 10- Mar-2021, after receiving the vaccine, the patient experienced tired, headache, chills like flu symptoms and passed out and hurt her knee and ankle. The patient felt better at the time of this report. The seriousness criteria for the event passed out was considered as medically significant. Action taken with mRNA-1273 in response to the events was not applicable. The outcome of event(s) experienced passed out, tired, headache, chills like flu symptoms and hurt her knee and ankle was recovering/ resolving. The reporter did not provide the assessment for the event's, passed out, tired, headache, chills like flu symptoms and hurt her knee and ankle.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded |

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| 1129688 | 3/24/2021 | CT | | F | 2/10/2021 | 3/11/2021 | passed out; arm a little sore; feeling dizzy; A spontaneous report was received from a consumer concerning herself 70 years old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and developed passed out/loss of consciousness, arm a little sore/pain in extremity, feeling dizzy/dizziness. The patient's medical history was not provided. Concomitant product use was Mometasone, Anastrozole, Rosuvastatin, Vitamin D and C. The patient received their first of two planned doses of mRNA-1273 (Batch number: 013L20A) on 10 Feb 2021 intramuscularly at left arm for prophylaxis of COVID-19 infection. The patient received their second of two planned doses of mRNA-1273 (Batch number: 030M20A) on 10 Mar 2021 intramuscularly at left arm for prophylaxis of COVID-19 infection. On 11 Mar 2021 on the morning the patient experienced her arm was a little sore. She used her usual nasal spray with Mometasone, started feeling dizzy and within seconds she passed out. The medically significant event was loss of consciousness. Treatment information was not provided. But the other treatment included Mometasone, Anastrozole, Rosuvastatin, Vitamin D and C. Action taken with mRNA-1273 in response to the events was not provided. The outcome of the events passed out, arm a little sore, feeling dizzy was not reported.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded |

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| 1129700 | 3/24/2021 | FL | | F | 3/11/2021 | 3/11/2021 | Dizzy; Sick to the stomach; Could not eat; Sore throat; Pain in arm; Horrendous headaches; Pass out the day after; Very sick; A spontaneous report was received from consumer concerning female patient of unknown age, who experienced pass out the day after (syncope), very sick (illness), horrendous headaches (headache), dizzy (dizziness), sick to the stomach (abdominal discomfort), could not eat (decreased appetite), pain in arm (vaccination site pain), and sore throat (oropharyngeal pain). The patient's medical history was not provided. Concomitant product use was not provided by the reporter. The patient received first dose of two planned doses of mRNA-1273 on 11 Mar 2021 intramuscularly for prophylaxis of COVID-19 infection. On 11 Mar 2021 the patient was very sick. On 12 Mar 2021 the patient passed out. Patient stated she had horrendous headaches, was dizzy, sick to stomach and could not eat. Patient stated she had pain in arm and sore throat. Treatment for the events was not provided. Action taken with mRNA-1273 in response to the event(s) was not provided. The event, pass out the day after (syncope), was considered as recovered on 12 Mar 2021. The outcome for the events of very sick (illness), horrendous headaches (headache), dizzy (dizziness), sick to the stomach (abdominal discomfort), could not eat (decreased appetite), pain in arm (pain in extremity), and sore throat (oropharyngeal pain) was unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. |
| 1129702 | 3/24/2021 | FL | 41 | M | 3/24/2021 | 3/24/2021 | Patient stated that he started to feel itchy, dizzy, and fainted when he bent over. Fell asleep and said he was dreaming when we woke him up a few seconds later. It started happening around 5 minutes after he received the vaccine. He stated that he felt fine and back to normal after he was woken up. Had him stay until paramedics came to check him out. Was cleared to go home. |

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| 1129828 | 3/24/2021 | NY | 55 | M | 3/16/2021 | 3/16/2021 | Arm hurt 1st like bad tetanus shot for 2 days Chills & sweats started the next day or so Left arm lymph node swollen/aching Lightheaded, nauseous, nearly passed out & vomit Thursday night Chills & sweats got worse, very lightheaded, heavy legs, fainted when having seizure Saturday Sunday things seemed to subside * Tinnitus was flaring most of the time **Chronic left jaw ache/pain flaring as well ***Mid back pain spot which has become chronic like jaw wrapped around torso and up/down spine, almost like a cross. This seems to be the lingering issue as of sunday night. |
| 1129728 | 3/24/2021 | VA | 38 | M | 3/24/2021 | 3/24/2021 | Pt. experienced Syncope, has dizziness, light headed, cold-sweat, and almost fainted. Pt. did not faint had remain in chair while being observed by pharmacist, administered a cold-compress to pt. with pt. reported immediate relief and continued to observe for 30 min. Pt reported feeling better and no signs or symptoms and left with parents. Told to check back with us if any new or further problems. |

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| 1129767 | 3/24/2021 | | 83 | M | 2/12/2021 | 2/15/2021 | Stroke; Passed out; Was flailing like a fish; Could not walk; lost motor skills and had to be fed; Could not speak; Did not understand where he was; was in La La land; A spontaneous report was received from a consumer concerning his father a 83– years-old male patient who received Moderna’s COVID-19 vaccine (mRNA-1273) and experienced stroke, passed out, was flailing like a fish, was in la la land for many day, could not walk, he lost his motor skills and had to be fed, he could not speak, did not understand where he was and he was wheelchair bound. The patient’s medical history, as provided by the reporter, included blindness in one and lost some hearing. Concomitant medications reported included diazepam, bisacodyl and oxycodone. On 12 Feb 2021, approximately three days prior to the onset of the events, the patient received his first of two planned doses of mRNA-1273 (batch 013m20a) via unknown route for prophylaxis of COVID-19 infection. On 15 Feb 2021, the patient experienced stroke, passed out, was flailing like a fish, was in la la land for many days, could not walk, he lost his motor skills and had to be fed, he could not speak, did not understand where he was and he was wheelchair bound. No tests were done, and it was previously agreed that he would not go to the hospital if anything should happen to him. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not reported. The outcome of event, he lost his motor skills and had to be fed, was considered resolving. The outcome of the events, stroke, passed out, was flailing like a fish, was in la la land for many days, could not walk, he could not speak, did not understand where he was and he was wheelchair bound were unknown.; Reporter’s Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |

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| 1129775 | 3/24/2021 | FL | 60 | F | 3/24/2021 | 3/24/2021 | PT REPORTED DIZZINESS TO US AFTER HER IMMUNIZATION. SHE DECLINED OUR OFFER TO CALL 911 FOR HER. WE TOOK HER BP AND PULSE. HER BP WAS 132/88 AND HER PULSE WAS SLIGHTLY LOW AT 57. WE ADVISED PT TO SIT AS LONG AS SHE NEEDS TO AVOID FAINTING, AND TO NOTIFY US IF HER STATUS CHANGES AT ALL. WE PROVIDED HER WITH A BOTTLE OF WATER. SHE WAS WITH A CAREGIVER OR SPOUSE HERE AS WELL. AFTER ABOUT 5 MINUTES, WE TOOK A SECOND BP AND PULSE READING. BP WAS 142/99 AND PULSE WAS 56. SHE AND HER CAREGIVER OR HUSBAND PROCEEDED TO GO TO EMERGENCY ROOM. THEY PREFERRED TO TAKE THEMSELVES INSTEAD OF CALLING 911 FOR AN AMBULANCE. |
| 1129393 | 3/24/2021 | FL | 63 | F | 3/11/2021 | 3/11/2021 | Patient received the first Moderna vaccine at nine o'clock Thursday morning, felt fine until 2pm. She began to feel feverish, achy, nauseous, weak. All symptoms lasted through Sunday when she passed out early in the morning. We found her on the kitchen floor, having hit her head and bleeding. She was conscious and alert but a little disoriented and very weak. We called for an ambulance which took her to the same facility where she had been vaccinated. She was diagnosed with a concussion and low blood pressure (62/49). Today she still feels weak and dizzy and nauseous. She has not returned to work yet, pending recommendation from her cardiologist and PCP. |
| 1128330 | 3/24/2021 | FL | 39 | F | 3/23/2021 | 3/23/2021 | Patient stated that her tongue felt numb, then her whole face became tingly and numb. The patient's left side of her face became droopy and she fainted at one point. |

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| 1129718 | 3/24/2021 | MD | 37 | F | 3/12/2021 | 3/13/2021 | I had only pain at the injection site after the first dose on February 12. I got my second dose on Friday, March 12 at 1pm and woke up at 2am Saturday with debilitating headache and severe nausea. I took tylenol and fell back asleep. I woke up again around 6am with the same severe headache and excruciating pain in my left arm at the injection site and tried to get up to get some ibuprofen. I felt extremely dizzy and could barely walk which ended up in me fainting in the kitchen. I somehow got back to bed, took ibuprofen and went back to sleep. I started feeling better after that, severe headache went away but I had low grade fever, chills, slight nausea and painful arm the whole Saturday up until Sunday morning. I had dizziness on Sunday, was very tired on Monday and still felt weak on Tuesday but after that I recovered and experienced no more symptoms. |
| 1128477 | 3/24/2021 | IN | 64 | M | 3/17/2021 | 3/19/2021 | Flu-like symptoms, sweating, chills, nausea, passed out twice during the first few hours after the onset of symptoms. Upset stomach, vomiting in the night. Felt better the next day and by the third day after the onset of symptoms felt recovered. |

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| 1130145 | 3/24/2021 | MO | 71 | F | 2/26/2021 | 2/26/2021 | <p>Syncope; things went dark; almost passed out twice; BP spikes; left arm pain at the site of the injection; fatigue; A spontaneous report was received from a Consumer concerning a – 71 Years-old female patient who received Moderna 's COVID-19 vaccine (mRNA-1273) and experienced almost fainted/presyncope, Fainting/Syncope, Blackout/Loss of consciousness, Injection site pain, BP spikes and Fatigue. The patient's medical history was provided as Atrial Fibrillation, Syncope and Diabetes (borderline). Relevant concomitant medications were reported as Warfarin, Cimetidine, Carvedilol, Spironolactone, Glipizide, Magnesium, MiraLAX, Probiotics, Stool softener and Clonidine PRN. On 26 Feb 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot/batch: unknown) unknown route in the left arm for prophylaxis of COVID-19 infection. On 26 Feb 2021, after receiving the first Moderna Covid -19 Vaccine the patient experienced dizziness, increased heart rate, left arm pain at injection site. She reported of "almost passed out, and things went dark" on day 4 (02FEB2021) and day 5 (03FEB2021) after the vaccination. She reported that she had one syncopal episode 02FEB2021 while she was standing around the stove, and 2nd syncopal episode occurred on 03FEB2021 while she was getting out of shower. She also has mild fatigue since the vaccination. Fainting and Blackout were medically significant. Laboratory details were provided by her BP readings which are as follows: BP reading on 02MAR2021 -- 102/56, 168/69, 103/54 BP reading on 03MAR2021 -- 180/90, 193/75, 201/91, 215/115 (took Clonidine) BP reading on 04MAR2021 -- 176/81, 200/87 BP reading on 06MAR2021 -- 200/90, 220/92 (took Clonidine) She checked her blood glucose levels daily, and its "within normal" limits. Treatment details was provided as Clonidine PRN. Action taken with mRNA-1273 in response to the events was unknown. On unspecified date, the outcome of the events injection site pain was Recovered/Resolved. At the time of this report the outcome of the events Fainting, Blackout and Fatigue were unknown.; Reporter's Comments: Based on the information provided, the established safety profile of mRNA-1273 vaccine and a strong temporal association between the reported events and the administration of mRNA-1273 vaccine, a causal</p> |

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| | | | | | | | association cannot be excluded. Injection site pain and Fatigue are consistent with the safety profile of the vaccine. |
| 1129981 | 3/24/2021 | PA | 72 | F | 2/27/2021 | 2/28/2021 | Awoke early morning with headache; felt dizzy. Went downstairs for Tylenol; on return to bed felt nauseated, sweaty, dizzy. Passed out on bed for approximately 15 seconds. Husband shook me and called out then I awoke and gained consciousness. Rested in recovery the remainder of the day and was able to take the Tylenol and resume normal activity by midday. |
| 1128154 | 3/24/2021 | CA | 64 | M | 3/12/2021 | 3/12/2021 | Felt fine initially. About 4 hours later got very light-headed and fainted while walking to rest room - resulted in 7 stitches (head laceration) and 2 broken ribs from fall. A "vaccident". I was taken to the ER for treatment and spent 2 nights in the hospital. Over the next 8 or so hours I experienced fatigue, chills/shakes, nausea (threw up 3-4 times), and fainted a second time (while lying down). |
| 1128181 | 3/24/2021 | CA | 31 | F | 3/17/2021 | 3/17/2021 | Patient fainted within 10 minutes after receiving vaccine |
| 1128240 | 3/24/2021 | MA | 38 | M | 3/23/2021 | 3/23/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: after receiving his vaccine passed out and eventually came to was pale for awhile but got better over time |
| 1128242 | 3/24/2021 | MA | 21 | F | 3/23/2021 | 3/23/2021 | Site: Itching at Injection Site-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient discussed when going over the list she has syncope that occurs randomly. In my better judgment patient looked normal and healthy at taht time. Patient 5 min later felt dizzy and fainted for 10 sec before recovering. I called 911 and gave water while the other rph gave cold compress. Patinet recovered quickly when ambulance came but patient refused further medical care and has had history when given vaccine this dizziness occurs. Family member came to pick her up and walked without issue |

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| 1128248 | 3/24/2021 | FL | 57 | F | 3/23/2021 | 3/23/2021 | Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Hypotension-Medium, Additional Details: Patient lost consciousness for ~1 minute, around 5 minutes after receiving first dose of Pfizer COVID-19 shot. Patient was spotted by other patients in waiting area and nearby technician immediately. Breathing never stopped, no epinephine/benadryl administered. Patient was sweating and was provided water. As soon as she regained consciousness, she was able to recite her name and DOB. 911 was called and paramedics arrived within 5 minutes. Taken by EMS to ER. |
| 1128260 | 3/24/2021 | MA | 71 | M | 3/23/2021 | 3/23/2021 | Systemic: Fainting / Unresponsive-Severe |
| 1128263 | 3/24/2021 | TX | 43 | F | 3/21/2021 | 3/21/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Weakness-Mild, Additional Details: PT. FAINTED, BUT HER VITALS WERE NORMAL AND LAID HER FLAT ON FLOOR. ACCORDING TO HUSBAND, PT. HAD NEEDLE FEAR AND WHEN SHE GETS ANXIOUS USUALLY FAINTS OR DIZZY. AFTER 3 TO 4 MINUTES , WITH WATER AND GATORADE DRINK, PT. WAS FINE WITH NORMAL VITALS AND LEFT STORE WITH SPOUSE |
| 1128487 | 3/24/2021 | NH | 23 | F | 3/19/2021 | 3/19/2021 | PT described tightness in through, chest tightness, asthma, Pt took personal pro-air rescue inhaler No fainting, few hives noted, able to speak on phone clearly, no LOC Observe, monitor VS, pulse, ooregular, BP 140/100, cest clear Outcome: PT transported to ER via EMS |
| 1128274 | 3/24/2021 | VA | 57 | F | 3/20/2021 | 3/20/2021 | Site: Pain at Injection Site-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: Hypotension-Severe |

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| 1129259 | 3/24/2021 | WA | | F | 3/5/2021 | 3/5/2021 | <p>Passed out; Chills during the night; Weak/weakness; Fever in the morning; Nausea; fatigue; dose 1 on 16Feb2021 15:00 and dose 2 on 05Mar2021 15:00; dose 1 on 16Feb2021 15:00 and dose 2 on 05Mar2021 15:00; This is a spontaneous report from a contactable consumer (patient). An adult female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) dose 1 (lot number EN6200) on 16Feb2021 15:00 and dose 2 (Lot Number: EN6198) on 05Mar2021 15:00 both via an unspecified route of administration in arm left as single dose for COVID-19 immunisation. Medical history included allergy to Thimerosal. The patient was not pregnant at the time of vaccination. Concomitant medication received within 2 weeks of vaccination included estradiol (ESTRADIOL TRANSDERMAL) 0.05 mg per day, Multivitamin and colecalciferol (D3 5000). Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Symptoms after the second vaccine on 06Mar2021 04:00 included chills during the night, weak, fever in the morning, fatigue. Took 2 extra strength Tylenol at 9:00 am, back to bed. Up at 12:00 pm and overwhelmed with weakness, nausea, passed out, when she woke up she was laying on the floor. She did not know how long she was out, but she did not think it was more than 5-10 minutes. No treatment was received for the adverse event. The outcome of events chills, weakness, nausea, passed out, fever and fatigue was recovered, other events was unknown.</p> |

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| 1128041 | 3/24/2021 | FL | | M | 1/22/2021 | 1/22/2021 | Fainted at home 2hs after the shot; A spontaneous report was received from a consumer who reported on behalf of her seventy-eight-years old husband who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced the event fainted at home 2hs after the shot. The consumer's medical history was not provided. No relevant concomitant medications were reported. The consumer received the first of two planned doses of mRNA-1273 on 22-JAN-2021 (Batch# 029L20A) intramuscularly for prophylaxis of COVID-19 infection. On 22-JAN-2021, the consumer experienced the event fainted at home 2hs after the shot. No treatment information was provided. Action taken with mRNA-1273 in response to the events was unknown. The outcome of the event was unknown. The assessment for the event was not provided.; Reporter's Comments: This case concerns a 78-year-old male who experienced a medically significant and serious unexpected event of syncope. Event onset occurred at home about 2 hours after the first dose of mRNA-1273. Treatment not reported. Event outcomes unknown. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. |
| 1128505 | 3/24/2021 | CA | 21 | M | 3/23/2021 | 3/23/2021 | Patient experience a fainting episode onhis way from vaccination area to observation area. Paramedics were summoned and responded and checked patioent Patient was "out" for approximately 15 seconds per EMT who witnessed event. |

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| 1128513 | 3/24/2021 | | 26 | M | 3/23/2021 | 3/23/2021 | ED Note: At 1650, patient was observed following another nurse to the observation area, when he began swaying from side to side, lost consciousness and landed on his right side. This nurse approached the patient while other co-workers were assisting him to a chair. The patient was regaining consciousness. The patient's vital signs were as followed: 112/96, pulse ox 99%, pulse 46. This nurse gave the patient water and the patient was alert and oriented X 3. The patient c/o left knee pain but denied any other symptoms. This nurse again checked his vital signs at 1655: 85/52, pulse ox 100%, pulse 86. At this point, rapid response was called and report was given. This nurse moved the patient to a wheelchair to prepare for transport to the E.R. The patient denied any further symptoms at this time except pain in his left knee. This nurse checked his vital signs at 1658: 102/64, pulse ox 100%, pulse 59. Rapid response arrived and this nurse gave report to them. Patient was transported to the E.R. via stretcher. No further issues noted at this time. Pt reports he has a history of getting nervous and "passing out" when getting blood drawn or getting a shot. Pt stated that when he stood up after getting his covid vaccine he felt lightheaded and passed out. ED staff responded to vaccine clinic. At 1658 where pt's VS were as follows: 102/64 HR: 59 Sats 100% At present time, pt reports feeling "totally normal" and does not feel that he needs to stay to be seen in ED. Pt comfortable with being monitored by RN for 10 min. Pt still does not want to be seen in ED, wants to leave. Pt ambulated out of ED without difficulty. |
| 1128537 | 3/24/2021 | TX | 34 | F | 3/9/2021 | 3/9/2021 | I passed out about 20 min. after the shot. I felt fine up until then. When I was walking to wash my hands, i felt intense heat, vision blacked out and I passed out for about 30 seconds. It was dizzy with delayed vision for the rest of the day. |

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| 1128844 | 3/24/2021 | OR | 59 | F | 2/7/2021 | 3/8/2021 | Fainted, unconscious for few minutes; Sweating; Funny feeling; Feeling very weak; A spontaneous report was received from a consumer who was also a 59-years-old, female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and who experienced fainted, unconscious for few minutes/loss of consciousness, sweating/hyperhidrosis, funny feeling/inappropriate affect and feeling very weak/asthenia. The patient's medical history was not provided. Concomitant product use was not provided by the reporter. The patient received their first of two planned doses of mRNA-1273 (Batch number: 004M20A) on 07 Feb 2021. On 07 Mar 2021, approximately 2 days prior to the onset of the symptoms, the patient received their second of two planned doses of mRNA-1273 (Batch number: 029A21A) via an unknown route in the left non dominant arm for prophylaxis of COVID-19 infection. On 08 Mar 2021, patient experienced sweating, patient felt funny, fainted and was unconscious for few minutes and patient felt very weak. No treatment was provided. The patient received both scheduled doses of mRNA-1273 prior to the events; therefore, action taken with the drug in response to the events was not applicable. The outcome of the events were not reported.; Reporter's Comments: This case concerns a 59-year-old female who experienced a serious unexpected event of loss of consciousness along with nonserious events of unexpected asthenia, inappropriate affect and hyperhidrosis. Event onset occurred on Day 2 after the first dose of mRNA-1273. Treatment not reported. Event outcomes unknown. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. |
| 1128997 | 3/24/2021 | | 68 | M | 3/11/2021 | 3/11/2021 | Patient was placed in observation area post Pfizer COVID vac administration. After Approximately 10 minutes, patient Passed out and was found on the floor with wound on (L) side of forehead with bleeding noted. Large knot noted above (L) eyebrow. BP 116/60 Awake, responsive, diaphoretic, bounding pulse, pale. Patient was assisted to stretcher with O2 at 2L NC and ED team transported to ER. Given fluids in ER. |

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| 1129111 | 3/24/2021 | TN | 21 | F | 3/24/2021 | 3/24/2021 | Patient became dizzy immediately after receiving vaccine. Blood pressure systolic 99. Was unable to stand due to fear of potential syncope. Gradually recovered with cold compresses and drinking water and full-sugar soda. |
| 1129120 | 3/24/2021 | MO | 24 | M | 3/19/2021 | 3/20/2021 | Patient passed out 5 minutes after receiving vaccine. 12 hours later the patient had severe chest pain and went to the ED. He received a ketorolac shot there and returned home. 36 hours later, red dots were noticed on the patients feet and ankles (appeared to be petechiae). No other s/sx of bleeding but extreme fatigue, nausea, head fogginess, etc. has been experienced over the past 4-5 days. Patient w/ no PMH of any significance. |
| 1129140 | 3/24/2021 | IL | 36 | F | 3/23/2021 | 3/23/2021 | Rash on face on face and neck, nausea, syncope. Patient refused epi, crew pushed 50 mg benadryl and oral gluacon 166/90, 100% RA,110, blood sugar 62 |

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| 1129256 | 3/24/2021 | | 44 | F | 3/7/2021 | 3/7/2021 | Dizzy; Lost all the strength in her arms and legs; Passed out; Nauseous; She dropped to her left when she passed out and fell in shower; Ear completely clogged up only on the left side; Headache; Tired; Soreness on my arm; This is a spontaneous report from a contactable consumer (patient). A 44-year-old female patient received her second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date were not provided), via an unspecified route of administration on 07Mar2021 at 11:00 at single dose for COVID-19 immunization. Medical history included underactive thyroid. Concomitant medication included unspecified thyroid medication. The patient was asking if her symptoms were normal following the vaccination. She got the second dose of the COVID vaccine yesterday, 07Mar2021 at around 11:00 (also reported as 10:00 to 10: 15 or 10:30). Throughout the day, she was fine and mentioned that she had soreness on her arm later. At around 22:00, she was driving home and started feeling a slight headache and reported that she didn't take anything. She was tired, so when she got home, the patient fell asleep. She woke up and did feel a slight headache and couldn't sleep on her left arm because it was killing her, but it was fine. At 5:30 this morning (08Mar2021), the headache was still there. She then stood and sat up, took her thyroid pill because she has an underactive thyroid and was on the highest dose of thyroid replacement. The patient stated that the events happened so fast, as soon as she got into the shower. She got out of bed and started walking, grabbed her stuff to shower and started feeling that her headache was building up more than it had all morning so far. She thought maybe it was just because she had just physically gotten up and started walking. She got into the shower, and for about 2-3 minutes into getting into the shower, she remembered she had started putting shampoo into her hands; grabbing the shampoo bottle; but she suddenly got so nauseous and the headache that came on was extreme. She did not have a lot of time to react. She thought she would throw up in the shower, she had no time to get out of the shower to the toilet to throw up; she suddenly felt dizzy, passed out in the shower and fell to her left side on the floor. All she could remember before she passed out was that she had the shampoo bottle in her hands and she said out loud, she heard |

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| | | | | | | herself say "What is happening to me". Then she lost all the strength in her arms and legs. She remembered for a split second she tried to hold on, she dropped the shampoo bottle on the floor and grabbed the rail or edge of the shower and tried to hold on because she felt herself when she went down. Her left ear was completely clogged up only on the left side. When she passed out, thankfully she thought by trying to hold on to the rail or edge of the shower that she kind of eased her fall down, so she did not fall hard or hit her head. She did not know if she passed out for seconds or minutes because she has no idea exactly when she went into the shower, maybe around 05:45; but when she woke up she realized she was on the floor, she was not flat on the floor but on her knees, having fallen to the left side with her head off to the side on the shower wall; the glass door to her shower was wide open and all the water was coming out of the shower; it scared her when she woke up. The outcome of the event passed out was recovered on 08Mar2021, not recovered for headache, and unknown for all other events. Information on the lot/batch number has been requested. | |
| 1128273 | 3/24/2021 | CA | 57 | F | 3/23/2021 | 3/23/2021 | Systemic: Chest Tightness / Heaviness / Pain-Mild, Systemic: Exhaustion / Lethargy-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Weakness-Mild |
| 1131551 | 3/24/2021 | TX | 34 | F | 2/12/2021 | 2/21/2021 | Debilitating heart palpitations/chest pain. Dizziness/ fainted momentarily. Sought emergency care- no physical cause found- not associated with any health issues. fever newly present at discharge from emergency room. |
| 1130931 | 3/24/2021 | CA | 20 | M | 3/24/2021 | 3/24/2021 | Pt. reported feeling light headed, after sitting experienced a syncopal episode. BP 98/45 p 75. Pt. was revived after about 35 seconds and stated feeling better. BP 112/72, p 76. Pt. stated has hx of syncope. Pt and family refused to be transferred via squad. Pt. states he will fu with PCP this week. |
| 1130976 | 3/24/2021 | MD | 19 | F | 3/24/2021 | 3/24/2021 | Syncope with seizure like activity lasting 20 seconds; occurred twice within 2-3 minutes while seated in car |

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| 1131041 | 3/24/2021 | AL | 28 | M | 3/24/2021 | 3/24/2021 | Pt received fist dose of Moderna vaccine. Within 5 minutes patient started exemplifying signs of syncope and began falling to the floor while seated. Another patient that happened to be near caught him from falling face to the floor and managed to set him upright against the wall. Patient regained consciousness within a few minutes and stated he may have had a panic attack while being told to wait 15 minutes for post observation period. He was able to stand himself up and sit in a chair to wait out the remainder of the 15 minutes. Patient decline any type of medical emergency services. |
| 1131079 | 3/24/2021 | PA | 25 | F | 3/24/2021 | 3/24/2021 | near fainting/lightheaded |
| 1131114 | 3/24/2021 | CA | 20 | F | 3/24/2021 | 3/24/2021 | Patient lost consciousness for a minute while waiting in the pharmacy after her vaccination. She slid down from the chair she was sitting on and recovered consciousness soon after laying down on the floor. She mentioned she was dizzy but otherwise alright. No signs of allergy, had cold hands. Symptoms indicated syncope but witnesses mentioned they saw her having a small seizure, where she threw her hands and head back before sliding down. 911 was called, they checked her and walked her to her car and let her go with a friend. |
| 1131277 | 3/24/2021 | CA | 17 | M | 3/24/2021 | 3/24/2021 | Per father patient has a history of "passing out" following vaccine administration and blood draws. Following this vaccination administration patient c/o of being lightheaded and displayed a brief moment of generalized syncope while seated in chair and diaphoresis noted. No trauma no fall. Vital signs taken and patient assessed by staff. HR 52, BP 98/76 . Patient a&o x4 conversing with staff. Patient able to eat and drink. |
| 1131320 | 3/24/2021 | CA | 45 | F | 3/22/2021 | 3/23/2021 | High BP 180/102 at doctors office resulting in prescription for Lisinopril with Hydrochlorothiazide, Vasovagal syncope resulted in loss of consciousness, falling and hitting head on bathtub. |

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| 1131395 | 3/24/2021 | UT | 33 | M | 3/24/2021 | 3/24/2021 | 10 to 15 minutes after receiving the vaccination. The patient reported to a pharmacy technician they were feeling unwell. As the patient went to sit down they fainted. Patient was unresponsive for roughly a minute exhibiting tensed arm and neck muscles. Muscles also contracted several times during the episode. Patients eyes were open during the episode but they could not be coaxed to speak signal or blink. Additional patient symptomology as follows: elevated pulse, constricted pupils, flushing/redness in the face & neck. For this reason, medical staff called 911. Patient became responsive and reported losing consciousness and having no recollection of majority of the event. Upon arrival EMT's took over patient care. Patient left with EMT's |
| 1131482 | 3/24/2021 | MO | 30 | M | 3/24/2021 | 3/24/2021 | shot given at 6:04pm, passed out at 6:04pm. Patient fell and hit his head on the bottom of the pharmacy shelves. He was snoring, sweating, urinated on himself and came to at 6:06pm. He drank water, sat up and felt better at 6:15pm. The ambulance arrived at 6:20pm and patient declined medical help. |
| 1130920 | 3/24/2021 | WY | 24 | F | 3/22/2021 | 3/23/2021 | muscle aches, syncope, fatigue, dizziness for 36 hours post vaccine |
| 1131541 | 3/24/2021 | MD | 89 | M | 3/24/2021 | 3/24/2021 | At 2:03 p.m, we received information that patient "passed out" in the parking garage. Patient brought back to Vaccine clinical area - unresponsive, cold and clammy. 911 called At 2:06 BP 12/33; HR 45, R 20 and O2 sats 100%, T 97.3. BG 161 Patient then opened eye after sternal rub and responded to name. HR and Pulse continue to decline. 911 arrived and take patien to hospital. |

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| 1131677 | 3/24/2021 | AZ | 63 | F | 2/18/2021 | 2/20/2021 | Hurt to even swallow water. I have GERD and Shotsky?s ring. Ended up taking 100mg if Omeprozole during the entire day (then Gaviscon Extra Strength. I had to talk to the on call Dr. 2x. After taking the Gaviscon, I burped and had excruciating pain at the base of my esophagus, broke out in sweat and almost passed out. I had to breathe as if I?m labor. It happened again about an hour later. The Dr. said it could be a cardiac issue and go to the ER. I ended up with normal EKG?s and normal bloodwork during the time I spent the nite for observation. The cardiologist said I had no heart issues and to go home. I can only come to the conclusion that the inflammatory response from the vaccine was the culprit. |
| 1131565 | 3/24/2021 | WI | 19 | F | 3/18/2021 | 3/18/2021 | patient received vaccination at 9:43 am , at 9:45 am she passed out briefly. We called 911, paramedics came and checked her out ,gave her the ok to leave |
| 1131583 | 3/24/2021 | CA | 42 | M | 3/24/2021 | 3/24/2021 | Pt. began to feel dizzy 10 min after vaccination. He had intermittent syncope, no AMS, symptoms resolved and pt. went home at 1801. BP: 102/67, HR 68, O2 95% |
| 1131634 | 3/24/2021 | AZ | 23 | M | 3/24/2021 | 3/24/2021 | Patient received COVID vaccination and was waiting his 15 minutes in the waiting room, a few minutes after injection, his GF called me over because the patient passed out. As I approach, patient was coming to as he was peeing himself. Patient reported that he felt lightheaded and then did not realize what happened. Gave patient some water and took his blood pressure. His DBP was a little low around 49. Had the patient sit there for another 15 minutes and took blood pressure again and it was 104/60. |
| 1131636 | 3/24/2021 | CA | 32 | M | 3/24/2021 | 3/24/2021 | After receiving his covid shot and then waiting for his family member to get his covid shot, the patient was asked to sit outside and wait for 20 minutes to monitor for any reactions to the vaccine. 5 to 10 minutes after leaving the immunization room, patient fainted in the front of the pharmacy. His family member laid him down and 911 was called. He regained consciousness and was answering questions. He remained laying down until the ambulance came to escort him to a hospital. |

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| 1131671 | 3/24/2021 | LA | 51 | F | 3/13/2021 | 3/15/2021 | Following the vaccine injection which was provided by the personnel, I have developed minor fainting spells and angina for the past 10 plus days. A large dried blood clot was noted on the first day of my period which occurred on March 16th. I continue to pass large blood clots while I was having my period. I also want to point out that a personnel who gave me an injection was incorrectly injected the vaccine outside of the area of the preferred injection zone. I have reported this event to the supervisor who was on site. I have not yet contacted my health care provider at this time but plan to contact her tomorrow as these symptoms have been persisting. |
| 1131674 | 3/24/2021 | NV | 43 | M | 3/23/2021 | 3/23/2021 | No issues immediately following vaccine. About 11am, mild symptoms like 99.4 degree fever, muscle aches, joint pain, very mild nausea, fatigue began. Severe nausea began about 7:15pm. At 7:45pm, severe dizziness resulting in loss of consciousness and fall. Seizure Syncope event lasted 2 1/2 to 4minutes. Slow to wake. Trembling/shaking in extremities, cold sweat. Delayed speech. Paramedics were called. Went to ER at approximately 8:30pm. |
| 1130028 | 3/24/2021 | ID | 24 | F | 3/23/2021 | 3/23/2021 | Patient fainted during waiting period after receiving the Moderna COVID-19 vaccine. Patient was laid down and feet were elevated. Patient came to after about 10 seconds and was maintained in lying position until they were aware of surroundings and felt stable. Patient was helped back to their chair and were monitored without any other issue. |
| 1131721 | 3/24/2021 | AZ | 64 | F | 3/24/2021 | 3/24/2021 | Customer received vaccine and shortly began to feel dizzy, lighted-headed, and fainted while seated. She became responsive and was sweating stating she did not feel well. Customer complained of feeling nauseated, hands were cramping and difficult to move. Finger tips were tingling. She sat in our waiting area and was observed for over 30 minutes. She began to feel better after 15-30 minutes. |

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| 1130141 | 3/24/2021 | GA | 66 | F | 2/4/2021 | 2/5/2021 | while taking blood pressure patient passed out; not feel well; fever; aches; headache; chills; A spontaneous report was received from a nurse concerning a 66-year old, female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced fever, aches, headache, chills, did not feel well and passed out. The patient's medical history included atrial fibrillation following symptoms of feeling sick, headache and chest discomfort in September 2020. Current conditions included elevated blood pressure (BP) and a shrimp/shellfish allergy. Concomitant medications included apixaban, carvedilol, lisinopril and vitamin D. On 04 Feb 2021, the patient received the first of two planned doses of mRNA-1273 (Batch Number: 013M20A) intramuscularly in left arm for prophylaxis of COVID-19 infection. On 05 Feb 2021, one day after receiving the vaccine, the patient experienced fever, aches, headache and chills. She took paracetamol and felt better. On that same day at approximately 1330, 24 hours after the vaccine, the patient was preparing a sandwich and was not feeling well. She sat in a chair to take her blood pressure and passed out. At some point, it was reported that patient was admitted to the hospital for a five-day stay. (admission/discharge dates not reported). Treatment for the events included paracetamol. There was not change planned to the dosing schedule of mRNA-1273 in response to the events as it is known that on 05 Mar 2021, the patient received the second of two planned doses of mRNA-1273 (Batch Number: 002A21A) intramuscularly in left arm for prophylaxis of COVID-19 infection. The outcome of the events, fever, aches, headache, chills, not feel well and passed out, was considered recovered/resolved on an unspecified date.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |

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| 1131517 | 3/24/2021 | WI | 31 | F | 3/24/2021 | 3/24/2021 | Patient reported in chart notes a history of fainting after vaccinations. Pharmacist asked patient about this before administering vaccine, and patient said she often faints in regards to blood draws or vaccines. Patient was prepared to sit in waiting area for at least 15 minutes. Patient was given vaccine and pharmacist confirmed patient was feeling okay. Patient returned to waiting area to sit, then allegedly decided to stand up and go to the in-window when beginning to feel faint. She fainted in this process. RPh and store manager immediately rushed to patient, who returned to consciousness right away. Patient stated to RPh that she did not hit her head nor did she have any pain in her legs or trouble breathing. She felt mostly embarrassed. Store manager called paramedics, who arrived, examined patient, and the patient let them leave and proceeded to shop in the store aisles until her husband arrived. |
| 1130100 | 3/24/2021 | MA | 74 | M | 3/24/2021 | 3/24/2021 | Systemic: Confusion-Severe, Systemic: Fainting / Unresponsive-Medium, Additional Details: A few minutes after the shot the patient had trouble breathing/wheezing, confused, pale, incoherent, and was possibly faint (was falling out of the chair they were sitting). The patient was diabetic and had diarrhea the morning of the shot. At the time of filing the report the patient was taken to the hospital in an ambulance |
| 1130884 | 3/24/2021 | CA | 37 | M | 3/24/2021 | 3/24/2021 | Patient turned white in face after shot, fainted and came by 2 minutes later. |
| 1130062 | 3/24/2021 | MO | 62 | F | 3/23/2021 | 3/24/2021 | Chills, nausea, passed out, muscle aches |

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| 1130143 | 3/24/2021 | WI | 73 | F | 3/1/2021 | 3/1/2021 | Extremely dizzy; Don't remember nothing; Felt like she was going to died; Felt so sick; Completely unconscious/passed out; High blood pressure 215 over 156; Vomiting for 1 hour constantly/threw up; Nauseate; Headache like someone is pressure her brain; Fast heartbeat; Weak; A spontaneous report was received from a consumer concerning a 73-year-old, female patient who received the Moderna COVID-19 (mRNA-1273) vaccine and experienced the following: completely unconscious/passed out(loss of consciousness), dizziness, vomiting for 1 hour constantly/threw up (vomiting), don't remember nothing (amnesia), felt like she was going to died (feeling abnormal), high blood pressure 215 over 156 (hypertension), felt so sick (malaise), headache like someone is pressure her brain (headache), fast heartbeat (tachycardia), nauseate (nausea) and weak (asthenia). The patient's medical history was not provided. Products known to have been used by the patient, within two weeks prior to the event, included atorvastatin, bupropion hydrochloride, cetirizine hydrochloride, anxiety medicines, clonazepam, metformin, metoprolol, and trazodone. On 01 Mar 2021, the patient received the first dose of two planned doses of mRNA-1273 (Batch number: unknown) and 45 minutes later was extremely dizzy. At home one hour later she started to vomit for one hour constantly, became completely unconscious, didn't remember anything, and was really scared. The last thing she remembered was telling her husband: you need to call somebody because she felt like she was going to die. The patient was taken by ambulance to the hospital and while in the ambulance, the patient was administered medicines for nausea and blood pressure. The blood pressure measurement taken in the ambulance was 215 over 156. The patient didn't know her address or anything else. She was released to go home after a few hours, but still felt so sick. On Sunday night (07-Mar-2021), the patient threw up again. On an unspecified date, she had a headache like someone was putting pressure on her brain; she also had a fast heartbeat. Since the vaccine, the patient reported feeling really nauseous and remembering nothing about it. She is still weak. Treatment information included ondansetron medicine for nausea. Action taken with mRNA-1273 in response to the events was unknown. At the time of reporting, the outcome of the |

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| 1130150 | 3/24/2021 | CA | 37 | M | 3/23/2021 | 3/23/2021 | event, weak, was considered not recovered/not resolved. The outcome of the events, completely unconscious/ passed out, dizziness, vomiting for 1 hour constantly/threw up, don't remember nothing, felt like she was going to died, high blood pressure 215 over 156 , felt so sick, headache like someone is pressure her brain, fast heartbeat, and nauseate were unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. |
| 1130255 | 3/24/2021 | TX | 62 | M | 3/16/2021 | 3/16/2021 | About 15 min after receiving the vaccine, patient started to stand after sitting in a chair for 10 min and fainted, falling with his head hitting the ground. He sustained a laceration above one eyebrow that required stitches to be placed. He was assessed by a medic on site, vitals taken, and oxygen administered. His blood sugar was in the 70s. Patient admitted to fear of needles, not eating much all day, and hx of similar episode after receiving an IM injection of a muscle relaxant about 10 yrs ago. |
| 1130259 | 3/24/2021 | WA | 73 | F | 3/23/2021 | 3/24/2021 | drive through setup, within minutes after injection, began to feel tingling in forehead which moved down my body. Between 5-10 minutes after injection, I just passed out (don't recall that happening). Woke to 2 EMT's by my side asking to check my blood pressure.. I don't recall the numbers however they stated I 'bottomed out'. shortly after gaining consciousness, I became nausea loosing contents of stomach twice. Remained under observation for 30+ minutes, then wife drove me home. Slept until 5:00 when I was steady enough to walk unaided, and finally eat some dinner. |
| 1130346 | 3/24/2021 | MI | 35 | M | 3/24/2021 | 3/24/2021 | During night, some body aches and headache. Woke up on 3/24/21 and got out of bed and had extreme nausea, dizziness, weakness, 2 bouts of diarrhea, and fainted once. Also some body aches and headache still. I am now taking it super easy as I don't want to fall again. |
| | | | | | | | Patient felt slight dizziness about 2 minutes after vaccine. About 8 minutes after his vaccine, he came to the pharmacy counter and almost passed out - he was dizzy and sweating. He felt better after about 40 minutes of resting (and water and protein bar). |

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| 1130358 | 3/24/2021 | IL | 30 | M | 3/24/2021 | 3/24/2021 | Fainted for approximately 5 seconds |
| 1130367 | 3/24/2021 | FL | 68 | F | 3/17/2021 | 3/18/2021 | Was at home, felt Dizziness,fainting,fever,strong headache,fatigue,cold sweat,body ache,clammy skin,nausea, short of breath ,dry mouth ,dehydrated, very bad I though lwas going to pass out at any time,weak. |
| 1130378 | 3/24/2021 | OH | 46 | F | 3/19/2021 | 3/19/2021 | This was this person's second dose. She had episode of syncope following the first dose that required prolonged monitoring in the EC. Patient was laid down on stretcher prior to vaccine administration. Patient immediately went syncopal following injection and became unresponsive. Breathing remained even and nonlabored with good pulse. Patient remained lying down for about 30 minutes before she sat in a chair for approximately 15 minutes. Attempt to have patient leave but patient became syncopal again in bathroom and needed to be assisted into wheelchair and brought back to observation area where she laid down for another 15 minutes. Patient was alternating back and forth between being alert and unresponsive. Patient was finally able to leave area with mother at 1719. Refused to be transferred to the Emergency Room for evaluation. |
| 1130823 | 3/24/2021 | OH | 27 | F | 3/24/2021 | 3/24/2021 | Has history of aversion needles and lightheadedness, has recurrence of lightheadedness, no syncope or falls, taken to a private section of the facility. Vitals WNL. |
| 1130388 | 3/24/2021 | IL | 70 | F | 3/19/2021 | 3/19/2021 | beginning 20 minutes after the vaccine, patient had near syncope and shortness of breath. no hives or flushing. fatigue persisted several days after, along with chest discomfort, worrisome for anaphylaxis reaction. |
| 1130391 | 3/24/2021 | MA | 27 | F | 3/11/2021 | 3/12/2021 | syncope the morning after vaccination |
| 1130466 | 3/24/2021 | | 26 | F | 3/24/2021 | 3/24/2021 | SYNCOPE, HYPOTENSION, NUMBNESS IN ARM OPPOSITE INJECTION SITE. MONITORED BY CNP AND EMS CALLED BUT NOT TRANSPORTED |
| 1130495 | 3/24/2021 | FL | 76 | F | 3/23/2021 | 3/24/2021 | POLIURIA, WEEKNESS, FAINTING. |

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| 1130507 | 3/24/2021 | NJ | 61 | F | 3/21/2021 | 3/22/2021 | Fainting, fever, chills, nausea. Had repeated fainting spells the morning after the day I was vaccinated. Felt better the next day, still had slight fever. By Wednesday (third day after vaccine day), felt fine. The reason I am reporting this is the fainting episodes. I do not see that online as a listed common side effect of the vaccine. |
| 1130511 | 3/24/2021 | CA | 23 | M | 3/24/2021 | 3/24/2021 | 5 minutes after shot, pt slid from chair and fell backward; witness said pt suffered from mild seizure; paramedics were called and pt was assessed; pt has no history of epilepsy but did have a fainting episode years ago when giving blood; he also stated he hasn't eaten or drank anything today; he declined transport to hospital but is getting a parent to pick him up; paramedics highly suggested that parent take him to the ER or urgent care |
| 1130579 | 3/24/2021 | TX | 48 | F | 3/17/2021 | 3/17/2021 | I had chills, fever, headache, extreme tiredness, almost passed out and tingling on right side arm/leg. When I almost passed out felt like tunnel vision. |
| 1130641 | 3/24/2021 | NC | 49 | M | 3/19/2021 | 3/20/2021 | 9 hours after shoot woke up feeling very poorly and feverish. Went to take Tylenol and passed out. Came to with wife shaking my arm. Suffered trauma to nose and back during fall as a result of passing out including laceration from hitting face on counter. After coming to sever body shakes. Temperature was taken twice and recorded 92.5 and 93.0. Blood pressure and pulse after moving to couch to lie sit down was normal. Next day couldn't do much and was very tired. By second day I was recovered but sealing with injuries from the fall. |
| 1130829 | 3/24/2021 | SC | 28 | M | 3/23/2021 | 3/23/2021 | Patient received first covid vaccine at 4:58 and walked to the observation room. He was seated in chair and had a syncope episode. BP was 100/50, pulse 50. Patient was diaphoretic and nauseated. Would regain consciousness but then would lose consciousness. He would answer questions appropriately but could not stay awake or remain conscious. A rapid response was called and ER arrived |

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| 1130385 | 3/24/2021 | TX | 42 | M | 3/9/2021 | 3/9/2021 | Around 8pm I became very cold and tired. I took a bath, which is out of character, and tried to sleep. By 9 pm I was alternating between hot and cold sweats. By 10 pm I was vomiting and defeating uncontrollably while still alternating between hot and cold sweats. I dry heaved until around 3 am and then finally passed out. My fever never exceeded right about 100 degrees. For the next 2 days I was incredibly exhausted with muscle aches and a minor headache. I didn?t return to baseline for approximately 6 days after the shot. |
| 1126062 | 3/23/2021 | CA | | F | | | The patient fainted; A spontaneous report was received from a consumer concerning her friend, a female patient of unspecified age, who received Moderna (mRNA-1273) vaccine experienced fainting after getting the vaccine. The patient's medical history was not provided. Concomitant product use was not provided by the reporter. On an unspecified date, prior to the onset of the symptoms, the patient received her first dose of two planned doses of mRNA-1273 (Batch number not provided) for prophylaxis of COVID-19 infection. On an unspecified date, the patient fainted after getting the vaccine. Treatment information was not provided by the reporter. Action taken with mRNA-1273 in response to the event(s) was not provided. The outcome of the event fainting after getting the vaccine was unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. |
| 1126021 | 3/23/2021 | | 29 | M | 3/20/2021 | 3/20/2021 | Anxious following vaccine with vasovagal response but no syncope. Reclined in car seat with pulse of 67 Blood pressure of 92/49 and oxygen saturation of 97%. EMS and Dr on site. Client felt better quickly and was released. Advised to seek medical attention later if needed. Client stated understanding. |

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| 1126020 | 3/23/2021 | WI | 32 | M | 3/23/2021 | 3/23/2021 | <p>Patient received Pfizer COVID 19 vaccine at 8:42am. This was patient's first dose. He was observed in clinic for 18 minutes afterwards without concern and left approximately 9:00am. Patient returned to clinic at 9:28am with complaints of sweating, nausea and lightheadedness. RN took patient to private observation room and started assessment. VS 9:30am O2 100%, BP 147/78, HR 50. Patient is laid back on bed with head at 45 degrees and legs elevated. Patient was given 6oz of water and neurological assessment completed. Patient alert and oriented without changes. Patient denies SOB, scratchy or tight throat, hoarse voice, trouble swallowing or itching. VS 9:40am O2 100%, BP 151/77, HR 54. Patient given another 6 oz of water and continues to lie back with feet elevated. Patient took clonidine, sertraline, propranolol, Adderall and vraylar this AM. He ate breakfast. Is not a diabetic. Patient states his lightheadedness has subsided, still complains of sweating and nausea but states he is "feeling better and ready to go home". Patient has a ride and is going home to his parent's house where they will both stay with him all day. VS 9:45 O2 100%, BP 143/81, HR 61. Patient appears more comfortable, less anxious and HR has risen. States his nausea is lessening. Patient would like to leave. RN educated patient on emergency signs to seek 911 for and they include SOB, throat swelling, sudden emesis, increased lightheadedness or nausea, fainting, new dizziness or any other sudden change in condition. He voices understanding; plans to go home with parents, have toast for lunch, push fluids and rest. Patient escorted to the door and visualized entering vehicle with family.</p> |
| 1125995 | 3/23/2021 | MN | 24 | M | 3/23/2021 | 3/23/2021 | <p>Patient had a vasovagal reaction and passed out. EMS was called and he was taken to the ED.</p> |
| 1125977 | 3/23/2021 | OK | 36 | M | 3/20/2021 | 3/20/2021 | <p>Sitting down on bleachers immediately after receiving COVID vaccine - started feeling lightheaded and had a witnessed syncopal episode. Patient hit his head on the back of the bleacher and passed out for a few seconds. Reports twitching movements. Reportedly does have a history of passing out with injections and piercings in the past. He had not had anything to eat or drink that day.</p> |

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| 1125958 | 3/23/2021 | TN | 62 | M | 3/23/2021 | 3/23/2021 | Patient received first dose of Pfizer. A couple minutes later patient felt dizzy and fainted. EMS responded and took vital signs HR 60, BP 144/87 O2 sats were 96%. Patient was offered to be transported if he felt like he needed it. Patient declined transport. |
| 1125928 | 3/23/2021 | FL | 58 | M | 3/23/2021 | 3/23/2021 | Patient started feeling lightheaded and fainted. Patient was responsive within seconds. The ambulance was called and he was taken away responsive. |
| 1125856 | 3/23/2021 | MI | 58 | F | 3/18/2021 | 3/20/2021 | Patient was febrile at 104F. Found passed out on floor at home. SIRS from vaccine administration is the likely cause of this event |
| 1126197 | 3/23/2021 | CA | 83 | F | 3/10/2021 | 3/12/2021 | Mom started complaining she was itching all over her body appx 2 days after 2nd injection. We saw red bumps and gave her topical benadryl, but irritation still persisted. We called her primary Dr and she recommended we give her oral benadryl. Yesterday we were out to lunch and the way home mom fainted in the car so we called an ambulance. They kept her over night for observation. |
| 1125919 | 3/23/2021 | | | U | | | When I woke up on Sunday, I felt dizzy and when I tried to get up, I lost my balance. After that I don't remember anything except that I was laying down on my bed and that I had fainted. |

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| 1126064 | 3/23/2021 | OK | 49 | M | 3/8/2021 | | <p>passed out completely for 15 minutes; fell backwards for about 15 minutes and was fine; sore arm; lethargic; little bit of chill every now and then; low grade fever; felt like he was about to see stars; felt chills up the back of his neck; A spontaneous report was received from a consumer concerning a 49-years-old male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced events sore arm, lethargic, little bit of chill every now and then, low grade fever, felt like he was about to see stars, passed out completely for 15 minutes, felt chills up the back of his neck, fell backwards for about 15 minutes and was fine. The patient's medical history was not provided. Concomitant medications reported were Singulair, Zyrtec, Rhinocort nasal spray for drug use for unknown indication. On 8 Mar 2021, prior to the onset of the events the patient received their first of two planned doses of mRNA-1273 (lot/batch: 003A21A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On an unknown date, the patient experienced the event sore arm, lethargic, little bit of chill every now and then, low grade fever, felt like he was about to see stars, passed out completely for 15 minutes, felt chills up the back of his neck, fell backwards for about 15 minutes and was fine. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not reported. The outcome of event, sore arm, lethargic, little bit of chill every now and then, low grade fever, felt like he was about to see stars, passed out completely for 15 minutes, felt chills up the back of his neck, fell backwards for about 15 minutes and was fine was unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p> |
| 1126091 | 3/23/2021 | MI | 59 | F | 3/19/2021 | 3/20/2021 | ?Fainting, ?body chills, ?fever, ?loss of appetite, ?weakness, ?sleepiness, ?headaches |

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| 1126125 | 3/23/2021 | | 41 | M | 3/20/2021 | 3/20/2021 | Vasovagal event with syncope and seizure activity fir 15 to 20 seconds Client stated he always responds this way to shots. Hx of TBI at age 4 years. Blood pressure 106/68 pulse 84 and O2 saturation 100%. EMS and Dr on site and client released when symptoms resolved. Advised to seek medical attention later if needed. Client verbalized understanding. |
| 1126473 | 3/23/2021 | OH | 41 | M | 3/23/2021 | 3/23/2021 | Pt recieved dose one of Moderna COVID19 Vaccine about 1255pm LOT 046A21A, Exp.9/3/21. Within about 3 min of entering waiting room, pt felt faint/ passed out, hit his head on end table, tried to get up into a seat and lost consciousness again for 1-2 SEC. Assissted byt wife and NP to the floor. 911 called by PCT, BP 90/52, HR 65, o2 99%. After evaluation per EMS team, pt chooses not to go with EMS to ED for further care, recommended by NP and EMS. Pt chose to go with wife and will go to ED if worsening symptoms. AMA signed for EMS and clinic |
| 1126184 | 3/23/2021 | IL | 42 | F | 3/22/2021 | 3/22/2021 | Syncope following vaccination |
| 1126252 | 3/23/2021 | RI | 74 | M | 3/11/2021 | 3/11/2021 | Acute - Got Johnson & Johnson COVID-19 vaccine this past Thursday - Thursday night starting cramping with abdominal pain radiating to the back; remained quite bothersome through Friday, Saturday, Sunday - Had nausea but no vomiting; mild HA - Some episodes of loose stools but no blood - No fever and chills but some diaphoresis - Has been drinking water but not eating - Has been a little bit of SOB and dyspnea on exertion - No lightheadedness, syncope or near syncope; no palpitations or chest pain - No clear alleviating factors, worsens when he drinks too much water - no recent history of alcohol intake |
| 1126360 | 3/23/2021 | TX | 33 | M | 3/23/2021 | 3/23/2021 | Complaint of diaphoretic, passed out, heard to arouse, appear drowsy, and lethargic. Obey command(directions) |

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| 1126406 | 3/23/2021 | | 25 | F | 3/23/2021 | 3/23/2021 | Patient received first dose of Moderna. More than half of the first dose leaked out due to faulty syringe. Nurse called over charge nurse to verify that more than half of the dose had not been administered to the patient. Charge nurse confirmed that second dose was approved after confirming with FD. Patient consented to 2nd dose. Patient informatoin was collected by charge nurse. Shift nurse proceeded to administer 2nd dose. Left arm was used to administer. Patient was in stable condition. Nurse explained after-care. Patient began to hyperventilate and said she felt like she was going to faint. Patient asked for water. Patient said she had a history of fainting and was going to faint. (CONTINUED BELOW)- |
| 1125767 | 3/23/2021 | MN | 29 | F | 3/14/2021 | 3/22/2021 | Had two syncope events 10 minutes after receiving first dose. On day 8 (3/22/2021) I started to get a red itchy circle around the injection site which I am assuming is "COVID arm." Still have a red circle today (3/23/2021). |
| 1125255 | 3/23/2021 | CA | 39 | M | 3/22/2021 | 3/22/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Exhaustion / Lethargy-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Weakness-Severe |
| 1126156 | 3/23/2021 | NC | 49 | F | 3/22/2021 | 3/22/2021 | The vaccine was administered and the patient said they were starting to feel lightheaded within 2 minutes of receiving it. The patient then fainted in the chair with their head back and their tongue out of their mouth. I was trying to wake the patient up to clarify whether the patient was having trouble breathing or if any part of her mouth or throat was swelling, but I could not wake the patient. Both arms were very red. It sounded like labored breathing for about 30 seconds once I got in the room and then the patient stopped making noise. I could not hear any breaths so I administered one dose of 0.3 mg epinephrine in an EpiPen. |
| 1127831 | 3/23/2021 | MN | 64 | M | 3/23/2021 | 3/23/2021 | syncope 10 min after receiving vaccine |

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1126549 | 3/23/2021 | CT | 67 | F | 3/9/2021 | 3/9/2021 | Under eyes feels like hives; No appetite; Left arm is stiff; Knees, legs and back all hurt; Having some chest pain; Left arm is swollen; Cheeks are puffy; Chills; Head hurts so bad can barley lift it off the pillow; Fainted after vaccine; High blood pressure; A spontaneous report was received from a consumer concerning a 67-year old female patient, who experienced fainting after vaccine (syncope), high blood pressure, head hurts so bad and can barley lift it off the pillow (headache), left arm is swollen (peripheral swelling), cheeks are puffy (swelling face), under eyes feel like hives (urticaria), left arm is stiff (limb discomfort), knees, legs and back hurt (pain), chills, no appetite(decreased appetite), and having some chest pain (chest pain). The patient's medical history included breast cancer, seasonal allergies, and asthma. Products known to have been used by the patient, within two weeks prior to the events, included chemotherapy unspecified (chemo pills for breast cancer). On 09 Mar 2021, prior to the onset of the events, the patient received the first of the two of their planned doses of mRNA-1273 (Lot number: 027A21A) for prophylaxis of COVID-19 infection. On 09 Mar 2021, the patient passed out at the facility right after her shot. The patient also reported that her blood pressure was very high, and she was rushed to the hospital for a few hours where vitals got down to stable, and she was sent home. On 10 Mar 2021, the patient reported that her head hurt so bad and she could barely lift her head off the pillow, her left arm is very swollen, her cheeks are puffy, under her eyes feels like hives, left arm is stiff, knees, legs and back all hurt. The patient also stated having chills, some chest pain, and no appetite. Treatment information for the events was unknown. Action taken with mRNA-1273 in response to the events was not provided. The events, fainting after vaccine (syncope) and high blood pressure were considered as recovered on 09 Mar 2021. The outcomes for the events of head hurts so bad and can barley lift it off the pillow (headache), left arm is swollen (peripheral swelling), cheeks are puffy (swelling face), under eyes feel like hives (urticaria), left arm is stiff (limb discomfort), knees, legs and back hurt (pain), chills, no appetite (decreased appetite), and having some chest pain (chest pain) were considered as not recovered.; Reporter's Comments: Based on the current available information and temporal association between the use of |

VAERS_ID RECVDATE STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

the product and the start date of the events, a causal relationship cannot be excluded.

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1125077 | 3/23/2021 | NJ | 55 | F | 2/27/2021 | | <p>She was hospitalized because she had an episode of shortness of breath when she was at neurologist's office; Patient experienced spasms after 11 days of receiving 2nd dose; Patient feeling she was falling to her left side after 11 days from second dose; Feels like she is going to pass out but she hasn't passed out; A spontaneous report was received from a consumer concerning a 55-year old female patient, who received Moderna's 2nd dose of COVID-19 vaccine (mRNA-1273) and experienced spasms, shortness of breath, feeling of falling to her left side, feeling of passing out and short of breath. The patient's medical history was not provided. Concomitant medications were not reported. On an unmentioned date, patient received her first of the two planned doses of mRNA-1273 (Lot number: unknown) for the prophylaxis of COVID-19 infection. On 16-Feb -2021, approximately 11 days prior to the onset of the events, the patient received her second of two planned doses of mRNA-1273 (Lot number: 012M20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. Patient received the vaccine on 16-Feb-2021. On 27-Feb -021, patient experienced spasms and felt like she was falling to her left side, short of breath feels like she is going to pass out, but she hasn't. On 05 Mar 2021 she was hospitalized because she had an episode of shortness of breath when she was at neurologist's office. Treatment for the events included heparin, meclizine, IV fluid at hospital, Tylenol (on the day after 2nd dose on 17-Feb-2021). Also mentions that her doctor has prescribed prednisone taper dose which she will be starting on 10-Mar-2021 for 6 days. Action taken with mRNA-1273 in response to the events was not applicable as the patient has already taken both doses of the vaccine. The outcome of the event, shortness of breath, was considered recovering/resolving. The outcome of the event, spasms after 11 days of receiving 2nd dose, patient feeling she was falling to her left side, feels like she is going to pass out and short of breath, was considered unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded</p> |

| <i>VAERS_ID</i> | <i>RECVDATE</i> | <i>STATE</i> | <i>AGE_YRS</i> | <i>SEX</i> | <i>VAX_DATE</i> | <i>ONSET_DATE</i> | <i>SYMPTOM_TEXT</i> |
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| 1125099 | 3/23/2021 | TX | 64 | F | 3/5/2021 | 3/5/2021 | dizzy; Then I passed out; Headache; Nausea; Arm soreness 2 hours after injection.; Chills for well over 12 hours; stomach pain; big bump on my head where I hit the tile floor; This is a spontaneous report from a contactable consumer. A 64-year-old female patient received the first dose of bnt162b2 PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot Number: EN6206), via an unspecified route of administration, administered in the left arm on 05Mar2021, 16:30 as a single dose for covid-19 immunisation. The patient's medical history included allergies to Sulfa based meds from an unknown date and unknown if ongoing. The patient had Covid prior to vaccination. Concomitant medications included cranberry; colecalciferol (D3), fish oil, and multi-vitamin taken for an unspecified indication, start and stop date were not reported. On 05Mar2021 at 18:30, the patient experienced headache, nausea, arm soreness 2 hours after injection. Chills for well over 12 hours. Most concerning, patient got up in the middle of the night. Used facilities. Washed hands, and was having stomach pain. Then she passed out. she came to, and have a big bump on her head where she hit the tile floor. Sunday Morning (07Mar2021) she was dizzy. Maybe from the bump on her head. The patient did not received treatment for the events. The outcome of the events was recovering at the time of the report. The has not tested positive for Covid-19 post vaccination. |

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| 1125100 | 3/23/2021 | TN | 48 | F | 3/5/2021 | 3/7/2021 | I passed out; This is a spontaneous report from a contactable consumer (patient). This 48-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 Vaccine, lot Number: EL3248), via an unspecified route of administration, administered in arm left on 05Mar2021 11:00 am as a single dose for COVID-19 immunization. Medical history included hypertension (blood pressure). The patient is not a pregnant. Concomitant medications in two weeks included ashwagandha taken for an unspecified indication, start and stop date were not reported, and blood pressure meds (unspecified). There is no other vaccine received in four weeks. The patient passed out Sunday night, 07Mar2021 23:00, she's not sure if it was related to the vaccine. The AE resulted in: Doctor or other healthcare professional office/clinic visit. No Covid prior vaccination. No Covid tested post vaccination. Therapeutic measures were taken for the AE. The outcome of event was recovered on an unspecified date in Mar2021. |
| 1125143 | 3/23/2021 | TX | 58 | F | 2/23/2021 | 2/23/2021 | Extremely fatigue, feeling of incoherent, extremely high blood pressure, almost passed out. |
| 1125200 | 3/23/2021 | CA | 20 | M | 2/20/2021 | 2/20/2021 | Patient had vaccination and placed in observation area. Patient had syncopal episode post vaccination. Was seen fall down and hit head and had seizure activity that lasted less than 10 seconds. Patient had brief postictal phase without loss of bladder or bowel control. After a few seconds patient was able to relay his name and was alert and oriented to time and place. Evaluated patient for bodily harm, after finding none moved patient to medical area. Took vital signs and called for transportation to hospital. Medical transport came and after evaluation asked to take patient to hospital patient refused transportation. Patient refused going to hospital and left AMA. Of note, Patient has a history of syncope post injection that was failed to inform us. He mentioned he was afraid to needles like most patients report. Patient said it has happened before after flu shot along with syncope and seizures. |
| 1125208 | 3/23/2021 | CA | 46 | F | 3/9/2021 | 3/9/2021 | I had extreme headache and could not focus I got dizzy and fainted and lots consciousness. I ended up lose muscle control and urinated . Afterwards, I could not speak well. I continued to have massive headaches |

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| 1125232 | 3/23/2021 | AL | 26 | M | 3/22/2021 | 3/22/2021 | Systemic: Chills-Mild, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: ANXIETY, monitored 1 hour post incident -Severe, Systemic: Flushed / Sweating-Severe, Additional Details: Prior to injection patient fainted/syncope, and slowly made his way to the floor with assistance of RN. Pt. was \"out\" for 3-4 sec. aRevived with gentle shaking. Pt was face down taking slow breaths, patient was completely diaphoretic and lost control of his bladder. Paramedics arrived on scene with in minutes and monitored vitals. Pt reported feeling fine but embarrassed and still wanted his shot. vaccine given, with paramedics present. pre-syncope rxn., due to anxiety, but fully responsive. |
| 1125279 | 3/23/2021 | MN | 24 | F | 3/22/2021 | 3/22/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient was in waiting area after receiving the first dose of the Pfizer COVID vaccination. Patient began feel dizzy and passed out and feel out of chair and hit head on ground. Pharmacist and nurse checked on patient. Gave patient water and ice and called 911. Patient left with boyfriend to drive her home after fire department and paramedics checked her out. |
| 1125260 | 3/23/2021 | CA | 23 | F | 3/22/2021 | 3/22/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Mild |
| 1125764 | 3/23/2021 | ME | 35 | F | 3/23/2021 | 3/23/2021 | Patient fainted after feeling dizzy. She remained in her chair and was uninjured. We placed her on her back and gave her fluids and food upon her regaining consciousness. She remained in the pharmacy area for another 30 minutes and was fine. |
| 1125317 | 3/23/2021 | MI | 29 | F | 3/22/2021 | 3/22/2021 | Patient felt funny and fainted |

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| 1125384 | 3/23/2021 | IL | 89 | M | 2/26/2021 | 3/11/2021 | 3/11/21 orthostatic hypotension, Fall and N-Stemi dx at a hospital -3/12 transferred to another hospital - 3/16 discharged to Swing bed at another hospital HPI: History of Present Illness: Patient is an 89-year-old Caucasian male with a medical history significant for atrial fibrillation on anticoagulation due to prior GI bleed, HTN, HLD, T2 dm, BPH who initially presented to outside facility following a fall. Fall was mechanical in nature and occurred whenever he slipped on water while walking with his cane out the front door. Primary point of impact was on his left leg in hip as well as possible head trauma. Preceding this event, patient denies any presyncope, syncope, chest pain, shortness of air, palpitations. An extensive workup was performed outside facility including CT scan of the left hip without contrast, CT scan of the head without contrast, lumbar x-ray, CT scan of the left knee without contrast all of which showed no acute fracture or abnormality. EKG showed normal sinus rhythm heart rate of 75 with incomplete RBBB. Labs are included below. Vital signs normal. Patient was getting ready to be discharged from facility and whenever they sat him up, he had an episode where he stared ahead and got diaphoretic as well as dizzy. Patient has recollection of this incident. Outside ER decided to get troponin at that time and came back elevated at 0.163. Patient continues to deny any chest pain. Denies other associated symptoms including fever, fatigue, chills, shortness of air, palpitations, abdominal pain, nausea, vomiting, diarrhea. CBC: WBC 9.2, HGB 13.4, HCT 39.3, PLT 223 BMP: Na 141, K 3.7, Cl 104, HC03 31, BUN 22, CRT 0.94, GLU 124. PT 10.5, PTT 24.7, PLT 1.07. Due to lack of Cardiology coverage at outside facility, patient transfer was requested for further troponin trending and possible cardiology evaluation should be deemed warranted. hpi 3/16 The patient is a 89 y.o. male with a past medical history notable for atrial fibrillation, CAD, diabetes, BPH, hyperlipidemia. The patient presents for evaluation of worsening issues of weakness status post recent hospitalization were patient was fainted and was found to have orthostasis. Patient had a cardiac workup which was negative for any significant cardiac disease. Patient's plan is to hopefully get stronger return home to more independent living. Patient was seen today in his room. Patient notes that he has done very well with therapy after his fall. Patient is |

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| 1125454 | 3/23/2021 | LA | 73 | F | 3/17/2021 | 3/19/2021 | hoping to get stronger. Patient has no issues with any bowel or bladder function. Patient denies any shortness of breath. Patient has had good intake. Patient's past medical history, past surgical history, social history, family history, medications allergies were reviewed. 3/19/2021- Dizziness, Abd discomfort, diarrhea, blood glucose greater than 1000 3/20/2021- syncope and collapse resulting in tib/fib fracture, decreased BP (admitted to local ICU) 3/22/2021- tested COVID positive |
| 1125479 | 3/23/2021 | VA | 23 | F | 3/23/2021 | 3/23/2021 | Patient stated that after she received her vaccination, she began to feel warm. Patient also reported dizziness. Patient does report a history of fainting after vaccinations. Reports no food was consumed this morning. Patient was hydrated, vital signs were taken. Patient reports feeling better and vitals and everything was good and patient was able to go home. |
| 1125498 | 3/23/2021 | | 47 | M | 3/22/2021 | 3/22/2021 | Patient stated prior to vaccine he has a history of fainting after vaccination. About 1 minute after vaccination he became pale, clammy, and lightheaded. Spoke with patient while someone else retrieved an ice pack and water. About 2 minutes after vaccination patient became unconscious and upper body had seizure like activity. Patient was moved to the floor immediately regained consciousness. Event lasted approximately 15-20 seconds. After regaining consciousness, stated he felt better. Remained on the floor for about 5 minutes, EMS was called as precaution. EMS stated vital signs and blood sugar were stable. Patient refused transport to hospital. Instructed to follow up with PCP. |
| 1125517 | 3/23/2021 | | 29 | F | 3/20/2021 | 3/20/2021 | Per EMS on site client "Passed Out" Syncope for 30 seconds following vaccine. Previous history of syncope with "shots" Anxious with O2 Saturation of 98% pulse 65 Blood pressure 96/66 at 16.55pm. At 17.00 client stated she felt better with Blood pressure up to 101/71 and pulse 85.. Released by Dr after being reclined in her car seat and reporting she felt better. Advised to seek medical attention later if needed. Client verbalized understanding. |

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| 1125649 | 3/23/2021 | LA | 33 | M | 3/23/2021 | 3/23/2021 | Patient got his first dose of covid vaccine and while sitting for 15 min for us to monitor him, patient fainted but regain consciousness after after few second and fully aware of situation. 911 was called but patient decline service |
| 1125718 | 3/23/2021 | TX | 39 | M | 3/22/2021 | 3/22/2021 | PT FAINTED FOR ABOUT 2-3MINSAND WAS AROUSED BY VERBAL STIMULI, BP141/85 HR 58 R18 O2SAT 98%. PTSTATED THAT HE IS SCARED OF NEEDLE,HE WAS TALKING. HE STATED THAT HE IS NOW FINE AND CAN DRIVE HOME. PT LEFT THE SITE AT5:35PMDRIVING HIMSELF. INSTRUCTED TO KEEP TALKING TO HIMUNTIL HE GETS HOME. |
| 1125241 | 3/23/2021 | FL | 26 | F | 3/23/2021 | 3/23/2021 | patient fainted but regain consciousness right away |
| 1127544 | 3/23/2021 | CT | 23 | F | 3/23/2021 | 3/23/2021 | The patient received her second dose of the Modern COVID-19 vaccine at approximately 7:20pm on Tuesday, March 23, 2021. Patient stated after receiving the vaccine that she had a "very long time ago passed out after a blood draw". The patient remained in the chair with her nurse for approximately 2 minutes, her color was good, skin was dry and had normal respiration. The patient then stated "I'm not feeling so well". Patient aware, assisted to floor, lying prone, lost consciousness (called EMS), proceeded to have a seizure, bilateral upper arm postured wrists out, lets still, body tremors. Episode lasted approximately 1 minute. During the episode, airway patent, head protected, respirations spontaneous, pulse regular 90-110. Patient awoke spontaneously, stated was somewhat confused, but making sense was able to voice event leading to episode. Patient spoke with her mother, nurse spoke with her mother to advise patient to be evaluated at the hospital due to seizure. Client and mother agreeable, report to paramedic, client transferred to Hospital by Ambulance with wallet, keys, and phone. |
| 1127288 | 3/23/2021 | WI | 66 | M | 3/23/2021 | 3/23/2021 | Pt reported that he had light headedness. Pt reports that he gets Vagal response. Pt passed out and was pale and sweaty. Pt came to and BP 114/71, sats of 94% and HR 62. Assoc redid Vital signs 130/73 and 3rd BP at 5 minutes after 119/73, SAO2 96%, HR 56. Patient was then escorted to ER. |

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| 1127315 | 3/23/2021 | MO | 30 | M | 3/23/2021 | 3/23/2021 | Pt received a covid imz, pt stated after about 5 minutes that he felt warm, we went to get him some water and were immediately notified by another pt that he fainted, he hit his head after falling out of the chair, he hit his head but awoke immediately and was coherent. after pt stated that he has anxiety and probably had a panic attack and fainted. there was a small cut on his head but he appeared ok, ambulance arrived at the location and ems gave him an ice pack and checked him out he mentioned that he would see a dr but refused any other treatment from ems |
| 1127386 | 3/23/2021 | WA | 66 | F | 3/1/2021 | 3/1/2021 | Mon-Tues 9:00pm-6:00am - paralyzed on back in full body pain, literally unable to move AT ALL Tues-Wed 6:00am-5:00am (next day) - able only to roll onto side; unable to get up except 2-3 times to bathroom; almost passed out one time; unable to keep down even sips of water; dry heaves; 100.8 fever; chills/fever; severe headache Wed-Sat - severe exhaustion; out of bed only occasionally and very briefly; able to keep down a little broth and then chicken soup; periodic chills, headache, nausea Sun-Mon - a little more improvement in all areas Tues - much better! At some point, I developed Livedo reticularis in left calf. Went to urgent care on March 19. EKG normal. No DVT. Possibly caused by spasm. Saw physician today March 23. Cause undetermined. |

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| 1127388 | 3/23/2021 | NY | 60 | M | 3/23/2021 | 3/23/2021 | IMMEDIATELY AFTER DOSE WAS ADMINISTERED PATIENT COMPLAINED OF DIZZINESS WHILE SEATED. IMMUNIZING TECHNICIAN IMMEDIATELY CAME AND NOTIFIED ME, AT WHICH POINT I ENTERED OUR VACCINATION ROOM AND KNELT DOWN NEXT TO SEATED PATIENT. HE CONFIRMED THAT HE FELT REALLY DIZZY AT WHICH POINT I ENCOURAGED HIM TO SIT BACK IN THE SEAT AND RELAX AND I WOULD STAND BY HIM. WITHIN APROX 5 MINUTES OF VACCINATION PATIENT FAINTED IN THE CHAIR AT WHICH POINT EMS WAS CONTACTED. WITHIN APROX 30 SECONDS PATIENT STARTED TO REGAIN CONCIIOUSNESS (NOTED BY EYE, MUSCLE MOVEMENT) OVER THE COURSE OF THE NEXT FEW MINUTES PATIENT SLOWLY BECAME ALERT AND ORIENTED AT WHICH POINT EMS ARRIVED AND TOOK OVER HIS CARE. AFTER APROX 15 MINUTES OF CARE FROM EMS PATIENT OPTED TO GO HOME WITH HIS DRIVER. I CONTACTED THE PATIENT AT APROX 130 TO CHECK IN ON HIM AND HE ADVISED ME HE WAS FEELING NORMAL AND THANKED US FOR HELPING HIM THROUGH HIS FAINTING EPISODE. |
| 1127390 | 3/23/2021 | OH | 39 | M | 3/23/2021 | 3/23/2021 | Shortly after receiving the vaccine, the patient passed out. I ran out to him and shook him after having someone call 911. He regained consciousness after about 45-60 seconds. EMT checked his pulse and blood pressure and released him. |
| 1127410 | 3/23/2021 | NY | 43 | F | 3/23/2021 | 3/23/2021 | Near syncope treated oral glucose and IV fluids. Transport to local ED. |
| 1127428 | 3/23/2021 | TX | 42 | F | 1/4/2021 | 1/13/2021 | 1st Moderna shot was 1/4/21. Had a syncope episode/potential seizure on 1/13/21 - unwitnessed loss of consciousness for a short period of time with loss of urinary continence. 2nd Moderna COVID shot on 1/29/21 with no reactions. My doctors evaluating me did not consider this as a COVID vaccine reaction, even though it did occur after the first vaccination. I am a nurse with a doctorate degree and do not believe the seizure was the reaction of the COVID vaccine. I was under extreme amounts of stress at work at the time. I also have a prior medical history of syncope episodes when I was a teenager (25+ years ago). |

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| 1127432 | 3/23/2021 | CA | 55 | M | 3/22/2021 | 3/22/2021 | Approximately 10 minutes after 1st dose of Pfizer vaccination. Pt. was fanning himself, appeared diaphoretic with mask down. He flagged down nurse and reported feeling hot/lightheaded. NP asked for BP machine, instructed patient to take slow deep breaths. Pt. reported he felt like he may lose consciousness. His eyes rolled and he became white/pale and appeared to stop breathing. Code assist called; didn't respond to sternal rub, but raspy breathing, weak/rapid pulse palpated; immediately transferred to the ground level without falling, 2 person assist. 9-1-1 called, BP machine didn't immediately work. As soon as his head was low, his face became bright red and he regained consciousness. He was disoriented briefly but then able to answer questions/oriented. BP elevated, HR 80s. BS 257. No s/s anaphylaxis. Hx of syncope r/t blood draw. Wife present and report hx of DM, HTN, Palpitations. He denied CP/SOB or palpitations. He had eaten and took regular medicine the morning. Paramedic arrived and patient was transported to the nearest ER. Pt. was later discharged. |
| 1127258 | 3/23/2021 | NJ | 42 | F | 12/21/2020 | 12/21/2020 | Dizziness & palpitations immediately post vaccine administration; resolved without medical intervention. Near syncope. |
| 1127488 | 3/23/2021 | MA | 58 | F | 3/23/2021 | 3/23/2021 | patient became clammy weak and almost fainted after shot she appeared pale and disoriented we call 911 and EMT came checked vitals her blood pressure was low and they took her by ambulance to hospital |
| 1127757 | 3/23/2021 | WI | 28 | M | 3/20/2021 | 3/20/2021 | Body Ache starting 9 hours after. Main concern, I fainted while walking from the bathroom and split my eyebrow open. Could've been much worse but is a bad side effect. This occurred about 16 hours after vaccine |
| 1127578 | 3/23/2021 | MN | 18 | M | 3/23/2021 | 3/23/2021 | Pt got his immunization, when to sit in the lobby and passed out after sitting in the lobby for about 2 minutes. We were able to provide the appropriate medical care and pt regained consciousness quickly and didn't have any other issues/injuries. |

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| 1127658 | 3/23/2021 | MA | 66 | F | 3/6/2021 | 3/21/2021 | I woke up after a normal night's sleep and found that everything was spinning. Was dizzy and could not properly walk. After trying to drink a bit of water, fainted and vomited it all back up. I was weak and tired. Slept or rested all day and by late afternoon was able to hold down some toast and by evening symptoms had resolved. Clearly, I am not sure that this was vaccine related since it occurred 2 wks after vaccination but felt should be reported. |
| 1127659 | 3/23/2021 | OH | 42 | M | 3/23/2021 | 3/23/2021 | Patient fainted at pharmacy approximately 7 minutes after receiving vaccine. Went to Emergency Room by ambulance. On follow up phone call patient stated he is doing fine. He received iv fluids at Emergency Room. |
| 1127662 | 3/23/2021 | | 50 | M | 3/23/2021 | 3/23/2021 | dizziness, bradycardia, sweating, fainted & fell. VS taken, observed, juice offered, symptoms resolved, pt transfer to ED for abrasion on right side of his forehead |
| 1128102 | 3/23/2021 | WA | 57 | M | 3/23/2021 | 3/23/2021 | After receiving his vaccine, patient had a slight syncopal episode. Patient reported that he was going to get lightheaded as he normally gets this way with vaccines or blood draw. Patient never passed out; however, he almost fell when getting up from the vaccine chair, he reports lightheadedness and requested to lay down on the ground and have his feet elevated. Oxygen was brought to patient by post observation and 2 Liters delivered maintaining 99% saturation. After approximately six minutes, patient decided to get up from the ground. Two staff including patient's wife assisted him to stand however, patient requested to be seated for a while. Patient was then moved to post observation where he was conscious, speaking clearly and monitored for an additional 30 minutes with no further incident. |
| 1127736 | 3/23/2021 | NJ | 31 | F | 3/21/2021 | 3/22/2021 | At 9pm, Muscle pain, fatigue, headache and soreness in the arm. Took Tylenol 2x325mg. At 3 am, woke up feeling dizzy and headache. After walking 2 steps I fainted and collapsed on the floor. During the following day, I had fever of 101.5F, extreme headache, dizziness, muscle ache and fatigue. |

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| 1128087 | 3/23/2021 | OR | 24 | F | 3/23/2021 | 3/23/2021 | Approximately after receiving the first dose of COVID-19 vaccine, a 24-year old female patient experienced an episode of syncope/near-syncope. She was immediately assisted by a pharmacist onsite, who helped the patient to lie on the ground with her legs elevated. The patient immediately regained consciousness and was speaking normally. The patient was monitored closely for approximately 45 minutes. At that time, the patient reported feeling no symptoms or side effects, and was allowed to leave with instructions to seek appropriate medical attention if needed for further symptoms. |
| 1126578 | 3/23/2021 | OH | 42 | F | 3/1/2021 | 3/20/2021 | I could feel the vaccine enter my body & feel it move up my arm & spread up across my back & up my neck. I was nauseous instantly. After 15 minutes I felt dizzy & weak. I started to twitch all over as the vaccine moved through my body. Later that day I had excruciating pain in all my joints & muscles & even bone pain. I got a headache. I felt sharp shooting pains in my chest. 2 days later intense nausea set in. I almost passed out. I am fatigued. I had strange abdominal issues like pressure, bloating, intense cramping, heartburn. I don't have much of an appetite. I am fatigued. I had diarrhea. |
| 1127469 | 3/23/2021 | PA | 70 | F | 3/21/2021 | 3/21/2021 | 13 hours after injection while sleeping had strong urge to go to the bathroom, bowel movement, resulting in massive diarrhea. During process, became very dizzy and felt nauseous and faint. Attempting to get up from toilet, and getting assistance from husband in an adjoining bedroom, made it to a second bathroom, passing out, again, complete empty of bowels severe diarrhea again while passed out on floor. Unconscious for about one minute, until revived by husband. Sweating, faint, very low BP. Taken to hospital by husband after getting composure admitted for observation due to apparent dehydration from massive diarrhea event. Results possible cardiac instability, dehydration from diarrhea, vegas nerve activity with Discharge the next day 03/22/2021 with follow up with cardiac Dr and primary, ongoing |
| 1126748 | 3/23/2021 | NH | 18 | F | 3/22/2021 | 3/22/2021 | Vasovagal syncope- felt lightheaded, almost passed out twice, and vomited. |

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| 1128083 | 3/23/2021 | WA | 60 | M | 3/9/2021 | 3/13/2021 | Arm pain first day. Lightheaded, feeling like fainting, dizziness, above stomach pain nausea, that happened parallel to erratic high blood pressure, 199/98. Chills, shakes, joints and muscle pain, headache, palpitations, night sweats, severe fatigue. From day 3 to day 17. Went to healthcare facility twice, and two doctor calls. |
| 1127194 | 3/23/2021 | TX | 71 | M | 3/2/2021 | 3/3/2021 | Nothing until approx 11 hours later. Awoke with severe lower abdominal pain. Very weak. Son helped me get up and clear liquid (water?) came out of eyes, nose, and mouth. Passed out. Son helped me to car and I passed out again getting in the car. Son drove me to the emergency room at hospital. In severe pain and very weak. Test done- Fever, Blood, Urine, CT-Scan. After about 4 hours I was given something for pain through IV and felt much better in about 10 minutes but still weak. Outcome- Doctor said it was reaction to vaccine and that I have a gallstone but it was not causing any problems. Referred to a doctor for the gallbladder. Told to take 600mg of ibuprofen three times a day for three days. Was fi |
| 1126592 | 3/23/2021 | AR | 22 | F | 3/23/2021 | 3/23/2021 | Patient fainted after vaccine. Patient was still breathing and had normal heart rate |
| 1126689 | 3/23/2021 | PA | 43 | F | 2/15/2021 | 2/15/2021 | After receiving the first shot, I had a taste of metal in my mouth. I sat down and in the next 30 minutes passed out. For the next three weeks, I had migraines more frequently than my usual migraines and a new pain behind my eye. After receiving my second doses, I felt extremely tired and within 3 hours of receiving got shooting pain on left side of my face. I was diagnosed with Trigeminal Neuralgia by Dr on March 22, 2021. This pain has been constant since receiving the second dose on March 8. |

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| 1126751 | 3/23/2021 | IL | 58 | M | 3/23/2021 | 3/23/2021 | pt passed out about 2 minutes after receiving vaccine. Pt was seated when he lost consciousness, pt was initially disoriented but was fully conscious and lucid within seconds. Pt stated that he did not hit head when falling from chair, blood pressure was normal at two separate readings minutes after the incident, pt was sweaty with loss of color but was more embarrassed than anything, wife and son returned from shopping, pt felt much better and left with his wife approximately 30 minutes after receiving the vaccine. A follow-up call 4 hours after the event was made. Pt stated he was at work and felt fine. |
| 1126767 | 3/23/2021 | VA | 56 | F | 2/9/2021 | 2/9/2021 | Fainted immediately after vaccination and fell to ground. No injuries noted. |
| 1126811 | 3/23/2021 | NJ | 63 | F | 3/17/2021 | 3/17/2021 | Wednesday night I felt tired and cold. Woke up Thursday morning and couldn't lift up my head. Migraine was in all of top teeth, ears, behind eyes, all over head. Pain was so extreme I fainted in bed. Came to and pain was a bit better but quickly came back full force. Woke up at 1am Friday morning drenched from sweat through to the mattress but migraine was better. Ran fever up to 102 and down and up all day Friday. Saturday fever was only 100 but came back after each sweat. Sunday I had almost no fever and just a regular head ache. Monday exhausted but okay. |
| 1126817 | 3/23/2021 | VA | 34 | F | 2/16/2021 | 2/16/2021 | Patient fainted shortly after vaccination (within 15 minutes) and had low BP. Patient refused transport to ER and was released to home. |
| 1126881 | 3/23/2021 | IA | 20 | F | 3/23/2021 | 3/23/2021 | Syncope |
| 1126902 | 3/23/2021 | CA | 48 | F | 3/21/2021 | 3/21/2021 | Patient experienced anaphylactic reaction which includes fainting, sudden increase in secretions from eyes and nose, weakness, numbness in upper extremity (fingertips) agitation, flushing dizziness, feeling something wrong, and extreme headache. The patient was treated with epipen and pharmacist called 911 and advised patient to go to the hospital. Patient recovered in approximately 30 minutes but refused to go to the hospital and called in a ride by the husband. |
| 1127089 | 3/23/2021 | IL | 20 | F | 3/23/2021 | 3/23/2021 | Syncope - 15 seconds, person sates always faints-scared of needles |

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| 1127140 | 3/23/2021 | WA | 25 | M | 3/23/2021 | 3/23/2021 | Patient fainted approximately 3 minutes after receiving his vaccine. He was in a monitoring chair and rested his head back. Pt did not fall or incur any injuries as a result of fainting. Pharmacy staff noticed it happening and gave him attention immediately. He revived right away. Patient was moved to counseling room floor and laid on floor with legs up for 15 minutes. Patient drank some apple juice and was monitored for a total of 30 minutes. Pt confirmed he felt ready to leave at that time and was advised to report any other symptoms to us immediately. |
| 1126914 | 3/23/2021 | KS | | F | | | passed out due to low blood pressure |
| 1127154 | 3/23/2021 | CA | 26 | M | 3/19/2021 | 3/19/2021 | Patient after receiving COVID vaccine and was waiting the required 15 minutes, patient fainted while getting up. First blood pressure was 100/60 while laying down. Patient was conscious, just said he got dizzy and lightheaded. Patient indicated he had not ate in the morning. Second blood pressure was 118/78. Patient does have history of syncope |
| 1127105 | 3/23/2021 | ID | 78 | M | 3/19/2021 | 3/20/2021 | Onset second morning after injection: headache, chills, nausea, loss of motor control in legs (unable to stand or walk, unable to roll over to get out of bed), profuse sweating. About 1pm my wife assisted me to the bathroom toilet, where I passed out for approx 30 mins. These severe reactions finally started to recede about 6pm, although the sweating continued into Sunday. Mild nausea, and mild headache continued into today Tuesday. |
| 1127003 | 3/23/2021 | FL | 26 | F | 3/23/2021 | 3/23/2021 | Passed out shortly after receiving vaccine. |
| 1126967 | 3/23/2021 | VA | 62 | M | 3/10/2021 | 3/10/2021 | Patient fainted post-vaccination. Low BP. transport requested. |

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| 1126954 | 3/23/2021 | CA | 30 | F | 3/15/2021 | 3/15/2021 | Patient came to Vaccination Clinic to receive first dose of Pfizer vaccine on 3/15/2021. Patient was vaccinated at 1147 and began to walk toward EMT monitoring area at 1153. While the patient was walking, the patient reported feeling faint. RN, followed the patient from behind. RN noticed patient beginning to fall and was able to catch her using her leg as support and guided patient to the floor. Both RN and patient decline sustaining any injuries related to this event. When on the floor, patient appeared pale, had cold and clammy hands, and was diaphoretic. RN assisted the patient by holding her legs in the air while the patient layed on her back. Patient was A&Ox4 at 1155 with a BP of 121/76. At 1159, patient reported feeling "better" and was transferred to zero-gravity chair. The patient's blood pressure was reassessed at 1201, 1221, and 1227 and reported to be 124/81, 122/74, and 125/79, respectively. The patient refused transport via EMS and stated she preferred to drive herself home. Patient able to ambulate without assistance. Patient left to her car at 1230. Upon departure, patient was ambulatory, A&Ox4, with no reports of trouble breathing, dizziness, or lightheadedness. The patient was given education related to when to seek medical care, including shortness of breath, chest tightness, and sensation of throat tightness. The patient was provided with additional guidance on what to do when receiving a second dose, including notifying the nurse that she has had a history of fainting. |
| 1126947 | 3/23/2021 | VA | 36 | F | 3/10/2021 | 3/10/2021 | Patient fainted after vaccination and fell on floor. Had right knee pain. IV was started and patient was transported to ER via EMS. |
| 1126938 | 3/23/2021 | VA | 77 | F | 2/15/2021 | 2/17/2021 | Patient fainted two days after receiving vaccine and was transported to ER via EMS. |
| 1122678 | 3/22/2021 | VA | 32 | F | 3/19/2021 | 3/19/2021 | After approximately 5 min after receiving the shot i started to feel a strong feeling of dizziness along with nausea, i could not stand and fainted, they carried me to a private area where i was picked up by the ambulance, my vital signs were not ok. |

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| 1122712 | 3/22/2021 | | | F | 2/5/2021 | 2/5/2021 | <p>Lost consciousness (passed out) for several seconds; Went pale; Started seeing stars; Remained weak for several hours; Nauseous; Chills; Fever; A spontaneous report was received from a consumer concerning a female patient of an unknown age, who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced lost consciousness (passed out) for several seconds, fever, chills, nauseous, went pale, started seeing stars and remained weak for several hours. The patient's medical history was not provided. Concomitant product use was not provided by the reporter. The patient received the first of two planned doses of mRNA-1273 (Batch number not provided) on an unspecified date. On 05 Feb 2021, approximately few hours prior to the onset of the symptoms, the patient received their second of two planned doses of mRNA-1273 (Batch number not provided) via an unknown route for prophylaxis of COVID-19 infection. On 05 Feb 2021 Friday night, the patient had chills and fever. On 06 Feb 2021, patient gradually became nauseous, went pale, started seeing stars and then lost consciousness (passed out) for several seconds (medically significant event). The patient remained weak for several hours but gradually recovered and was back to normal at the time of this report. Treatment information was not provided. The patient received both scheduled doses of mRNA-1273 prior to the events; therefore, action taken with the drug in response to the events is not applicable. The events, chills, fever, lost consciousness (passed out) for several seconds, nauseous, went pale, started seeing stars and remained weak for several hour was recovered on an unspecified date.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p> |

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| 1123377 | 3/22/2021 | AL | 24 | M | 3/12/2021 | 3/12/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Additional Details: pt did not report history of syncope after vaccination. only told me after event occurred. pt said he felt dizzy and sat back down in the post-vaccination area chair. monitored for approximately 40 minutes and pt's appeared to be stable and mobile alert and oriented and asked to go home. followed up with patient at 4 pm and he reported that he was feeling much better and appreciated us reaching out to him |
| 1122962 | 3/22/2021 | FL | 68 | M | 3/19/2021 | 3/19/2021 | Vaccinated at 8:30AM. Abrupt onset on extreme dizziness at 11AM. Passed out for 4 hours in a recliner at Noon. When awoke at 4PM was unable to sit, stand, or walk. Had to crawl to bathroom. Symptoms largely abated by 7PM. Was able to participate in 2 hours of outdoor vigorous racket sports the following morning. No apparent residual effects. |

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| 1122976 | 3/22/2021 | CA | 57 | F | 3/19/2021 | 3/19/2021 | 57y/o female presents with mild throat tightness ~15min after receiving Pfizer vaccine into the left arm. She states that it feels as though something small got stuck in her throat and is causing mild discomfort. She reports associated injection site pain, body cramps, and headache. She denies itching, difficulty breathing, shortness of breath, chest pain, palpitations, blurry vision, presyncope, difficulty swallowing water, or lip/tongue swelling. She reports no change in symptoms after 40min. post-injection. Physical Exam: Heart Rate 66bpm, Blood Pressure 115/74, Repeat Blood Pressure at 40min post-injection 120/80 Cardiac: regular rate and rhythm Lungs: unlabored breathing, clear to auscultation bilaterally Skin: no injection site erythema or swelling. No rash. No lip/tongue swelling or narrowing of oropharynx. Plan: Patient reports that her symptoms have improved at 1hr post-injection and would like to leave. I advised her that she should wait until all of her symptoms have resolved as throat tightness is a concerning adverse reaction. I provided her with options including contacting EMS right now to take her for observation at the hospital, however, the patient declined and said she would not go in the ambulance. She insisted that she wanted to go home and that her husband was driving and would take her to the emergency room if her symptoms worsen. Patient was well-appearing when she left the vaccination site. |
| 1122990 | 3/22/2021 | WV | 39 | F | 3/22/2021 | 3/22/2021 | Patient received the shot and was fine. Afterwards, she stood up and fainted. Patient came to on the floor and was offered water. Patient stated she was ok and we continued to monitor for 15 minutes at which time she said she believed she was fine to leave. |
| 1123080 | 3/22/2021 | LA | 22 | F | 3/22/2021 | 3/22/2021 | pt received shot around 8:53 am. She fainted around 9:05 am during her 15 minute after shot waiting period. She said she had not eaten and was nervous. she felt dizzy and lightheaded. an ambulance was called and she refused medical treatment. she was alert and was able to walk out of the store on her own |

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| 1123171 | 3/22/2021 | OH | 37 | F | 3/22/2021 | 3/22/2021 | Patient passed out about 5 minutes after injection. Patient has history of passing out from vaccines, was counseled to sit and wait 30 minutes after vaccine was given. She passed out in chair in the waiting area about 5 minutes after injection. Nurse practitioner next door was notified and she contacted 911. Patient then came to but was slightly disoriented, EMS walked patient out to car. |
| 1122959 | 3/22/2021 | OH | 29 | F | 3/22/2021 | 3/22/2021 | PATIENT STATED SHE WAS DIZZY AND WITHIN ONE MINUTE HAD PASSED OUT. 911 WAS CALLED AND EMS CAME TO PHARMACY TO CHECK HER OUT. SHE CAME TO QUICKLY AND WAS SWEATING AND "OUT OF IT". SHE WAS ABLE TO SPEAK AND DRINK WATER BY THE TIME THEY ARRIVED. SHE RECOVERED AND SPENT AN ADDITIONAL 30 MINUTES IN THE PHARMACY AREA FOR OBSERVATION. |
| 1123189 | 3/22/2021 | TX | 35 | F | 3/18/2021 | 3/18/2021 | Vasovagal syncope |
| 1123551 | 3/22/2021 | OK | 18 | F | 3/17/2021 | 3/17/2021 | Client received first dose of Moderna Vaccine at 15:31. 15:32--sat down in observation area F. Without warning, client lost consciousness, fell from chair and hit head/left side on concrete floor. Was unresponsive x 1min. Used Syncope protocol. APRNs assessed client and local on-site paramedics notified. Client denied difficulty breathing, or any other symptoms typically associated with anaphylaxis. 15:36: BP 87/57, pulse 67 15:37--client awake and talking. Complaining top of head hurts. Client reports she has not eaten today, as she indicated she was very anxious about getting the covid immunization and reports she did not sleep last night. Next page 15:39: BP 110/65, pulse 87 15:41: BP 119/77, pulse 91 15:47: BP 110/77, pulse 88 15:50--paramedics started IV and checked blood sugar at 103. Client very anxious, but agreed to be transported to ER due to hit to head. Local transport unit called. 16:01: BP 98/64, pulse 76. 16:03: EMS transport unit arrived/transported to Emergency Room. |
| 1123263 | 3/22/2021 | MI | 30 | M | 3/16/2021 | | Patient felt syncope / fainting. On site EMS was called vitals BP 147/91 HR 72. Patient refused evaluation or care and released against medical advise. |

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| 1123396 | 3/22/2021 | WI | 18 | F | 3/19/2021 | 3/19/2021 | Received first COVID shot on 3/19/21. On 3/20/21 presenting to ER with weakness, achiness, fever, shortness of breath after having coronavirus vaccination yesterday. Patient is sure she had coronavirus back in November. Received the vaccination yesterday about 11 am. Within a couple hours she developed severe myalgias, low-grade fever. Reports she feels a little short of breath from a myalgias. No history of DVT or PE, urinary complaints. Patient has syncopal episode while in triage. No seizure activity. Felt lightheaded with standing. Clinical Impression: 1. Syncope 2. Vaccination reaction, initial encounter Presentation consistent with orthostatic, vasovagal episode from recent vaccination. Patient coronavirus previously stimulating a stronger immune response. doubt infection, PE, worrisome arrhythmia. Advised against second vaccination. return if any problems, worsening |
| 1123496 | 3/22/2021 | IN | 57 | F | 3/20/2021 | 3/21/2021 | Chills, fever, severe headache, neck and shoulder muscle pain, dizziness and almost passed out. |
| 1122592 | 3/22/2021 | IN | 50 | F | 3/20/2021 | 3/21/2021 | Sudden onset of weakness and extreme light headedness. Avoided fainting by putting head between legs. Became very weak. Had to leave the appointment I was at and go home. Became very fatigued and temperature went up to 99.5. All symptoms came out of nowhere. There was no feeling bad or strange before onset. |
| 1121887 | 3/22/2021 | NY | 17 | F | 3/22/2021 | 3/22/2021 | At 5AM a 17 year old female accompanied by her sister which is her legal guardian, received first dose of Pfizer. While patient was in observation she became dizzy, passed out, and fell on the floor and hit her forehead. Patient was immediately attended to by clinical staff. Within less then a minute patient was alert and oriented X3 but could not recall what happened. Ambulance was called, and site lead was made aware. Vital signs at the time were BP: 90/45, O2 100%, HR: 55. Ambulance arrived on scene and assessed patient. Vital signs upon transfer to hospital 111/56 HR78. Patient was transfer to hospital. |
| 1123573 | 3/22/2021 | NY | 42 | M | 3/22/2021 | 3/22/2021 | Prophylactic vaccination in bed, due to fear of needles and related syncope. Pt had no adverse reaction and further care by EMT was not needed. |

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| 1123231 | 3/22/2021 | | 70 | F | 3/18/2021 | 3/18/2021 | stared with a metallic taste in mouth and fatigue. next day nausea light headed and fainted. Body aches and no appetite, joint aches. |
| 1122017 | 3/22/2021 | MN | 47 | F | 3/12/2021 | 3/20/2021 | 4:30 am on the morning of Saturday 3/20/21 I had used the bathroom and when I stood up I had ringing in my ears and when I went to grab the door handle I lost my balance and passed out. |
| 1124092 | 3/22/2021 | NY | 43 | M | 2/10/2021 | 3/3/2021 | Passed out 9 hours after injection on 03Mar2021; This is a spontaneous report from a contactable consumer. A 43-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 2 via an unspecified route of administration on 03Mar2021 18:00 (Batch/Lot number was not reported) as SINGLE DOSE, and dose 1 via an unspecified route of administration, administered in Arm Right on 10Feb2021 18:00 (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient previously took amoxicillin and experienced drug hypersensitivity. The patient experienced passed out 9 hours after injection/also reported as 03Mar2021 03:30. The outcome of the event was recovering. The patient did not receive treatment for the event. Information on the Lot/Batch number has been requested. |
| 1123582 | 3/22/2021 | AL | 46 | F | 3/22/2021 | 3/22/2021 | Patient fainted about 5 minutes after receiving vaccine. After being evaluated by EMTs, they recommended she go to the ER to get checked out. |
| 1121699 | 3/22/2021 | OR | 36 | F | 3/18/2021 | 3/18/2021 | Dizzy w/ HA, Nausea-passed out in chair. Aprox 2 mins immediately came too when moved to wheelchair. Previous Hx of passing out with IV's. IUD removed today at 11:00am. No recall of event prior to passing out. Urinary incontinence. Vitals 107/71; 71; 99%SaO2. |
| 1121710 | 3/22/2021 | CA | 49 | M | 3/9/2021 | 3/9/2021 | Blood pressure dropped to 65, body temp shot up, passed out |

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| 1121845 | 3/22/2021 | WI | 74 | F | 2/9/2021 | 2/9/2021 | Faint; Dizzy; Slight reaction; Very tired; A spontaneous report, was received from a consumer (patient), a 74 years-old female patient, unknown race and ethnicity, who was administered Moderna's COVID-19 vaccine (mRNA-1273), and experienced faint (syncope), dizzy (dizziness), slight reaction (vaccination complication) and very tired (fatigue). The patient's current conditions included atrial fibrillation, back trouble and peripheral neuropathy (diagnosed years ago). The patient had medication allergies to pain medications and non-steroidal anti-inflammatory drugs (NSAIDs). Concomitant products included digoxin, carisoprodol, metamizole sodium and warfarin sodium. On 09-FEB-2021, prior to the onset of events, the patient received their first of two planned doses of mRNA-1273 (Lot number: 012M20A) intramuscularly in left arm for prophylaxis of COVID-19 infection. On 09FEB--2021, after receiving the vaccine, the patient had a slight reaction and became very tired, faint and dizzy. The patient's husband helped her to bed. The next morning on 10-FEB-2021, the events were resolved. The patient was scheduled for next Moderna vaccine (second dose) on 09-MAR-2021. No treatment information was provided. Action taken with second dose of mRNA-1273 in response to events was unknown. The outcome of the events, faint, dizzy, slight reaction and very tired was recovered/resolved on 10-FEB-2021.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |

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| 1121855 | 3/22/2021 | | | M | 3/2/2021 | 3/5/2021 | <p>diagnosed with neurocardiogenic syncope; P.O.T.S/-POTS; tired the next day; experienced a headache for a couple hours; This is a spontaneous report from a contactable nurse. The nurse reported similar events for 2 patients. This is 1st of 2 reports. A 58-year-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiration date unspecified), via an unspecified route of administration on 02Mar2021 as single dose for COVID-19 immunisation. Medical history included open heart, prostate cancer, Lyme disease, neobladder, and sepsis, all from Aug2020; and blood pressure (abnormal). Concomitant medication included fludrocortisone for blood pressure (abnormal). Reporter stated that her husband seemed tired the next day, although husband says he wasn't. Today, 05Mar2021, patient experienced a headache for a couple hours, and was tired today. On an unspecified date, the patient was diagnosed with neurocardiogenic syncope and Postural orthostatic tachycardia syndrome (POTS) and given medication Florinef 0.1mg. Patient had been taking for about a week. Reporter was asking if it would cause issues with the vaccine since it was a corticosteroid and if it would cause issues if he was going to get a flu shot. Reporter was also asking what the efficacy after the first dose was. Outcome of events was unknown. Information about the Lot/batch number has been requested.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate. ,Linked Report(s) : US-PFIZER INC-2021261960 same drug/reporter/event, different patient</p> |

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| 1121910 | 3/22/2021 | CO | 64 | M | 3/21/2021 | 3/21/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: initial dizziness, loss of consciousness for roughly 30-60 seconds, body rigidity before waking up-Severe, Systemic: Flushed / Sweating-Mild, Systemic: Weakness-Medium, Additional Details: 4-5 minutes after vaccinating patient he reported feeling dizzy, when accessing patient he became unresponsive and breathing became louder, he became pale and lost consciousness. 911 was called. His face began turning red and with the help of 2 individuals we lowered him to the floor, his arms became rigid for abotu 5 seconds, and upon trying to wake him/checking for vital signs, he came to and was aware of where he was and that he had just got a vaccine. he did not recall the event post dizzine |
| 1121899 | 3/22/2021 | VA | 31 | M | 2/21/2021 | 2/21/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Syncope-Medium, Additional Details: Patient was in the waiting area after recieving vaccine where he fainted and fell out of his chair. His female friend asissted him and reached out to us. He regained consiousness and was able to speak to us clearly. There was a small cut above the left eye. He expressed that he has a fear of needles and this has happened before to him as well. He had no symptoms of an allergic reaction, no headache or visual disturbanes. We monitored him for 30 minutes and did not feel the need to call 911. |
| 1122587 | 3/22/2021 | KY | 50 | F | 3/22/2021 | 3/22/2021 | anxiety before receiving vaccine, received vaccine, felt sick to her stomach, lightheaded, passed out and vomited while unconscious and very diaphoretic |

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| 1122080 | 3/22/2021 | PA | 46 | F | 3/12/2021 | 3/19/2021 | Patient's received 2nd dose of Moderna vaccine Friday 3/12. Her husband reported she had not unexpected fatigue, malaise, and fever for 1 day but better after that. On Monday she began complaining of shortness of breath. This progressively worsened and she started having presyncopal episodes. On Saturday she was unable to come down the stairs in the house so husband planned to take her to the hospital but she stood up and passed out and woke up quickly. He decided to call EMS. By the time she presented to our hospital she was cyanotic and agonal breathing. On moving her from EMS stretcher to ED bed she had PEA cardiac arrest. She underwent mechanical device CPR with only brief (<1 min) ROSC x1. She at some point did have a shockable rhythm. Cath lab was notified and she was taken emergently to the cath lab with ongoing mechanical device CPR. Peripheral VA ECMO was placed after about 1.5 hours. Pulmonary angiogram was done which showed massive saddle PE with near complete obliteration of the right pulmonary tree and some filling defects in the left tree as well. At that time she had severe mixed respiratory and metabolic acidosis with a lactate of 24. She also had no gag or corneal reflex, minimally responsive pupils, and no response to noxious stimuli. Mechanical thrombectomy was attempted with some result. She was transferred to the SICU with increasing pressor requirement, and DIC. Ultimately, the venous catheter of the ECMO circuit malfunctioned thought to be secondary propagating IVC thrombosis. Family decided to withdraw care and she passed away. |
| 1122086 | 3/22/2021 | NE | 58 | F | 2/16/2021 | 2/17/2021 | Normal reactions such as body aches, fatigue, pain at injection, but also Extremely high temperature (not taken) which resulted in fainting and brief loss of consciousness. |
| 1122164 | 3/22/2021 | NJ | 28 | F | 3/3/2021 | 3/3/2021 | Patient post-vaccine felt hot and anxious. Patient passed out and fell out of chair. She was witnessed by staff. No LOC, post-fall immediately AAOx3. Vital signs 120/64, HR 90, rr 20, spO2 99%. ice pack applied to forehead, denies any pain. Patient able to go home. |

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| 1122174 | 3/22/2021 | NY | 30 | F | 3/18/2021 | 3/20/2021 | Patient reports she got her Covid-19 vaccine 2 days ago, first dose and has felt fatigued since then. Patient states she vomited in the lobby and then passed out, now feels better, able to drink a glass of water. No other symptoms, no CP, no SOB. |
| 1122296 | 3/22/2021 | CO | 23 | F | 3/19/2021 | 3/19/2021 | Within about 5 minutes of patient receiving the vaccine, she began to feel dizzy and nausea. She proceeded to have several episodes of vomiting afterward. She was treated with oral Benadryl 25mg PO x1, but vomited afterward. She was later administered Benadryl 25mg IM x1 and Zofran 4mg ODT x1 with improvement in her symptoms. Vital signs remained stable throughout 2 hours of observation and she was discharged home. Subsequent telephone follow-up indicated patient's initial symptoms continued to improve by the evening and the following day. Patient never developed syncope, rash/hives/SOB/lip, tongue or throat swelling. |
| 1122524 | 3/22/2021 | NV | 49 | F | 3/4/2021 | 3/6/2021 | I fainted and once I woke up I could not muster the strength to get up. I couldn't get my legs underneath me, I couldn't push myself up with my arms. I had to call a friend to come help me get to my bed. It took me 15 minutes to scoot myself to get to the front door. It took another 10 to try to unlock it. I spent the next 2 days in bed very fatigued with my legs feeling like jelly. I am still very fatigued but getting better every day. I was also experiencing hot and cold chills for about 2 weeks after the vaccine. I did not seek any medical treatment. |
| 1122554 | 3/22/2021 | WI | 33 | F | 3/19/2021 | 3/20/2021 | Vaccinated at 12:00 19Mar2021. Sore arm started a couple hours afterward and is still present. Started experiencing fogginess and feeling cold at 1:00 am 20Mar2021. Went to bed at 1:00 and dreamed of being sick until waking up at 8:30 am 20Mar2021. Woke up and was very weak (could not push toothpaste through toothpaste tube), almost passed out in trying, so I sat on the floor. Tried getting back to bed and was extremely nauseous and started vomiting. After that, I had the sweats/fever/chills for a couple hours (until ~11:00am), and was fatigued until 4:00 pm. Spent most of the day sleeping, unable to do anything. Today, 22Mar2021, feel slight tingling on palm of left hand and fingers. Injection site is still sore and bruised |

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| 1121859 | 3/22/2021 | NY | 79 | F | 3/6/2021 | 3/1/2021 | I went to the bathroom and the next thing I know was that I woke up on the bathroom floor, I passed out for couple of minutes; Chills; Weak; Dizzy; Nausea; Sore arm; This is a spontaneous report from a contactable consumer (patient). A 79-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; Lot number was not reported) via an unspecified route of administration, at the age of 79-year-old, on 06Mar2021, as SINGLE DOSE for covid-19 immunisation. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; Lot number was not reported) via an unspecified route of administration, on an unspecified date, as SINGLE DOSE for covid-19 immunisation. After taking the second dose on 06Mar2021, the patient waited for half an hour and there was no problem. The patient came home no problem. In the middle of the night, the patient woke up with chills, the patient know that is one of the side effects, she was okay and not worried about it. The patient took her temperature that was normal but then couple of hours later, she went to the bathroom and the next thing she knew was that she woke up on the bathroom floor, the patient passed out for couple of minutes. Then she went to bed and was very weak and dizzy and nausea. The patient didn't want to call right away or did not wanted to go to the emergency room. The patient called her friend because she got very nervous and she said come back to her house. The patient took a Benadryl (treatment) and came back home and slept few hours. The patient woke up this morning, felt pretty good and took Benadryl (treatment) and then came here of her friend house and took Benadryl (treatment) again few minutes ago and four hours later. The patient had several things like these like she was dizzy and had nausea. The patient felt okay now and she doesn't want to go to emergency room and she seems to be fine now. The patient was dizzy, nausea and passed out. The patient had a chills and experience sore arm. Outcome of the events was recovered in Mar2021. Information on the lot/batch number has been requested. |

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| 1124638 | 3/22/2021 | OH | 30 | M | 3/22/2021 | 3/22/2021 | During the 15 minute observation period after injection, patient returned to the check-in desk complaining of dizziness. He was brought immediately to exam room where he became pale, diaphoretic, and stated he "felt like he was in a dream." Seated BP was 74/palp. He was placed in supine position on exam table, cool compresses placed on forehead and back of neck. He complained of some nausea, which quickly improved. He never lost consciousness. His color and alertness improved steadily over the next 10 minutes. Repeat BP (lying) was 100/50. After a few minutes he sat up on exam table, dangling legs. BP remained stable at 110/60, HR 84. He continued to improve and stated that he felt better, drank some water and ate some goldfish crackers. Reported that he just remembered he had not eaten since lunch. After another 5-10 minutes he was alert, oriented, able to walk unassisted. Final BP 114/70, HR 80. His wife remained with him and confirmed she could drive him home. Discussed that although I feel confident this was a vasovagal near-syncope, if symptoms recur or worsen, he should go to ER for evaluation. Understanding verbalized. |
| 1124221 | 3/22/2021 | TX | 63 | F | 3/18/2021 | 3/19/2021 | 22 hours after being vaccinated, I fainted (approximately 7:00 AM the next day), the duration of fainting was more or less than a minute. The rest of the day I felt very weak. I had a fever of 37.5C. My blood pressure was normal (good), just my heart rate a little high (I usually monitor 70 and it was close to 100 for several hours after fainting). During the night before the event, I got up to urinate several times and usually I only get up once. I did not take any medications or supplements on the day of the vaccination. I also did not take painkillers after vaccination. |
| 1124252 | 3/22/2021 | TX | 38 | F | 3/22/2021 | 3/22/2021 | PT C/O PASSING OUT,ANXIETY O/E BP115/78 PULSE 74,O2SAT 99%,AFTER SOMETIME PT RESPONDED AND STATED SHEALWAYS PASSED OUT ANYTIME SHE GOT VACCINE. FLUID OFFERED PO,ACCEPTED. CONTINUE TO MONITOR. PT STABLE BEFORE LEAVING,DROVE HOME BY SPOUSE. |

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| 1124369 | 3/22/2021 | IA | 41 | M | 3/22/2021 | 3/22/2021 | Patient passed out during the observation time. Patient was moved to the floor and feet were elevated. Patient regained consciousness and was monitored by the pharmacist. 911 had been called by the time patient regained consciousness. EMTs arrived and took over scene. Patient was able to walk with EMTs on his own. No medications were given by the pharmacy/pharmacist. |
| 1124452 | 3/22/2021 | TX | 53 | U | 3/11/2021 | 3/12/2021 | She was treated with a diagnosis of myocarditis in the post vaccination period. She felt ill post vaccination, mainly with GI upset. This worsened by day 6, she had syncope and brought to the hospital. Her troponin was elevated and she developed transient heart block. Coronary arteries were normal, hemodynamics were consistent with cardiogenic shock. LV EF decreased mildly. She responded to IV stress dose steroids. Endomyocardial biopsy showed lymphohistiocytic infiltrated and eosinophils. |
| 1123593 | 3/22/2021 | IL | 33 | F | 3/20/2021 | 3/20/2021 | Increased heart rate, syncope at 11:30pm. about 6 hours after vaccination. |
| 1124511 | 3/22/2021 | CA | 21 | F | 3/18/2021 | 3/18/2021 | Patient fainted in the waiting area after receiving her vaccination. Paramedics were called. While talking to the paramedics she began to faint again. They transported her to the ER. She was released from the ER |
| 1124218 | 3/22/2021 | NJ | 52 | F | 3/16/2021 | 3/16/2021 | Pfizer-BioNTech COVID- 19 Vaccine EUA: During the post-vaccination observation period, vaccine recipient developed dizziness, near syncope, and hypotension. They were seen by EMS and given fluids then transported to emergency department. They were discharged to home the same day. |
| 1124572 | 3/22/2021 | TN | 30 | M | 3/22/2021 | 3/22/2021 | Vasovagal syncope approximately 5- 10 minutes post vaccination. Pt reports that he started to feel lightheaded and stood up and passed out. pt then hit his chin on a low setting wall and had a small 1cm laceration on his anterior chin. pt fell prior to my arrival to finding him down. when I arrived pt seemed to be mildly disoriented for about 30 seconds to 1 minute. pt reports that he had + LOC for a few seconds while he fell but was conscious when I arrived. pt was advised to seek out wound closure for chin laceration. |

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| 1124466 | 3/22/2021 | AZ | 73 | F | 3/9/2021 | 3/16/2021 | Symptoms of muscle ache, then fever, then chills.started late afternoon, Tue., March 16, at 4:15 pm. At 2:am next morning, March 17, sudden severe nausea and diarrhea, severe headache, hot flashes and sweats continued for 2 hours. Intermittent syncope twice. |
| 1124707 | 3/22/2021 | UT | 71 | F | 3/12/2021 | 3/13/2021 | passed out, vomiting, diarrhea, high blood sugars, generalized weakness, rash at injection site, head ache....did not seek treatment. vomiting, diarrhea, fatigue continued for 2-3 days days. |
| 1124738 | 3/22/2021 | GA | 47 | M | 3/22/2021 | 3/22/2021 | PATIENT EXPERIENCED VASOVAGAL SYNCOPE, A FEW MINUTES AFTER RECEIVING THE VACCINE. PATIENT REGAINED CONSIOSNESS IN MATTER OF SECONDS. PATIENT SAT ON FLOOR AND THEN MOVED TO CHAIR. PATIENT REPORTS HE FELT BETTER SEVERAL MINUTES AFTER THE REACTION. PATIENT REMAINED WITHIN PHARMACY AREA FOR DURATION OF ~30 MINUTES. NO OTHER ADVERSE EVENTS OCCURRED . |
| 1124802 | 3/22/2021 | MN | 31 | M | 3/22/2021 | 3/22/2021 | Pt went to sit down to wait 15 minutes after his Pfizer/BioNTech COVID-19 shot at about 7 pm on March 22, 2021. Approximately five minutes later he mentioned to his female colleague who was with him that he felt feverish and sweaty and when he reached over to get a drink from his water bottle he fell over and passed out for a few seconds. By the time I ran out to check on him he was already getting up and I had him sit in the chair while my technician called 9-1-1. The paramedics soon came out (I think it was about 10 minutes) and checked him out. Both theirs and my IR thermometers showed a normal temperature. His BP was normal according to the paramedics. They asked some more questions and ultimately let him go home under his own power with his female cohort. |
| 1124842 | 3/22/2021 | LA | 42 | M | 3/19/2021 | 3/21/2021 | syncope |
| 1124851 | 3/22/2021 | NV | 45 | F | 1/17/2021 | 1/21/2021 | Severe syncope vertigo dizziness pressure headache in my head and in my neck . I need to go to the hospital twice tremors The symptoms have been debilitating I?m having tachycardia every time I stand up and I?m having to take Xanax because of my panic attacks. |

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| 1124860 | 3/22/2021 | WA | 32 | M | 3/22/2021 | 3/22/2021 | dizziness and fainted |
| 1125104 | 3/22/2021 | NY | 70 | F | 3/22/2021 | 3/22/2021 | Fainting/Loss of consciousness. Fall. |
| 1124046 | 3/22/2021 | RI | 65 | F | 3/22/2021 | 3/22/2021 | Called over to patient by observer. Patient c/o feeling near syncope. She was pale, diaphoretic, and bradycardic to 58. Patient reports history of previous near syncope/syncopal events with blood draw and immunizations. She reports no adverse reaction to the first dose. |
| 1123724 | 3/22/2021 | NY | 67 | F | 3/17/2021 | 3/19/2021 | I was walking out of my apartment building to my car inside the garage on Friday at 6:00 pm. As I was walking, my arms & legs began to feel heavy. By the time I reached the garage I was feeling extremely fatigued. I got inside of my car and thought to myself that I've never felt this tired in all of my life. I then felt very cold and decided it was best to go back upstairs. When I into my apartment unit - my cats greeted me as if I was gone for an extremely long time - and I noticed the sun coming in through my windows when the sun should have been on the other side of the building at 6:00 pm. Both the cats & the sunshine told me something was very wrong. I looked at the clock - it said 8:08. I put on the tv and discovered it was 8:08 A.M. on Saturday morning. I had fallen asleep (or passed out) in my car from 6pm Friday evening until 8am Saturday morning. I have no sleeping disorders & do not require naps during the day. Today I still feel fatigued, but only slightly. From the time I entered my car at 6pm Friday - until the time I exited my car at 8am Saturday - it felt as though only moments had passed. I had no idea I had fallen asleep or passed out. |

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| 1124513 | 3/22/2021 | PA | 44 | F | 3/17/2021 | 3/18/2021 | 3am- 15 hrs post injection: excruciating pain in joints to point of tears 6am- 18 hrs post injection: 10 min after waking sudden onset of extreme nausea and abdominal pain and urgency to vomit. I sat down on toilet and passed out, was unconscious and aware for approximately 2 minutes, falling off toilet onto floor. Woke hyperventilating and in dead sweat. Temp was 100.3. With help sat up and moved back to sitting on toilet for 10 min; then walked 10' to bed, blacking out again for about 15 seconds as i made it into bed. I rested in bed for approximately 4 hours prior to moving again. Moderate moments of lightheadedness and brief mild nausea continued through 24 hours but no further blacking out |
| 1123678 | 3/22/2021 | NY | 26 | M | 3/22/2021 | 3/22/2021 | Pt was 15 minutes after his first vaccine when he passed out in his chair and fell to the floor. |
| 1124206 | 3/22/2021 | CA | 30 | F | 3/22/2021 | 3/22/2021 | syncope |
| 1123767 | 3/22/2021 | WA | 91 | F | 3/11/2021 | 3/12/2021 | Morning after receiving vaccine patient experienced transient near syncope. Was non-responsive for up to a minute. Needed to be held up in her seat. Paramedics were called and found her BP and pulse normal and normal neurologic exam. Was transported to ED and had clinical evaluation and was released to home having fully recovered even prior to arrival in ED. |
| 1123821 | 3/22/2021 | | 24 | M | 3/19/2021 | 3/19/2021 | Reported by EMS on site. client had syncope following vaccine and was transported to a local hospital. no phone number given to this writer after the event. EMS called at 11 am and arrived at 11.01. blood pressure 101/68 pulse 71. second reading was 108/76 and pulse 69. |
| 1123894 | 3/22/2021 | MD | 33 | M | 3/22/2021 | 3/22/2021 | Had a syncope episode right after vaccine lasting a few seconds. |

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| 1123901 | 3/22/2021 | VA | 55 | F | 3/21/2021 | 3/21/2021 | On 3/21/21 - 30 minutes after the shot I developed a bad headache. Took Tylenol. 3/22/21 - At 1:30 AM body aches, legs and feet throbbing. Left-arm very painful. Intense headache. 4:00 AM chills and severe pain in my limbs. Limbs felt heavy. 12:00PM soaked feet in Epsom Salt for pain relief. 1:15 PM felt queasy then had diarrhea. Afterwards, nn my way upstairs legs felt heavy, flash of heat in my head and almost fainted. Been in bed and symptoms have not subsided. Still taking Tylenol. |
| 1123920 | 3/22/2021 | | 35 | M | 3/20/2021 | 3/20/2021 | following vaccine client complained of feeling dizzy and nervous. Per Dr he was experiencing a vasovagal event with no syncope. Blood pressure initially 83/43 then within 5 minutes 129/65. Pulse 54 then 79. O2 saturation 100%. juice given x 2 then released once symptoms resolved. EMS on site also. |
| 1123986 | 3/22/2021 | NJ | 23 | F | 3/9/2021 | 3/9/2021 | EUA Pfizer-BioNTech vaccine reaction Patient fainted after receiving vaccination. Medical alert team RRT called , patient escorted to ED for observation. She lost consciousness for a period of less than 1 minute. |
| 1124005 | 3/22/2021 | IN | 67 | M | 3/18/2021 | 3/18/2021 | Moderna COVID-19 Vaccine EUA That evening started with headache, muscle aches, nausea. About 4:30 am next morning I got up to use bathroom and passed out for unknown length of time. I tried to go back to bed and passed out two more times. The 3rd time my wife says my eyes rolled back in my head and she could not arouse me for 3 to 5 minutes. I went back to bed to sleep. Several hours later I was still to dizzy to stand and had a knot on the back of my head from the falls. We called 911 and I went to ER at Hospital for further evaluation. |
| 1124073 | 3/22/2021 | | 27 | M | 3/20/2021 | 3/20/2021 | Client complained of feeling dizzy and light headed after receiving the vaccine, He reports an allergy to Bananas which causes anaphylaxis. He does not carry an Epi Pen. Vasovagal event with no syncope. Blood pressure 87/41 pulse 78 with O2 saturation 96%. Se4cond set of vitals in 5 minutes was blood pressure 116/70 with pulse 75 and o2 saturation 98% . Released by Dr after second vitals by EMS on site. Advised to seek medical attention later if needed. Client stated understanding. |

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| 1124115 | 3/22/2021 | FL | 50 | F | 3/15/2021 | 3/16/2021 | Moderna COVID-19 Vaccine The morning post second dose of vaccine, I felt nausea like symptoms which followed by fainting spell. In the afternoon had similar nausea like symptoms but felt okay after few minutes without fainting. Next day, 2 days post second dose of vaccine, felt like little nausea like symptoms but resolved quickly. |
| 1124133 | 3/22/2021 | | 49 | M | 3/20/2021 | 3/20/2021 | Vasovagal event without syncope post vaccine. Clammy and nauseous with tingling to hands. EMS and Dr on site. Blood pressure 90/49 at 18.10. at 18.15 blood pressure was 114/81. Released home and advised to seek medical attention later if needed, client verbalized understanding. |
| 1124201 | 3/22/2021 | ND | 33 | F | 3/15/2021 | 3/17/2021 | Call received from patient who was advised to call to report a reaction to the COVID-19 vaccine. Patients history includes contracting COVID back in June of 2020 for which she spent 2 days in the hospital. In November of 2020, she reports she ended up in the hospital for another 2 days and was diagnosed with post-COVID POTS. She then went to medical facility and underwent 6 treatments of hyperbaric oxygen in February of 2021. Patient states that after these treatments, she felt great. She has reportedly been out of work since November, I believe, and was given the OK to return on 3/10/21. She was also advised by her neurologist that she should take the COVID vaccine which she did on 3/15/21. Two days later, on 3/17/21, she states that her POTS was "triggered" and she began to experience dizziness, fainting, fatigue, headaches, nausea and vomiting and various GI issues. Currently, she states these symptoms are getting worse, instead of better, and she has been unable to work, missing last Thursday and Friday, and will be going home early today. She asks if she should get her second COVID vaccine. I advised that is something she needs to discuss with her primary care provider. |

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| 1123967 | 3/22/2021 | FL | 30 | F | 3/20/2021 | 3/20/2021 | Fever, Chills, Body Aches, Tired 14 Hours Post vaccine: Woke up with Nauseous and stomach cramps. I fainted and hit my head twice landing. My husband heard and ran to the bathroom. He held me and I fainted again in his arms. He called 911, while the medics were on the way I threw up very dry and hard throw up. I started to feel a little better after that. Medics said everything looked ok and did not take me to the hospital. The following morning we went to the hospital, got a cat scan and everything luckily came up fine. Currently, I have a terrible ear ringing and muffledness from the concussion. |
| 1123656 | 3/22/2021 | OH | 33 | F | 3/22/2021 | 3/22/2021 | Patient reported feeling light-headed and dizzy immediately following vaccine, then fainted in a sitting position in chair. Pharmacist and customer assisted unconscious patient into lying down position on floor and patient promptly awoke. Patient remained lying down for 10 minutes while pharmacist directly observed with emergency kit nearby. Patient reported feeling better and then was able to sit upright. She was given a bottle of water and sat for observation for a remaining 20 minutes, then felt comfortable exiting the pharmacy. |

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| 1119802 | 3/21/2021 | ME | | F | 2/10/2021 | 2/10/2021 | Dizzy/dizziness; Nausea; Fatigue; first day after administration of the vaccination the patient fainted; Diastolic in the 40s; Heart squeezing; Unresponsive for 30 seconds; A spontaneous report was received from a consumer concerning a female patient who experienced unresponsiveness for 30 seconds/altered state of consciousness, dizzy/dizziness, diastolic in the 40s/blood pressure diastolic decreased, heart squeezing/palpitations, dizziness, fainting/syncope, nausea and fatigue. The patient's medical history was not provided. Concomitant product use was not provided by the reporter. On 10 Feb 2021, approximately 10 days prior to the onset of the symptoms, the patient received second of two planned doses of mRNA-1273 (Batch number not provided) for prophylaxis of COVID-19 infection. On 10 Feb 2021, the patient reports she received the second dose of the vaccine. On day one was unresponsive for 30 seconds and has been dizzy since. The next day she fainted after administration of the vaccine. The first 5 days after receiving the vaccination, patient felt like her heart was being squeezed. Diastolic dropped to 40s and heart rate has not been higher than 70. On following up, she reports having nausea and fatigue now along with dizzy feelings. Treatment information was not provided/unknown. The patient received both scheduled doses of mRNA-1273 prior to the events therefore, action taken with the drug in response to the events is not applicable. The outcome of the events, unresponsiveness for 30 seconds/altered state of consciousness, diastolic in the 40s/blood pressure diastolic decreased, heart squeezing/palpitations and fainting/syncope, were considered resolved. The outcome of the events, dizzy/dizziness, nausea and fatigue, were considered unknown. Follow-up received on 19 Feb 2021 included that the patient now has nausea, fatigue and dizziness.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |
| 1120626 | 3/21/2021 | CO | 45 | M | 3/21/2021 | 3/21/2021 | syncope after receiving vaccination |

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| 1120569 | 3/21/2021 | NY | 32 | M | 3/18/2021 | 3/18/2021 | Called over to see a patient with C/O of feeling lightheaded. He reports an episode of a vasovagal response > 10 yrs ago. After responding and while waiting for wheelchair transfer from the observation floor, the patient became diaphoretic and pale and soon experienced an episode of syncope. The patient regained consciousness after sternal rubs and after about 30 seconds started responding to verbal instructions and was able to self transfer to a wheelchair. Patient was placed in a supine position and vitals taken. Which was WNL.. BP 117/78 HR. 73 O2sat 97%. He was hydrated and later regained his baseline and was DC'd home with instructions to F/U as needed with PCP . |
| 1120526 | 3/21/2021 | PA | 35 | M | 3/21/2021 | 3/21/2021 | Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Exhaustion / Lethargy-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Nausea-Mild, Systemic: Seizure-Medium, Additional Details: Patient recieved first dose of Pfizer vaccine administered by Staff. Patient appeared confused and lethargic appearing to pass out. Staff administered epinephrine. Patient then started to seize ~2 mins. Patient was then reponsive. Emergency services came and took patient to hospital. |
| 1120466 | 3/21/2021 | NY | 21 | F | 3/20/2021 | 3/20/2021 | pt fainted and fell out of chair around 10 minutes after receiving Pfizer covid vaccine rx# 487548. rph on duty immediately went out and cradled pt's head as pt regained consciousness and talked to her until she was fully conscious and could sit up. pt asked for water, got for her and rph sat with pt talking to her until she felt well enough to leave on her own. She was asked several times if she wanted an ambulance and pt declined. pt waited around for another 10 minutes and left without incident. |
| 1120447 | 3/21/2021 | IN | 45 | F | 3/19/2021 | 3/19/2021 | 5 hours after receiving the shot I fainted |
| 1120290 | 3/21/2021 | IL | 19 | F | 3/17/2021 | 3/17/2021 | PATIENT FAINTED UPON STANDING IMMEDIATELY AFTER RECEIVING SHOT. REMAINED UNCONCIOUS FOR A FEW SECONDS. CONTACTED 911 SINCE PATIENT HIT HER HEAD WHEN SHE FELL. WAS ABLE TO WALK HERSELF OUT AFTERWARDS. |

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| 1120185 | 3/21/2021 | FL | 77 | F | 3/1/2021 | 3/14/2021 | 2-3 WEEKs after receiving vaccine...pain in right foot (rheumatoid arthritis) sore and weak all over, tired-lethargic on 3/19- woke up, sat at edge of bed to text daughter, got up walking to bathroom, got dizzy and collapsed = passed out. Got up and again collapsed passed out =don't remember it happening Went to ER for fall and analysis as to what , why, etc. I would be having this acute autoimmune reaction... blood work etc. you can contact the LWRM and Dr for details. |
| 1120152 | 3/21/2021 | MD | 45 | M | 3/21/2021 | 3/21/2021 | 45 yo M had syncopal episode after getting vaccine. Has hx of vasovagal syncope, usually with medical procedure or blood draws. Passed out for about 40 seconds, witnessed by son who was in the car. On my evaluation, symptoms had resolved,pt was asymptomatic, vitals unremarkable. Given juice, and observed in car. Subsequently discharged home. |
| 1120145 | 3/21/2021 | PA | 52 | F | 3/18/2021 | 3/19/2021 | The morning after receiving the shot I ran 104 fever all day 102 with Tylenol was very tired and slept through to Saturday Saturday was running between 102 and 100° temperature with Tylenol cannot take Advil. I was experiencing headaches all day. The following morning on Sunday I woke up and passed out, I guess my blood pressure dropped and I don?t know why and this is never happened. Had no appetite since Friday and maybe that?s why but my BP is 120/60 as of 10:08am AFTER I passed out at around 8:30am. I?m now feeling better all of a sudden, can drink coffee and hopefully I?ll get a shower..... oh and my joints are sore, I think whatever could go wrong , did! |

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| 1119976 | 3/21/2021 | FL | 80 | F | 1/7/2021 | | passed out; Did not get second Covid 19 vaccine when scheduled; 50 days since las shot; first Covid 19 vaccination lot number says RL3246; This is a spontaneous report from a contactable consumer, the patient via the Pfizer sponsored program. A 80-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), intramuscularly on 07Jan2021 at 12:00 (at the age of 80-years-old) as a single dose in the right arm for COVID-19 vaccination. Medical history included ovarian and endometrial cancer. Concomitant medications were not provided. The patient did not receive any other vaccinations within four weeks of immunization. On 07Jan2021, the patient received the first Pfizer shot. When she went for the second shot, she was waiting outside in the heat (she is a cancer victim) and she passed out so they wouldn't give her the second shot. She mentioned that, then, she couldn't go back because of cancer treatments she was being given and the facility was only open in that community for a certain amount of time. She finally went for a second shot at a different facility ("Institute") but she was told that she couldn't get the shot because "they didn't know if the first shot was real" as they had a different lot number than the Pfizer lot number that she had. She explained further that her first COVID 19 vaccination lot number is recorded on her vaccination card as "RL3246." Her husband's COVID 19 vaccination card says "EL3246" for lot number and they received injections on the same day. The caller believes her lot number should also say "EL3246" - she thinks it's a small written 'e.' The patient added that, as of the reporting date, "It is 50 days since I had the last shot." She also asked if she has to retake the vaccines or if she can just take the second dose. The clinical outcomes of the event "passed out" was not provided. |
| 1119390 | 3/21/2021 | NJ | 60 | M | 3/20/2021 | 3/20/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Small laceration on right ear from falling into shelving area. Cleaned and applied pressure by who was first on scene. |

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| 1121047 | 3/21/2021 | GA | 30 | M | 3/21/2021 | 3/21/2021 | PATIENT PASSED OUT OF CHAIR ABOUT 12 MINUTES AFTER RECEIVING VACCINATION. SLOWLY FELL TO GROUND. DID NOT HURT HIS HEAD OR ANY OTHER BODY PART. IMMEDIATELY REGAINED CONSCIOUSNESS. KNEW WHO HE WAS AND WHERE HE WAS. REQUESTED WATER WHICH WAS GIVEN TO HIM. WAS VERY WARM TO TOUCH AND LIGHTLY SWEATING AROUND THE FOREHEAD. 911 WAS CALLED. EMTS CHECKED VITAL SIGNS AND COGNITIVE FUNCTIONS. PT COULD STAND UP AND WALK ON HIS OWN BUT WAS ESCORTED OUT OF STORE ON STRETCHER FOR SAFETY. |
| 1120628 | 3/21/2021 | FL | 62 | F | 3/13/2021 | 3/15/2021 | No symptoms after the vaccination on the day of or the day after getting the vaccine. Two days after the vaccine, while at orthopedist (for a Rotator Cuff Surgery), I began to feel dizzy. I sat down for a few minutes, drank some water, and then resumed my therapy. After the first set of my 4th exercises I began to get dizzy, I sat down on the PT table, then laid down and fainted for about 1-2 seconds. My blood pressure plummeted to 60/?. EMT's and an ambulance were called. I was given an IV and taken to hospital. In the ER, my blood pressure elevated to 205/121. (I think that was it.) I was given a cat scan, ekg, chest X-ray, blood tests, etc. All tests were normal except a very slight (by one number) magnesium level. I was admitted for observation and more tests were performed. My blood pressure remained high, but I had no more dizziness or syncope. I was given many more blood tests, imagining, ultrasound of heart, ultrasound of carotid arteries, ultrasound ?bubble test,? nuclear heart treadmill stress test. All tests were normal. The only change in my health that can be attributed to this episode is the Covid vaccine. |

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| 1120131 | 3/21/2021 | FL | 55 | F | 3/17/2021 | 3/17/2021 | I had awful nausea, loud ringing in the ears, I fainted. The medics provided help, gave me oxygen. I started having convulsions. After some time I felt like the lower part of my face went numb and it took tremendous effort to move my lips to talk. At that point, the medical called the ambulance and sent me to ER, where I was under supervision for some time. I was very weak and nauseated. After I was released, I was very weak could not keep the vertical position. The next day I was very nauseated, with awful tinnitus, lightheadedness, and weakness. Staying vertical for more than 15 minutes brought fainting symptoms. I was not able to get out of the house to work. The next day the fainting symptoms disappeared, everything else continued. Too weak to go to work. I started moving about only on the 4th day after the shot. During this event, I did not have any fever or muscle ache, no virus0tyle symptoms. |
| 1121125 | 3/21/2021 | MD | 74 | F | 3/11/2021 | 3/12/2021 | Woke Friday am with no control over my bladder and violent shaking of my legs with pain radiating from my hips. Fever of 100.9. Couldn't move my legs or sit up and eventually fell to the floor on my back. Spent over an hour using my elbows to scoot across floor. Hit head 3 times and passed out for awhile. Got help and went to the ER. CT showed no concussion. Pain reliever helped and after several hours was discharged with instructions to use a walker. Used walker for 2 days and then cane. Still have leg pain on occasion and now the Vertigo is worse. Also had reaction to first vaccine but just high fever, 101.4 and aches. |
| 1120638 | 3/21/2021 | TN | 48 | F | 3/20/2021 | 3/21/2021 | I went to bed with a stomach ache around 10:00pm. At 3:00am I was awoken by severe abdominal pains/cramps and in a cold sweat. When I got out of bed I was lightheaded and passed out in the bathroom as I was getting Tylenol. I took 2 Tylenol and had diarrhea about 10 mins later. I went to get some gatorade and passed out again in the hallway on the way to the kitchen. About an hour after taking Tylenol symptoms began to improve but became nauseous and couldn't get back to sleep. As of 2pm Sunday current symptoms are extreme nausea and extreme exhaustion. |

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| 1121002 | 3/21/2021 | VA | 21 | F | 3/21/2021 | 3/21/2021 | Patient experienced syncope after administration of her first COVID vaccine. Her mother is a physician and was present, providing care for her by fanning, comforting and helping her to lie down on the floor next to the waiting chairs. The patient did not faint. She did experience what appeared to be heavy breathing and light-headedness. We provided an ice pack from the immunization cart. The mother stated that the patient experiences this reaction every time she receives a vaccine due to her fear of needles. After about 30 minutes the patient was up and smiling. The family was thankful for our concern and help. |
| 1121275 | 3/21/2021 | NY | 31 | F | 3/18/2021 | 3/19/2021 | Patient got up middle of the night to use the restroom feeling extreme dizziness. Patient fainted while seated on the toilet, did not suffer any known injuries. Regained consciousness and was still very dizzy. Went back to sleep and woke up without dizziness. Fatigue and weakness for the next day. Patient feeling back to normal minus the rash on injection site and slightly worried about dizziness at the second shot scheduled for April 15th. |
| 1121014 | 3/21/2021 | IN | 28 | F | 3/21/2021 | 3/21/2021 | Syncope, tachycardia, shortness of breath, chest pain/tightness, throat tightness. Resolved in 10 minutes. No treatment needed. |
| 1121335 | 3/21/2021 | NJ | 47 | F | 3/20/2021 | 3/21/2021 | Headache, dizziness followed by blackout/fainting resulting in head bruise and swelling. Rest at home, cold compress for swelling, Tylenol. |
| 1120987 | 3/21/2021 | FL | 19 | F | 3/21/2021 | 3/21/2021 | Pt had a fainting spell. At first it appeared as if she was potentially having a seizure. After about 3 minutes she came to and was fine. She was examined by EMS and was released to going home own her own with her friends. |

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| 1120981 | 3/21/2021 | OK | 16 | M | 3/21/2021 | 3/21/2021 | Patient received vaccine and went to sit down in front of pharmacy. He then immediately started feeling lightheaded, his eyes rolled into the back of his head and he had a couple of convulsion. He did not lose consciousness and was immediately aware. He was pale, lips were blue tinged, pulse was 60, sweating and blood pressure was 98/50. Paramedics were called but he had recovered by the time they got there. They said he had a fainting episode due to the vaccination and did not have a seizure. The patient had not eaten anything the whole day and he felt that contributed. Followed up with patient's parent and he is feeling just fine now. |
| 1120881 | 3/21/2021 | CA | 68 | F | 3/13/2021 | 3/14/2021 | 3/14, 1 AM--awoke with fever, could not sleep for more than an hour or more at a time. Got up at 7 AM and took a Tylenol and drank water. Extreme weakness for the rest of the day with chills, some body aches, a little nausea. 3/15, 7 AM--woke up after 9+ hours of sleep and felt great. Drank water, took the dog for a walk (about an hour). Returned to my house and was talking to a neighbor when I was overwhelmed with lightheadedness and nausea, told her I needed to sit down and suddenly passed out. Came to in about a minute, had a cut in my head from hitting the concrete and could not stand without feeling dizzy. An ambulance was called and I was transported to the local hospital. Was given fluids and anti-nausea medication in the ambulance. |
| 1120810 | 3/21/2021 | TX | 19 | F | 3/21/2021 | 3/21/2021 | Patient passed out shortly after receiving first dose of pfizer covid 19 vaccine. Pt stated that she has fainted before after receiving IM injection, but failed to mention on consent form |
| 1120804 | 3/21/2021 | IL | 22 | M | 3/21/2021 | 3/21/2021 | Upon administration patient passed out in chair within minutes. Patient became very limp and jerky. Within minutes patient came to and was able to respond to questions |
| 1120721 | 3/21/2021 | NC | 77 | F | 1/15/2021 | 2/4/2021 | 19 days after the first shot I fainted and injured left ankle and bump on left forehead, 13 days after the second shot I fainted and injured my left ribs and bump on right forehead . I have not fainted before in 77 years. |

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| 1120639 | 3/21/2021 | PA | 28 | M | 3/16/2021 | 3/17/2021 | I started to get uncontrollable shakes the night of my vaccine for 10-15 minutes. I had chills for about an hour afterwards and a sleepless night. The next morning I woke up with a headache and was achy/sore throughout my body. While I was eating I passed out without any signs. I was unconscious and do not remember the episode. Once I was alert, I felt nauseas and was heading to the restroom when I passed out again and was unconscious. I do not remember the episodes. There were no signs of passing out before I did either time. |
| 1120935 | 3/21/2021 | OH | 51 | M | 3/1/2021 | 3/1/2021 | About 10 minutes after the shot I started feeling hot, started sweating, clammy hands, dizzy and then I passed out walking to get help. I hit my head on a chair when I was falling and cut my head. I stayed laying down because I was still dizzy and hot. They called the squad and did vitals and I was fine. I sat there for about another half an hour and I went home. I have felt fine ever since. Only thing that hurt was my head from the fall. |
| 1120696 | 3/21/2021 | ME | 21 | F | 3/21/2021 | 3/21/2021 | after receiving immunization patient felt hot and dizzy. She then fainted and lost consciousness for about 10 seconds. |
| 1118671 | 3/20/2021 | CA | 38 | M | 3/20/2021 | 3/20/2021 | Pt. was screened twice about allergic reactions any medical conditions/immunocompromised etc. Pt. responded no to all of the above questions. He was vaccinated IM on left arm. Pt. was educated about post care. Pt. was alert. I moved on to the next two cars and on the third car and about three minutes after his female partner called out for help and said that the Pt. passed out. That's when the other nurse ran to the car to check on him and told me he was having a seizure. I ran to the lead to explain what happened and to call the medical team right away. The other nurse was stabilizing the patient. The patient was going in and out of consciousness for about ten seconds. The medical team arrived and took vitals. |

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| 1118510 | 3/20/2021 | | 29 | M | 3/20/2021 | 3/20/2021 | Patient reported fast heartbeat, sweating. Patient was pale, HR 112, O2Sat 96%, BP 108/60, reported feeling dizzy, vision changes, had brief moment of syncope, then aroused, Oxygen applied at 2l via NC, patient continued with sweating, HR now 78, EMS called, patient continued with sweating and feeling weak gradual improvement, EMS arrived, patient evaluated and did not want to go to ER for eval. Vitals rechecked and patient ambulated to private vehicle with no further difficulty. |
| 1118540 | 3/20/2021 | CA | 18 | M | 3/20/2021 | 3/20/2021 | Syncope after vaccine rest and vitals |
| 1118555 | 3/20/2021 | MA | 50 | M | 3/20/2021 | 3/20/2021 | 50 year old male patient with a history of well controlled T2DM and HLD who presents to the Emergency Department with chief complaint of syncope after 1st dose of Pfizer COVID-19 vaccine 30 minutes prior to arrival. Patient reports that while he was waiting after receiving his first dose of the COVID-19 vaccine, he developed a feeling of dizziness and reports that "things were going black slowly". He called for help. Per triage note, he was observed by the staff passing out. He did not fall/there was no head strike. He was found to be hypotensive with SBP of 69, followed by an SBP of 100 after sitting up, then again to the 60s. He received 250cc bolus fluid en route. Patient remembers feeling better after sitting up and now reports that he is at his baseline mental status and feels "completely normal". Patient received 1L normal saline in the ED. |
| 1118575 | 3/20/2021 | OH | 23 | F | 3/20/2021 | 3/20/2021 | Syncope after receiving vaccine |
| 1118708 | 3/20/2021 | NY | 28 | F | 3/20/2021 | 3/20/2021 | Patient seemed to have fainted 1 minute after vaccination, then had a seizure, and then had an episode of syncope following the seizure. |
| 1118632 | 3/20/2021 | IL | 22 | F | 3/20/2021 | 3/20/2021 | patient passed out about 10 minutes after receiving vaccine. She started to feel faint and then passed out completely. Was out for about a minute. |
| 1118697 | 3/20/2021 | MA | 69 | F | 3/18/2021 | 3/19/2021 | Extreme chills fever101.2 Fainted |
| 1118467 | 3/20/2021 | | 63 | F | 3/19/2021 | 3/20/2021 | syncope |

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| 1117993 | 3/20/2021 | FL | 39 | M | 3/15/2021 | 3/17/2021 | Feeling of manic depressive event. First a euphoric high day after dose. Then depressive feeling on second evening. Then near-syncope on day 3 post vaccine. Patient felt a sense of impending dread while lying down and receiving physical therapy on TENS unit with heat. Then, a heat throughout the body, followed by sweating. Lastly, a near loss of consciousness. Patient was inverted with legs up. Patient requested an ambulance. Airway was clear. The incident occurred again 2 hours later with same presentation. Patient went to ED and received IV and vertigo medication. No episodes after. |
| 1118583 | 3/20/2021 | CO | 62 | M | 3/13/2021 | 3/14/2021 | Janssen COVID-19 Vaccine EUA 2 1/2 days of severe flu symptoms. Nausea, Fever, Chills, weakness, no sleep. The next days nausea and light headedness Day 7 (today 3/20/2021) nausea, weakness, and fainting spells. Fainting spells include vision impairment (everything looks fuzzy like a bad tv reception). |
| 1118317 | 3/20/2021 | PA | 31 | M | 3/20/2021 | 3/20/2021 | Patient received vaccine and was fine until after a few minutes. He started to say he felt lightheaded. He placed his head between his knees, he started to sweat and I gave him some water at his request. He sat back and started to get pale and more sweaty, he complained about pain in his arm and neck. He then began to slightly shake and passed out. He was awoken very quickly by his wife who was standing in front of him. We kept talking to him and I checked his pulse and called 911. After about 30 minutes he was feeling much better and did not need to go to the hospital. His vitals were strong and he walked out on his own. I contacted him 3 hours later and he was resting but feeling fine. |

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| 1118256 | 3/20/2021 | MN | 28 | F | 3/20/2021 | 3/20/2021 | Patient had appointment at 9:20 am. She was fine during the check in process, while receiving the imz and the 15 mins post vaccination wait time. Approx 10 am she left the IMZ room and about halfway through the store, she fainted. CSM said she fell outside of patient's room and did not seem to hit her head or neck. 911 wasn't called because she came to right away. They got her water and a chair. I was brought over approx 10:10 am. I talked with her and she seemed cognitive, lucid and understands who she is, where she is and what happened. She said she waited the 15 min and felt totally fine but then she got up and fell about halfway through store. Approx 10:20 am we brought her over to pharmacy area for more privacy and RPH checked her BP. reported 130/90. I asked patient if she wanted the paramedics called just in case of a head injury. I asked her before palpating her head and neck. She said she felt no pain, no visible bleeding or lacerations, no inflammation or redness and she has full mobility in her neck with no pain. Patient said she did not want paramedics called and instead called her mother in law who lives nearby to see if they can come get her. She is worried about 40 min drive home. Pt overall physically seemed fine. She was just shaken, nervous and embarrassed as she's never had something like this happen before. She waited for about 20 mins until her father in law came and picked her up. I updated him of the situation and they left together. |
| 1118194 | 3/20/2021 | NJ | 51 | F | 3/11/2021 | 3/12/2021 | I had stomach pain about 2 hours after the injection. I went to sleep at 10 pm and woke up at 2 am to go to the bathroom. My legs felt like I could barely move them but I was able to go the bathroom. Once I got up and walked toward the bathroom door I hit my head into the door. I ended up on the floor. I sat up and my husband came in. He said I was mumbling incoherently and then passed out for about 28 seconds. He said my arms were moving up and down while passed out. I woke up covered in sweat and he put me in bed. I slept until 8 am and then woke up with a headache, nausea, body aches and dizziness. The headache and dizziness lasted until 3/18/21. |

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| 1118136 | 3/20/2021 | NY | 67 | F | 3/20/2021 | 3/20/2021 | Patient became diaphoretic and cold 10 minutes after vaccination. Vital signs: BP 170/90 , Repeat after 15 mins 165/90 HR 74, SPO2 100% RR 28 She denied chest pain, syncope, difficulty breathing, itching. Preferred to go home, refused offer to be transported to Emergency room. |
| 1118752 | 3/20/2021 | AZ | 67 | F | 3/18/2021 | 3/19/2021 | Vomiting (many times..couldnt even keep a sip of water down), extreme sweating, fainting (twice), severe diarrhea (several times), dizziness, chills, even with 3 long sleeve shirts, t-shirt, bra, winter coat, 3 blankets, pants socks, etc. headache, fever, heart racing a little, couldn't stand up (husband had to help me)....12 hours. |
| 1118006 | 3/20/2021 | TX | 39 | M | 3/19/2021 | 3/19/2021 | Patient was dizzy and then passed out. It was two minutes after vaccination that patient passed out. Patient was pale and clammy. |
| 1118182 | 3/20/2021 | IA | 58 | F | 3/19/2021 | 3/19/2021 | She had received her first Covid vaccination this afternoon and following that she became dizzy and had a syncope spell. She tells me that with previous vaccinations this has routinely happened and so it is not different. She was not aware of her surroundings for about 2 minutes after this happened although there was no witnessed jerking or seizure movement. At this point she feels about 90 to 95% back to normal and denies any pain anywhere including in her chest. Initially she had some tingling in her arms although that has resolved. |
| 1117847 | 3/20/2021 | MI | | U | | | Friday evening arm & neck pain. Saturday arm and neck pain, got hot went turn heat down and fainted landed on tail bone. . Felt nauseated, flush and sweaty. Sunday to current neck pain and very foggy in the head, lightheadedness. |
| 1117756 | 3/20/2021 | NJ | 22 | M | 3/19/2021 | 3/19/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient indicated to having had previous fainting episodes. Had a bruise around the right eye after fainting. |

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| 1117748 | 3/20/2021 | CA | 57 | M | 3/17/2021 | 3/17/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Seizure-Mild, Systemic: Vomiting-Severe, Additional Details: After couple minutes receiving second dose of covid vaccine, patient passed out and lost consciousness for less than a minute. Patient woke up with brief seizure(jerky movement) and vomited couple times. Patient complained about dizziness. Patient was taken to the emergency room. |
| 1118018 | 3/20/2021 | MA | 67 | F | 3/18/2021 | 3/19/2021 | I got up around 8:30 , went to the toilet, and as I was washing my hands, I blacked out. I slipped to the floor and then vomited several times. Fortunately, I had not eaten since about 7 pm the night before, but I still expelled material. Stayed in bed all day. Drank lots of water and slept. FEEL MUCH BETTER today....eating and vertical. PS After the first shot, I slept most of the next day, felt very achy, sweated, and had a headache. Those symptoms disappeared after about 24 hrs. BUT about a week after the first shot, I developed a large rash not on, but rather near the injection site. It was itchy for a day or two, as well. As I said, I feel much better today, but just thought you should know, especially because the fainting and vomiting are not listed as common reactions. THANKS |
| 1118982 | 3/20/2021 | CA | 27 | F | 3/20/2021 | 3/20/2021 | Lightheadedness, sweating, syncope |
| 1118054 | 3/20/2021 | CA | 50 | M | 3/1/2021 | 3/19/2021 | Light headed Stomach upset Headache Passed out and shook on the ground Called paramedics |

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| 1119162 | 3/20/2021 | CA | 27 | F | 3/20/2021 | 3/20/2021 | Patient stated that she was fainted from last year travel vaccine. Immunizer and patient both aware it might happen. immunizer told patient will monitor closely then gave the shot. Right after shot, patient stated that she is feeling dizzy and is going to faint. she fainted. gained conscious right after (about 2- 5 seconds) and offered to call 911 and she said it is ok. She was sitting that same chair for 10 minutes, then she wanted to sit on the ground (not lying down) . after she was sitting on the ground, she felt better, so we moved to outside of immunization area chair for monitor. She felt fainting is coming again so she sit on the ground. but she did not faint again. She wanted to lying down. she lied on the ground for about 20 minutes , then sit up for another 15 minutes. she felt find and went home . checked back 3:30 pm on same day, she was ok . |
| 1119123 | 3/20/2021 | AK | 24 | F | 3/17/2021 | 3/18/2021 | Sudden nausea and vomiting the morning after vaccine (8:30am; got vaccine at 6:10 the night prior). After getting sick, suddenly got very lightheaded and dizzy and fainted in shower. Awoke and had severe fever and headache the rest of the day after vaccine (102°F fever). |
| 1119113 | 3/20/2021 | CA | 24 | M | 3/12/2021 | 3/12/2021 | Patient fainted after vaccination, while waiting in the seating area during the 15 min observation period |
| 1118763 | 3/20/2021 | NY | 23 | M | 3/13/2021 | 3/13/2021 | Shortly afte receiving the vaccine, the patient fainted. The paramedics were called and the patient attributed this to his underlying anxiety; he also stated he was anxious about getting the vaccine. |
| 1119057 | 3/20/2021 | MO | 18 | F | 3/20/2021 | 3/20/2021 | Patient had a vasovagal syncope response tonight (3/20/2021) after receiving her first dose of the Moderna Covid-19 shot. Patient did not make contact with the ground. A friend was present who caught her and made sure that she wasn't injured. Patient was monitored for 1/2 hour after vaccination and left under her own power after that time. Patient was asked if they wanted to make a report and they declined. |

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| 1119226 | 3/20/2021 | CA | 76 | F | 3/10/2021 | 3/11/2021 | Extreme fatigue from 3/11/21 to 3/19/21; Severe headache from 3/12/21 to 3/18/21; light-headed sensation 3/12/21 to 3/20/21; fainted 3/17/21; gastrointestinal issues and severe cramping the evening of 3/15/21 to 3/17/21; gastrointestinal issues (constipation followed with diarrhea without cramping).Colo |
| 1118979 | 3/20/2021 | CA | 55 | F | 3/17/2021 | 3/20/2021 | Severe vertigo and syncope upon awakening. Vertigo persists. |
| 1118927 | 3/20/2021 | MN | 23 | F | 3/20/2021 | 3/20/2021 | Fainting |
| 1118919 | 3/20/2021 | NE | 26 | M | 3/9/2021 | 3/9/2021 | Syncope: laid pt down, elevated feet, cold pack, water. Approx 45 min later patient left pharmacy refusing any more care. |
| 1118910 | 3/20/2021 | NE | 47 | M | 3/16/2021 | 3/16/2021 | fainted followed by fatigue and continued dizziness |
| 1118829 | 3/20/2021 | TX | 50 | F | 3/19/2021 | 3/19/2021 | Doctor and EMT on site and provided care. Vasovagal syncope. Symptoms presented within 5 minutes of vaccine given. Tingling started in Left arm tingling own to fingers and traveled to right arm and down through both legs. Rapid heart rate and disorientation prior to fainting. Sternum rub given to revive. Patient vomited. Able to drive home after 30-45 minutes. Continues to feel weak and dizzy. Currently 24 hours after incident. Pain in arm preventing me from normal daily activities. |
| 1118773 | 3/20/2021 | NV | 21 | M | 3/19/2021 | 3/19/2021 | Patient was nervous and afraid of needles during the vaccine process. Patient was asked to sit and wait 15 minutes after vaccine administration but he apparently went to get a soda and fainted at the self-check out stand 1 minute after getting the vaccine. Patient returned to his seat and was okay afterwards. Patient's father was also present during the whole process as he got the vaccine at the same time also. |

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| 1119080 | 3/20/2021 | WA | 27 | M | 3/20/2021 | 3/20/2021 | Patient became pale and then experienced syncope. Friend caught him as he fell. Did not hit his head. Patient was placed on the ground in Trendleberg. Due to him not having eaten in the previous several hours, he was provided with orange juice after approximately 10 minutes. Colour soon returned to his face. He was placed upright and asked to wait for an additional 30 minutes. |
| 1118902 | 3/20/2021 | | 61 | M | 3/20/2021 | 3/20/2021 | After receiving vaccination, patient proceeded to observation area. He passed out briefly, then regained consciousness, but was sweaty, disoriented, dizzy and drowsy. EMS was called, he asked to lie down and was helped to ground into a recovery position. EMS arrived and took him for further evaluation. |
| 1118789 | 3/20/2021 | CA | 32 | F | 3/11/2021 | 3/11/2021 | On Thursday March 11, 2021 I received my first dose of Pfizer COVID vaccine. Within about 5 second after administration I began to feel severe arm pain spreading from the injection site down to my fingers that were tingling and numb. Then within about 20 seconds of the vaccine I fainted. The fainting spell was brief, a few seconds, but the symptoms that continued after were long lasting. My blood pressure after was about 80/50, I was diaphoretic, pale, had moderate arm pain (tingling, numb, painful to move) and severe nausea. I was also light headed. These symptoms lasted through the night but I felt overall improved the next day other than fatigue and lingering arm pain. Then on March 16, 2021, 5 days later, I woke up with extreme fatigue. Over the course of the day I then began to get a headache. I got back in bed and then in the afternoon started to feel moderate arm pain again at the injection site and down the entire arm. Then severe nausea set in again along with more diaphoresis, chills and light headedness. The symptoms this time again lasted through the night and I felt better again the next morning. |
| 1118832 | 3/20/2021 | NC | 21 | M | 3/20/2021 | 3/20/2021 | Patient fainted approximately 2 minutes after the vaccine was administered |

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| 1118838 | 3/20/2021 | OH | 34 | F | 3/18/2021 | 3/20/2021 | Of course I had side effects like aches, bone pain (mainly spine and sternum), kidney pain, abdominal pain, sweating with no fever, etc. But none of that is an adverse effect. The adverse effect happened when I was taking a shower 45 hours after my second vaccine. I was starting to feel better at this point. I started to feel like I was going to pass out. I quickly turned off my shower and sat down. I would have passed out had I not focused to not. I felt nauseous, lost my hearing and started to lose my sight. After I was ok, my lips were blue/Gray. I don't pass out. I've passed out twice in my life when I was much younger. That's how I knew what was happening. I'm scared this will happen again and I don't know what this means. |
| 1118853 | 3/20/2021 | WI | 17 | F | 3/20/2021 | 3/20/2021 | Patient fainted roughly 5 minutes after receiving the vaccine. She was sitting down on a chair resting her head on a table in the waiting room. She felt lightheaded and then fell down to the ground. Her mom was with her at the time. We made sure she was not having an allergic reaction. Patient responded seconds after she was on the floor but was not coherent. EMS was called and arrived within minutes. Patient was accessed and transported to the hospital. |
| 1118861 | 3/20/2021 | OH | 37 | M | 3/19/2021 | 3/19/2021 | Joint and muscle pain, Low heart rate, low blood pressure, syncope |
| 1118884 | 3/20/2021 | NC | 35 | F | 3/15/2021 | 3/15/2021 | At an offsite J&J clinic. She has a history of fainting from needles. About 10-15 minutes after her vaccine, she passed out in her chair losing consciousness. We called 911, moved her to the floor, elevated her feet, and monitored her breathing. She was out for about 1 minute. EMS arrived and evaluated her for about 1h before she walked out on her own. |

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| 1118894 | 3/20/2021 | CA | 40 | F | 3/20/2021 | 3/20/2021 | <p>PI: The pt is a 40 year old female who presents with syncope 20 minutes post Moderna dose #1 vaccination to the left deltoid. Pt syncopized from a seated position, falling forward and catching herself with her arms outstretched. +LOC before immediately regaining consciousness. No head or neck injury, +abrasion to the left elbow. Pt notes similar episode following an influenza vaccine 15 years ago. Pt denies any medical Hx, daily medications, or Hx of anaphylaxis. Pt denies swelling or itching of the lips, eyes, or face. She also denies any swelling of throat, difficulty breathing, or SOB. Exam (update as needed): GEN: Alert and oriented x 3 upon immediate evaluation, HEAD: NCAT EYES: PERRL, EOMI ENT: Ears normal, Nose normal, OP normal, no evidence of angioedema NECK: Supple, without LAD. CV: RRR,+Bradycardic, +hypotensive, no m/r/g PULM: Clear to auscultation bilaterally, no accessory muscle use ABD: Soft, no tenderness. SKIN: +pale, +diaphoretic, +1cm circular abrasion to left elbow, No rashea MSK: FROM, MS 5/5 NEURO: Alert and oriented x 4, CN 2-12 grossly intact, no ataxia Clinical Impression/Field Tx: Syncope post moderna does #1 vaccination. Impression supported by clinical scenario, vital signs, and Pt?s endorsement of similar incident in the past, Suspicion for anaphylaxis low due to no signs of angioedema, no SOB, and no complaints of itching. Pt also denied any Hx of anaphylaxis or allergic reaction. Vital signs stabilized in the field and pt reported improvement following 30 minutes of repositioning and observation. Because of limited resources on site, the Pt was evaluated by EMS where repeat vital signs, blood glucose, and EKG were obtained. Medications administered: None Disposition: Pt was evaluated by EMS and transported to the Hospital.</p> |

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| 1118774 | 3/20/2021 | OK | 23 | M | 3/20/2021 | 3/20/2021 | After giving the patient his Covid Vaccine, he tensed up and said he was feeling like he may vomit. He then became very pale and fainted while in the vaccination chair. After a few seconds he regained consciousness. We then helped him to the floor and elevated his legs and placed a cold pack on his neck. He started feeling better instantly but we kept him there for about 5 minutes. We then had him move to a chair and the technician sat with him for an additional 40 minutes. He then said he was fine and that he has fainted before (which was not disclosed) and left. |
| 1115214 | 3/19/2021 | IN | 22 | M | 3/17/2021 | 3/18/2021 | Felt weak, dizzy and passed out about 3 hours after receiving vaccine |
| 1115660 | 3/19/2021 | UT | 57 | F | 3/18/2021 | 3/18/2021 | DURING THE 15 MINUTE OBSERVATION PERIOD, ABOUT 5 TO 10 MINUTES POST VACCINE THE PT FAINTED WHILE SITTING IN HER CHAIR AND FELL OUT OF THE CHAIR. I INSTRUCTED A TECH TO 911 WHILE RAN TO THE PT. AS I TOUCHED HER TO FEEL FOR A PULSE SHE REGAINED CONSCIOUSNESS. I EXPLAINED WHAT HAPPENED AND ASKED HER TO STAY WHERE SHE WAS AT UNTIL PARAMEDICS CAME. SHE WAS ALERT AND ABLE TO ANSWER QUESTIONS. THE PARAMEDICS ARRIVED ABOUT 5 MINUTES LATER. THEY GOT HER UP AND SHE HAD A SEIZURE. THE TOOK HER TO AND UNKNOW HOSPITAL |
| 1115841 | 3/19/2021 | OH | 44 | M | 3/19/2021 | 3/19/2021 | Five minutes after receiving the vaccination on her left arm, she developed nausea and lightheadedness and weakness. No vomiting or syncope. She was escorted to a private session of the arena and monitored. Her initial blood pressure was 140/80. She was given water to drink and ate an apple. |
| 1115789 | 3/19/2021 | CA | 30 | F | 3/18/2021 | 3/18/2021 | First Moderna Covid Vaccine administered in the right deltoid. Patient felt fine, and ambulated to the observation area. She took a seat, and then shortly thereafter passed out in her chair. Nursing responded; vitals were taken, and recorded in her chart. Patient was transported via wheelchair to the Urgent Care within the facility. Patient was observed, assessed by a Physician's Assistant and released home without further incident. No medications or diagnostic tests were ordered at the time. |

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| 1115649 | 3/19/2021 | NY | 65 | F | 3/17/2021 | 3/18/2021 | Patient reports receiving the second dose of the vaccine on 3/17, feeling weak that night. on 3/18 she passed out x2 for several seconds each time. No postictal response. Patient was brought to the ER, diagnosed with vasovagal response Chest xray, EKG, labs normal |
| 1115599 | 3/19/2021 | | 42 | F | 1/19/2021 | 1/20/2021 | Passed Out; Possible Seizure; Swollen Tongue; itches; Headache; shivering; shaking really bad; A spontaneous report was received from a nurse who was a 42- year-old, female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and who experienced shivering, shaking really bad, had a headache day afterwards, tongue was swollen, passed out and doesn't know if she had a seizure and itchiness. The patient's medical history was not reported by the reporter. Concomitant medications were not provided. On 19-Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: 039K20A) intramuscularly for prophylaxis of COVID-19 infection. On 20-Jan-2021, 24 hours after vaccine administration, the patient reported that she was shivering and shaking really bad and had a headache day afterwards. On an unknown date, she reported that her tongue was swollen. She also reported that the she passed out and doesn't know if she had a seizure (date unknown). The patient reported that she took ibuprophen for her headache and diphenhydramine for itchiness. On 28-Jan-2021, she reported that she felt fine. Treatment for events included ibuprophen and diphenhydramine. Action taken with mRNA-1273 in response to the events was unknown. The outcomes of events, experienced some side effects was unknown, shivering, shaking really bad, had a headache day afterwards, tongue was swollen, passed out and doesn't know if she had a seizure and itchiness, were considered recovered/resolved on an unknown date.; Reporter's Comments: Based on the information provided and a strong temporal association between the reported events and administration of mRNA-1273 vaccine, a causal association between the reported events and the product use cannot be excluded. Headache and chills are consistent with the known safety profile of the vaccine |

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| 1115578 | 3/19/2021 | MN | 25 | M | 3/18/2021 | 3/18/2021 | Within 2 minutes following injection, grew pale, clammy, dizzy, and also had tonic contraction (fanning) of fingers. Client hyperventilating- was helped to a cot, elevated legs. Mask removed for ease of breathing. Was offered food and water, which he took- hands softened within 7-8" and color returned to face and arms within approximately 12 minutes. Had some food and water, which he stated helped. He felt he was dehydrated, hungry, and fearful. Never had episode of fainting or dizziness in the past. |
| 1115507 | 3/19/2021 | FL | 66 | F | 2/16/2021 | 3/17/2021 | 30 days after my second shot. I am experiencing chills, fever, headaches, joint pain, sweating, a week of fatigue, dizziness and fainting. 48 hours of chill fever headaches joint pain. 24 hours of dizziness and fainting. |
| 1115241 | 3/19/2021 | MA | 75 | F | 2/10/2021 | 2/11/2021 | severe headache; complete loss of taste and smell; complete loss of taste and smell; This is a spontaneous report from a contactable consumer (the patient). A non-pregnant 75-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot number: EN9581), via an unspecified route of administration, in the left arm on 10Feb2021 at 4:15 PM (at the age of 75-years) as a single dose for COVID-19 immunization. Medical history included asthma, mite allergy, allergy to animal (cats, guinea pigs), Vasovagal Syncope. The patient had known allergies to sulfa and Iodopropynyl Butylcarbamate. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications taken within two weeks of vaccination included pravastatin, ciclosporin (RESTASIS), calcium, and senior multivitamin. On 11Feb2021 about 9 hours after vaccine, at 01:00, the patient experienced severe headache and complete loss of taste and smell. No treatment was given for the events. The clinical outcome of severe headache, complete loss of taste and smell was not recovered. It was also reported that since the vaccination, the patient had not been tested for COVID-19. |

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| 1115262 | 3/19/2021 | TX | 40 | F | 2/26/2021 | 2/27/2021 | severe body aches; slight fever; chills; severe diarrhea; dizziness almost fainted; fast heart beat; headache; pain in the injection site; This is a spontaneous report from a contactable consumer (patient). This 40-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiry date unknown), via an unspecified route of administration in the right arm on 26Feb2021 09:30 at a single dose for COVID-19 immunisation. Medical history included allergies: dairy. Concomitant medications included ergocalciferol, retinol palmitate (VITAMINS A & D), apple cider vinegar (APPLE CIDER VINEGAR), cranberry, and allium sativum (GARLIC (DEODORIZED)). Patient is not pregnant at time of vaccination. The patient was not diagnosed with COVID-19 prior to vaccination. Patient has not been tested for COVID-19 since the vaccination. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 27Feb2021 14:30, on the first day, patient experienced moderate headache and pain in the injection site. On 28Feb2021, the second day, patient experienced severe headache, severe body aches, slight fever, chills, severe diarrhea, dizziness almost fainted, fast heart beat. Patient is recovering from the events. No treatment was received. Information on about lot/batch number has been requested. |
| 1115842 | 3/19/2021 | IL | 39 | M | 3/19/2021 | 3/19/2021 | 39 y/o found in chair having a syncope episode. Patient retained consciousness and moved to ambulance. Vital stable. complained of dizziness, and feeling light headed. Patient refused transport to hospital. Refusal signed. |
| 1115879 | 3/19/2021 | TX | 53 | F | 3/13/2021 | 3/16/2021 | 3 days after the vaccine i passed out. I threw up several times. My husband called 911 and ambulance took me to ER. Took blood work, urine sample, chest xray and ekg. Everything came back normal. |
| 1115888 | 3/19/2021 | MN | 34 | M | 3/19/2021 | 3/19/2021 | Dizziness followed by fainting. Black vision for a 20 seconds after regaining consciousness. |
| 1115902 | 3/19/2021 | AZ | 67 | M | 3/4/2021 | 3/5/2021 | 1. Headache 2. Swelling at redness at injection site 3. Fatigue 4, Muscle weakness and pain 5. One fainting episode |

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| 1115920 | 3/19/2021 | FL | 34 | M | 3/19/2021 | 3/19/2021 | Patient fainted after administration of vaccine, while seated in vaccination waiting area |
| 1115948 | 3/19/2021 | | 35 | F | 3/19/2021 | 3/19/2021 | Patient experienced brief fainting, and recovered quickly after 30 seconds. Then patient experienced nausea for around 10 minutes. Had patient remain in chair and provided supportive care and encouragement. |
| 1115952 | 3/19/2021 | CA | 31 | F | 3/18/2021 | 3/19/2021 | fainting from sitting position preceded by dizziness and nausea. Returned to lying down and did not reoccur |
| 1116054 | 3/19/2021 | | 28 | F | 3/19/2021 | 3/19/2021 | Patient with syncope after vaccination and unconscious for at least 5 minutes. BP initially low, but later recovered when alert. Provided rest and water. After about 20 minutes, patient asymptomatic and back to baseline. Sent home. |
| 1116239 | 3/19/2021 | | 19 | F | 3/15/2021 | 3/15/2021 | chills, body aches, near-syncope the following day, and tinnitus |
| 1115172 | 3/19/2021 | IL | 71 | F | 3/10/2021 | 3/10/2021 | Received the vaccine, and at 3:00 to 4:00 her left arm felt like it was in a vice, being squeezed tighter and tighter, and could not lift or move her arm. Took Tylenol which did not improve any symptoms. Got headache and had that with the arm in the pain all night long. Woke up totally drenched by sweating, and went to the bathroom and felt dizzy yelled for her husband and passed out, and her husband caught her while passing out and woke up on the floor. On the Thursday she was in her recliner the entire day, had nausea, fever, chills, headache, continued with the pain of the arm in a vice, which lasted all day long. Her husband forced crackers and water down her as she had no appetite either for 3 days. She felt so fatigued and her head was not clear. She slowly gradually improved, and yesterday 3/18/21 she feels her head fogginess has improved, and her arm is gone as she has been exercising with a band. It is a little sore but otherwise fine. The excruciating pain lasted for 2 full days. She put some Lidocaine and it possibly helped. She called her doctor and they told her to exercise the arm, and to take more Tylenol, which she had tried which did not improve anything. |

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| 1116264 | 3/19/2021 | VA | 24 | M | 3/17/2021 | 3/17/2021 | Patient became hot and receiving the injection and he passed out. Upon arrival, patient was sweating profusely and was pale. |
| 1114415 | 3/19/2021 | CA | 21 | M | 3/14/2021 | 3/14/2021 | Systemic: Fainting / Unresponsive-Medium, Additional Details: patient fainted and fell from the chair he was sitting while being observed. after a few minutes, he woke up by him self and got up by himself.when i (rph at the store) got there,he was awake and able to talk to me .i took his blood pressure and it was normal and oxygen sat was also normal.we advised him to contact his pcp asap and fainted again and go to er. |
| 1116254 | 3/19/2021 | MA | 26 | F | 3/18/2021 | 3/18/2021 | Patient was 18 min post vaccination when she fainted in the observation area. Nursing staff and EMS on site attended to the patient. Nurse reports "patient was sitting in observation. Patine rolled out of her chair on to her stomach on the floor. Patient was unresponsive. Time was 16:50. Patient was rolled onto her back. Patient was sternal rubbed. Patient came to 16:52. She was oriented to person, place, and time." Carotid pulse strong and palpable, spontaneous breathing. EMS vital signs; BP 100/80, HR 92, O2 sat 97%. Pt assisted to wheelchair and taken to private EMS area where she was observed, called family for a ride home. Patient refused EMS transport to hospital. |
| 1114419 | 3/19/2021 | CA | 28 | M | 3/16/2021 | 3/16/2021 | Systemic: Fainting / Unresponsive-Mild |

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| 1114316 | 3/19/2021 | NC | 66 | M | 2/11/2021 | 2/12/2021 | Fainted; unresponsive; Chills; cool; pale; This is a spontaneous report from a contactable consumer (patient). A 66-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number: EN9581), via an unspecified route of administration, administered in right arm on 11Feb2021 at 01:30 AM (at age of 66 years old) at a single dose for COVID-19 immunization. Medical history included elevated cholesterols, prostate cancer-low-Gleason scale-7. Known allergies: Seasonal allergy, pollen. The patient previously took BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number: 3L3247), via an unspecified route of administration, administered in right arm on 21Jan2021 at 02:30 PM (at age of 66 years old) at a single dose for COVID-19 immunization. The patient did not had Covid prior vaccination, also not did Covid tested post vaccination. Concomitant medications included atorvastatin calcium and tamsulosin. On 12Feb2021 at 12:30 AM, the patient experienced chills, cool, pale, moist skin. Fainted 22 hours' after received the second dose of vaccination. Was unresponsive about 30-40 seconds. After getting cold compress on the neck and face splashed with cold water, was able to answer basic question to EMS team who was called by patient's wife at 12:28 PM. EMS advise to drink a lot of fluids with/electrolytes also took 500 mg Tylenol rapid release gels and 4 hours later Aspirin 325 mg as Tylenol did not help. Stay warm in bad until next day. The events resulted in Doctor or other healthcare professional office/clinic visit. The outcome of the events was recovered in Feb2021. Information on the lot/batch number has been requested. |
| 1116278 | 3/19/2021 | PA | 28 | F | 3/18/2021 | 3/18/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient passed out after receiving the Pfizer covid vaccine from a sitting chair position. |

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| 1113922 | 3/19/2021 | NY | 77 | F | 2/23/2021 | 2/24/2021 | Fainted; lightheaded; This is a spontaneous report from a contactable consumer (patient). A 77-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), via an unspecified route of administration, administered in left arm on 23Feb2021 10:00 (lot number: EN6201) at the age of 77 years old, as single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient was not pregnant at the time of vaccination. The patient previously took codeine and experienced allergies. The patient previously received first dose of bnt162b2 on 04Feb2021 for COVID-19 immunization (product: COVID 19, brand: Pfizer, lot number: EL9264, administration time: 09:45 AM, vaccine location: left arm). Next morning after vaccination (occurred on 24Feb2021 08:00), the patient felt lightheaded while bending over to empty dishwasher. The patient sat down on chair; and the patient's husband found the patient on floor, as she had fainted. The patient had no recall of fainting. No treatment was given for the events. The patient was not diagnosed with COVID-19 prior to vaccination. The patient has not been tested for COVID-19 post vaccination. The patient did not receive other vaccines four weeks prior to COVID vaccine. The patient recovered from the events on unspecified date. |

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| 1113949 | 3/19/2021 | FL | 60 | F | 2/11/2021 | 2/11/2021 | Dizzy; Nausea; Vomit; Pain on all body; Frequent fall; Severe fatigue; Strange feeling; Abdominal pain on and off; Arrhythmia; This is a spontaneous report from a contactable physician. A 60-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), intramuscular, administered in left arm on 11Feb2021 09:00 (batch/lot number was not reported) as single dose for COVID-19 immunisation. Medical history included (G60.9) PN - Peripheral neuropathy (SCT42658009), (M79.2) A Neuralgia (SCT16269008), (R55) Syncope (SCT271594007), (I10) HTN - Hypertension (SCT38341003), (R00.0) Tachycardia (SCT3424008), (E16.2) Hypoglycemia (SCT302866003), (R55) Vasovagal symptom (SCT248229009), (M25.50) Joint pain (SCT57676002), (F41.9) Anxiety (SCT48694002), (K21.9) Acid reflux (SCT235595009), and (M06.4) Polyarthritis (SCT416956002); all were current or ongoing. The patient was not pregnant at the time of vaccination. The patient's concomitant medications were not reported. The patient previously received first dose of bnt162b2 on 12Jan2021 for COVID-19 immunization (product: COVID 19, brand: Pfizer, administration time: 09:00 AM, route: intramuscular, vaccine location: left arm). On 11Feb2021 11:00, the patient experienced dizzy, nausea, vomit, pain on all body, frequent fall, severe fatigue, strange feeling, abdominal pain on and off, and arrhythmia. The AEs resulted in doctor or other healthcare professional office/clinic visit, disability or permanent damage. There were no treatments given for the events. The patient was not diagnosed with COVID-19 prior vaccination. The patient has not been tested for COVID post vaccination. The patient has no known allergies. No other vaccines received within four weeks prior to COVID vaccine. The events were reported as serious and disabling. The patient has not recovered from all the events. Information on the lot/batch number has been requested.; Sender's Comments: Drug causality for suspect drug in the onset of the reported events cannot be excluded assuming a plausible temporal association and considering the known safety profile of the product. The impact of this report on the benefit/risk profile of the Pfizer drug is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse |

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events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.
Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Severe, Systemic: Hypotension-Severe

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| 1114243 | 3/19/2021 | ME | 34 | F | 1/12/2021 | 2/10/2021 | <p>Passed out for 40 secs; Chills; Cardiac issues; A spontaneous report was received from a consumer who was also a 34-year-old, female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and who experienced passed out for 40 secs/ loss of consciousness, chills, and cardiac issues/ cardiac disorder. The patient's medical history included depression. Products known to have been used by the patient, within two weeks prior to the event, included quetiapine fumarate (Seroquel) since 2014. The patient received the first of two planned doses of mRNA-1273 (Batch number: 039K20A) on 12 Jan 2021. On 10 Feb 2021, approximately one day prior to the onset of the symptoms, the patient received the second of two planned doses of mRNA-1273 (Batch number: 028L20A) for prophylaxis of COVID-19 infection. On 10 Feb 2021, after receiving the second dose of the vaccine the patient, had experienced cardiac issues. On 11 Feb 2021, the patient started experiencing chills and passed out for 40 seconds (secs). The patient had visited the emergency room (ER) and EKG (electrocardiogram) showed slight abnormality. She was given heart monitor for 14 days. She was scheduled for Stress test and Echo. She was on antipsychotic medications for seven years. She was curious whether the antipsychotic drugs caused the cardiac abnormalities in response to Covid-19 vaccine. Treatment information was not provided. The adverse event of passed out for 40 secs was assessed as medically significant. The patient received both scheduled doses of mRNA-1273 prior to the events; therefore, action taken with the drug in response to the events was not applicable. The outcome of the events chills and cardiac issues was unknown. Outcome of the event passed out for 40 secs was recovered on 11 Feb 2021.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p> |

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| 1114246 | 3/19/2021 | MD | 68 | F | 1/27/2021 | 1/27/2021 | Diagnosed with C. difficile.; Nasty abdominal cramps; Passing out; Lack of appetite; Diarrhea; Falling; Arm pain; A spontaneous report was received from a consumer concerning a 68 year old, female patient who developed severe stomach cramps, passed out, lack of appetite, falling and diarrhea. The patient's medical history was not provided. Concomitant product use included Tums (up to 2 tabs five times per day), Gas-X, Pepto, Probiotic (30 billion units) and clindamycin, all were used for an unknown indication. The patient received the first of two planned doses of mRNA-1273 (Batch number: 010M20A) on 27 Jan 2021. On 24 Feb 2021, approximately 5 hours prior to the onset of the symptoms, the patient received the second of two planned doses of mRNA-1273 (Batch number: 013A21A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. After the first shot of vaccine the patient reported no reactions other than mild arm pain. After the second dose of vaccine the patient had gastrointestinal distress. The patient had severe stomach cramps, she passed out while on the toilet, she fell in toilet and her husband helped to stabilize, lack of appetite and diarrhea. Patient had been instructed to adhere to a bland diet consisting of toast, rice, bananas, broth, and Pedialyte by her physician. She reported that she was hospitalized on 09 Mar 2021 and was released on 11 Mar 2021. She stated that she ended up being diagnosed with C. difficile. She stated the gastroenterologist did not believe the C. difficile was caused directly from the second dose in the series from Moderna's COVID-19 vaccination. Consumer reported that she was originally was taking a three days course of clindamycin which is a suspect for C. difficile. She was prescribed a 10 days course of vancomycin. Treatment for the event included Bland diet, Tums, Gas- X, Pepto, Probiotic. The patient received both scheduled doses of mRNA-1273 prior to the events; therefore, action taken with the drug in response to the events is not applicable. The events, severe stomach cramps, passed out, lack of appetite, diarrhea, was considered resolving.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |

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| 1114248 | 3/19/2021 | MD | 68 | F | 3/1/2021 | 3/2/2021 | Fever (T101F); Passed out for 10 minutes; Felt sick; Arm swollen and big; Big rash on the area; Felt like vomiting; A spontaneous report was received from a consumer concerning a 68 Years-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced arm swollen and big rash on the area, felt sick (illness), felt like vomiting (nausea) , passed out for 10 minutes (loss of consciousness), and fever (pyrexia). The patient's medical history was not provided. No information of the concomitant medication was given. On Mar-01-2021, prior to the onset of the events, the patient received the first of two planned doses of mRNA-1273 batch no: 022M20A in the left arm for prophylaxis of COVID-19 infection. On Mar-02-2021, The patient experienced arm swollen and big, big rash on the area, felt sick, felt like vomiting, passed out for 10 minutes. On Mar-03-2021, The patient experienced fever(101F). No treatment information was given. The outcome of the events arm swollen and big rash on the area, felt sick (illness), felt like vomiting (nausea) , passed out for 10 minutes (loss of consciousness), and fever (pyrexia) was unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |

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| 1114303 | 3/19/2021 | CA | 46 | F | 2/4/2021 | 2/12/2021 | <p>Vomiting fainting took a nap as the day went on the pain on my R leg got worse; Vomiting fainting took a nap as the day went on the pain on my R leg got worse; vomiting fainting took a nap as the day went on the pain on my R leg got worse; Symptoms of fatigue; Pain on my R knee; Went to fever 102.2 then; Chills, into the entire night/Shivers and shakes; Headache; Into the morning could not walk on my R leg/Can not walk on either foot; Numbness to my face; Found a cyst on the back of my knee; Shivers and shakes; Damage to my ligaments; This is a spontaneous report from a contactable other HCP (patient). A 46-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection), via intramuscular in the left arm on 04Feb2021 at single dose for covid-19 immunisation. The patient was not pregnant. The patient medical history was none, and concomitant medications were not reported. The patient was not sure about allergies. The Patient not received other vaccine in four weeks. Historical vaccine included first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Lot number: EL3249), via intramuscular Left arm on 14Jan2021 04:30 PM at single dose for COVID-19 immunization (at the age of 46-years). The patient stated, "on 12Feb2021 at 03:30 PM, (as reported: one week after the second dose) after the second dose of vaccination. I started having symptoms of fatigue, pain on my R knee, went to fever 102.2 then, chills, into the entire night, headache, into the morning could not walk on my R leg, numbness to my face, vomiting fainting took a nap as the day went on the pain on my R leg got worse. Went to the ER (emergency room) x ray and ultrasound was done, found a cyst on the back of my knee not sure if it was from the shivers and shakes caused damage to my ligaments, 2 hours later my right foot was in a lot of pain, two bumps onto of my L foot lots of pain went back to the ER on Sunday morning (14Feb2021), x ray was done only no broken bones foot was red turned purplish, this started Friday 12th (12Feb2021) and her Monday the 16th Tuesday missed work and still in a lot of pain cannot walk on either foot very far without my boot or crushes." No covid prior vaccination. The patient underwent lab tests and procedures which included post vaccination sars-cov-2 test Nasal Swab: negative on 23Dec2020; body</p> |

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temperature: 102.2 on an unknown date; ultrasound scan and X-ray: cyst on the back of my knee on 12Feb2021, x-ray: no broken bones foot on 14Feb2021. Took the following treatment measures, shot for pain, cortisone shot, naproxen 500. The adverse events resulted in doctor or other healthcare professional office/clinic visit/Emergency room/department or urgent care. The outcome of the events was not recovered. Information on the lot/batch number has been requested.; Sender's Comments: Based on the temporal relation, the association between the event syncope and the vaccination with BNT162B2 cannot be completely ruled out. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

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| 1114460 | 3/19/2021 | WV | 72 | F | 2/12/2021 | 2/12/2021 | hair was coming out, lost all of her hair, bald; sore arm; passed out; tingling in face and hands; head was burning; A spontaneous report was received from a consumer concerning a 72-year-old ,female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced events passed out(loss of consciousness), tingling in face and hands (paraesthesia), head was burning (burning sensation), hair was coming out, lost all of her hair(alopecia), and sore arm(pain in extremity). The patient's medical history was not provided. No relevant concomitant medications were reported. On 12 Feb 2021, prior to the onset of the events, the patient received the first of two planned doses of mRNA-1273 (lot/batch: 030M20A) intramuscularly for prophylaxis of COVID-19 infection. On 12 Feb 2021,immediately after the vaccination, the patient passed out, and when she woke up she had tingling on her face and hands, a sore arm, and head was burning. On 13 Feb 2021, the patient's hair was coming out and by 19 Feb 2021, she had lost all of her hair. She was bald by the end of the week. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not reported. The outcome of events, loss of consciousness, paraesthesia, burning sensation, alopecia and pain in extremity were unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |
| 1114403 | 3/19/2021 | MD | 58 | M | 3/18/2021 | 3/18/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild |
| 1115113 | 3/19/2021 | MO | 41 | F | 3/18/2021 | 3/18/2021 | VASOVAGAL SYNCOPE- PATIENT FELT FAINT, AND LIGHT HEADED BUT DID NOT PASS OUT. PATIENT FELT WARM FOLLOWED BY A PERIOD OF COLD CHILLS. PATIENT STATED WAS SIMILAR TO A PREVIOUS EPISODE AND IDENTIFIED A VASAVAGAL REACTION IN THE PAST. |
| 1114504 | 3/19/2021 | PA | 64 | M | 3/12/2021 | 3/12/2021 | Spots in vision, dizziness, light headed, passed out multiple times, BP and sugar fluctuations on day of vaccine. approximate 5 days later developed a fever, vomiting and pneumonia. currently being treated at Hospital in by Dr. |

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| 1114505 | 3/19/2021 | AL | 37 | M | 3/16/2021 | 3/16/2021 | Well I?m alive. It started about 45 minutes after taking the vaccine. It began as heavy salivating and turned into a numb tongue. I have never had an allergic reaction, so didn?t pay much attention to it. After returning home I became severely lightheaded and almost passed out. I immediately took a Benadryl and Motrin. Then my heart rate shot up to 160BPM according to my smart watch and maintained that for around 5 minutes. The home medicine helped it to subside, but the same feelings would return in moderate waves. By 2pm, I decided I should seek professional help and was taken to the ER by a family member. By this time I had moderate chest and jaw was very tight. At the ER I was monitored for 1 hour and then given an IV injection of Benadryl, Pepcid, and Decadron(steroid). I immediately get relived and well. I was released from the ER around an hour later and sent home with a prescription of Benadryl, Pepcid, and Prednisone Oral Steroid. I have since had a few different side effects like chest pain, extremely flushed face, and low grade fevers. The medicine taken at home immediately stopped the face flushing. |
| 1114525 | 3/19/2021 | FL | 56 | F | 3/13/2021 | 3/13/2021 | Fever, chills, headache, N/V, injection site pain beginning 3/13/2021, reports that she "passed out" on 3/13/2021. Spoke with PCP who advised her to go to hospital but she did not go. Taking tylenol as needed. Started feeling better yesterday, eating and drinking. Advised to follow PCP recs and we will follow up with her tomorrow. |
| 1114725 | 3/19/2021 | NY | 59 | F | 3/19/2021 | 3/19/2021 | Pt typically has an adverse reaction to needles, with the most common reaction being syncope. The Pt was vaccinated on a bed to be proactive about the Pt fainting during vaccination. Pt was fine during and after vaccination, speaking with EMT before, during, and after the vaccination. No action was needed by EMT. |
| 1114771 | 3/19/2021 | TX | 34 | F | 3/18/2021 | 3/19/2021 | Dizziness and fainted the next morning and busted my chin. |

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| 1114946 | 3/19/2021 | OH | 38 | F | 2/26/2021 | 2/27/2021 | Episode of Syncope which caused a fall; Episode of Syncope which caused a fall; Headache; Chills; Fever; Body Aches; This is a spontaneous report from a contactable consumer (patient). A 38-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN6202), via an unspecified route of administration, administered in the left arm on 26Feb2021 at a single dose (at the age of 38-years-old) for Covid-19 immunisation in a workplace clinic. Medical history included allergies, migraines, low vitamin D and penicillin. Concomitant medication included cetirizine hydrochloride (ZYRTEC [CETIRIZINE HYDROCHLORIDE]) taken for an unspecified indication, start and stop date were not reported. The patient previously took Bactrum and doxycycline and experienced allergies. The patient was not pregnant at time of vaccination. The patient took the first dose of BNT162B2 on 05Feb2021 10:30 in the left arm at the age of 38-years-old for Covid-19 immunisation. No other vaccine was received in four weeks. The patient did not have COVID prior to vaccination. On 27Feb2021 at 02:30 AM, the patient experienced headache, chills, fever, body aches and an episode of syncope which caused a fall. The events resulted in emergency room/department or urgent care. The patient had a CatScan, EKG, IV medications, blood and urine test. The patient was not tested for COVID post vaccination. The patient recovered from the events on an unspecified date. |

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| 1115041 | 3/19/2021 | | | F | 2/25/2021 | 2/26/2021 | <p>passed out for 15 minutes; Felt woozy; felt so overheated; Felt feverish; felt extraordinarily tired; extreme chills; extraordinarily nauseous; A spontaneous report was received from a physician concerning their patient, 66 years old, female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and who developed passed out for 15 minutes/loss of consciousness, felt woozy/dizziness, felt feverish/pyrexia, felt extraordinarily tired/fatigue, extreme chills/chills, extraordinarily nauseous/nausea, felt so overheated/feeling hot. The patient's medical history was not provided. Products known to have been used by the patient, within two weeks prior to the event, included Vitamin D NOS, levothyroxine. The patient received the first of two planned doses of mRNA-1273 (Batch number: 014M20A) on 25 Feb 2021 intramuscularly at her left non-dominant deltoid for prophylaxis of COVID-19 infection. On 26 Feb 2021 the patient experienced noticeably sick, felt woozy and felt not quite there. By the evening of 26 Feb 2021, she felt feverish and extraordinarily tired. She got extreme chills later that night. She discloses that she normal does react to other vaccines such as the flu vaccine. The strangest side effect that happened to her was that she woke up in the middle of the night and felt ill and extraordinarily nauseous. She went to the bathroom and felt so overheated that she passed out and woke up on the floor (15minutes). Treatment of the events was not provided. Action taken with mRNA-1273 in response to the event was not provided. The event passed out for 15 minutes was considered resolved. The outcome of the events felt woozy, felt feverish, felt extraordinarily tired, extreme chills, extraordinarily nauseous, felt so overheated was not provided.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p> |
| 1115075 | 3/19/2021 | GA | 55 | F | 3/18/2021 | 3/18/2021 | <p>tingling in lower legs. At minute five afterwards, passed out several times, Paramedics called. Low blood pressure. Low heart rate. Overall weakness. Treated in ambulance, stabilized, and taken to hospital. Released several hours later after bloodwork and ekg.</p> |

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| 1115091 | 3/19/2021 | AL | 41 | F | 3/18/2021 | 3/19/2021 | Sore arm all day. Woke up at 1am extremely nauseated, headache, and in sweats. Went to kitchen to get some nausea meds and felt my ears closing. I couldn't breathe and apparently passed out. My husband called 911 and I came in and out for about 30 min he said. I couldn't open my eyes and couldn't feel my legs. Bp was normal and so was blood glucose. They gave me some fluids and nausea meds and I started coming too. Today I am extremely achy and terrible headache, scared to get out of bed. |
| 1114365 | 3/19/2021 | | 36 | F | 3/1/2021 | 3/2/2021 | Fainted; This is a spontaneous report from a non-contactable nurse. A 36-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in arm right on 01Mar2021 (at the age of 36-years-old; Batch/Lot number and expiry date were not reported) as single dose for covid-19 immunisation. The patient's medical history was not reported. There were no concomitant medications. The patient fainted on 02Mar2021 and recovered from the event on an unspecified date. No treatment was received for the event. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: As an individual case report there is not enough evidence to establish a causal relationship with the suspect vaccine. Currently there is no clear biological plausibility between the vaccine use and the even onset. More information such as complete medical history and concomitant medications are needed for fully medical assessment. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate. |
| 1117160 | 3/19/2021 | | 36 | F | 3/19/2021 | 3/19/2021 | Patient with syncope after vaccine. Recovered well. Provided rest and water. Vitals stable. Sent home. |

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| 1116868 | 3/19/2021 | MA | 52 | M | 3/18/2021 | 3/18/2021 | Patient was nervous due to his shellfish allergy and was apprehensive. He went to get a glass of water after he was vaccinated and when he sat down, missed his chair and had a syncope episode. Taken back by EMS to secluded area, vitals and glucose checked. Glucose was normal, BP reported as low and EMS decided he should be transported. EMS provided fluids, monitored at ER, BP came back to normal and he was released. |
| 1116869 | 3/19/2021 | CA | 38 | M | 3/19/2021 | 3/19/2021 | Pt recieved vaccine @ 1112 and immediately fainted, eyes rolled back in his head. Noted to be very pale, diaphoretic and cool to touch. B/P 72/42, HR-44, O2 sat 96%ra. Pt reports anxiety and history of passing out at dentist office. 1120 b/p 58/40, 98%ra, hr-68. cont to be diaphoretic, cool to touch and pale. 1137 pt reports feeling better was given crackers and water @ 1115. EMS called by site lead. EMS assessed pt and he refused to go to the hospital. Pt encouraged to follow up with MD. 1157 O2 sat 96% hr-62, pt ambulated with staff for 20 minutes prior to discharge at 1158. Team Lead okayed pt to drive himself home. |
| 1116882 | 3/19/2021 | MO | 22 | M | 3/17/2021 | 3/17/2021 | Patient became lightheaded and diaphoretic and passed out |
| 1116894 | 3/19/2021 | VT | 67 | F | 3/19/2021 | 3/19/2021 | Approximately 20min prior to admin of 1st dose of vaccine, patient developed tingling and numbness sensation of lips. Over the course of 3min this tingling and numbness sensation progressed to the left side of her face and the left side of her tongue. 0.3mg of epinephrine was administered via autoinjector 3min following onset of s/s. 50mg PO diphenhydramine was administered 5min following onset of s/s. Pt developed no further s/s, No: rash, pruritus, chest tightness, chest pain, angioedema, abdominal pain, nausea, emesis, dizziness, syncope. VS stable throughout evaluation. Ambulance arrived approximately 10min following onset of s/s and pt was transported to ED for evaluation. |

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| 1116937 | 3/19/2021 | OR | 53 | F | 3/17/2021 | 3/17/2021 | Passed out within 2 minutes of getting the shot. I don't know how long I was out. The EMT's were called, my blood pressure was really low, but as I sat up for a while it got better and I was able to go home. The next day my arm was really sore, I took too ibuprofen twice that day which helped. The next morning I woke up with hives all over my upper body that's itchy. |
| 1116947 | 3/19/2021 | NJ | 20 | M | 2/28/2021 | 2/28/2021 | Syncope |
| 1116975 | 3/19/2021 | WI | 34 | M | 3/18/2021 | 3/18/2021 | Patient reported to vaccinator before receiving vaccine that he normally passes out when he gets shots. After receiving shot, patient passed out for about 20 seconds and head fell back. Vaccinator called for assistance. Patient regained consciousness and stated, "I didn't even know where I was." Patient noted to be diaphoretic. He also had pulse rate of 42 and Bp of 98/48 which he reports as being normal for him as he is a runner. Patient stayed seated, vitals assessed, ice applied for sweating, and juice given. After 15 minutes, patient escorted in wheelchair to monitoring area where he remained in a cot for 20 minutes. Vitals reassessed with Bp 113/73 and pulse 49. Patient reported feeling well and able to ambulate steadily. Patient left at that time |

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| 1117101 | 3/19/2021 | IN | 30 | F | 3/18/2021 | 3/18/2021 | 1022 - Patient received her 1st Pfizer vaccine by RN. She noted a history of vasovagal syncope to needles in the past (did not seem like it was complete syncope to all needle sticks per RN). RN offered for her to lie down, but she said she felt ok sitting. She did not endorse any history of severe allergies or reactions to injectables in the past; she was asked the necessary questions prior to vaccination. We later learned she has Crohn?s and is on immunosuppressant Imuran for this disorder. 1023ish ? walked to checkout area 1025 - While sitting at the checkout registering for her second shot she started to feel faint and checkout staff called for help 1026 - RNs were getting the BP cuff on her. She appeared obtunded and slouching in her chair- eyes closed. Gentle sternal rub and she was able to open her eyes and tell us what her name was and ask to call her dad. BP 90/58. Cold cloths placed on her neck. Continuous pulse ox monitor placed, showing 99%. 1030 - Still drowsy and diaphoretic. Able to tell us that "she passes out when she gets shots" C/O nausea and vomited. Still in and out of awareness. NP is site coordinator is now present and suggests taking patient by wheelchair to safer and more private area for evaluation in SR Room. Patient able to stand and transfer to wheelchair, which we did slowly and carefully. 1034 ? Now in safer and more private area SR room with NP and RN and Dr. Firemen are here and assessing the scene with medic assessing patient. Ambulance in route, about 5 - 10 minutes out per radio communication. Checking BP every 2 minutes. Now is 68/44. C/O nausea and vomited. Pulse ox won?t pick up. Patient with decreasing LOC, eyes rolling back in head, unable to maintain posture seated, and not able to describe symptoms to us (unknown if she felt itchy but no obvious cutaneous manifestations). Unable to visualize oropharynx. 1037- BP 57/40. NP administered Epi pen 0.3 mg dose to L lateral thigh due to s/s of systemic allergic reaction/anaphylaxis including 3 known body systems: hypotension (cardiovascular), vomiting (GI), and decreased LOC (neuro). No IV fluids immediately available but were preparing to obtain. Staff getting cot for patient to lie down. Provider spoke with her mom on the phone and informed her of event. Mom confirmed that she has often before passed out with vaccines and blood draws. Dad was on his way to center and rerouted to ER. 1038 - BP 68/45 Talking to medics and able to tell |

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| | | | | | | | them she ate breakfast and that she has a hx of Crohn's and takes a monthly injection. Informed provider that her dad was on his way. EMS team here to transport to ER. We were preparing to put her on a cot so help with her blood pressure/blood flow when she started to stabilize and EMS arrived with stretcher. 1040 - BP 97/53. Patient is now alert and talking to us. Says she has had syncope in the past ?but never anything like this.? 1041 - BP 115/53. Patient still alert and talking. Oriented x 3. 1042 - Transported to ER by EMS ambulance on stretcher. DEBRIEF: Somewhat atypical (no obvious cutaneous manifestations) and rapid, severe reaction. Ddx vasovagal vs anaphylaxis. Response to epi consistent with anaphylaxis reversal. Perhaps immunosuppressant medication contributed to severity and rapidity of reaction. |
| 1117119 | 3/19/2021 | MO | 29 | M | 3/15/2021 | 3/19/2021 | Patient fainted 3 times - Called EMS and they checked him out before he left - tried to call patient to follow-up 3/19/21 5:30pm - no voicemail set up |
| 1116859 | 3/19/2021 | IL | 39 | M | 3/19/2021 | 3/19/2021 | Syncope lasting 15 seconds, Patient assessed. vitals normal. Patient refused transport. |
| 1117154 | 3/19/2021 | IL | 46 | F | 3/19/2021 | 3/19/2021 | came in to our store for her COVID 19 vaccine appointment on 3/19/21 at 10:30am. On her VAR form, she indicated "no" on #5 that if she ever had a reaction after receiving a vaccination, including fainting or feeling dizzy questions on the VAR form. She also had history of Wolff-Parkinson-White (WPW) syndrome. We gave her Covid 19 vaccine and noticed she was nervous about the shot that she is getting. We ask her to stay in the pharmacy for at least 15 minutes for adverse reaction observation. About 5 minutes in while she was sitting , my technician noticing that the patient is not normal like she is about to faint and call the pharmacist on duty for attention. The pharmacist ran to the patient right away and noticed the patient starting to faint and unconscious, the pharmacist told technician on duty to call 911. We laid her down on the floor to see if we need to process CPR but she regained her concious and alert after about 30 seconds. The paramedic arrived within couple minutes and check her vital and they said her BP is low and she agreed to go to the Hospital for check up. Paramedic took the patient with on stretcher. |

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| 1117259 | 3/19/2021 | MA | 29 | F | 3/15/2021 | 3/15/2021 | Patient reported history of queasiness after injection. Patient fell weak, diaphoretic after injection. Patient was escorted to a chair when she fainted and became unconscious for approximately 1 minute, had an episode of incontinence. EMS service was ordered. Patient's BP was recorded by the EMS and was hypotensive. Patient refused to go to ER and was escorted to the car where her family member was waiting to take her home. |
| 1117166 | 3/19/2021 | NY | 37 | F | 3/19/2021 | 3/19/2021 | Tongue swelling, dizziness, brain fog, fainting. Lasted 3 hours. |
| 1117196 | 3/19/2021 | CA | 16 | F | 3/19/2021 | 3/19/2021 | PT RECEIVED 1ST DOSE OF PFIZER COVID VACCINE. SHE SAT ON A CHAIR FOR 15 MINUTES AND WAS FINE WHILE SEATED. AFTER 15 MINUTES SHE STOOD UP TO LEAVE AND WALKED ABOUT 25 YARDS WHERE SHE SUDDENLY FELT DIZZY AND PASSED OUT. SHE FELL TO THE GROUND, HER FACE SLAMMING THE FLOOR. AFTER A FEW SECONDS SHE WAS CONSCIOUS AND BREATHING. WE KEPT HER LAYING ON THE GROUND AND TOLD HER TO KEEP BREATHING. SHE WAS CONSCIOUS AND RESPONDING TO OUR QUESTIONS. WE CALLED 911 AND EMT ARRIVED AND TOOK OVER HER TREATMENT |
| 1117606 | 3/19/2021 | WA | 38 | F | 1/27/2021 | 1/28/2021 | I got up around 8 am to use the restroom was the last thing I remember. I had a syncopal event and my partner found me unconscious on the bathroom floor. When I fainted I hit my forehead causing a large hematoma. I also got a laceration on my chin about 2 inches across. I hit my right cheek as well but no skin was broken just a big bruise. The chin laceration required stitches. I have never fainted in my life. All the medications I am currently taking I have been on for years. |

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| 1117205 | 3/19/2021 | VA | 52 | M | 3/19/2021 | 3/19/2021 | Patient received vaccine at 3:42 pm. At 3:50pm, patient was unconscious but breathing in his chair in the post-vaccine waiting area. 911 was called. Patient was placed on the floor in the recovery position, he regained consciousness after about 1 minute. He stated that he has passed out previously after giving blood as he has a fear of needles. EMS took his BP several times (last reading at 4:13 pm was 96/63) after arriving at 3:57pm. At 4:13 pm he signed a waiver that he did not want to go to the ER. |

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| 1114251 | 3/19/2021 | GA | 83 | F | 3/3/2021 | 3/3/2021 | faints when she gets up; Yesterday started to get itch and rash around the injection site; Yesterday started to get itch and rash around the injection site; Was sick for days; joint pains; fatigue; headache; muscle pain; chills; sore arm; A spontaneous report was received from a consumer who was an 82-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced sore arm, was sick for days, fatigue, headache, muscle pain, joint pains, chills, itch and rash around the injection site and faints when I get up. The patient's medical history was not provided. No relevant concomitant medications were reported. On 03-Mar-2021, prior to the onset of the events the patient received the first of two planned doses of mRNA-1273 (lot/batch: 013A21A) intramuscularly for prophylaxis of COVID-19 infection. On 03-Mar-2021, the patient experienced the events sore arm. She reported that she was sick for days, suffered fatigue, headache, muscle and joint pain and chills. On 06-Mar-2021, she stated that her vaccination site started to itch and a rash developed around it and that she felt tired all day. On 07-Mar-2021, she reported that the redness and itchiness at the injection site was gone and that she felt better but still like when she had Covid in the past. Additionally, patient reported that she fainted when she got up (date unknown). Treatment included paracetamol 2 tablets on 06-Mar-2021 in the evening. Action taken with mRNA-1273 in response to the events was not reported. The outcome of events, itch and rash around the injection site, was considered recovered/resolved. The outcome of the events, sore arm, was sick for days, fatigue, headache, muscle pain, joint pains, chills and faints when I get up, were considered unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. |

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| 1117274 | 3/19/2021 | CA | 88 | F | 3/17/2021 | 3/17/2021 | 1538- pt in vaccine observation area after receiving Moderna vaccine dose 2. 1539-Pt was minimally responsive and diaphoretic in her sit/walker. BP not reading , perhaps too low, pulse 70, R20,O2 sat 99% RA, No obvious sign of anaphylaxis. Family reported same symptoms previously, last on 3/12/21 and was eval in outside ED for syncope. 1540-Pt now less responsive but responds to simple commands, BP 63/45,P64,R16, O2sat 98% RA, cold compress applied to forehead. 1546- transferred to gurney in Trendelenburg & decision made to call ambulance. 1550- 911 called. Pt was transferred to ED |
| 1117459 | 3/19/2021 | IL | 23 | M | 3/19/2021 | 3/19/2021 | Syncope, patient awoke on his own after ~15 seconds |
| 1117493 | 3/19/2021 | TX | 54 | F | 3/17/2021 | 3/17/2021 | PATIENT OBTAINED 'SHOT.' ABOUT 10 MINUTES LATER (SHE) BEGAN TO FEEL CLAMMY PT STATED THAT SHE MAY HAVE 'BLACKED OUT' A LITTLE - PT HAS A HISTORY OF FAINTING IN EMOTIONAL SITUATIONS |
| 1117559 | 3/19/2021 | AZ | 68 | F | 3/19/2021 | 3/19/2021 | Within two hours had headache, violent diarrhea, clammy skin and sweating. Light headed to the point of almost fainting. I called 911 which I never would do normally but there was no one but me and I wasn't sure what was happening. Medics took vitals and all was ok. By the time they arrived I was shaky but all other symptoms had gone. |
| 1116314 | 3/19/2021 | PA | 34 | F | 3/19/2021 | 3/19/2021 | Patient passed out and fell to the floor after standing up from a chair about 5-10 minutes after vaccine. She had low blood pressure, was pale, and had difficulty seeing clearly. EMS came to the scene to evaluate and her blood pressure recovered and she went home. She did not go to the emergency room, was just treated by EMS. She remained conscious and breathing and did not require CPR. |

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| 1117137 | 3/19/2021 | CA | 25 | F | 3/4/2021 | 3/4/2021 | Pt had the pfizer Covid shot. she was sick from the first shot on Feb 4 2021. Fever , headache and chills. She decided to get the second pfizer on March 4. Immediate chest pains then 15 min later, syncope , followed by myoclonic or seizure type activity of both the RT upper and lower extremities. This was seen by me in the emergency room. She was given ativan and the seizure type movement stoped. I called her today on 03-19-2021, She told me she was sick for five days following the second pfizer, Had headaches. body aches and fevers. but today was doing well. |
| 1116357 | 3/19/2021 | TX | 38 | F | 3/19/2021 | 3/19/2021 | Within minutes of vaccination, patient reported that her arm felt a warm sensation that extended across her chest. 10:20 Stated her chest felt tight. Feeling lightheaded. Denied any tingling sensations of the mouth and throat. Lungs Clear to auscultation, no facial swelling noted. BP: 69/112. P: 119. O2Sat: 99%. R: 20. Pt did not eat this morning. States she is on Keto diet. Pt. became jittery, Juice provided. BP rechecked: 10:35 BP 140/115, P: 77. R-20. O2Sat%: 99%. Lungs CTA bilat. Continued observation, BP: 158/104. 11:05 C/ O increasing pain in both arms and chest. Pain in abdomen. Increased anxiety, Fainted momentarily. Placed supine. Crying stated she was feeling "weird" , tingling hands, ears, increased pain. Lips tingling, face flushed. BP: 183/102. R: 20. O2Sat: 99. Became chilled. EMS activated. 11:12 Patient transported via ambulance to Hospital. Husband notified of transport by NP. |
| 1117442 | 3/19/2021 | | 44 | M | 3/19/2021 | 3/19/2021 | pt got vaccine and was sitting for observation. Pt thought he was having a panic attack so he put his head between his knees, he fainted, hit is head on the floor, and a witness said he was shaking on the floor. The patient came to quickly and said he passed out due to stomach cramps . EMS was on site and did an evaluation. Pt was given ice for his head and had vitals checked and and EKG done. EMS recommended hospital transport but patient refused. |

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| 1116772 | 3/19/2021 | NY | 27 | F | 3/19/2021 | 3/19/2021 | The pt doesn't like needles. Gave her the shot no problem. She waited 15 minutes then walked out with her boyfriend. She said she felt faint, then passed out. He caught her then put her in the car. Then she passed out again. He called 911. The ambulance came and brought them back in the store. She got checked out and refused to go to the hospital. She claimed she was fine and left. |
| 1116325 | 3/19/2021 | WA | 32 | M | 3/19/2021 | 3/19/2021 | Pt received vaccine at 1025,waiting to finish his 15 min observation.At10:38 pt called the RN observer because he felt lightheaded. RN came to help him ,30 sec later, pt fainted and loss consciousness for about 10 sec. Assisted to the floor in T-position. 911 called.Pt regained consciousness, BP and O2 saturation monitored. Initial BP 102/57, 10:46 107/62,10:50 115/72,10:56 131/74. 10 Pt is alert, sat up in a chair.911 arrived |
| 1116338 | 3/19/2021 | CA | 20 | F | 3/17/2021 | 3/17/2021 | SYNCOPE REACTION , DEVELOPED 10 MINS POST IM INJECTION |
| 1116343 | 3/19/2021 | NJ | 28 | F | 3/19/2021 | 3/19/2021 | SYNCOPE |
| 1116362 | 3/19/2021 | WI | 73 | M | 3/18/2021 | 3/18/2021 | Syncope and generalized weakness. Blood pressure taken 90/50 with a heart rate of 38. First response notified. Blood pressure repeated 113/56 with a heart rate of 40. Patient was transported to the Emergency Department via first response. |
| 1116379 | 3/19/2021 | IN | 73 | F | 3/19/2021 | 3/19/2021 | rapid breathing high blood pressure almost fainted super flushed face |

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| 1116398 | 3/19/2021 | NY | 68 | F | 3/6/2021 | 3/7/2021 | She had the vaccine at the facility where she lives. She fainted less than 24 hours after the vaccine, got up from that and had dry heaves, lost her speech and had loose stools. The aide caught her as she was fainting as she would have fallen on the floor. She said it was weird, she looked at people and it looked like they were 2 dimensional and knew something was wrong, but couldn't figure out what as they attended to her. They asked her questions, but she was not able to speak to them. They apparently spent 2 hours with her, but she doesn't believe it was that long, and then they knew she wanted to go to one Hospital and not the other. She had been loosing words before this happened, but not as bad as this one. This was about the same reaction that she had when she got the COVID virus in January. She was then taken to the hospital where she was given fluids and hydrated her and checked her heart, saw a cardiologist and a neurologist to see if those things caused the fainting and had blood work done. They also did a CAT Scan of her head and neck. They told her that she was fine and was discharged back home after 5 days, which was 3/11/21. Since then she has been very tired, she does have GERD and her stomach has been hurting a lot as well. |
| 1116417 | 3/19/2021 | WA | 89 | F | 3/12/2021 | 3/13/2021 | patient reported 20 minutes of visual hallucinations about 15-17 hours after 2nd dose of COVID-19 vaccine and passed out for possibly 5 minutes. during fall she injured right low leg, but no evidence of DVT on exam today (6 days after fall). |
| 1116424 | 3/19/2021 | IL | 23 | M | 3/19/2021 | 3/19/2021 | Syncope episode, nausea and vomiting .Patient needed a minute to catch breath. Patient stated felt better after a minute. |

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| 1116469 | 3/19/2021 | PA | 21 | F | 3/19/2021 | 3/19/2021 | gave patient immunization,told her to wait for 15 minutes. After 5 minutes patient experienced dizziness and feeling light headed. i was talking to patient constantly to keep her alert as much as possible. Her eyes started to roll back slightly and I laid her flat on ground with support behind her head, The patient remained conscious. Took her pulse which was steady and regular, breathing on own without difficulty. 911 was called immediately. After about 2-3 minutes patient was becoming more responsive .After a few more minutes we placed patient on the chair, at which time the paramedics arrived. Patient has had past experiences of fainting due to body piercings or had problems as a child when she was immunized that was later revealed to me by her father. Patient had a flight or fright experience and after another 20 minutes left with her father and boyfriend |
| 1116688 | 3/19/2021 | VA | 38 | M | 3/19/2021 | 3/19/2021 | Patient received vaccination and passed out. Patient states that he has a history of fainting after receiving vaccination. Patient was given water and cold compresses was applied to patients head to help cool him off. Patient's vitals were obtained and everything was normal except blood pressure. Blood pressure was found to be 99/42. After approximately 15-20 mins patients BP was 100/60. |

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| 1116711 | 3/19/2021 | IL | 84 | F | 2/25/2021 | 3/15/2021 | 2/23/21 84 y.o. female who presents with complaint of syncopal episode that happened about 6:30 p.m.. Patient was working with a family member to has across the street for a visit when she started feeling dizzy with unsteady gait and shortly after passed out and was cut by the family member. Family member says she was out for about 10 min and then came around. The patient complained of some headache but denies chest pain, nausea vomiting, abdominal pain, cough or shortness of breath. Patient has not been eating or drinking because she has and lost some. Has some food after this episode but was brought in because of continued dizziness. 3/15/21 84 y.o. female who presents with a skin tear on the left forearm and abrasion on the left temporal area after she tripped at home prior to arrival. Patient states she has mobility issues and normally uses a walker but she did not. Patient is on home oxygen. Patient denies loss of consciousness or neck pain but is on Eliquis due to atrial fibrillation and stroke. She does have a pacemaker. Patient denies any other injuries.. |
| 1116471 | 3/19/2021 | MN | 69 | F | 3/18/2021 | 3/18/2021 | Patient developed headache, nausea, dizziness, and weakness hours after receiving Moderna vaccine (dose number unknown). Seen at Medical Center in the ER; determined to be vasovagal syncope. Location of vaccine administration unknown. |
| 1116705 | 3/19/2021 | MI | 62 | M | 3/18/2021 | 3/18/2021 | Dizziness and syncope; required IV fluids and hospital observation. Fully recovered. |
| 1116712 | 3/19/2021 | CA | 37 | F | 2/3/2021 | 2/3/2021 | Patient passed out after getting the injection. Per RN, patient with Stridor. 37yo female presented to the UC and was pale with complaints of tightness in chest. Heart rate up to 160s. BP 114/83. EKG shows sinus tachycardia at 116. s/p anaphylactic versus vasovagal reaction to vaccine. Support the later consider vitals stable, no signs of angioedema/rash notes on examination. Possibly stridor at the tent, but patient notes she does recall starting to breathing heavy before loosing cautiousness. Patient was s/p epi pen x 2 (investigating if the pens fired properly) when presented to the UC. She was tachy and pale, but otherwise clinically was stable. |

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| 1116704 | 3/19/2021 | NY | 21 | F | 3/19/2021 | 3/19/2021 | Patient fell on floor at 3:45pm. Patient states that "felt room starting to spin. A little lightheadedness. I do not remember falling on the floor." Patient states "every time I've gotten a shot I have almost always passed out." Patient is afraid of needles. Patient came to and was laying on stomach. EMTs got patient up slowly to cot. B/P 147/89, pulse 67, O2 97%. Patient once moved to cot was alert and oriented. |
| 1116638 | 3/19/2021 | OH | 51 | M | 3/17/2021 | 3/17/2021 | 3-17-21 1:10PM PT STATES HE 'DOESN'T FEEL WELL'. SYNCOPE APROX 1 MIN - WIFE HELD PT IN CHAIR. RN X3 AND MEDIC ASSISTED PT TO FLOOR AND ELEVATED LEGS. PT BECAME RESPONSIVE. PT PALE AND DIAPHORETIC. 1:16PM ASSISTED PT TO CHAIR 'FEELS BETTER NOW'. A/O, PINK, W/D, RESP REG WITH EASE. WIFE HERE TO DRIVE PT HOME. 3-19-21 3:30PM TC: PT STATES 'FULL RECOVERY'. |
| 1116611 | 3/19/2021 | CA | 19 | F | 3/19/2021 | 3/19/2021 | Patient was found on the ground laying on the right side. Patient stated she fainted about 5 mins after the vaccine and hit her head. Denies pain to head and back. C/O dizziness and lightheadedness. History of fainting with blood draw. VSS. BG 114. Patient stated she felt better after laying down so we sat her up and gave her a snack. As soon as she finished snack, patient c/o dizziness and lightheadness. Patient was laid back down on the ground. EMS was called. |
| 1116522 | 3/19/2021 | NY | 75 | F | 3/8/2021 | 3/9/2021 | Fainted suddenly the morning after receiving the vaccine. I couldn't get off the floor. I had no strength and I was covered in sweat. I felt pretty bad the rest of the day and stayed in bed. I was lethargic for a couple days. |
| 1116509 | 3/19/2021 | IL | 66 | F | 3/18/2021 | 3/19/2021 | Discomfort. Body and Muscle aches. Nausea, vomiting, headache, fever, chills, abdominal pain, light headedness followed by fainting. |

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| 1116475 | 3/19/2021 | IL | 32 | F | 3/18/2021 | 3/18/2021 | Approximately 10min after shot, client fainted. Was unconscious for approx. 15 sec. Client was monitored for approximately 1hr. For 40min after event, client was very slow to process words and thoughts. BP 90/60. States she had a banana at 5:30 AM and 9:00AM. No other foods. As client became more alert, she was taken back to work by a coworker. She taught class. Had no further problems. Spoke with her 3:40PM for follow-up. |
| 1116472 | 3/19/2021 | IN | 21 | M | 3/17/2021 | 3/17/2021 | The patient informed the vaccinator that he passes out during any immunization, TB test and blood draw. The patient passed out approximately 5 minutes after the vaccine. We laid him on the floor and elevated feet for 7 minutes then patient wanted to sit in a normal chair. |
| 1111000 | 3/18/2021 | TX | 28 | M | 3/16/2021 | 3/16/2021 | 07:40 patient reported to mother that he was "lightheaded and dim vision" then mother witnessed syncope. Nurse assessed patient LOC but breathing was recorded at approximately 1 minute with pallor, cool, and clammy skin. ED was notified of patient transport. Vitals were obtained BP - unobtainable, HR - 44 faint and thready, Resp -10. Patient regained consciousness and informed nurse that he had "white coat syndrome and history of fainting with blood drawn and doctor visits" he apologized for not notifying nurse prior to vaccination. 07:43 patient has second witnessed syncopal episode after reporting "dim vision", patient was lowered to floor with assistance from 3 nurses and bystanders. Vitals obtained - BP - 117/76, HR - 46 Resp - 12. LOC lasted 30 seconds, patient was pallor, skin was cool and clammy. Patient regained consciousness and was alert and oriented x 3. 07:48 patient was assisted to sitting position and then assisted to W/C and escorted to the ED with a nurse, CNA and family for examination and further treatment. Upon leaving patient had pink color, skin was warm, but diaphoretic. Pt entered ED at 07:55 VS BP - 141/83 MAP - 102 HR - 66 RR- 20 SPO2- 96% Temp - 97.9. Pt was observed in ED for an hour and was provided food and liquids after report of not eating or drinking since previous night. |

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| 1111018 | 3/18/2021 | GA | 55 | F | 3/18/2021 | 3/18/2021 | Patient stated she was feeling nauseous ~13 minutes post vaccination. Patient's husband called for assistance. Patient then fainted. She came to but was incoherent. She could not form sentences and proceeded to go in and out of consciousness. Paramedics were called and arrived on the scene within 5 minutes. Patient was taken away on a stretcher. |
| 1111526 | 3/18/2021 | FL | 61 | M | 3/18/2021 | 3/18/2021 | fainting, sweating, eyes rolled back, slouched over in chair then perked back up. still complained of dizziness and sweating. called 911 within 1 min of episode and paramedics came to take over. Patient was talking and coherent but sweaty. |
| 1111265 | 3/18/2021 | | | F | | | passed out after 1 day of having the vaccine; A spontaneous report was received from a consumer concerning a 66-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and passed out. The patient's medical history as provided by the reporter included dementia. No concomitant medications were reported. On an unknown date, prior to the onset of the event, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On an unknown date, the patient passed out after one day of having vaccine. No treatment information was provided. Action taken with mRNA-1273 in response to the event was not reported. The outcome for the event, passed out was unknown.; Reporter's Comments: This case concerns a 66-year-old female patient, who experienced a serious unexpected event of Loss of consciousness. The event occurred approximately one day after first dose of mRNA-1273, lot # unknown. Treatment details were not provided. Based on the current available information and temporal association between the use of the product and onset of the event a causal relationship cannot be excluded. |

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| 1111278 | 3/18/2021 | NY | 32 | F | 1/27/2021 | 1/27/2021 | fever/temperature reached 101 degrees; Chills; Swollen lymph node in left armpit/swollen lymph node under her left arm, which is the same side that she received her vaccine; Passed out; Body aches; This is a spontaneous report from a contactable nurse (patient). This 32-year-old female patient received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot# EL1283, Expiry Date: Apr2021), via an unspecified route of administration on 27Jan2021 09:00 at single dose in the left arm for COVID-19 immunization. The patient's medical history and concomitant medications were none. No family history. The patient previously took first dose of BNT162B2 (Lot# EL1283) on 07Jan2021 for COVID-19 immunization. Vaccination facility type was nursing home patient was employed at; administered by pharmacy. No additional vaccines administered on same date of Pfizer suspect. No prior vaccinations received within 4 weeks. No adverse events follow prior vaccinations. Patient had fever: temperature reached 101 degrees, early morning on 28Jan2021; chills on 28Jan2021; body aches: at night of 27Jan2021; passed out: later on day of 27Jan2021, didn't get out of bed, didn't remember passing out. Remembers waking up on the floor; swollen lymph node: under her left armpit/left arm noticed on 28Jan2021, which was the same side that she received her vaccine. Hurts less when she puts her arm down. Really was sore to the point where she had to keep her arm open. She can rest her arm now, but it is still sore. Everything has subsided except for the swollen lymph node. Her energy was back. No relevant tests. Relatedness of bnt162b2 to events for Fever/Chills/Body aches/Passed out/Swollen lymph node in left armpit: Source of assessment: Primary Source Reporter, Method of assessment: Global Introspection, Drug result: Related. Event relatedness between COVID-19 Vaccine and fever/Body aches/Swollen lymph node in left armpit was Related. Outcome of the event was swollen lymph node was not recovered, outcome of other events was recovering. No investigation assessment.; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 at 2nd injection cannot be excluded for the reported events based on the known safety profile and the plausible temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures |

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for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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| 1111279 | 3/18/2021 | IL | 85 | F | 1/23/2021 | 1/23/2021 | fainted; passed out and was unconscious; still kind of feel weak; bruise on both knees; fall; This is a spontaneous report from a contactable registered nurse (patient, Retired RN). An 85-year-old female patient received her 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL8982) at single dose via an unknown route injection in left arm on 23Jan2021 around 08:15 for Covid-19 immunization. Medical history included ongoing blood pressure high which was controlled with medication, allergic to penicillin and acetylsalicylic acid;ascorbic acid (ASPIRIN). She had lost weight and shrunk according to when she went to the doctor 2 months ago. No other products were taken. No history of all previous immunization with the Pfizer vaccine considered as suspect; no vaccines administered on same date with the Pfizer vaccine considered as suspect. No other vaccinations within four weeks prior to the first administration date of the suspect vaccine, no events following prior vaccinations. No family medical history relevant to the events. Patient passed out on her way home on 23Jan2021 (unknown time). The event required a visit to Emergency room, but not a Physician office. The event clinical course was as follows: She got the first dose of the Covid-19 vaccine on Saturday 23Jan2021. Patient reported that after being monitored at the vaccination site for 20minutes, she left to go catch the bus and fainted before boarding the bus. She remembered getting on the bus, but did not remember crossing the street. She passed out and was unconscious. An ambulance was called and they took her back to the hospital where she got the vaccine. She was taken by ambulance back to the ER, stayed for half the day, she received IV fluids, and a brain scan due to her fall. She stated that she still feels kind of weak as of 29Jan2021. She did not know what time it happened, because she lost her sense of time on that day because she did not remember. When she got to the hospital she woke up and wondered where she was because she did not remember what happened. They got an x-ray of her head to see if she had bumped it, but it was negative. She did have a bruise on both knees. They gave her IV fluids, and kept her there for a little while, then sent her home. She called her doctor the next day, but he was busy, so she talked to the nurse. No treatment was recommended, just said to get a lot of rest. She was |

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scheduled for the 2nd dose on 13Feb2021 and was scared to death. Patient verified that she was not admitted to the hospital. Investigation assessment were performed. They hooked her up to the monitor, did an x-ray and a CT scan while at the hospital on 23Jan2021 which were normal (both fine), and gave her IV fluids. Outcome of fainted, fall, passed out and was unconscious was resolved on 23Jan2021. Outcome of kind of feel weak was not resolved. Outcome of the other event was unknown.; Sender's Comments: Considering the temporal association, a causal association between administration of BNT162B2 and the onset of fainted and unconscious cannot be fully excluded. The underlying history of high blood pressure for this 85 years old patient might provide an alternative explanation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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| 1111282 | 3/18/2021 | NY | 45 | F | 1/5/2021 | 1/20/2021 | body rash; tachycardic; near syncope; This is a spontaneous report from a contactable other health care professional (patient). A 45-year old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date unknown) via an unspecified route of administration on the left arm on 05Jan2021 at a single dose for COVID-19 immunisation at the hospital. Medical history included asthma, clotting disorder and allergies. The patient was not pregnant at the time of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. However, it was reported that the patient had other medications received within 2 weeks of vaccination. The patient was not diagnosed with COVID019 prior to vaccination. The patient experienced body rash, tachycardia, near syncope on 20Jan2021. As a result, the patient went to the doctor office; clinic visit and emergency room/ department or urgent care. The patient received Cortisone injections, oral steroids and antihistamine in response to the events. The events were considered as non-serious by the reporter. The outcome of event recovering. Since the vaccination, the patient has not been tested for COVID-19. The patient received the second dose of bnt162b2 (lot number: e13246, expiration date unknown) on 26Jan2021 at 9:30 AM via an unspecified route of administration on the left arm at a single dose for covid-19 immunization. No follow-up attempts are possible, information about batch number cannot be obtained.; Sender's Comments: Based on the information received, the reported serious events of Generalized rash, Tachycardia and Pre-syncope were plausibly consequent to single dose for COVID-19 immunisation. The impact of this report on the benefit/risk of profile of the Pfizer drug is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate. |

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| 1111303 | 3/18/2021 | MN | 22 | F | 2/2/2021 | 2/3/2021 | fainting; Fatigue; dizziness/sleep disturbance (wake up with hot, dizzy, nauseous every few hours); nausea/sleep disturbance (wake up with hot, dizzy, nauseous every few hours); hot flashes/sleep disturbance (wake up with hot, dizzy, nauseous every few hours); chills; loss of appetite; unable to focus; sleep disturbance (wake up with hot, dizzy, nauseous every few hours); This is a spontaneous report from a contactable consumer (patient). A 22-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, LOT#EL9269), via an unspecified route of administration in left arm from 02Feb2021 14:00 at first single dose for Covid vaccine. Medical history included known allergies: Oak trees, kiwi. Concomitant medication in two weeks included hydroxyzine hydrochloride (ATARAX), sertraline hydrochloride (ZOLOFT). No other vaccine was received in four weeks. The patient experienced fatigue, dizziness, nausea, hot flashes, chills, fainting, loss of appetite, unable to focus, sleep disturbance (wake up with hot, dizzy, nauseous every few hours). Adverse event start date: 03Feb2021 02:00 AM. AEs resulted in doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care. No treatment was received for the events. No covid prior vaccination. Covid was tested post vaccination: nasal swab on 05Feb2021: negative. Symptoms lasting 6 days and counting. Outcome of the events was not recovered. |

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| 1111264 | 3/18/2021 | IL | 21 | F | 1/28/2021 | 1/28/2021 | fatigue; fainted; shaking; arm cold (felt like ice); red spots on forehead; chills; A spontaneous report was received from a consumer's relative concerning a 21-years-old, female patient who received Moderna's COVID-19 Vaccine, and experienced fainting, shaking, cold arm, red spots on forehead, chills and fatigue. The patient's medical history was not provided. Concomitant medications were not provided by the reporter. On 28 Jan 2021, prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 (Lot number 031L20A) intramuscularly for prophylaxis of COVID-19 infection. On 28 Jan 2021, the patient experienced fainting, shaking, cold arm, red spots on forehead, and chills. Reporter stated that no treatment drugs were prescribed for the events. A complete blood count and an electrocardiograph was performed (results not provided). On 29 Jan 2021, the patient experienced fatigue. Action taken with second dose of mRNA-1273 in response to the events was not provided. The outcome of the events fainting, shaking, cold arm, red spots on forehead, chills and fatigue was not provided.; Reporter's Comments: This case concerns a 21-year-old female patient, who experienced a serious event of syncope and non-serious events of tremor, feeling cold, rash macular, chills and fatigue. Based on the current available information and temporal association between the use of the product and the onset date of the events, a causal relationship cannot be excluded. |

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| 1111305 | 3/18/2021 | SC | 71 | M | 1/22/2021 | 1/23/2021 | <p>suspect anaphylaxis; passed out while driving.; entire body itching; vision issue; This is a spontaneous report from a contactable physician. A 71-years-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular Right arm on 22Jan2021 11:00 at single dose for covid-19 immunisation. Medical history included diabetes mellitus (DM), hypertension (HTN), hypercholesterolaemia. No other vaccine in four weeks. There were other medications in two weeks. No covid prior vaccination. Clinical course reported as: Patient got vaccine with no issues. 36 hours later he developed entire body itching. He then developed vision issues and passed out while driving. He was hospitalized and no cardiac or neurologic issues were found. The reporting physician suspected anaphylaxis since patient had severe itching with the event. There were no other likely triggers found during history other than the vaccine. Events onset date reported as 23Jan2021. Events resulted in Emergency Room Visit and Physician Office Visit. Covid test type post vaccination: Nasal Swab on 06Feb2021 result: Negative. Treatment received for the events. Outcome of events was Recovered/Resolved with Sequel. Information on the lot/batch number has been requested.; Sender's Comments: A causal relationship between the events suspect anaphylaxis, passed out while driving, entire body itching, and vision issue and suspect product bnt162b2 is possible based on the information provided, drug profile and a temporal association in this 71-year-old male patient. This case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.</p> |

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| 1111384 | 3/18/2021 | CO | 40 | F | 1/21/2021 | 1/21/2021 | Increased heart palpitations; almost passed out; This is a spontaneous report from a contactable healthcare professional (patient). A 40-year-old female patient received her second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date were not reported), via an unspecified route of administration on 21Jan2021 at a single dose for COVID-19 immunization. Medical history included allergies. The patient's concomitant medications were not reported. The patient had not been diagnosed with Covid prior to vaccination. She was not pregnant. On 21Jan2021, the patient experienced increased heart palpitations and almost passed out immediately after second shot. No treatment was received for the events. Events resulted to doctor or other healthcare professional office/clinic visit. Outcome of events was not recovered. The patient was not tested for Covid post vaccination. Information on the batch/ lot number has been requested. |

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| 1111441 | 3/18/2021 | GA | 44 | F | 3/17/2021 | 3/17/2021 | <p>Patient stated that she almost immediately felt nausea after the injection appx 3:15, was able to ambulate to observation on her own and then signaled staff for help, felt hot, felt dizzy, felt nausea, staff immediately assisted to chair, RN @ side; inquired re food; had lunch; sips of beverage w sugar given able to eat cracker. She stated she felt better, was upright in her chair, no SOB, no complaints of swelling throat, itchy etc. After some initial sips of liquid, still feeling dizzy lowered to floor by staff w wedge cushion and legs and feet elevated above heart per protocol b/p 140/96 pulse 86. Stated she had been anxious re injection, but denied ever having this experience after injection. Additional information for Item 18: Reviewed the POD form questions again with her, denied any issues. She then stated she was feeling much better again, her warm feelings were going away from ice in a glove that we had used from her initial dizzy, warm/hot feeling. Around 3:30 she felt nausea again, so we sat her up and gave her a bucket to use to vomit if needed. She was unable to vomit. She wanted to sit up on floor. We sat with her and she sipped on clear beverage. She began to get cold. We put her legs back up took b/p 140/91 pulse 86. No change. We called nursing DON for District to make her aware and by that time patient experiencing chills. We called her husband to be on his way to drive her home after 30 minutes @ 3:45. She continued to tell us she felt better for a few minutes only to then tell us she was feeling nausea again. Rolled her to left side, helped her to prop us to vomit but she was unable to vomit anything. B/p readings 147/91, 150/90, 140/87, 150/88 She desired to sit upright again. So on floor with nurse holding and b/p cuff on sat her up to try to vomit, unable to do so. Lowered back to floor with legs upright where she remained local Paramedic on site and he came to assist, a portable recliner that allowed for legs to be elevated above heart was set up. Patient felt that she could transfer with paramedic and staff help and passed out while attempting briefly, chilling when she was alert, then passing out again; 911 was called and arrived by 3:55, patient and husband initially wanted to take patient home after hearing patient state she felt better once paramedics had evaluated her. However in front of husband, patient again passed out, and after she was conscious stated she could not feel her arms. and when</p> |

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| 1111534 | 3/18/2021 | CA | 66 | F | 3/17/2021 | 3/17/2021 | he observed this he agreed it was best for her to be evaluated and then was transported to ER. Per phone conversation this morning, at 10:41 husband stating that patient still not able to stand without passing out on her own and they were continuing to evaluate her. No additional medication given on site at Mass vaccine site. |
| 1111513 | 3/18/2021 | FL | 24 | M | 3/17/2021 | 3/17/2021 | Scared of needles. Syncope, flushing/sweating. BP 111/51 (pulse 90). Patient placed in supine position - appeared to show signs of convulsion. Taken to the ED. |
| 1111533 | 3/18/2021 | IL | 25 | M | 3/17/2021 | 3/17/2021 | Patient presented in our Pharmacy in good health but feeling very anxious about receiving his first in series COVID 19 Pfizer vaccination. Patient was able to ambulate on his own after receiving the vaccine. Patient was sitting with his father and stated to him that he didn't feel right. Patient then fainted 10 min after receiving vaccine. 911 was immediately called and Epi pen was not administered. Patient was not transported to the hospital. |
| 1110910 | 3/18/2021 | VA | 60 | F | 3/17/2021 | 3/18/2021 | syncope x2 episodes 142/66, 82,18, 100% RA |
| 1110079 | 3/18/2021 | FL | 18 | F | 3/12/2021 | 3/12/2021 | Initially Experienced Vasovagal syncope 6 hours after vaccination along with Hot flash and extreme weakness Severe abdominal cramps followed about 3 hours later with bowel movements turning into diarrhea. |
| | | | | | | | Pt. stated she started feeling dizziness 5 mins. after getting vaccinated. Seconds later she had a syncope episode for around 10 seconds. At 5:10 pm she was conscious and dizziness went away. Vital signs were done BP101/60, R 19, O2 sat 100%, HR 62. Pt stated, "I always have episodes of syncope when I get medical procedures, This is not the first time." At 5:25 pm pt stated she is feeling ok, pt is alert and oriented x4. At 5:38 pm pt stated she wants to go home. Pt. went home at 5:40 pm. |

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| 1111544 | 3/18/2021 | PA | 51 | F | 1/13/2021 | 1/13/2021 | I got the shot and waited for 15 minutes. My arm started hurting really bad that evening and it lasted until day two. During the night I felt really dizzy. I got up during the night and I fainted. We called an ambulance my blood pressure was a little low. I went to my Primary care doctor the next morning. My brain was foggy, and I was a little confused. The doctor checked my blood pressure, and it did not change on standing. I saw my allergist and he is going to run tests to check for allergies to ingredients in the vaccine. I have not taken the second dose. |
| 1111466 | 3/18/2021 | TX | 29 | M | 3/12/2021 | 3/12/2021 | About 5 to 10 minutes after the shot I felt extremely lightheaded and then fainted. When I came to about 10 seconds later, there was a public health official there rubbing my chest asking me if I knew where I was. It took me a second to fully come to my senses but then I realized where I was and what had happened. I was very pale, felt chills, was sweating, and it took effort to open my hands. The EMTs ran a bunch of tests, my Blood pressure was low (I think the number I remember was 104/33), but the rest of the measurements like blood sugar or the number of ekg like tests they did all came back normal. The EMTs in the field said they think it was a response to the vaccine. After about 20 minutes of the EMTs monitoring me, my numbers came back up and I was feeling relatively normal. I waited another 30 minutes before leaving just to make sure. It has been almost a week and I haven't felt any symptoms close to that since then. |
| 1110140 | 3/18/2021 | MD | 25 | F | 3/16/2021 | 3/17/2021 | I had a moment yesterday evening where I almost passed out (tunnel vision and my arms and legs went numb) followed by an intense urge to vomit. I instantly broke out in cold sweats and completely soaked through my shirt in about a minute. The intense sensations passed, but happened again at around 10pm as well. I've just woken up for the day today, and so far I feel okay but I'm a little weak and extremely tired. |
| 1112053 | 3/18/2021 | | 78 | F | 1/21/2021 | 1/22/2021 | ALLERGIC REACTION Syncope and collapse |

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| 1111635 | 3/18/2021 | TX | 23 | F | 3/15/2021 | 3/15/2021 | <p>Patient had history of fainting noted on patient also notified immunizer of history. Vaccine was administered and patient appeared to be ok. She was told to have a seat and wait 30 minutes to ensure patient safety. Immunizer notified me/pharmacist of patient's history and staff was informed to watch her for any adverse events. 5-10 minutes later patient walked up to counsel window and notified pharmacist she was going to faint. I asked her to please return to her seat and immediately a technician and I went out and assisted her to a chair. We provided a bottle of water and advised her to sip some. After a few more minutes she passed out in the chair. At that point we called 911. The operator advised us to lay her flat. We moved her into the training room and waited for EMT to arrive. They arrived a few minutes later. At that point she was beginning to come around. I left to return to pharmacy as she was being cared for. 20 minutes later the EMT consulted me and patient vitals were good and she was feeling much better and refused to be transported to hospital. I signed off their form as a witness of her refusal.</p> |

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| 1109885 | 3/18/2021 | OH | 70 | F | 2/2/2021 | 2/2/2021 | fainted and woke up on floor; sweating thru pajamas; throwing up; sore arm; A spontaneous report was received from a consumer concerning a 70-years-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced events sore arm,, fainted and woke up on floor, sweating through pajamas and throwing up. The patient's medical history was not provided. Concomitant medications reported were unspecified statin, blood pressure medication, antiviral medication. On 02 Feb 2021, prior to the onset of the events the patient received their first of two planned doses of mRNA-1273 (lot/batch: 007M20H) intramuscularly for prophylaxis of COVID-19 infection. On 02 Mar 2021, prior to the onset of the events the patient received their second of two planned doses of mRNA-1273 (lot/batch: 012A21A) intramuscularly for prophylaxis of COVID-19 infection. On 02 Feb 2021, the patient experienced the event, sore arm. On 03 Mar 2021, the patient fainted in the kitchen and woke up on floor. The patient reported sweating through pajamas and started throwing up. Patient did not take any treatment for second dose events. Action taken with mRNA-1273 in response to the events was not applicable. The event, fainted, was considered resolved on 03 Mar 2021. The outcome of events sore arm, sweating and throwing up were unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |
| 1110043 | 3/18/2021 | FL | 49 | M | 3/16/2021 | 3/16/2021 | 11:06 am Experience syncope episodes after receiving vaccine. Vital signs BP 102/55, HR 65. Sweaty and dizzy (afraid of needles). BP 127/75, HR 73, O2 sat 99 RA Accucheck 103. Client request to go home w/ spouse. Cleared by EMT. |
| 1110071 | 3/18/2021 | FL | 49 | M | 3/17/2021 | 3/17/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: loss of color, unresponsive, sweating. epipen given. ems evaluated and determined stress rxn and sent home. - Medium, Systemic: Flushed / Sweating-Medium |

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| 1110074 | 3/18/2021 | NJ | 30 | M | 3/17/2021 | 3/17/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Additional Details: Patient was very nervous about getting covid vaccination. Shortly after patient recieved covid vaccine, he sat in the chair of waiting area. He got up from chair after a few mins to try to notify someone he was not feeling well and subsequently started to fall to the ground. Rx technician caught his fall and brought him safely to the ground where he laid. he was unconscious for a 15 seconds and regained consciousness. 911 was called and paramedics subsequently came, bp was ok after |
| 1110078 | 3/18/2021 | TX | 71 | F | 3/17/2021 | 3/17/2021 | Systemic: Allergic: Anaphylaxis-Severe, Systemic: Allergic: Difficulty Breathing-Severe, Systemic: Confusion-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Shakiness-Severe, Systemic: Weakness-Medium |
| 1110082 | 3/18/2021 | CA | 26 | F | 3/17/2021 | 3/17/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Hypotension-Mild |
| 1110093 | 3/18/2021 | TX | 31 | M | 3/17/2021 | 3/17/2021 | Patient received Pfizer vaccine on 3/18/21. Approximately 15 minutes after administration he fainted. Aid was rendered and he recovered quickly. Vitals were checked, and ice pack given. 911 was called and patient left with paramedics. |
| 1110716 | 3/18/2021 | NY | 47 | M | 3/18/2021 | 3/18/2021 | Pt. was monitored for 15 minutes after receiving the first dose of the COVID-19 vaccine, Pfizer. Complained of chest discomfort, tightness, diaphoresis, and syncope when attempting to stand. HR was 166 at initial presentation, BP was 117/75, SPO2 98% on room air, R 18 equal and unlabored. |

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| 1110290 | 3/18/2021 | IL | 63 | M | 3/12/2021 | 3/17/2021 | 3/17/21 63 y.o. male who presents with sudden onset of chest pain and palpitations, which occurred while patient was exerting himself. Pain is substernal, radiated to the left arm, associated with lightheadedness. Denies diaphoresis or nausea. Per EMS there were short runs of nonsustained ventricular tachycardia 3/18: - remains inpatient admission as of 3/18/21 @ 0900 63 y.o. male with a past medical history of nonsustained ventricular tachycardia. He states he was lifting a couch yesterday and his heart started beating fast. He did not really have any chest pain, but felt a little bit lightheaded. He called an ambulance and they brought into the ER. In the emergency room his EKG did show some frequent PVCs. However, he did not really require any intervention. He was given 3 nitro, but it really did not make any difference in the way he was feeling. The patient denies multiple times that he actually had chest pain. He states he just felt like his heart was beating funny. The patient's most recent stress test was a nuclear stress test in May of 2019. Overnight, the patient has felt very well. He denies any significant chest pain. He denies any further heart palpitations. On the monitor he would occasionally going to bigeminy, which is not abnormal for him. EKG this morning was unremarkable. After speaking with the patient's wife, she told me that he has had a several month history of very limited exertion. She states every time he exerts he becomes extremely dyspneic and has heart palpitations and sometimes almost passes out. She states last night he was extremely diaphoretic and very nearly passed out. |
| 1110342 | 3/18/2021 | NE | 20 | F | 3/17/2021 | 3/17/2021 | Patient felt flushed after vaccine, then started to have increased heart rate and dizziness. patient passed out for an estimate of 15-20 seconds. Patient was sweating. Patient came to and started to feel better. Gave water, after a few minutes patient denied shortness of breath, dizziness, or racing heart. Had patient walk hallways and denied any symptoms after and during walk. No dizziness. Patient did not fall and was assisted to chair by RN before patient passed out for 15-20 seconds. |
| 1110433 | 3/18/2021 | IN | 46 | F | 3/18/2021 | 3/18/2021 | Patient fainted due to an anxiety attack after receiving her 1st covid immunization. An ambulance was called and she was taken to the hospital. |

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| 1110477 | 3/18/2021 | MN | 26 | F | 3/17/2021 | 3/18/2021 | Developed a sore arm around 10pm, woke up with severe 7/10 body aches that quickly worsened leading to almost fainting, and sick to stomach along with mild headache. |
| 1110481 | 3/18/2021 | VA | 70 | F | 3/16/2021 | 3/16/2021 | Can not lift my arm as of 3/18 and excruciating pain nite of 16 and 17 . Extra strength Tylenol did not phase pain. Pain eased up on 3/18 but still minimum movement. Chills on 16 ,17. Fainted on 3/17 at 3:30 a.m. when I went to get a drink of water. |
| 1110574 | 3/18/2021 | CO | 30 | F | 3/13/2021 | 3/14/2021 | She says she had her second dose of the COVID vaccine on Saturday 3/13/2021 and she woke up that night around 1 am with lots of pain in her armpit and neck with dizziness. Before she could go sit down she passed out. She later woke up on the floor, got up and threw up. Since then her neck and shoulders area has been more tense and tight than normal. She says that other than muscle tension she feels "back to normal" now (three days later). |
| 1110674 | 3/18/2021 | PA | 83 | F | 1/22/2021 | 1/23/2021 | I don't have all the info you want, but my Mother In Law, who resides at this senior assisted living center, had falls the day after her Moderna first and Moderna 2nd vaccine. Each landed her in the ER, suspected fainting episode. Lots of testing done, bruised eye and forehead each time. It may be noteworthy to report that she contracted covid 19 dec 30, about 3 wks prior to the first dose of vaccine. |
| 1110710 | 3/18/2021 | NE | 67 | F | 2/27/2021 | 2/27/2021 | About 12hours after the vaccination I had a 101.3 fever (normally 98.1) Body aches; when I got up about 9am the next morning I was dizzy and then fainted. The fever persisted until mid afternoon that day, as did the body aches, and a headache. I spent the day dozing or sleeping. I did eat some oatmeal and have a cup of black coffee about noon. That helped the headache. That evening I was more tired than usual, but no fever or aches. The next day I was also very tired, but I did go to work. The rest of the week I had no energy, but that was the only other side effect. After the first shot, I had only had an achy arm at the injection site that persisted for 2 or 3 days. |

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| 1110080 | 3/18/2021 | CA | 35 | M | 3/17/2021 | 3/17/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Additional Details: Pt last intake was 8pm, 3/16/21, felt lightheaded, dizzy, thirsty post injection. Pt fainted, but quickly recovered. 911 called. O2 saturation=92 then went up to 98 to 99 to 100. Blood pressure=134/100 initially then 107/80. Pulse=88-90 |
| 1112723 | 3/18/2021 | ME | 24 | F | 3/18/2021 | 3/18/2021 | Patient fainted after immunization. |
| 1112481 | 3/18/2021 | PA | 48 | F | 3/11/2021 | 3/11/2021 | within about 10 minutes of receiving the vaccine my lips began to tingle and then my throat felt like it was closing. I was given 50 mg of Benadryl by injection and then began developing hives. Another 25 mg of Benadryl was given. I became dizzy and nauseous and when i stood up, the room went black and I passed out. I was then transported to the ER by ambulance. |
| 1112504 | 3/18/2021 | MN | 61 | M | 3/18/2021 | 3/18/2021 | Had suddenly didn't feel good. Passed out was out for five minutes, Had a strange reaction when he came to, His vision was blurred, he has vomited 6-7 times. I contacted the pharmacy where the shot was given and the clinic. He refused to go to E R The have taken notes to this. He sat in his recliner and took a nap. Took temp he does not have a fever. If his symptoms get worse I will call for ambulance. |
| 1112556 | 3/18/2021 | CA | 70 | F | 3/17/2021 | 3/18/2021 | Today I started to have a bad stomach ache and thought I was having indigestion. Then I had loose bowels. This continued and got worse. This started around 11 a.m. Around 3 p.m. I felt dizzy and faint and nearly passed out. I was very weak. I had to lie down. I still feel weak and dizzy and it is now 4 pm but I feel a little better. My stomach is still gurgling |
| 1112558 | 3/18/2021 | CA | 73 | F | 3/17/2021 | 3/17/2021 | I saw the buildings around me tilt as I walked away from vaccination site, 3 minutes after waiting 15 minutes. I called out to people near me that I was fainting, so they grabbed my arm. I supported myself on the building, which was 3 feet away. The sensation of a tipsy world left immediately. But they still called a nurse, who wheeled me in to the vaccination site to take vital signs. |

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| 1112581 | 3/18/2021 | | 55 | F | 3/7/2021 | 3/7/2021 | elevated bp, increased heart rate, dehydration, dizziness, fainting, lasting 2 hours, over 3rd and 4th hours after fluids given and rest symptoms went away |
| 1112608 | 3/18/2021 | IN | 48 | M | 3/17/2021 | 3/17/2021 | Received vaccine, proceeded to observation area, while setting there started reading the material regarding the product, started to feel lightheaded got up to alert someone and fainted. Lowered to the floor, HR 78, 98% O2, BP 118/80. At 4:09 BP 116/82 sat patient up and gave water. HR and O2 remained the same. after 15 minutes stood patient up. After a few minutes had patient walk around supervised for 5-10 minutes. |
| 1112640 | 3/18/2021 | WA | 37 | M | 3/18/2021 | 3/18/2021 | Patient fainted out of the chair he was waiting in after receiving his COVID shot 10 minutes prior. A shopper alerted our staff and when I came to check on him, he was just rousing but had his eyes closed due to blurred vision. He was able to speak and look directly at me. He said this reaction had never happened to him before. He seemed jittery probably due to the reaction. Asked for water and was able to drink. He said that he most likely hit his head and compressed his finger during the fall but feels okay. We are not sure how long he was out for. |
| 1112462 | 3/18/2021 | IA | 21 | F | 3/18/2021 | 3/18/2021 | Patient had COVID vaccine. Exited vac room & sat in waiting chair by her mother. A few minutes later came out of the vaccine room to let mother know it was her turn for vaccine. Mother said patient was going to pass out. the mother supported the patient as she passed out & they slid down to the floor. yelled for the pharmacist & called 911. Got her feet up, cold packs to cool & water. EMTs came, bp ok, sugars ok. Denied ambulance. Rested then left with mother. |

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| 1112695 | 3/18/2021 | CA | 40 | F | 3/18/2021 | 3/18/2021 | Patient is a 40 y.o. female who received the Pfizer-BioNtech Covid-19 Vaccine, mRNA, BNT162b2 (PF) 30 mcg/0.3 mL IM Susp, Lot ER2813 on 3/18/2021. The patient experienced the following reaction(s) during the immediate of observation: Pt notified staff of feeling faint. Site Lead attended to pt before pt fainted. Patient was treated/managed as follows: At approx. 2:50pm pt was given ice pack and gatorade. VS BP 86/50, HR 92, RR 20, O2 sat 97% on room air. Pt taken to treatment area and laid down on mat with legs raised. 3pm VS BP 122/81, HR 85, RR 18, O2 sat 99% on room air. EMT called. 3:20pm EMT arrived. Pt refused hospital transfer for further evaluation. Patient reports feeling better. Patient given educational material regarding vaccine and advised to continue to self-monitor per the CDC guidance. 3:45pm Pt escorted to car by RN |
| 1342171 | 3/18/2021 | | 43 | M | 3/17/2021 | 3/17/2021 | Narrative: Within minutes of J&J vaccine patient's BP dropped to 60/30 and he then passed out. Patient was arousable but BP remained low -- Was transported to local ER via ambulance for evaluation. |
| 1112760 | 3/18/2021 | NJ | 61 | M | 3/16/2021 | 3/17/2021 | Maderna Covid Vaccine 2nd dose Extreme chills that night, got up to go the bathroom,, had sweats and suddenly felt very dizzy and fainted on the bathroom floor. Felt very weak and couldn't get off the floor. Had a fever of 101.6, Wife had to help me get up after some time on the floor. |
| 1112804 | 3/18/2021 | CO | 38 | M | 3/17/2021 | 3/17/2021 | About 5 minutes after receiving the Moderna COVID-19 vaccine, patient reported feeling light-headed; as staff approached, pt. was sitting down and fainted in a chair in the lobby. No fall or physical harm occurred as the patient was sitting. He regained consciousness within 10-15 seconds, and reported feeling nauseated. Pt. supervised by pharmacy staff, and offered water and crackers as tolerated. Pt. able to leave after resting for about 30 minutes. |

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| 1112813 | 3/18/2021 | IL | 68 | M | 2/5/2021 | 2/8/2021 | Lyme symptoms, which had been dormant for 5+ years, began in earnest. Pain, fatigue. Unable to work a full day (he is still working full time). As days progressed the pain worsened as well as the fatigue. After the second vaccine (booster) he became lightheaded and dizzy. Passed out at least once. Needed help with shower. Dizziness comes and goes, but is active more than inactive. Appetite is small. |
| 1113599 | 3/18/2021 | KY | 20 | F | 3/18/2021 | 3/18/2021 | trouble breathing and weakness 5 minutes following vaccine, fainted shortly after symptoms appeared |
| 1111663 | 3/18/2021 | FL | 68 | F | 3/4/2021 | 3/4/2021 | Within 30-minutes of vaccination, the patient reported sudden onset dizziness when they stood up and near-syncope. EMS evaluated the patient on-site. The patient was hypertensive (171/92). EKG performed by EMS demonstrated sinus brady, rate 58bpm, No ST elevation. FSBG: 71mg/dL. EMS administered IV fluids. EMS transported the patient to Hospital Emergency Department. In the ED, the patient remained hypertensive (159/82). Pertinent lab tests were EKG: NSR, No ST-T changes, no ectopy, normal PR & QRS intervals and CMP/CBC/UA: Unremarkable. During evaluation the patient reported feeling improved and was discharged with diagnoses of dizziness and hypertension. |
| 1350046 | 3/18/2021 | | 85 | M | 3/13/2021 | 3/14/2021 | Narrative: VETERAN REPORTED THAT HE LOST CONTROL OF BLADDER, HAD SHAKING AND TREMORS IN HANDS LEGS AND BODY. FELT LIKE HE HAD SYNCOPE. LOST ALL STRENGTH. FELL WHEN TRYING TO PICK UP THINGS. COULDN'T GET BACK UP. HAD HA/FATIGUE AND MUSCLE ACHES. TEMPERATURE, GIVEN APAP. DRANK GATORADE. TEMP WAS 101.6, BP 141/68 AT 6AM. |

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| 1111985 | 3/18/2021 | NY | 51 | F | 3/17/2021 | 3/17/2021 | 20 min after vaccine , tingling in the mouth and throat . She stated she could not swallow. redness and swelling noted during examination BP 135/87 O2sat 99% RR16 P80 Reg rhythm. Benadryl 25mg given, Tingling sensation improved. After a couple of minutes, she complained of light headedness and felt warm from head to face. Repeat BP 124/87 HR80 RR16 O2 sat 99%.. Advised to go to Hospital but refused. She verbalized that she was very anxious to go to the Hospital. She agrees to call 911 for difficulty breathing,, severe dizziness, syncope and severe rash. she left site with son and friend |
| 1353793 | 3/18/2021 | | 72 | M | 2/18/2021 | 2/19/2021 | difficulty swallowing Narrative: He reports PMH significant for "throat cancer" s/p radiation. At baseline, he reports occasional difficulty swallowing large pills and consumes food with liquid to a/w swallowing. About a day after the initial vaccination, Patient reported difficulty swallowing large pills. This concern lasted less than another day before spontaneous resolving (which is typical for him). He did not think to report it to his healthcare team previously b/c this has occurred in the past. He denied pruritus (except minimally over injection site), urticaria/hives, flushing, swelling/angioedema, difficulty swallowing, confusion/disorientation, lightheadedness/dizziness, weakness, LOC/syncope, SOB, stridor/wheezing, tachycardia/palpitations, nausea/vomiting/diarrhea or abdominal cramping. He was able to complete his normal activities of daily living w/o any issues and able to additionally eat/drink w/o any disruption. |

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| 1112671 | 3/18/2021 | GA | 24 | F | 3/18/2021 | 3/18/2021 | Patient came to the center for a Moderna vaccine at 5pm. The patient expressed that she felt dizzy shortly after immunization (before leaving the immunization chair). Her head began to fall backwards so I quickly supported the patient's head and neck area and was able to keep her from falling out of her chair. The patient fainted but regained consciousness approximately 3 seconds later. The patient came back alert but nauseous. The patient vomited in a trashcan and then felt fine. The patient blamed the reaction on her severe anxiety and said the exact same thing happened after a nose piercing. I observed the patient for 30 minutes and sent her on her way. The patient left healthy and happy. I told the patient to warn the pharmacist prior to receiving her second dose. No drugs were administered. Written up in SCRT and VAERS. I followed up with the patient at 7 pm and she was home safe. |
| 1111865 | 3/18/2021 | KS | 69 | F | 3/15/2021 | 3/16/2021 | Client reports she started to feel "off" just before bed on the day of the vaccination. She felt tired and "not well" all day the day following the vaccination then at 1030pm on the 16th she passed out while sitting at the table. She was unconscious for 1-2 minutes and began vomiting when she came to. Her husband called the ambulance and she was transported to the County Hospital. ER provider told Client that it was a reaction to the vaccination. |

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| 1353789 | 3/18/2021 | | 45 | M | 2/18/2021 | 2/18/2021 | Narrative: He states experiencing mild disorientation/fog and mild dizziness ~ 20 minutes at the initial vaccination. While he was still oriented to person/place/time, he states having difficulty in trying to find his car (no issues reported during the 15 minute waiting period). Both concerns resolved w/in 5 minutes spontaneously. He had not had a prior similar reaction to a past vaccination. Denied pruritus (other than over injection area), urticaria/hives, flushing, swelling/angioedema, lightheadedness, weakness/difficulty ambulating, syncope/LOC, SOB/dyspnea, tachycardia/palpitations, nausea/vomiting/diarrhea, abdominal cramping. He has no allergies that he is aware of and was able to work afterwards. RN reviewed common adverse effects and when to seek care. Advised 30 minutes of supervised post-vaccination wait time. Reinforced to alert staff if he experiences any of the adverse effects we discussed related to concerns for immediate allergic reaction. Patients intention is to return to work today (works with health care professional). He was checked on during/at the end of the observation period and reported no issues. |
| 1112449 | 3/18/2021 | NY | 34 | M | 3/18/2021 | 3/18/2021 | Pt felt light headed and passed out for approx. 30 seconds |
| 1111864 | 3/18/2021 | | 70 | F | 3/9/2021 | 3/9/2021 | Symptoms began 2 hours after dose, including headaches, myalgias, and lower extremity weakness. Tried Tylenol with no relief. Symptoms progressively worsening. Fell and hit head the following day, denied loss of consciousness. Never had a reaction to vaccine before. No response to first dose. No lightheadedness/presyncope prior to falls. Came to ED after fall (evening of the day after receiving the vaccine). Found to have elevated troponin. CK elevated, aggressive fluid repletion initiated, determined to be in rhabdomyolysis. Hypokalemic. Patient improved with fluids and electrolytes, determined to be stable for discharge after 2 days. |

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| 1111918 | 3/18/2021 | FL | 30 | F | 3/12/2021 | 3/12/2021 | Within 15-minutes of vaccination, the patient had a syncopal event preceded by nausea and lightheadedness. EMS evaluated the patient on-site. The patient was pale, diaphoretic, and hypotensive (67/37). EKG (3/12): Sinus brady, rate 46 bpm, no ST elevation. FSBG (3/12): 89mg/dl. EMS administered 500mL IV saline. EMS transported the patient to Hospital Emergency Department. In the ED, the patient feels back at baseline and was normotensive (119/72). Patient stated they have a history of vasovagal response and vasovagal vomiting, but had never experienced a vasovagal syncope episode. Physician administered 0.5mg Lorazepam. The ED physician admitted the patient to the telemetry unit for vasovagal syncope due to patient's prodrome and prior history of similar near syncopal episodes. Inpatient attending agreed that the patient's vasovagal response may be secondary to poor PO intake with extreme stress. Patient's admission was less than 1-day and stated they were anxious to return home. Discharged with diagnoses of Mild leukocytosis, Vasovagal response, and Orthostatic hypotension secondary to dehydration. |
| 1111978 | 3/18/2021 | NM | 59 | F | 3/3/2021 | 3/3/2021 | Shortly after I got home, within the hour; My husband told me when I got home I started acting loopy. by 5pm - it was if I was drunk, hallucinating and talking jibberish. By 6pm I passed out but restless - no fever but knocked me out for over 10.5 hours (I normally sleep 6 hrs a night). Woke up the next morning with no other reaction but a sore arm. |
| 1112037 | 3/18/2021 | TN | 28 | M | 3/18/2021 | 3/18/2021 | Patient was given the immunization and as I was talking to him after the immunization he told me his palms were sweaty and he wasn't feeling well. His pupils got large and he then passed out. Code white was called, 911 was called, we got an ice pack and placed on his chest and a cold rag on his head. After about 10 seconds, he regained alertness. EMT arrived and accessed the patient. His blood pressure was normal and pulse was normal. He was given a cold drink and sat in the chair until he felt better. |
| 1112171 | 3/18/2021 | OH | 64 | F | 3/16/2021 | 3/17/2021 | I was not feeling quite right and I fainted after getting up in the morning. |

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| 1112184 | 3/18/2021 | OH | 46 | M | 3/18/2021 | 3/18/2021 | pt had adverse rxn after his covid vac. he told me he felt hot, and his heart was racing. had him put his feet up, and take off his coat. we took bp @1pm=156/98, 1:08=150/96, 1:16 158/109, 1:30 139/92, 142Pm 134/91. We gave him benadryl 15 mls at 1:05pm. I gave him 3 benadryl 25mg for tonight if needed same with 3 ibuprofen 400 mg tablets. I called him at 2:20 pm to see if he got home okay. he did and was feeling better. he takes diabetic medication but doesn't know the names of the medications. he had eaten breakfast before his vaccine. dx syncope. |
| 1112267 | 3/18/2021 | CT | 28 | F | 2/13/2021 | 2/13/2021 | Syncope: 15 min period of unconsciousness while standing in shower. Did not realize that she sustained head trauma 2nd episode of loss of consciousness for 10 min Nausea & severe headache. Seen at Urgent Care on 2/15/21. Practitioner performed scans and x rays. Made diagnosis of cerebral concussion. Patient also reported sustaining fracture to incisor which was repaired by a dental practitioner |
| 1112191 | 3/18/2021 | MO | 51 | M | 3/18/2021 | 3/18/2021 | PATIENT FAINTED. EMS CALLED. PATIENT ASSESSED UNTIL EMS ARRIVAL. PATIENT VITAL SIGNS TAKEN AND ARE AS FOLLOWS; PATIENT ALERT AND ORIENTED, PULSE 82, BLOOD PRESSURE 98/62, RESPIRATION 18, SP02 97%. PATIENT LEFT UNDER CARE OF EMS. |
| 1112225 | 3/18/2021 | NC | 47 | F | 3/9/2021 | 3/9/2021 | Within 3 or 4 minutes I receiving the vaccine, I fainted. Then I was very weak and broke out in a sweat. I was unable to drive for two hours. I had a dull headache for 6 hours. |

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| 1112230 | 3/18/2021 | MD | 21 | F | 1/8/2021 | 1/8/2021 | Immediately, I had increased heart rate - 194 - I fainted to the ground. I became nauseous, sick and had seizure like episode and then I had tingling sensation in my face and limbs. They gave me shot epi-pen - two doses. I was pretty much paralyzed for hands and legs. I was brought to hospital and they treated me there for about a week and I had muscle weakness. I gained feeling back in my hands but not in my feet. I was at Haywood for a week. Outpatient therapy and a visiting nurse for three weeks. B12; Iron; Gabapentin and that was for anxiety through it all. Test results came up as neuropathy on left side of my body. I have pins and needles pain now. I did gain my walking back. I take Gabapentin for neuropathy pain. I went to hospital - went one day and I didn't get anything back from them. I now use handicap parking for disability. |
| 1112395 | 3/18/2021 | IN | 46 | M | 3/18/2021 | 3/18/2021 | Patient fainted, laid patient down immediately -HR 46, Oxygen 99%, Blood Pressure 100/70 at 11:46 continued to monitor 11:48 HR 48, BP 110/80, O2- 98% 11:51 HR 51, BP 100/70, O2- 99% 11:56 patient sat up and drank some water, HR 54, BP 122/80, O2-99% 12:08 HR 45, BP 116/76, O2-99% patient waited and felt better. Wheeled to car and wife drove him home. |
| 1112250 | 3/18/2021 | TX | 59 | M | 3/18/2021 | 3/18/2021 | lightheaded, nausea; B/P- 160-97, P-58, pulse ox- 96%. Client reports history of diabetes, took med this morning but had not eaten lunch. Client also past history of fainting with blood draws and injections |
| 1112254 | 3/18/2021 | NY | 75 | F | 3/16/2021 | 3/17/2021 | I woke up at 3am. Could not get back to sleep for 2 hours, so decided to drink some liqueur (Kahlua). Because I very rarely drink alcohol, a little bit makes me sleepy. After about 4 sips, I broke into a cold sweat, could barely manage to stand up and call out to my husband. I then lost consciousness (and wet myself). (My husband caught me). I have never fainted or passed out in my entire life! I regained consciousness about 2 minutes later and then had the shakes for quite a while. For the next day and a half I felt as if a truck had run over me. |

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| 1111822 | 3/18/2021 | OH | 52 | F | 1/27/2021 | 1/27/2021 | I received the second dose of the Moderna COVID-19 vaccine on 1/27/21 at 07:30 a.m.. Around 11:30 p.m. I developed a throbbing headache, chills, and severe muscle and joint pain. Throughout the night I developed dizziness, crushing chest pain and my left ear felt plugged. In the morning, I was up walking and started to not feel right due to the dizziness and fainted. After 6 days of feeling this way, I contacted my PCP and had a virtual visit. I was given a step down dose of Prednisone and a medication for the dizziness. My PCP advised me that I needed to report my reaction to this vaccine to the CDC. I contacted my Manager and also had to contact the nurse here. |
| 1112288 | 3/18/2021 | TX | 45 | M | 3/18/2021 | 3/18/2021 | Lightheaded, shaky; B/P-135/78, P- 78, pulse ox- 95%; cleared by onsite nursing supervisor Client reports past history of fainting with blood draws |
| 1112189 | 3/18/2021 | | 60 | F | 3/16/2021 | 3/17/2021 | The day after her vaccine patient went to the bathroom and passed out. EMS came, but she started to feel better and did not go to the hospital. |
| 1108363 | 3/17/2021 | TX | 64 | F | 1/2/2021 | 1/2/2021 | 11AM Called to assess patient reports pre syncope in post vaccine observation area. Patient is stating that she is "lightheaded" BP 122/70, pulse 83, RR 16, provided with Sprite and pretzels as patient states that "this has happened before after an injection." Presyncope resolved in 10 minutes and released. Instructed patient to contact provider for follow up. Patient verbalized understanding and dismissed at 11:50AM |
| 1108357 | 3/17/2021 | UT | 68 | M | 3/11/2021 | 3/12/2021 | Very sick, sore everything, diarrhea, couldn't wake up, fainted and couldn't get up. Was out for a half hour or so. Twisted ankle and lower leg in fall. |
| 1108323 | 3/17/2021 | CO | 86 | F | 2/26/2021 | 2/27/2021 | Presents to ED the day after 2nd covid vaccine with syncope,general weakness, nausea, headache, vomiting. Admitted for 2 days for syncope workup. Improved with IV fluids. d/c'd home in stable condition. |

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| 1108238 | 3/17/2021 | MO | 63 | M | 3/4/2021 | 3/5/2021 | Patient wife called clinic at 1156 am. Patient lethargic, too weak to stand or walk, dry heaves. Advised to call 911 and take to ER. Called patient 3/17 for details. States on 3/4/21 in the evening, he developed HA, chills, and body aches. 3/5/21 took a shower and became light-headed, near-syncope or syncopal episode reported by patient. Wife gave him a Zofran ODT, which relieved the dry heaves. He rested remainder of day. Felt mostly better by 3/7/21, with remaining fatigue until 3/9/21. |
| 1108430 | 3/17/2021 | TX | 60 | F | 3/16/2021 | 3/17/2021 | Hot Flash with Sweats, Followed by fainting, Non-responsive, Elevated blood pressure |
| 1108163 | 3/17/2021 | FL | 32 | F | 3/14/2021 | 3/15/2021 | On the night of Monday 15, I started to have a fever over 102.2 degrees. Took Ibuprofen for the fever. At 3:00 AM of the same day started to feel weak. On that moment I lost consciousness and passed out. In my opinion, I experienced a down on sugar, which had never happened before. My husband was able to catch me and sat me on the floor. A minute after I recovered and my husband gave me fruit (Melon) to raise my blood sugar. On that moment I had lots of nauseas and diarrhea. I was feeling weak and dizzy all night and the next day. Today Wednesday March the 17 I have been feeling much better. |
| 1108162 | 3/17/2021 | WI | 31 | F | 3/12/2021 | 3/12/2021 | Moderna COVID-19 Vaccine EUA. Client was vaccinated and proceeded to the monitoring area. Several minutes after sitting down in the monitoring area, she passed out and fell onto the floor. The client responded immediately after being repositioned. She was very pale and stated that she was having her menses. She received juice and water. Her vital were taken--BP 124/70, pulse in the 70s, pulse oximeter was 100%, no elevated temperature. EMS was called and arrived within 3 minutes of being called, before a second set of vitals could be taken. |
| 1108244 | 3/17/2021 | VA | 31 | M | 3/11/2021 | 3/11/2021 | immediate syncope, hypotension, and bradycardia after vaccine. refused hospital transfer resolved with observation |
| 1108374 | 3/17/2021 | MA | 91 | F | 3/9/2021 | 3/10/2021 | She found passed out on the floor by a friend. The ambulance was called. She was hospitalized for 24 hours and treated for dehydration. She had fever and diarrhea. |

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| 1108386 | 3/17/2021 | NV | 59 | F | 3/16/2021 | 3/16/2021 | After the injection the patient grabbed her arm and when she was asked if she was ok she didn't respond and seemed slouched down. It didn't seem like she passed out but she was slouching and not responding. She seemed like she was having convulsion that lasted less than 5 seconds. Then she calmed down and her breathing was fine. I got her to respond to me that she was awake and ok. She responded with head nods. She seemed to come to a little more after a minute and she said she was fine but I wanted to call 911. I called the paramedics. During the wait she seemed to get better, we gave her water and she was slowing starting to move around more. We asked her about any under lying issues or any problems with any vaccine before. She said no to everything. The paramedics came and took all of her vitals and she was cleared that everything was ok. She called her boyfriend and we asked him to come by to help her and give her a ride home and assist. He got here and she still didn't feel totally better. After a few more minutes I took her blood pressure and it was 87/55 and her pulse was around 60. We called 911 again because she stated she wasn't feeling well again. The paramedics came back and she had a 89/41 blood pressure with a pulse of 40. They indicated that she may be having a cardiac issue so they took her to the ER. |
| 1108406 | 3/17/2021 | LA | 26 | F | 3/17/2021 | 3/17/2021 | The patient sat for about 5 minutes after receiving the vaccine then told a tech that she did not feel good. By the time I got to her she, was passed out. We put paper towels on her neck and fanned her but that didn't work so we gave an EpiPen. She started feeling better for a few mintues then passed out again. We called 911 and by the time they got here, she was alert and talking. They brought her to ER |

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| 1108431 | 3/17/2021 | CA | 43 | F | 2/11/2021 | 2/11/2021 | After the first injection, I noticed mild mouth tingling, but nothing else, did not report as it was so mild and it was more notable in retrospect. A week after the first injection developed vertigo for the first time in my life. This lasted about a week had mostly resolved when I got the second dose. Immediately upon receiving the second dose I felt faint. I went to the observation area and when the feeling got stronger, reported it. My blood pressure was taken and although I always have normal blood pressure, it was extremely high - 195/100. My heart was racing. I was observed for longer because of this, and was asked to lie down. The faint feeling and high blood pressure lasted 30 min, at which time it started to improve and was sent home. I persisted in having bouts of feeling faint (but never fainting) in the days and weeks following, joined with shortness of breath which started the second day after the second injection. I also had the normal fever, aches and pains for 4 days. It is now a month after the second injection, and while the faintness and vertigo are mostly gone, I have persistent shortness of breath. Prior to the vaccine I had an albuterol inhaler that I would use 1-5 times a year for allergies. Almost never used it. I began having to use it multiple times daily after the second dose of the vaccine. I am not on a steroid inhaler. I have never had shortness of breath like this before. I was examined at the doctors office, not much can be seen that is wrong. An allergist believes that I did not have an allergy because my blood pressure was high instead of low as in anaphylaxis. |
| 1108137 | 3/17/2021 | NJ | 28 | M | 3/16/2021 | 3/17/2021 | Roughly 8 hours post vaccination, patient fainted spontaneously. |
| 1107549 | 3/17/2021 | FL | 57 | F | 3/5/2021 | 3/5/2021 | Patient complained of dizziness, abdominal pain, nausea, and near syncope. |
| 1108454 | 3/17/2021 | TN | 19 | F | 3/15/2021 | 3/17/2021 | Sudden syncope - under one minute |

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| 1107189 | 3/17/2021 | FL | | F | 2/23/2021 | 2/23/2021 | Tired; Passed out, was semi-unresponsive; Vein was hit on vaccination; Arm blew up after the shot (swelled); Arm was still back and blue; Extreme weakness; Wanted to sleep/slept for 24 hours/slept the rest of the day; A spontaneous report was received from a consumer, concerning herself, a 71-year-old female patient, who received Moderna's COVID-19 Vaccine (mRNA-1273) and was passed out, was semi-unresponsive; vein was hit on vaccination; arm blew up after the shot (swelled); arm was still back and blue; extreme weakness; wanted to sleep/slept for 24 hours/slept the rest of the day and tired.~ The patient's medical history includes leukemia ongoing since on an unspecified date and was not being treated. Concomitant medications were not reported. On 23-Feb-2021, prior to onset of events, the patient received their second of two planned doses of mRNA-1273 injection, (Lot/Batch number: 001A21A) intramuscularly in their left arm for prophylaxis of COVID-19 infection. On 23-Feb-2021, after the second dose of vaccine, the patient's arm blew up (swelled) and passed out, duration unknown, followed by less responsive with extreme weakness and sleepiness. Patient was sent to the ER (Emergency Room) where she was administered with fluids and anti-nausea medication and was released. Patient also informed that her vein was hit during the vaccination. Patient slept for 24 hours. On 24-Feb-2021, she was only awake for five hours. She again slept the rest of the day. At the time of this report, patient's arm was still back and blue, and was still tired but she was also much improved and is staying hydrated. Action taken with mRNA-1273 in response to the events were not applicable. The outcome for the event, arm was still back, and blue was considered not resolved at the time of this report. The outcome for event tired was resolving at the time of this report. The outcome for events, passed out, was semi-unresponsive; vein was hit on vaccination; arm blew up after the shot (swelled); extreme weakness; wanted to sleep/slept for 24 hours/slept the rest of the day were resolved on 23-Feb-2021.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. |

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| 1108390 | 3/17/2021 | TX | 36 | F | 1/2/2021 | 1/2/2021 | 10:29AM Pt reports pre syncope in post vaccine observation area. Patient is 33 6/7 gestation and states that she ate about 2-3 hours prior to this vaccine administration. BP 115/80 HR 93, RR 16. Patient given room temperature Sprite and pretzels as she states that she was slightly nauseous. Nausea resolved within 10 minutes. Patient states that she feels well. Instructed her to contact her OB/Gyn and also advised to register for Moderna Pregnancy Registry. Patient verbalizes understanding. Dismissed at 1050AM |
| 1107446 | 3/17/2021 | NY | 19 | F | 3/11/2021 | 3/11/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Additional Details: she fainted shortly after administration. when i went back to her..she was conscience and breathing ok. She felt like it was typical to what she experiences with vaccines and did not blame the vaccine at all. She was responsive and did not seek additional help. she refused an ambulance. she had a friend pick her up so she didnt have to drive home. |
| 1108654 | 3/17/2021 | KY | 43 | F | 3/15/2021 | 3/16/2021 | Patient experienced a fever within 24 hours of second Moderna dose. Temperature was 103. Patient passed out and was taken the ER by ambulance on 3-16-2021. The ER kept this patient until fever subsided at about 12 midnight on 3-16-2021. |
| 1108462 | 3/17/2021 | NV | 73 | F | 2/12/2021 | 3/12/2021 | passed out VOMITING DIDN'T TAKE TYLENOL couldn't open mouth PRESSURE TOP OF HEAD |

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| 1107192 | 3/17/2021 | CA | 71 | M | 2/15/2021 | | fainting spells or passing out; severe stomach pain, abdominal pain; nausea; Swollen lymph nodes in three places like a triangle; low blood pressure with faint pulse; faint heart beat or rate with flutters; lightheadedness; blurry vision; right ear ache; face flush or red face; burning sensation on his hands; red rash on under arm; HEART FLUTTER; A spontaneous report was received from a Consumer concerning himself as a 72 Years-old male elder patient who experienced severe stomach pain, nausea, abdominal pain, swollen lymph node in three places like a triangle, low blood pressure with a faint pulse, faint heartbeat or rate with flutters, dizziness, lightheadedness, fainting spells or passing out, blurry vision, right earaches, facial flushness or red face, burning sensation on his hand and red rash on his under arm. The patient's medical history was low glycemia and atrial arrhythmia. His concomitant medications were reported as Vitamin D31000 IU as supplement, Prevacid 30 for acid reflux prevention and Magnesium 400mg as supplement. On 15 Feb 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot/batch: 007M20A) for prophylaxis of COVID-19 infection. On an unspecified date, the patient experienced fainting spells which is medically significant and the other events are severe stomach pain, nausea, abdominal pain, swollen lymph node in three places like a triangle, low blood pressure with a faint pulse, faint heartbeat or rate with flutters, dizziness, lightheadedness, blurry vision, right earaches, facial flushness or red face, burning sensation on his hand and red rash on his under arm. No treatment information was provided. Action taken with mRNA-1273 in response to the events was Unknown. The outcome of the event(s) severe stomach pain, nausea, abdominal pain, swollen lymph node in three places like a triangle, low blood pressure with a faint pulse, faint heartbeat or rate with flutters, dizziness, lightheadedness, fainting spells or passing out, blurry vision, right earaches, facial flushness or red face, burning sensation on his hand, red rash on his under arm were Unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded. |

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| 1107204 | 3/17/2021 | NC | 68 | F | 3/1/2021 | 3/2/2021 | <p>Passed out; Sweats; Lightheaded; Fatigue; Chills; Nausea; Vomit; Headache; A spontaneous report was received from a consumer concerning herself, a 68 year old female patient who experienced passed out/loss of consciousness, sweats/hyperhidrosis, lightheadedness/dizziness, fatigue/fatigue, chills/chills, nauseas/nausea, vomit/vomiting, headache/headache. The patient's medical history was not provided. Concomitant product use was not provided. The patient received her first of two planned doses of mRNA-1273 on unknown date for prophylaxis of Covid-19 infection. On 01-Mar-2021, prior to the onset of events, the patient received the second of two planned doses of mRNA-1273 (Batch number 014M20A) intramuscularly into her left arm for prophylaxis of Covid-19 infection. On 02-Mar-2021, the patient stated she "passed out", she also experienced sweats, lightheadedness, fatigue chills, nauseas, vomit, and headache. No other treatment information was provided. The patient received both scheduled doses of mRNA-1273 prior to the events; therefore, action taken with the drug in response to the events is not applicable. The events, passed out/loss of consciousness, sweats/hyperhidrosis, lightheadedness/dizziness, fatigue/fatigue, chills/chills, nauseas/nausea, vomit/vomiting, headache/headache.was considered unknown.;</p> <p>Reporter's Comments: Based on the information provided, a strong temporal association and the established safety profile of mRNA-1273 vaccine, a causal association between the reported events and the product use cannot be excluded. Fatigue, chills vomiting, headache and nausea are consistent with the known safety profile of the vaccine</p> |

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| 1107214 | 3/17/2021 | MI | | F | 3/3/2021 | 3/3/2021 | <p>passed out; could not breath; twitching of foot; extremely cold; became warm; upset stomach; room began to spin; unusually tired; A Spontaneous report was received from a health care professional concerning an female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced unusually tired, extremely cold, became warm, upset stomach, room began to spin, could not breath, pass out, twitching foot. The patient's medical history, included cancer, prior radiation and chemotherapy and surgery. Concomitant product use included unspecified inhaler. On 03 Mar 2021, the patient received their first of two planned doses of mRNA-1273 (lot number 011az1a) intramuscularly for prophylaxis of COVID-19 infection. On 03 Mar 2021, the same day of vaccination the patient was unusually tired and slept ten hours. Next day, the patient felt extreme cold and decided to take warm bath. Then within ten minutes after the bath, patient became warm, had an upset stomach, and noted the room began to spin. The patient subsequently could not breath and passed out. The patient's husband noted the patient's foot twitching, and felt that she was still alive. Per the patient's spouse, the patient was unresponsive for one minute. Once awakened, the patient took her inhaler and Benadryl. Within 30 minutes all the symptoms were gone and have not returned. The patient noted having this same type of experience during her Sep 2020 first round of chemotherapy. The patient has been cancer free for five months. Treatment information included inhaler and Benadryl. There was no change planned to the dosing schedule of mRNA-1273 in response to the events. Patient's physician stated it was okay to take the second dose. The events unusually tired, extremely cold, became warm, upset stomach, room began to spin, could not breath, passed out, and twitching foot were considered resolved on 04 Mar 2021.; Reporter's Comments: Very limited information regarding this event/s has been provided at this time. Further information has been requested</p> |

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| 1107260 | 3/17/2021 | VA | 79 | F | 2/27/2021 | 2/28/2021 | Dizziness; feels unsteady at times; nearly passed out/totally passed out; This is a spontaneous report from a contactable consumer. A 79-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection; lot number: EN6198), via an unspecified route of administration, administered in Arm Left on 27Feb2021 as SINGLE DOSE for covid-19 immunisation. The patient's medical history was reported as none. There were no concomitant medications. It was reported that the patient received first COVID shot Saturday. She confirms the Pfizer COVID 19 Vaccine. She says 24 hours after she had the shot she nearly passed out, she got really dizzy and someone asked, are you okay, and she said no and they caught her before she totally passed out and she sat down. She is still having waves of dizziness and she feels unsteady at times, not every second but she is a little scared to drive a car. She just thought someone should know that. It was reported that dizziness began the next day on 28Feb2021 around 3pm. She closes her eyes and says she doesn't want to look at that. It is ongoing but it is not so bad after she gets up. It seems to have lessened after about 3 pm yesterday it is bothersome. She confirms it is ongoing but improved a little since it began. The outcome of the event dizziness was recovering, while unknown for the other events was unknown. |
| 1107722 | 3/17/2021 | NC | 70 | F | 3/16/2021 | 3/17/2021 | I awoke this morning feeling feverish. I walked to the kitchen to take tea and a Curamin tablet since I had run out of Advil.. I began to feel as though I was going to vomit so walked slowly to the toilet, knelt in front, then made a quarter turn,, thinking this would not happen, and I fainted/blacked out. I found myself face down in front of toilet and a good bump on my right eyebrow....face turned inward. I stayed still long enough to feel safe to rise and so did. No more sense of vomiting, thank goodness. Just very very tired. I did make oatmeal with blueberries for breakfast and ate this slowly. Just wanted to ask if this is to be expected. It is now four hours fifteen minutes since this happened. As I walk carefully , I am trusting all will be well ...but when? |

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| 1107442 | 3/17/2021 | FL | 36 | M | 3/16/2021 | 3/16/2021 | Systemic: FAINTING - LOSS OF CONSCIOUSNESS FOR A FEW SECONDS AND HIT HIS HEAD. BITTED HIS TONGUE.-Medium, Systemic: Flushed / Sweating-Medium, Additional Details: PARAMEDICS CAME. HE WAS FEELING MUCH BETTER. HE WAS RESPONSIVE. |
| 1108050 | 3/17/2021 | NY | 24 | M | 3/16/2021 | 3/16/2021 | Patient was sitting in observation area following vaccine administration when he fainted in his seat. He started sliding down and was unresponsive for a moment according to witness. Pharmacist laid patient down and raised legs, removed coats to make patient more comfortable. Patient re-gained consciousness spontaneously. As patient felt better he was made comfortable , observed longer until he felt confident to leave (refused suggestion to call for escort). Pharmacist called patient at home to make sure he was feeling good. |
| 1107657 | 3/17/2021 | NY | 22 | F | 3/15/2021 | 3/15/2021 | Pt reported to the vaccination area stating that she had a history of fainting after medical procedures, including vaccination. Was with her mom, in case she had an issue. Vaccination without incident. Kept pt at the vaccination area to observe. About three minutes after receiving the vaccination, pt started to shake. Was conversing. Stated she was warm, so got her a cold bottle of water. Stated she was dizzy so helped her to the floor to lay down. She had contractions of her hands, which she stated that they were numb. She recovered from the dizziness, but then had a panic attack. Her BP was normal, but her heart rate became elevated. Had her lay down until she felt better, helping to slow her breathing. After about 40 minutes, p t felt good enough to sit in the recovery area. Ensured she had water and some food to help prevent a blood sugar drop. |

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| 1107782 | 3/17/2021 | MI | 57 | F | 3/17/2021 | 3/17/2021 | Patient was sitting in waiting area post vaccination. A pharmacist from the vaccination area was called over to her because she was not feeling well. As the pharmacist was speaking with her patient fainted. Pharmacist was holding on to her to keep her from falling. I went over and took her BP which was 65/44, pulse 53. After a few minutes patient regained consciousness and was able to give us her information. 911 was also called. Patient reports a history of severe reaction to Penicillin. Patient reports history of syncope at eye doctor's office. Her BP was taken again at 10:20am and was 98/72, pulse 70. 911 arrived and patient chose to be taken to hospital. |
| 1107820 | 3/17/2021 | CT | 19 | M | 3/17/2021 | 3/17/2021 | A few minutes after the pt received his first dose of the Moderna COVID19 he began to feel light headed and nearly passed out. Pt was laid on cot. BP 100/60 HR 91 RR 16 O2Sat 99% . EMS called and evaluated pt. Pt reported feeling "much better." Pt signed refusal with EMS for transport to the hospital. RN called pt's mother to come pick him up. Pt was advised not to drive. Pt was given ED precautions and advised to contact his PCP. Pt was also given the contact information to have his second dose at the high risk clinic. |
| 1107927 | 3/17/2021 | VA | 67 | M | 3/12/2021 | 3/12/2021 | Member had a syncope episode/ vasovagal immediately following the vaccine administration while sitting in the chair. He immediately recovered after the episode and was AAOx3 when transferred to urgent care. |

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| 1108029 | 3/17/2021 | IN | 48 | M | 3/16/2021 | 3/16/2021 | 48-year-old male who received his Covid vaccine states that he waited the mandatory 15 minutes and actually stayed over a few extra minutes after the vaccine and felt fine got in his car and decided to attempt to drive home when he was driving he became somewhat sweaty diaphoretic and felt lightheaded states that he thought himself he should probably pull over but proceeded to continue driving for short distance until he states the last thing he remembers was thinking he needed to merge into this traffic and then the next thing he knows he woke up to the onstar representative asking if he is okay he noted that he had struck a tree when EMS arrived the patient was approximately quarter of a mile into a field and then struck a tree. The patient states he was ambulatory at the scene he was having right-sided chest wall pain especially with movement or breathing he is noted to have seatbelt sign to that side. The patient denies being on blood thinners denies any other complaints at this time. Restraints: air bag deployed, lap and shoulder. Do to the severity of his syncope, he was admitted for observation overnight. |

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| 1108042 | 3/17/2021 | OH | 59 | F | 3/16/2021 | 3/16/2021 | Patient received Janssen COVID19 vaccine (LOT#1802068) at approximately 12:00 pm on 3/16/21. During the 15 minute observation period, she expressed "I don't feel good" and endorsed nausea. Shortly thereafter at approximately 12:10 pm, she started to slouch and nearly fainted while sitting in a chair. She did not fall or hit any part of her body. She was easily aroused with a touch on her arm and responded to verbal questions within seconds (less than a minute). She denied trouble breathing or chest pain. She then reported nausea again and was offered a receptacle to vomit in if needed; however, she did not vomit. Patient was encouraged and instructed to sit on the floor to prevent injury in case of fall but she refused stating that she didn't think she would be able to get back up given her preexisting knee problems. Pharmacy staff offered her water, a fan, and opened windows. Her jacket was removed in order to monitor blood pressure/ pulse, which was not abnormal. Patient did not have any trouble breathing, rash, swelling, abdominal cramps, or mental status changes. She was contacted via phone a few hours later for follow up on the incident, at which time she denied any issues and reported feeling well. |
| 1108045 | 3/17/2021 | ID | 43 | M | 3/17/2021 | 3/17/2021 | Client observed kneeling by chair as diaphoretic. immediately post vaccine. I asked client if he would lie down to be assessed. Client fainted and fell to the floor and hit the back of his head on the floor. Called code team with immediate assistance. Supported head and neck. Vital signs consistent with fainting episode and stabilized within fifteen minutes. Transferred by EMS to hospital for evaluation of head injury. Initial assessment showed no immediate neurological deficits and no superficial bleeding at head impact location. |

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| 1107437 | 3/17/2021 | MA | 26 | F | 3/14/2021 | 3/14/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Nausea-Severe, Systemic: Vomiting-Severe, Additional Details: Patient went to sit at observation area for 15 minutes. Observer noticed pt was pale and called over pharmacists. Patient was on the verge of passing out then vomited. We put cold compress on her neck and gave her water. Patient appeared better but then voseemed like she was going to pass out again. We called 911. EMT came, patient vomited again and seemed like she was going to pass out again. EMT took patient to ER. Patient was later discharged that night. |
| 1109547 | 3/17/2021 | KS | 48 | F | 3/17/2021 | 3/17/2021 | Vaccine given at 3:14 pm, She fainted for 10 seconds then vomited twice. 3:18 pm Pulse: 60, SPO2: 96, 3:20 pm BP 88/56 Left Arm, 3:21 pm BP 87/67 Right Arm |
| 1109166 | 3/17/2021 | TX | 43 | M | 3/17/2021 | 3/17/2021 | Client lightheaded post vaccination, brief vasovagal syncope, lasting about 10 seconds. No fall or injuries, vitals stable, fully recovered in about 10 minutes time. |
| 1109342 | 3/17/2021 | TX | 34 | M | 3/17/2021 | 3/17/2021 | Reports dizziness, fainted for few minutes. history of same symptom with venipuncture. BP: 71/42; Repeat: 110/69 HR: 57 SpO2: 97% Refused to be transported to ER, refusal form signed. Seen and cleared by EMS |
| 1109368 | 3/17/2021 | MI | 37 | F | 3/1/2021 | 3/11/2021 | Shortness of breath, fainting with fall loss of consciousness, Racing heart 160s for prolonged period of time, feeling of squeezing of chest/lungs, dizziness, severe nausea, muscle pain, severe back pain. |
| 1109392 | 3/17/2021 | GA | 20 | F | 3/17/2021 | 3/17/2021 | Vaccine was administered. Within approximately 1 to 2 minutes after administration patient got very clammy, lost color in her face and passed out while sitting in the chair. Patient regained consciousness within a matter of seconds. Patient remained seated and was observed for another 30 minutes before she was allowed to leave facility. Patient did state that she has a history of fainting with vaccinations. |
| 1109453 | 3/17/2021 | NC | 50 | M | 3/17/2021 | 3/17/2021 | Syncope, clammy/sweaty/grey skin, loss of bodily function and non-responsive for 1 minute, with O2 sat dropped to 91% after event. Onset approximately 2 minutes following injection. |

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| 1109474 | 3/17/2021 | KY | 26 | F | 3/16/2021 | 3/16/2021 | Vasovagal Syncope-patient began to faint. |
| 1109159 | 3/17/2021 | MN | 27 | M | 3/17/2021 | 3/17/2021 | PATIENT COLLAPSED/FAINTED 5-10 MINUTES AFTER RECEIVING VACCINE. DID NOT FULLY GO UNRESPONSIVE, BUT WAS DAZED AND CONFUSION. WAS SHAKING, SWEATING, LIGHTHEADED, NAUSEOUS, FLUSH, AND WARM TO TOUCH. AFTER 10-15 MINUTES PATIENT FELT FINE. |
| 1109542 | 3/17/2021 | OK | 53 | F | 3/17/2021 | 3/17/2021 | Patient fainted about 5 minutes after receiving immunization. Patient came to with in a minute of fainting and felt fine shortly after. |
| 1109475 | 3/17/2021 | CA | 33 | M | 3/16/2021 | 3/16/2021 | Passed out 5-10 seconds after injection. Passed out a 2nd time after waking up the first time. Blood pressure & heart rate dropped. |
| 1109622 | 3/17/2021 | AZ | 85 | F | 2/16/2021 | 2/17/2021 | Weakness, vomiting, dizziness, passed out, occurred multiple times post-vaccination |
| 1109676 | 3/17/2021 | AZ | 35 | M | 3/17/2021 | 3/17/2021 | Syncope - Pale face and hands, Shortness of breath, dizziness |
| 1109694 | 3/17/2021 | CA | 38 | F | 3/4/2021 | 3/16/2021 | Nystagmus for less than a minute at onset. Syncope, cold sweats for about 5 hours after onset. Lightheadedness and dizziness for about 30 hours (and counting) after onset. |
| 1109935 | 3/17/2021 | | 97 | F | 2/24/2021 | 2/24/2021 | pt presented at the pharmacy on 03/17/21 to say after getting her second dose of the moderna covid vaccine on 02/24/21, she fainted at the entrance of Dr's office less than one hour afterwards (she waited at the pharmacy for 15mins after receiving the vaccine) per pt she was taken by ambulance to the hospital were she spent 3 days in the ICU after she was released under the care of her family member. Pt stated that she did not experience any other symptoms. She stated that the Dr didn't think it was related but she thinks it is. she is feeling a little better now |
| 1108509 | 3/17/2021 | AR | 56 | F | 3/17/2021 | 3/17/2021 | Vasovagal syncope |

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| 1108535 | 3/17/2021 | CA | 70 | F | 3/1/2021 | 3/1/2021 | Very high fever (I think), sweating (lost 4 lbs of 123), nausea, passed out. Husband found me on the ground (just a short time), shook me, and I responded. Went to bed, stayed in bed the next day. |
| 1109481 | 3/17/2021 | CA | 61 | F | 3/17/2021 | 3/17/2021 | Syncope, hypotension |
| 1108768 | 3/17/2021 | | 37 | F | 3/17/2021 | 3/17/2021 | PT RECEIVED FIRST DOSE OF PFIZER COVID-19 VACCINE (LOT NO. EN6207, EXP 07/2021). FIVE MINUTES AFTER RECEIVING DOSE, PT COMPLAINED OF FEELING HOT, DIFFICULTY SWALLOWING, AND DIFFICULTY BREATHING. HX OF ANAPHYLAXIS AND CARRIES AN EPIPEN AROUND. PT RECEIVED ONE DOSE OF EPIPEN (LOT NO. 0FM407, EXP 02/2022). NO OTHER VACCINES RECEIVED WITHIN THE LAST 14 DAYS ON PATIENT'S RECORD. TRANSPORTED TO EMERGENCY DEPARTMENT FOR FURTHER EVALUATION. EMERGENCY DEPARTMENT VISIT TIME SEEN BY PROVIDER: 0958, 17 MAR 2021. CHIEF COMPLAINT: ALLERGIC REACTION. NO SKIN RASH, DIZZINESS, OR FAINTING EPISODE. HAD DIFFICULTY BREATHING BUT NOT HAD ITCHING OR SWELLING. SYMPTOMS STARTED PRIOR TO ARRIVAL AND IS STILL PRESENT BUT IMPROVING. VAERS REPORT: . PATIENT DISCHARGED FROM THE EMERGENCY DEPARTMENT AT 1143, 17 MAR 2021. CONDITION: STABLE. CLINICAL IMPRESSION: ANAPHYLAXIS DUE TO A DRUG. |
| 1108587 | 3/17/2021 | CO | 69 | F | 3/8/2021 | 3/10/2021 | Presents to PCP 2 days after 2nd covid vaccine with fevers, chest heaviness, palpitations, syncope (fell and hit head), swollen lymph node under arm, bilateral ear pain. Sncyope thought to be vasovagal and not related to vaccine. OTC treatment for symptoms. |
| 1108686 | 3/17/2021 | OH | 46 | F | 3/16/2021 | 3/16/2021 | Fainting & abnormal EKG at time of vaccination. Day after- low grade fever & pain at site of injection |
| 1109497 | 3/17/2021 | OR | 26 | F | 3/17/2021 | 3/17/2021 | Dizziness, Pallor and pre faint feeling, diaphoresis then syncope for 20-30 seconds with inconstancy. |

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| 1109142 | 3/17/2021 | MD | 18 | M | 3/17/2021 | 3/17/2021 | patient "saw black"and nearly passed out was grey, sweaty HR 39, BP 96/60 after a few minutes his color came back after vomiting x2 observed in tent, BP 136/78, HR 69 |
| 1108705 | 3/17/2021 | MO | 35 | F | 3/16/2021 | 3/16/2021 | patient had slight arm swelling and pain and developed headache after injection. she showed no dizziness or fainting . patient stayed in pharmacy for 30 minutes and showed no other symptoms . I checked with her later in the day and she said she was fine. |
| 1108735 | 3/17/2021 | IL | 34 | M | 3/17/2021 | 3/17/2021 | Syncope episode and feeling warm right before event |
| 1108758 | 3/17/2021 | IL | 41 | F | 3/16/2021 | 3/16/2021 | I got my vaccination at 4pm, waited the 15 minutes at the united center waiting area and felt fine. I went home to pickup my daughter and at 6pm was back on the road driving and started to feel tired. I stopped at the light at foster and had just called my parents to tell them i had gotten the shot. I mentioned I was starting to feel tired and as I said it started to feel more tired. My mom responded maybe you should pull over and that was the last thing i remember as I fainted/blacked out immediately after. When I awoke my daughter (in the back seat along with my dog) explained that I had accelerated and hit the back of another car and then drove around that car, ending with both cars facing the direction of travel with my car in front of the car i had rear-ended. I was completely disoriented and had not recollection of hitting the gas or break much less driving. I was told two times that the driver in the other car was fine and was told when asked a third time that he did have some pain possibly and went in the ambulance to get checked out. I felt disoriented and jittery last night, took 2 Tylenol before bed and have felt fine today beyond feeling confused and horrible about what happen. My husband picked me up form the site and took me to my parents a few blocks north of the accident. |
| 1108784 | 3/17/2021 | AZ | 63 | F | 3/17/2021 | 3/17/2021 | PATIENT FAINTED AND WAS UNCONSCIOUS FOR A FEW SECONDS ONLY. SHE GAIND CONSCIOUSNESS VERY QUICKLY. 911 WAS CALLED |

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| 1108987 | 3/17/2021 | NY | 61 | F | 3/16/2021 | 3/17/2021 | Janssen COVID-19 Vaccine EUA; at 4:15 a.m. I took a tylenol for the headache I'd had since around 8 pm; ate a few crackers with it; then as I was going back to bed I immediately felt weak/dizzy and then I passed out on the floor. My life partner started calling my name and check my pulse (which he said was strong); then I came to but was really dizzy; I was nauseous and vomited for a few minutes; extremely hot/sweating; and after I stopped vomiting, then had a bowel movement (He had to aid me in getting to the bathroom). About 20 - 25 minutes later I felt much better; everything calmed down. I was ultimately able to fall back to sleep. |
| 1109072 | 3/17/2021 | TX | 39 | M | 3/17/2021 | 3/17/2021 | Reports he fainted for few minutes. History of similar symptom with venipuncture. BP: 134/94 and 150/103 (repeat) Fingerstick: 121 HR: 60 SpO2: 99% RA Refused to be transported by EMS to ER. Refusal form signed by patient Seen and cleared by EMS, |
| 1109064 | 3/17/2021 | ME | 31 | F | 3/17/2021 | 3/17/2021 | No pain at the time of injection, but fainted after returning to sit outside. After about twenty minutes, with fluids and a snack kindly provided by the pharmacy staff, recovered quickly. |
| 1108752 | 3/17/2021 | OR | 53 | F | 3/17/2021 | 3/17/2021 | She sat down after getting shot then started to lean forward after saying she was nauseous. Rph caught her as she started to lean forward and she almost fell but I was able to get her to turn sideways and instead lay down on bench rather than fall forward. So she basically fainted for a minute and then laid for awhile while 911 was called. Ambulance arrived and patient remained conscious. |
| 1109001 | 3/17/2021 | NY | 30 | F | 3/17/2021 | 3/17/2021 | Pt states she has a history of fainting after I.M. Injections. Pt states she is feeling faint. Pt was moved to the exam room and monitored. Pts vitals are stable. Pt states she is feeling better and would like to leave. Pt didn't require transport to hospital. |

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| 1108964 | 3/17/2021 | DE | 39 | F | 3/17/2021 | 3/17/2021 | Syncope Patient felt faint after a few minutes after receiving the vaccine. Purchased a water and sat down again. She then passed out while sitting down and fell out of her chair. Patient was unconscious for about 10 seconds before coming back. EMTs arrived on site a few minutes later, assessed the patient and escorted her out on a stretcher to the ambulance |
| 1108883 | 3/17/2021 | CO | 51 | M | 3/17/2021 | 3/17/2021 | 5 minutes after receiving vaccine patient fainted, pharmacist and Intern got him into where he was given water and crackers. sat with him for one hour talking and getting updates on symptoms. He continued gradually improving through out the hour. Patient called to come pick him up. informed the pharmacy that he has had fainting spells before with other vaccines and medical procedures. walked them to the car to ensure no fainting spells or other symptoms occurred. Advised patient to call 911 or go to the emergency room if other symptoms arose. Also told them pharmacy will follow up with them later in the evening. |
| 1108840 | 3/17/2021 | NJ | 67 | F | 2/24/2021 | 3/10/2021 | Exactly 2 weeks after receiving the 2nd moderna dose , i donated a pint of blood on march 10, 2021. I have given many times in the past. I had consulted with the blood bank to see if i could donate blood on 3/10/21 two weeks following my 2nd moderna dose I passed out twice following the donation &,they were quite concerned due very low BP. When i got home late afternoon, i did not feel well with nausea, fatigue & headache. The symptoms resolved by the following morning |
| 1104813 | 3/16/2021 | NY | 67 | F | 3/12/2021 | 3/12/2021 | Chills, body aches, fainting and falling |

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| 1105044 | 3/16/2021 | CA | 39 | M | 3/16/2021 | 3/16/2021 | 39y/o male presents with syncope, head injury and body shaking within 5min of receiving Pfizer vaccine in left arm on 3/16/21. Patient lost consciousness, fell from a seated position and hit the left side of scalp on the floor. Patient then experienced uncontrolled body shaking for <5sec. He had drool from his mouth during episode. Patient regained consciousness after cessation of shaking. He reports associated sweating and head pain. He denies throat enclosing, difficulty speaking, lip/tongue swelling or itching, injection site pain or itching, blurring of vision, light headedness, chest pain, palpitations, or shortness of breath. He reports history of syncope when getting his blood drawn and at site of blood. He denies allergies to medication or vaccinations. He denies any current medical conditions or h/o seizures. On physical exam: Vitals: Heart rate 88, blood pressure 150/100 Skin: his skin is diaphoretic and ~4x2cm skin abrasion to his left scalp is noted. Cardiovascular: Radial Pulse 2+ . Heart regular rate and rhythm. Lungs: clear to auscultation bilaterally Patient was examined by EMS and informed that he could be transported to hospital via ambulance for immediate consultation with provider or can decline services and seek care at a later time. Patient opted to drive on his own to seek care at a later time. He was advised to contact his primary care provider regarding his adverse reaction, seizure and head injury. Note: MA called for PA on site when patient fell and hit head. PA told site manager to call 911 while attending to patient. When PA arrived to patient's side, he had regained consciousness and PA proceeded to provide care and investigate incident. |

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| 1104811 | 3/16/2021 | FL | 47 | M | 3/16/2021 | 3/16/2021 | On 3/16/21 at approximately 12PM a middle-aged male patient came in to get his first dose of Moderna vaccine. I took in this patient into the IMZ room to give his vaccination and reviewed his form he filled out. On the question related to "have you ever had a reaction to a vaccine (fainting/dizzy)" the patient answered "No". The patient walked outside to the waiting area and sat down to begin his 15mins, at that point another customer yelled for medical attention for him because he passed out in the chair. I ran out with an EpiPen in case it was anaphylaxis. After I got outside the patient regained consciousness in the matter of seconds but was still dazed/confused and I applied a cold compress to the back of his neck and gave the patient some water to drink while feeling for his pulse in the wrist. He began to lose his color/pallor in his face again for a second time at that point I told my technician to call 911, after we dialed them, the patient came back to fully again this time and all color was restored to his face and he was fully conscious this time and able to speak in complete sentences. He wanted me to cancel the 911 call and since he came back to consciousness again in the matter of seconds so we canceled it. I made the patient wait an extra 30 minutes to observe him and he was fine from there on out, his wife was accompanying him and stated he has done this in the past for vaccines (despite answering no in the assessment form) and said she will be driving him home and checking in with his doctor later. |
| 1105415 | 3/16/2021 | CA | 52 | F | 3/16/2021 | 3/16/2021 | S: is a 52 y/o female on the floor on presentation after receiving Moderna vaccine 1st dose. Nurse reports holding her to the floor did not hit her head. O: 10:47 1st blood pressure 150/100. HR 104 Oxygen saturation 97 Resp. 17 2nd Blood pressure 140/ 80 No signs of trauma. No hematoma of the head. No bleeding. No acute distress noted. Talking a/o x4. Integumentary: normal dry, Intact skin, neg abrasion or lacerations. Resp. Normal . No rapid breathing, neg wheezing or shortness of breath Cardio: Tachycardia, neg for murmur, positive for syncope neuro: Negative for slurring, negative facial drop, negative for weakness, negative for numbness and tingling Assessment Syncope Monitored for 20 |

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| 1104837 | 3/16/2021 | AZ | 76 | F | 3/15/2021 | 3/15/2021 | Fainted & throat tightened up |
| 1104844 | 3/16/2021 | AL | 20 | M | 3/15/2021 | 3/15/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium |
| 1104860 | 3/16/2021 | ME | | F | 3/10/2021 | 3/10/2021 | Patient sat for about 5 minutes after dose then reported not feeling well. She stated she was extremely hot then fainted. She was conscious but stayed out for about 3 minutes before fully coming to. |
| 1104816 | 3/16/2021 | | 31 | F | 3/16/2021 | 3/16/2021 | Patient reports feeling slightly dizzy, sweating, shaking and dry mouth. Patient think she passed out and has history of anxiety and passing out with shots. |
| 1105066 | 3/16/2021 | PA | 37 | M | 3/15/2021 | 3/15/2021 | Patient was standing with hands on knees and stated that he was "going down". Paramedic was standing nearby. Patient's eyes rolled back into his head and paramedic helped to guide patient to the floor. Pt tried to crawl while on his hands and knees prior to rubbing his face into the carpet as he continued to crawl. Paramedic rolled patient over onto his back and patient rested there for about 10 minutes. Pt got up with standby assistance and sat in chair. After 5 minutes pt passed out again and was turned over on his back on the floor. Pt vital signs were taken and were stable. Ice pack placed on patient head. Pt had visible bruises to the face (nose, eye and forehead). Pt has a history of passing out with vaccines and stated that he had not taken his blood pressure medicine today. Pt placed in wheelchair and taken by EMS to the hospital. |
| 1105068 | 3/16/2021 | NY | 22 | F | 3/12/2021 | 3/13/2021 | Vomiting, Dizziness, Fainting, light sensitivity |
| 1105072 | 3/16/2021 | TN | 32 | F | 3/16/2021 | 3/16/2021 | patient fainted , regained consciousness in 15 to 20 seconds |
| 1105088 | 3/16/2021 | VA | 38 | F | 3/16/2021 | 3/16/2021 | Janssen COVID-19 Vaccine EUA Extreme dizziness leading to fainting five minutes after the shot. Blood pressure was extremely low for about 20 minutes after episode. I?m 36 weeks and 3 days pregnant. Baby is expected on 04/10/2021. |
| 1105164 | 3/16/2021 | GA | 19 | F | 3/16/2021 | 3/16/2021 | Approximately 5 mins after vaccine administration, patient became lightheaded and fainted. Patient regained consciousness and recovered quickly. |

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| 1105308 | 3/16/2021 | | 34 | M | 3/16/2021 | 3/16/2021 | Called to obs area due to patient passing out. He is passenger in the car due to history of similar episodes of syncope with giving blood, getting shots in the past. Wife states that he was out from time it took to drive from injection area to obs area (less than 20 seconds). He is coherent, AOx4, RRR, CTAB on exam. He states that he does feel back to normal at time of my exam/questioning. BP 113/84, pulse 68, oxygen saturation 100% on room air. Extended observation time by 15 minutes, no further issues and patient left under wife's care. |
| 1104787 | 3/16/2021 | PA | 27 | F | 3/12/2021 | 3/13/2021 | Warm and red skin, bloodshot eyes, dropping blood pressure, fainting, dizziness, nausea, purple feet |
| 1103779 | 3/16/2021 | NC | 55 | F | 3/15/2021 | 3/15/2021 | Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Mild, Systemic: Seizure-Severe, Additional Details: Event occurred during observation period, roughly 5-10 minutes after administration. Patient was seated and appeared close to fainting (unresponsive, head down, unsteady) which prompted closer observation when she began to have seizure. Patient was moved to cleared floor and EMS contacted immediately; transported offsite soon after. Her husband reported history of epilepsy with drug regimen during event. |
| 1105303 | 3/16/2021 | PA | 36 | F | 3/16/2021 | 3/16/2021 | Patient fainted after administration for approximately 10 minutes. Was laid in supine position until she felt well enough to sit upright. |
| 1104347 | 3/16/2021 | NC | 54 | F | 2/12/2021 | 2/13/2021 | patient started complaining about arm soreness, dizziness, frequent headaches daily, and feeling sluggish starting 1 day after administration and continuing til today. patient has had some chest pain with palpitations and syncope episodes. Felt very fatigued with feeling of nausea and has had some diarrhea. |

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| 1103670 | 3/16/2021 | CA | 71 | M | 2/26/2021 | 2/26/2021 | 102 degree fever starting about 10 hours after vaccination. The fever lasted the night of the injection, and the next two days. I was unable to sit up in bed without getting dizzy, had a headache, after walking 25 steps in my house I had to sit down due to shortness of breath and rapid heartbeat. Now, two weeks after vaccination I am experiencing a cough, syncope and occasional irregular heartbeat. |
| 1105210 | 3/16/2021 | | 36 | M | 3/15/2021 | 3/15/2021 | Patient appeared to experience vasovagal syncope within 30-60 seconds of injection. Patient briefly lost consciousness for approximately 30 seconds and complained of severe nausea following the incident. After recovering, he stated that he has a history of vasovagal syncope and usually receives injections lying down. He described tingling sensation of hands and feet, nausea, and was perspiring. Patient had gatorade and water and tried to eat crackers before complaining again of nausea. Observed him for about 20 minutes at which point he was still complaining of nausea but was able to ambulate unassisted and left with his nurse wife. Checked in with him three hours later and he stated that he was feeling better. |
| 1103811 | 3/16/2021 | SC | 57 | F | 3/12/2021 | 3/12/2021 | Syncope, arrhythmia, chills, |
| 1105432 | 3/16/2021 | CT | 57 | M | 3/4/2021 | 3/4/2021 | Got an increasing headache - annoying fuzzy and headache by 11pm and went to sleep. Had plenty of water/fluids throughout the night. urinated often about ever 1 3/4 hrs-I cath and good at it (big prostate) and use a bucket. Had a nasty headache by 3am and while cathing I stayed low because I felt real sick sweaty nauseous and went blind passed out, covered with half quart of urine, woke up on the floor with face against the wall-didn't know anything for a few seconds. Went back to bed-headache lasted for about four days. |
| 1103986 | 3/16/2021 | NY | 70 | M | 3/12/2021 | 3/12/2021 | passed out three hours later, came to fine. was light headed and cold like for a day. |

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| 1104130 | 3/16/2021 | NY | 66 | M | 3/9/2021 | 3/10/2021 | Body chills. In going to bed I had heavy clothing, bathrobe and multiple blankets to offset the chills. During the night I woke up overheated and bathed in sweat. Got up to go to the bathroom for BM but was nauseous, feeling need to vomit at the same time. After BM I stood and still felt need to do one or the other or both when I passed out. Wife came upstairs and found me sitting up against the corner wall. She was able to shake me awake while calling 911. I was groggy but aware I was still nauseous and stayed down next to toilet until stomach settled. I came downstairs and EMTs arrived. Took blood pressure. Result was it was low. Took EKG and that was normal. Second blood pressure test showed that I rebounded. When offered I felt it unnecessary to go to hospital. |
| 1104270 | 3/16/2021 | VA | 23 | M | 3/1/2021 | 3/16/2021 | Patient passed out and slid out of his chair while waiting after receiving his vaccine. The fall was witnessed by NP and aid was provided, immediately. Patient was laid flat on the floor and his Covid mask was removed. Patient returned to conscious state <5 seconds after onset of event. BP was checked while laying down (130/76 HR 80) and patient was given water and a pillow. Patient was allowed to sit after 5-7 mins but began to get dizzy, again. He was taken by wheelchair to clinic and allowed to lay on an exam table. A snack was provided and NP remained with patient until he was d/c'd at 10:05 am. His d/c BP was 128/78 (HR 65). Patient was reminded to alert staff to this event with his next vaccination. |
| 1103896 | 3/16/2021 | IN | 31 | F | 3/15/2021 | 3/15/2021 | Patient was at check out. She told that she felt faint. Check out woman went around and caught her before she hit the floor and lowered her down. Patient was out for about 10 seconds. Patient reports a hx of fainting with vaccines. She has no hx of HTN. Her bp was 90/50 at 4:13 pm when she was assessed. Her oxygen was 97% and pulse was 60. 5 minutes later she was assessed again. bp was 100/60 oxygen 98% and HR 70. At 4:25pm her bp was 104/62. oxygen 99% and pulse 69. She was still lethargic from the event. We had her picked up. |

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| 1104345 | 3/16/2021 | MO | 37 | M | 3/16/2021 | 3/16/2021 | Patient fainted from a seated position approximately 10 to 15 minutes post vaccination. The patient hit the ground and regained consciousness. He was alert to time, date, and place. Ambulance was called, the blood glucose and blood pressure were within normal ranges. |
| 1104633 | 3/16/2021 | OH | 28 | F | 3/16/2021 | 3/16/2021 | Lightheadedness, nausea (no vomiting), anxious. She has a history of anxiety with needle injections. She laid down on the floor (voluntary, no syncope, no mental status changes), when taken to private section of the Center via EMS stretcher. Symptoms lasted 20 minutes, then resolved on their own. |
| 1104384 | 3/16/2021 | FL | 69 | F | 2/13/2021 | 2/16/2021 | Being in the Mall, accompanied by her cousin, felt a severe headache and pain in both shoulders followed immediately by fainting, cardio-respiratory arrest that required call 911 for emergency transfer to Hospital. She was intubated in the emergency room treated by the doctors, Cardiologist and Intensive care where she was subjected to hypothermia and other treatments due to the serious neurological damage that she presented. No other organ seemed compromised. Never came out of the coma, passing away on February 26, 2021. |
| 1104480 | 3/16/2021 | OR | 44 | F | 2/6/2021 | 2/7/2021 | About 12 hours after the second Covid vaccine, I woke up with chills and severe body ache. When I got up, I experienced a vasovagal syncope. Mild fever, chills and body ache lasted for about 24 hours and resolved fairly suddenly. Only one syncope event. |
| 1104537 | 3/16/2021 | GA | 47 | F | 3/16/2021 | 3/16/2021 | Immediately after immunization patient began to feel lightheaded and dizzy and had a strange taste in her mouth. 25 mg of Diphenhydramine was administered by patient as she was alert. Patient continued to feel ill and fainted. EMS was called and presented to determine the patients blood pressure was low. |

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| 1104548 | 3/16/2021 | NC | 67 | F | 3/13/2021 | 3/13/2021 | Chills & shivering began around 11:00 pm of the evening of the vaccine day and lasted through the night and next morning. Very bad headache. Upon rising around 3:00 pm the following afternoon to use the bathroom, feeling very weak, passed out in the bathroom for just a second or two. Felt nauseous. Husband picked me up and put me back in bed. Registered low fever of 99.6. Took 2 Tylenol which seemed to alleviate the headache about 50%. Stayed in bed for balance of day. The Monday following the Saturday of the vaccine, neck was very sore to the touch on both sides underneath my ears. Could not lift head without aid. Remained in bed the balance of the day. Tuesday morning, felt good enough to get out of bed and resume regular activities but still only about 90%. |
| 1104580 | 3/16/2021 | WA | 55 | F | 3/9/2021 | 3/9/2021 | Patient experienced near syncope after vaccination. Lasted less than 5 minutes. No cardiac symptoms. No Resolved with orange juice as patient had not had PO intake for longer than 12 hours prior to vaccination. |
| 1104582 | 3/16/2021 | CA | 18 | F | 3/7/2021 | 3/7/2021 | PATIENT WAS DESCRIBED AS HAVING SYNCOPE WITH PALE SKIN RAPID HEARTBEAT AND BP OF 147/103 |
| 1104587 | 3/16/2021 | | 59 | F | 3/9/2021 | 3/10/2021 | Dizziness, hypotension, fainting, confusion, sweating |
| 1104621 | 3/16/2021 | | 22 | F | 3/16/2021 | 3/16/2021 | 10 minutes after receiving the first dose of Pfizer, the patient began feeling dizzy and had a syncope event. BP 105/59. HR 59. 100% saturation on room air. Repeat vitals 10 minutes later: BP 95/39, HR 66, 100% sat on room air. Blood glucose 109. Patient noted she came from the gym and had not eaten a full meal. Patient reports passing out after donating blood, and felt similar to that experience. No history of syncope events related to vaccines. |

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| 1104313 | 3/16/2021 | KS | 28 | F | 3/12/2021 | 3/12/2021 | <p>Progress Notes Expand AllCollapse All Patient: DOB: 9/4/1992 Date: 3/12/2021 MRN: Subjective Patient is a 28 y.o. female who was seen at COVID Vaccine Clinic today for her second dose of the COVID 19 vaccination. She was given the Pfizer vaccination in the left deltoid muscle. During her 15 minute waiting period after the injection, the patient began to experience lightheadedness and feeling faint and hot. She denied difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, facial swelling, lip swelling and tongue swelling. This provider was notified of patient reaction and she was then assessed in the emergency bay area. Monitored patient for severe reaction symptoms, including but not limited to blood pressure abnormality , collapse, hypotension, rapid progression of symptoms and skin changes. Past Medical History: Diagnosis Date ? Acne ? Acute gastritis ? ADD (attention deficit disorder) ? Allergy ? Anxiety ? Depression ? Migraines ? Shingles 2017 ? Wears glasses in the past ALLERGY REVIEW OF SYSTEMS: Patient denies chills, fever, malaise/fatigue, facial swelling, sore throat, frequent throat clearing, cough, chest tightness, shortness of breath, wheezing, rash, hives, eczema, vomiting, abdominal pain, dizziness and headaches Previous Reactions: She reports hx of fainting with vaccines in the past. She didn't have problem with 1st dose of Pfizer. Today she is here for 2nd dose. Objective Vitals Vitals: 03/12/21 1437 03/12/21 1450 BP: 115/70 124/64 Pulse: 70 76 SpO2: 98% 100% Physical Exam Constitutional: Appearance: She is obese. She is diaphoretic. Comments: flushed HENT: Mouth/Throat: Mouth: Mucous membranes are moist. Pharynx: Oropharynx is clear. Eyes: Extraocular Movements: Extraocular movements intact. Conjunctiva/sclera: Conjunctivae normal. Pupils: Pupils are equal, round, and reactive to light. Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Pulses: Normal pulses. Heart sounds: Normal heart sounds. Pulmonary: Effort: Pulmonary effort is normal. No respiratory distress. Breath sounds: Normal breath sounds. No wheezing. Skin: General: Skin is moist. Neurological: General:</p> |

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No focal deficit present. Mental Status: She is alert, oriented to person, place, and time and easily aroused. Gait: Gait normal. Psychiatric: Mood and Affect: Mood normal. Behavior: Behavior normal. Behavior is cooperative. Thought Content: Thought content normal. Judgment: Judgment normal. Pt wheel chaired to the medical bay. Pt given ice packs x 2 and brought to the bed and placed in trendelenburg position. Pt vs taken and is stable. Pt feels better in this position. Slowly inclined to sitting position. Tolerating well. Skin dry. Assessment/Plan Treatment included: water, snacks and ice packs Follow up response to treatment: good. Patient discharge: Stable to go home and follow up with PCP. Differential Diagnosis: Systemic reaction (hypoglycemia, hypotension, generalized rash) She reports having improvement of symptoms after observation in medical bay for 40 mins. She is to be taken home by dad who was able to come in to pick her up. Pt wheeled to front by this provider and able to stand and walk w/o assistance to car. Monitor symptoms at home and follow up with pcp as needed.

1106773 3/16/2021 AR

55 F

3/16/2021

3/16/2021

Numbness in arm, fainting, nausea for a thirty minute period. Treated in emergency room for nausea

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| 1106332 | 3/16/2021 | | | F | 2/10/2021 | 2/1/2021 | I was lethargic; had no energy; appetite was gone; nauseous; head was a little dizzy, especially when I lay down/dizzy spells; I also felt unbalanced; I was shaky; I was unable to sit or stand up by myself. I was so weak.; Whiplash; fainted or passed out; fallen down the whole flight of stairs; I had no recollection on how I got there.; acromioclavicular joint separation; right thumb fracture; thumb was very sore; back was sore; felt so sick; My right thumb was very sore and I could not move my left shoulder or arm.; temperature was high; felt terrible; pale; pain; I had bruises all over my shins, knees, right elbow and 2 bumps on my head; headache; chills; no idea when I will fully heal, or when I will be able to get back to normal activities; Concussion; imbalance in my inner ear from the fall and from the bangs I received on my head; This is a spontaneous report from a contactable consumer, the patient. A female patient of an unspecified age received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Lot number unknown), via an unspecified route of administration on 10Feb2021 at 09:30 as a single dose for COVID-19 immunization. The patient's medical history included an unspecified immune system disorder from an unknown date and unknown if ongoing. The patient's historical vaccinations included the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) on 20Jan2021 after her Remicaide infusion. The patient's concomitant medications were not reported. The patient experienced loss of consciousness on 11Feb2021, fall on 11Feb2021, joint dislocation on 11Feb2021, thumb fracture on 11Feb2021, concussion on an unspecified date in Feb2021, dizzy spells beginning on 13Feb2021, headache on 10Feb2021, chills on an unspecified date in Feb2021, fever on 11Feb2021, being unwell on 11Feb2021, being pale on 11Feb2021, pain beginning on 11Feb2021, contusions on 11Feb2021, decreased appetite on 14Feb2021, nausea on 14Feb2021, back pain on an 11Feb2021, sickness on 11Feb2021, pain in arm on 11Feb2021, memory deficit on 11Feb2021, weakness on 11Feb2021, balance difficulty on 13Feb2021, had no energy on 14Feb2021, being shaky beginning on 12Feb2021, whiplash injury on 11Feb2021, lethargic on 17Feb2021, inner ear disorder in Feb2021 and ADL impaired in Feb2021. Event descriptions were provided in the |

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following first person account which was provided by reporter (the patient): "This is a chronological record of my experience after the Pfizer Vaccine 20Jan2021, I received my first shot of the Pfizer vaccine after my Remicade infusion in (hospital name) Wednesday, 10Feb2021, I received my second shot of the Pfizer vaccine at 9:30am at (hospital name). I started getting a headache before I went to bed at around 8pm. During the night, I got a severe headache and very bad chills. So bad my teeth were rattling and I had to pull an extra blanket over me. Thursday, 11Feb2021, I got up at 7.08am. I went into the bathroom and washed my face. I was very pale and I felt terrible. I went downstairs to the kitchen. I put the kettle on and took my temperature. I had three doctor appointments that morning in and I was worried I would not be able to get into them if my temperature was high. It was 100.1. I went into the ground floor bathroom. I left the bathroom when I heard the kettle was fully boiled. The next thing I remember was the feel of carpet on my left cheek. I knew the only floor in my house that had carpet, was the basement floor. I opened my eyes and to my horror, I was able to see the basement storage room. I had no recollection on how I got there. I knew straight away, that I had fainted or passed out, on the stairs landing and had fallen down the whole flight of stairs. I was afraid to move because I didn't know if I had broken my back or my neck. I was home alone. After laying there for a few minutes, I knew I had to try to get back up the stairs so I could get to a phone. If I didn't, I knew my husband would not find me there, until after 2:30pm. I tried to get up. I struggled but I got to my knees. The next thing I recall is waking up again on the carpeted floor. This time I was sprawled out in the opposite direction, this time my head was near the thread mill. I had obviously passed out again. Now this really frightened me, I was terrified to stand up in case I fell back down again. I literally crawled up the stairs on my hands and knees. I grabbed my cell phone and called my husband to come home from work. I made that call at 7.34am. I didn't move from the sofa until he came home. He made me a cup of tea. He then brought me into the bathroom to wash my teeth. When I was finished washing my teeth, I passed out again. I woke up this time to my husband tapping my face and calling my name. I had fainted again; he had caught me and had carried me

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into the sofa. I was unable to sit or stand up by myself. I was so weak. I felt so sick, I couldn't even drink the tea. My husband brought me up to bed. He checked on me every hour. I came back downstairs at 4pm. I hurt all over. I had bruises all over my shins, knees, right elbow and 2 bumps on my head. My back was sore. My right thumb was very sore and I couldn't move my left shoulder or arm. I put ice on my shoulder and thumb all night. I took Tylenol pm to help me sleep. Friday, 12Feb2021, my husband helped me to get dressed. I came down the stairs with him. I was very weak. I was shaky and did not trust myself to walk down the stairs. He was having knee surgery that morning. His friend took him to the hospital as I was not fit to drive. I did not move from the sofa until he came home at around 2pm. We talked about going to the ER but I really didn't want to go because of Covid. I was not steady on my feet and I would have to be dropped outside the hospital on my own. I took pain killers all day and iced down my left shoulder and right thumb. Saturday, 13Feb2021: I was still in a lot of pain and my head was a little dizzy, especially when I lay down. I went to Urgent care at 9am. I was seen by Dr. (Name provided). She sent me for 4 x rays and took my blood. My back and right shin were x rayed, I had no broken bones. My shins and knees were badly bruised. The other 2 x rays showed I had a fracture on my right thumb and there was something wrong with my left shoulder. She suggested I go to see an orthopedic doctor on Monday. I forgot to tell her about the dizzy spells and my neck been sore. She did not examine my head or neck. She found no other reason for my fainting, except that I got the Pfizer vaccine the day before. Sunday, 14Feb2021, I continued with the pain killers and ice on my shoulder and thumb. I continued to have dizzy spells. I also felt unbalanced. My appetite was gone and I felt nauseous sometimes when I was eating. I had no energy and I hurt all over. Monday, 15Feb2021, I got an appointment with an Orthopedist at 4.30pm. My husband dropped me off. Nurse and his assistant looked after me before I saw the doctor. I was told I have a separated bone in my left shoulder. It's called acromioclavicular joint separation. AC (collar bone) separates from the scapula (shoulder blade). So, I will have to wear a sling for a few weeks. I will also have to wear a temporary cast on my right hand for a few weeks to heal the fracture on my

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right thumb. No surgery is needed for either. They also put me on steroids for 2 weeks, Prednisone. Tuesday 16Feb2021, I rested all day. I was still having dizzy spells and I felt off balanced & very shaky. My husband, a close friend and a coworker thought I may have a concussion and advised me to get it checked out. I spent all day on the phone trying to get an appointment with a neurologist. I did get an appointment for the next day. Wednesday 17Feb2021, I still felt the same dizziness and I was lethargic. I had an appointment with the neurologist, Dr. (Name provided) at 2pm. I had a CAT scan and it was normal, no bleeding. The doctor said I had whiplash and a concussion. He did not find any other reason for my fainting, except for the side effects of the Pfizer vaccine. He told me, I just have to rest and the symptom from the concussion should subside in a few weeks. Wednesday 24Feb2021. The Dr.'s nurse called to see how I was. I told her there was not much improvement and that I was still having dizzy spells. She called me back after she related everything to the doctor He is concerned and wants to see me again on Monday 01Mar2021. He may do an MRI to see if there is anything else going on, other than the concussion. Friday 26Feb2021. I am still having dizzy spells. Monday 01Mar2021. I had another appointment with the neurologist at 9:30 am. I need to stay off work for another week and he will re-access me again next Monday. He says I have an imbalance in my inner ear from the fall and from the bangs I received on my head. He demonstrated some EPLEY exercise, that he wants me to do. The dizzy spells have not improved. I don't feel well at all. I cannot complete house hold tasks. I still cannot drive. I can" go to work. I have used over 40 hours of sick leave already. Now I have to be off work for another week and probably longer. I am worried and I have no idea when I will fully heal, or when I will be able to get back to normal activities. Prior to getting the vaccine, I was an ardent runner. I exercised every day and exercise is very important to me. I don't know how long it will be before I can go back to work or back to my exercise routine. I would never be in this situation, if I had not taken the Pfizer vaccine. I feel I was overdosed. I think one shot of the Pfizer vaccine would have been sufficient. I just went through 12 months without getting Covid. My immune system is suppressed so I am seriously careful about picking up germs. I have been

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| | | | | | <p>using sanitizer wipes and hand gel for years because of my immune system being suppressed. Long before the whole world heard about Covid, I was acutely aware of germs & viruses in public places. I am so sorry now that I got this Pfizer vaccine. I think I could have gone on living for the rest of my life, without catching Covid, because I am so careful. If I had to do it all again, I would not get this vaccine. The research was not completed. The trials were not long enough. The trails were conducted in a controlled setting. They do not know all the side effects. They do not know the extent of the adverse effect on anybody, never mind somebody with my suppressed immune system. They said the side effects could be chills, fever, flu symptoms, tiredness, joint pain, muscle pain and headache. Nobody told me I might pass out or faint. Nobody warned me. If I had known fainting was a possibility, I would not have been home on my own. The word needs to get out about this side effect. The media needs to know. The public needs to know. I do not want this to happen to anybody else. Since this happened to me, I heard or someone else, that also fainted. These vaccines need more research period." The patient underwent lab tests and procedures which included unspecified blood test on 13Feb2021 with unknown results, body temperature of 100.1 on 11Feb2021, computerised tomogram: normal on 17Feb2021, X-ray on 13Feb2021 had no broken bones but otherwise with unknown results. The clinical outcome of loss of consciousness, fall, joint dislocation, thumb fracture, concussion, dizzy spells, headache, chills, fever, being unwell, being pale, pain, contusions, decreased appetite, nausea, back pain, sickness, pain in arm, memory deficit, weakness, balance difficulty, fatigue, shaky, whiplash injury, lethargic, inner ear disorder and ADL impaired were unknown. Information on Lot/Batch number has been requested.</p> | | |
| 1106386 | 3/16/2021 | OH | 52 | M | 3/16/2021 | 3/16/2021 | <p>After receiving the vaccination, he started feeling lightheaded, then started sweating. He asked for water and drank water prior to a brief episode of syncope. He denies any trauma to his head or any part of his body. No mental status changes. He was assisted to the supine position on the floor, then was able to ambulate to a private section of the area and lay recumbent on an EMT gurney. He has a history of syncope with needlesticks.</p> |

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| 1106432 | 3/16/2021 | CA | 25 | M | 3/16/2021 | 3/16/2021 | 10:00 am client received his COVID19 vaccination. Immediately the client fainted and fell out of his chair on his left shoulder. He did not hurt his head. Client was lying flat on the floor and then started having seizures and was placed on his left side. Episode lasted 3 seconds. Client was able to answer questions and alert and oriented x 4 and no complaints of pain or discomfort. 10:07 1st vitals taken. 10:09 am client stood up and walked to observation area. Client was under observation for 30 minutes. |

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| 1106475 | 3/16/2021 | CA | 60 | F | 3/16/2021 | 3/16/2021 | At approximate 1435- this RN at patient's side. Speaking with patient, patient c/o feeling hot. Patient verbalizing, state not feeling well. RN called to bedside for assistance. Pulse ox 96% HR 46. Patient attempting to drink some water, states not feeling well. Patient noted to be slightly pale. ? Adm team notified- RN (Lead RN in post recovery) and site lead ? Adm team at bed- and RN ? Patient became pale, states feeling funny, assisting to lie down, syncope episode for approximately 10 seconds noted ? Patient laid down on floor with assistance by RN and RN ? no trauma ? Legs elevated ? 1435 Hr 46, B24 BP 139/90, pulse ox 96% ? 1436- Legs remain elevated, patient verbalizing giving history ? 1437- patient denies allergies, states has never received any type of vaccine before ? 1438- patients states prior history of MI in Dec/2019. On medications- Benazepril, Asa, Lipitor ? Patient denies pain, states feeling better, refusing 911 ? 1443 BP 160/100, P63, R-20 Pulse ox 94%. Patient states feeling better refusing 911. Skin color improving, remains verbalizing ? 1450- patient refusing 911, requesting husband ? 1451- skin color improved, perfused, assistance to chair, calling husband ? 1453- husband at bedside ? 1454 patient remains awake, alert, oriented x4. Skin color perfused, warm and dry to touch. Husband remains at bedside, patient states ?feels fine? states at baseline. ? 1458 vital signs updated- BP 130/90, Hr 61, R 16 pulse ox 96 percent. Patient laughing, states feel fine, RN remains at bedside, speaking and educating patient. ? 1459 Patient signing for refusal of transport. Patient educated by this RN and RN any changes in status to call 911. Patient and husband stated understanding. ? Patient signed for refusal of further observation and refusal of transport. Patient ambulatory on leaving with strong, steady gait. |
| 1106549 | 3/16/2021 | NJ | 22 | F | 3/15/2021 | 3/16/2021 | I fainted 14 hours after the vaccination after I got up in the middle of the night. |

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| 1106590 | 3/16/2021 | AK | 32 | M | 3/16/2021 | 3/16/2021 | Patient stated extreme anxiety of needles and history of syncope post-vaccination. He tensed up immediately prior to vaccination. After administration, patient got light headed lost consciousness (syncope) for about 20-30 seconds before becoming alert again. He brought someone else with him to the vaccination, and she helped keep him seated until he was aware again. He remained light headed for a few minutes afterward, so he remained in the booth for about 25 minutes and drank some pop and had a snack. |
| 1106614 | 3/16/2021 | | 30 | M | 3/16/2021 | 3/16/2021 | patient fainted. was only unconscious for a few seconds, came to, and was fine afterwards. pt admitted afterwards that he has a fear of needles and was nervous. |

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| 1106317 | 3/16/2021 | NY | 69 | F | 2/13/2021 | 2/17/2021 | Blacked out; fractured nose; fainting; very tired and cold; very tired and cold; light headed; thirsty; nausea; This is a spontaneous report from a contactable consumer (patient). A 69-year-old female patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number: EL9266), via an unspecified administered in the left arm on 13Feb2021 at 08:15 AM at SINGLE DOSE for COVID-19 immunisation. The patient had no other vaccine in four weeks. The patient had no COVID prior to vaccination. The patient was not pregnant at the time of vaccination. Medical history included arthritis (No chronic health conditions besides arthritis). Concomitant medications included venlafaxine hydrochloride (EFFEXOR), simvastatin, and colecalciferol (D3). The patient previously took cipro [ciprofloxacin hydrochloride] and experienced allergies. Historical vaccine includes first dose of (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number: EL9262), via an unspecified route of administration in the left arm on 22Jan2021 at 5:00 PM for COVID-19 immunisation. It was reported that for 2 days, patient was very tired and cold. At day 4 while at her trainer, the patient experienced light headed, thirsty, nausea, and had blacked out. All tests were normal at emergency room (ER), but have fractured nose. The patient wanted to understand if this fainting can be related to the second shot. Cardiologist said no problems in the heart. All events started on 17Feb2021. There was no treatment received for all events. The patient had COVID test post vaccination via nasal swab on 17Feb2021 which showed negative result. On an unspecified date in 2021, the patient recovered from all events. |
| 1106694 | 3/16/2021 | MN | 29 | F | 3/16/2021 | 3/16/2021 | Pt had a reaction to vaccine. Specifically, she fainted and had seizure. It happened within seconds after the immunization delivery. Pt had upper body seizure waist up in the chair. This lasted about 30 seconds at a time. This occurred roughly 3 or 4 times. Emergency services were called. EMTs responded to scene. Pt was well enough not to go to the hospital. Eventually, left with boyfriend feeling better. |

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| 1106683 | 3/16/2021 | CO | 41 | F | 3/16/2021 | 3/16/2021 | <p>Patient felt faint nearly immediately after but said she wasn't having problems breathing. She was told to breath deeply and she quickly started feeling "a little better" so she was helped to a chair with arm rests in the room. She said she had an orange in her bag, so she started eating her orange. Just a minute later she said she was going to pass out, so the pharmacist caught her. He held her up in the chair and tried to revive her for a few moments but noticed that the blood was draining from her face and her lips were turning blue so yelled for one of his technicians to call 911 and the other to grab an epi pen. He then lowered her to the floor in case he needed to begin to resuscitate while the technician brought him the epipen. While lowering her she urinated on herself. As the pharmacist went to check her vitals before administering the epipen and beginning cpr if necessary the patient suddenly gasped once and her eyes opened widely, but not continue to breath. Upon inspection in her mouth there was a piece of orange near the bottom of the throat. The pharmacist asked if she was choking and she did not response at all, but did not start visibly breathing either. So the pharmacist swiped the piece of orange out quickly, in case it was either previously lodged or patient would have to be resuscitated. She did not seem to enjoy this and this seemed to wake her up and she quietly gasped not choking. She started to quickly improve and admitted that she was feeling better, and had passed out before after getting blood drawn but never after a shot so didn't mention this. While this was happening a police office was going through the drive through so the technician called him in for assistance and he arrived around this time. He asked her a few questions like "what's her name, who's president, how many quarters are in a dollar" which she was able to answer. She said she was mostly embarrassed and was feeling much better. She sat up in the chair again about the time the emts came in. The checked her out, but she didn't want to go to the Emergency Room. She was driven home by her father. I called her later around 6 pm that night and she said she was feeling totally fine and I advised her to please call her PCP and discuss this incident with him or her.</p> |

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| 1106780 | 3/16/2021 | DE | 21 | F | 3/16/2021 | 3/16/2021 | Patient fainted after getting vaccine. She had history of syncope after getting HPV vaccination. |
| 1106791 | 3/16/2021 | SC | 54 | F | 3/9/2021 | 3/10/2021 | On the morning of March 10th, upon sitting up in bed I felt dizzy like I wanted to faint. I lied back down. After 30 minutes, I attempted to sit up on the side of bed and still felt like I wanted to faint. Waited for 5 minutes, got up but was still dizzy. While standing beside counter, I passed out. |
| 1106840 | 3/16/2021 | AZ | 56 | F | 3/12/2021 | 3/13/2021 | Dizziness, fainting, muscle pain, fatigue, headache |
| 1106915 | 3/16/2021 | OH | 53 | F | 2/26/2021 | 2/26/2021 | Pain down left arm, arm eventually hard swollen at site then black n blue in color. Stood up to leave after 18 minutes. Almost passed out. Dizzy, light-headed, sat down. Legs tingled. Waited 20 more minutes. Headache. Chills. Chills lasted 24 hours. Sore, swollen arm lasted 3-4 days paramedics at vaccine location assessed, monitored, |
| 1107311 | 3/16/2021 | CA | 37 | F | 3/9/2021 | 3/9/2021 | The patient was observed for 15 minutes in the observation area without incident. She arose and walked to the exit and then apparently fainted on the sidewalk outside the vaccination clinic. She was attended to by medical staff on site and because she was responding slower than expected and complained of pain on the right side of her head and weakness of her left arm and leg an ambulance was called via 911. Care was assumed by paramedics who placed her in the ambulance where she was warmed and examined further. She eventually denied any continuing pain or weakness (per ambulance crewman) and she was released to the care of her boyfriend / fiance. |
| 1105457 | 3/16/2021 | CT | 35 | M | 2/4/2021 | 2/5/2021 | 12 hours after shot developed intense nausea and dizziness. Passed out for short period of time. Woke up in puddle of sweat and suffering chills and severe bodily exhaustion. For a period of 4 hours could not stop shaking my body and moaning. Following morning had headaches and chills. Headaches last several days. |
| 1105132 | 3/16/2021 | TX | 71 | F | 3/12/2021 | 3/12/2021 | Pt got vaccination at waited 15 minutes before leaving. She called me 4 days later to let me know that she fainted approximately 1 hour after getting the vaccination resulting in a trip to er and stiches to her face. |

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| 1106671 | 3/16/2021 | TN | 42 | M | 3/16/2021 | 3/16/2021 | Notified by pharmacy technician that patient had 'passed out' in parking lot. Patient found lying on the ground, pale but awake. Patient had been instructed to wait in the store for 15 minutes after vaccination in case of any adverse reaction but, per police, decided to wait in the car instead. He then began to feel lightheaded and decided to come back into the clinic. He passed out on his way. Civilian notified policeman that patient was passed out and EMS was called. EMS arrived shortly after I went out to parking lot to check on the patient. Patient was alert and oriented for EMS, reported history of HTN. He continued to c/o feeling lightheaded and BP per EMS was 77/48mmHg. Patient taken by ambulance for further evaluation and treatment. |

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| 1105638 | 3/16/2021 | KS | 34 | F | 3/16/2021 | 3/16/2021 | <p>Progress Notes APRN (Nurse Practitioner) ?? Infusion Center Cosign Needed Expand AllCollapse All COVID VACCINE CLINIC 3/16/2021</p> <p>Patient: DOB: Date: 3/16/2021</p> <p>MRN: Subjective Patient is a 34 y.o. female who was seen at COVID Vaccine Clinic today for her second dose of the COVID 19 vaccination. She was given the Pfizer vaccination in the left deltoid muscle. During her 15 minute waiting period after the injection, the patient began to experience lightheadedness. She denied rash, hives, shortness of breath This provider was notified of patient reaction and she was then assessed in the emergency bay area. Monitored patient for severe reaction symptoms, including but not limited to blood pressure abnormality and chest pain, SOA, rash. Pt felt light headed, diaphoretic PMH of vaso vagal syncope. No event with Dose #1 of 2 ALLERGY REVIEW OF SYSTEMS: Patient complains of chills and ear popping Patient denies facial swelling, ear pain and runny nose Previous Reactions: vasovagal syncope Objective Vitals Vitals: 03/16/21 0926 BP: 98/55 Pulse: 68 SpO2: 100% Physical Exam Constitutional: Appearance: She is diaphoretic. Comments: In chair, pale, diaphoretic, hyperventilating HENT: Nose: Nose normal. Mouth/Throat: Mouth: Mucous membranes are dry. Cardiovascular: Rate and Rhythm: Normal rate. Pulmonary: Effort: Pulmonary effort is normal. No respiratory distress. Breath sounds: Normal breath sounds. Musculoskeletal: General: Normal range of motion. Cervical back: Normal range of motion. Skin: Capillary Refill: Capillary refill takes less than 2 seconds. Coloration: Skin is pale. Neurological: General: No focal deficit present. Mental Status: She is alert. Motor: No weakness. Psychiatric: Comments: Anxious, hyperventilating. PMH "vasovagal syncope". No issues with Dose #1 of 2. Pt pale, diaphoretic and hyperventilating. Initial BP 98/55-HR 68. Pt provided water, ice pack to base of neck and placed supine BP improved 10 109/68. HR 70. Pt sat 45 degrees x 10", became light headed again. BP 97/60. HR72/min. Returned to supine position, encouraged to eat granola bar. Position change after 45"observation: BP 11/74. HR</p> |

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| | | | | | | | 74/min. Pt discharged ambulatory without event Assessment/Plan Treatment included: snacks, prolonged observation and slow position changes Follow up response to treatment: excellent. Patient discharge: Stable to go home and follow up with PCP. Differential Diagnosis: Vaccine-Related Anxiety (include misc mental health) Ddx: Vasovagal response APRN Electronically Signed 3/16/2021 9:28 AM |
| 1105476 | 3/16/2021 | CA | 24 | M | 3/16/2021 | 3/16/2021 | Client stated that he was waiting in observation and told his father he felt dizzy at which time he closed his eyes and passed out per his father for approximately ten seconds. Onsite paramedics responded and evaluated client. Client released to go AMA and advised to go emergency services. |
| 1106700 | 3/16/2021 | NC | 22 | F | 3/16/2021 | 3/16/2021 | pt looked a bit disoriented after administration and then fainted. after asking if okay a couple times, she came to, and said she was okay. We had her lie down on the floor and she said that made her feel better. She said she had a buzzing sound in her ears and that decreased with time. She said that is a normal symptom of when she is having a panic attack. |

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| 1106307 | 3/16/2021 | TN | 65 | F | 2/22/2021 | 2/22/2021 | Patient felt like going to pass out and she did then, she was probably out less than in a minute; Severe headache; Nauseous; Throwing up/Vomiting; Sore arm; This is a spontaneous report from a contactable consumer (patient). A 65-years-old female patient (weight: 81.65 kg, height 170 cm) received the first dose of BNT162B2 (Pfizer-Biontech Covid-19 Vaccine, Lot. EN6201) at single dose, on 22Feb2021, for COVID-19 immunisation. Relevant medical history included thyroid disorder from an unspecified date. Concomitant medication included levothyroxine sodium (SYNTHROID) for thyroid disorder. On 22Feb2021, the patient experienced sore arm. On 25Feb2021, the patient developed severe headache, nauseous, and vomiting (throwing up) and the patient felt like going to pass out and she did then, she was probably out less than in a minute. The patient described as following: so, on 25Feb2021, the headache increased throughout the day and her nauseousness continued throughout the day and in the afternoon with the pain of the headache she thought she passed out, she vomited that gave her little bit of relief but then she took "two (not clarified) Advil and went to bed". Clinical outcome of the adverse events was unknown at time of this report. Patient asked if should be expected the same kind of reaction when she got her second shot. |
| 1105592 | 3/16/2021 | KY | 50 | F | 3/12/2021 | 3/12/2021 | near syncope occurred about 25min after administering injection, patient reports she became flushed, felt lightheaded and slid down the wall to the ground, evaluated at site. transferred to ED for further evaluation. Discharged home from ED in good condition. |

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| 1105598 | 3/16/2021 | KS | 40 | F | 3/16/2021 | 3/16/2021 | <p>Progress Notes Expand AllCollapse All Patient: DOB: 4/11/1980 Date: 3/16/2021 MRN: Subjective Patient is a 40 y.o. female who was seen at COVID Vaccine Clinic today for her second dose of the COVID 19 vaccination. She was given the Pfizer vaccination in the left deltoid muscle. During her 15 minute waiting period after the injection, the patient began to experience generalized weakness, "need for a quick snack". She denied rash, shortness of breath, difficulty swallowing or syncope This provider was notified of patient reaction and she was then assessed in the emergency bay area. Monitored patient for severe reaction symptoms, including but not limited to red flag findings ALLERGY REVIEW OF SYSTEMS Previous Reactions: none Objective Vitals Vitals: 03/16/21 0944 BP: (!) 158/103 Pulse: (!) 102 SpO2: 100% Physical Exam Constitutional: General: She is not in acute distress. Appearance: She is not ill-appearing or diaphoretic. Comments: Anxious on arrival to bay, "I think I just need a snack to feel better." HENT: Head: Normocephalic. Mouth/Throat: Mouth: Mucous membranes are moist. Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Pulmonary: Effort: Pulmonary effort is normal. Musculoskeletal: General: Normal range of motion. Skin: General: Skin is warm and dry. Neurological: Mental Status: She is alert. Motor: No weakness. Psychiatric: Comments: Anxious affect Clinically, post injection anxiety related event. Elevated BP on arrival, improved with rest and granola bar. Salient anxious affect, post injection histamine response, requiring warm blanket, prolonged rest Ambulated with assist, additional snacks provided and pt discharged after 45" stay Assessment/Plan Treatment included: snacks Follow up response to treatment: good. Patient discharge: Stable to go home and follow up with PCP. Differential Diagnosis: Vaccine-Related Anxiety (include misc mental health)</p> |
| 1105632 | 3/16/2021 | PA | 48 | M | 3/16/2021 | 3/16/2021 | Patient fainted in store shortly after the dose of vaccine. |

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| 1105587 | 3/16/2021 | OR | 27 | F | 3/12/2021 | 3/12/2021 | I noticed a very mild headache and slight coldness within 2 hours of my vaccine. Onset of my severe symptoms began around 10PM on 03/12/2021 with a stabbing headache (Felt like someone took an air pump and kept 'blowing up' my head. My eyes felt achy and heavy and every time I looked in a different direction I would get a zapping/electric feeling throughout my head that would cause my head and neck to spasm (longer duration) or twitch (quick jolt). This also caused dizziness). I got really cold and had intense shivering and shaking. Around midnight, my skin started feeling bruised all over my body (very sensitive to touch, including my bed sheets against my spine felt like rubbing up against a wound). At the same time, my joints (especially my neck, hips, and knees) got hot to the touch and were incredibly painful (induced tears). My muscles developed a deep ache that also caused significant pain. I felt very weak and confused. I didn't take my temperature until the early morning, and it was 102.9 at that time. I alternated taking Tylenol and Ibuprofen throughout the day, but my temperature stayed between 102 and 103.1 for about 24 hours, as did the previously noted symptoms. I noticed a gradual improvement of my symptoms over the next two days. On the evening of 03/14/2021, my headache worsened some, and I had an unexpected episode where I nearly passed out (dropped to the floor but stayed conscious). I also had intermittent foot tingling (very noticeable, not mild) over the course of a few hours. For 3 full days (but by far the most severe within the first 24 hours), I experienced some strange sound processing. Things like the sound of a car driving by or the ceiling fan felt like it echoed throughout my whole body and gave me an uncomfortable shivering feeling. As of today (03/16/2021), I am mostly recovered. I am still experiencing fatigue, a very mild headache, and some mild pain. My nausea has completely resolved, though that was never a chief complaint of mine. I realize that some of my symptoms are to be expected with this vaccine. But especially the level of pain I experienced throughout my entire body was very concerning and not something that I was aware could happen as a result of the vaccine. |

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| 1105640 | 3/16/2021 | IL | 33 | F | 3/16/2021 | 3/16/2021 | Patient fainted following vaccination and hit her head. Pharmacist provided first aid and verified patient was ok. Patient refused medical transport, pharmacist sat with her until another person came and picked the patient up. |
| 1105641 | 3/16/2021 | OH | 36 | M | 3/13/2021 | 3/13/2021 | Patient fainted and ended up falling and hitting her head on the floor. Once she came to, she felt "tingling" and ended up breaking into a sweat. |
| 1105902 | 3/16/2021 | SC | 38 | M | 3/16/2021 | 3/16/2021 | Patient received his pfzier covid vaccine. immediately after he had the vaccine administered, he stated that he started to feel very hot, dizzy, nausea and tingling down his arm that he received the vaccine in. We immediately got a yoga mat, asked the patient to remove his shirt. He fell to the ground. We placed a cold pack under his head around the neck area and cold paper towels on his head. We took his blood pressure it was 136/88. He started to mention his chest hurting. His past medical history includes fainting in the past (due to low blood sugars) and open heart surgery as a child. He is currently under the care of a cardiologist. More recently he has had several fainting spells which he believes is due to low blood sugar. He stated he had eaten a good lunch around 11:30. It was about 2:30 when this incident occurred. We offered the patient, a banana, orange, chicken sandwich and water. He ate the orange. We called EMS. When they arrived, they checked his blood sugar which it was 95. He started to feel better and his wife drove him to the cardiologist. |
| 1105645 | 3/16/2021 | MS | 58 | F | 3/16/2021 | 3/16/2021 | Before receiving her first dose of the one-dose series, pt stated that she always "faints or passes out" with IM injections/vaccines - in an attempt to prepare for this, another pharmacist assisted during the time of vaccination, and the patient did well. We sat with the patient for about 5 minutes and asked that she stay seated for the remainder of her "15 minute wait period." She was accompanied by her husband. Roughly 10 minutes after administration, one of our technicians alerted the pharmacists that the patient had experienced vasovagal syncope, so we rushed to the patient, called 911, and remained with her until she woke up (which was within less than 1 minute after the event) and was in the care of other healthcare personnel. |

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| 1105766 | 3/16/2021 | NY | 32 | M | 3/1/2021 | 3/1/2021 | Syncope shortly after administration |
| 1105783 | 3/16/2021 | MO | 60 | M | 3/16/2021 | 3/16/2021 | Pt began to feel lightheaded and dizzy. He did pass out while sitting in chair. Quickly came back, woke back up and was able to answer orientation questions. He did report that this always happens to him when he takes antihistamines. Observed for a period of 5-7 minutes and felt / looked better. Told him we would observe him for a period of 30 minutes. Within 5 minutes, he had the exact same reaction. Patient passed out, was pale and diaphoretic. Blood pressure was 65/39 with HR 45 (3/16 @ 1430). At that time, he was moved to a gurney and placed in Trendelenburg position. Patient observed. repeat blood pressure at 1435 was 104/64 with HR 68. Patient continued in Trendelenburg position. Patient observed until 1455. Repeat blood pressure at 1452 was 105/69 with HR 73. Patient looked and felt better. He refused to go to ED. Wife to stay with patient and observe this evening and afternoon. |
| 1105829 | 3/16/2021 | CA | 26 | F | 3/16/2021 | 3/16/2021 | Patient experienced a vasovagal response 5-10 minutes after receiving their first dose of the Moderna vaccine on their left arm. After receiving their dose, patient felt dizzy and lightheaded and passed out. During period of syncope, patient hit their head and reported to have woken up crying on the ground. Medics was informed, vitals taken, and neurological exam was performed. Everything WNL, no abnormal findings, and patient advised to stay another 15 minutes and to request a ride home from a family member. Patient expressed that this is a common occurrence after receiving vaccines, shots, and blood draws. |
| 1105858 | 3/16/2021 | TX | 32 | F | 3/16/2021 | 3/16/2021 | Client given vaccine at 2:00pm and went to waiting area. Around 2:15pm, she felt unwell and notified staff. An EMT responded and caught her from falling out of the chair when she fainted. She was brought to medic station. VS at 2:18pm HR96, BP 118/86, O2 97% on RA. She was given water and an ice pack and started feeling better. Client left at 2:30pm, stating that she felt 'normal'. |

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| 1105899 | 3/16/2021 | IL | 74 | M | 3/10/2021 | 3/15/2021 | 3/15/21 ER HPI - Transferred to Hospital, remains inpatient as of 3/16/21 74 y.o. male who presents with near syncopal episode. Patient states he was getting ready for his doctor's appointment this morning and when he started walking outside he fell dizzy.Wife states that before leaving for his doctor appointment this morning the patient complained of not feeling well, was sweaty and complained of upper chest pressure radiating into both arms. This symptoms have pretty much subsided on arrival to the emergency room. After initial dizzy episode, he almost collapsed, stood up, recovered and then felt dizzy again and was helped down by his wife and denies any injury except for some redness on his left knee. Patient denies chest pain or palpitations. He does not have any prior history of syncope. He is diabetic and hypertensive. Recently underwent bladder surgery due to cancer and now has a urostomy(ileal conduit). This was performed by Dr., urologist at Hospital He is on clindamycin postoperatively due to incisional infection on 03/08. 3/15/21 Hospital H&P: The patient is a 74 y.o. male with history of bladder cancer s/p open radical cystectomy resection with ileal conduit urinary diversion, type 2 diabetes, hypertension, diabetic neuropathy and chronic back pain presented to ED at Hospital because of dizziness and weakness in addition to chest discomfort. He stated that he was walking in the parking lot of his doctor's office when he suddenly felt dizzy weak and started falling on the ground. His son helped him and the ambulance was called. He stated that he felt pressure in his chest with radiation to the shoulders. He also felt short of breath. Stated that the symptoms lasted for about half an hour. He stated that he has never had any similar episodes in the past. He is not known to have any heart or lung disease. He was treated for bladder cancer and had open radical cystectomy with ileal conduit. He has been diabetic for the last 16 years. He has diabetic neuropathy. He stated that he gets out of breath walking a notice increasing swelling in the lower extremities |

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| 1105604 | 3/16/2021 | IL | 25 | F | 3/16/2021 | 3/16/2021 | Pt received 2nd COVID vaccination at 1024. Once in observation area, pt became unresponsive shortly after sitting down. This provider was called over by staff to pt, which was noted to have dropped her water bottle and become unresponsive while sitting in the chair. Pt remained in the chair, did not fall or injure self. Upon arrival to patient, she was noted to have moderate pallor, with shallow, slow breathing, no cyanosis noted. Her head was aligned/adjusted to maintain an open airway. Pt noted to have some muscular rigidity and not verbally responsive. Another provider advised to call 911 due to unresponsiveness and seizure-like activity. 911 called @1027, meanwhile pt lifted and placed into a wheelchair and moved to treatment area where vitals were obtained, patient became verbally responsive @1034, responses/speech was clear but slow, pt was oriented to self, place, time and situation. Oxygen applied via facemask @4L. Pt provided staff with phone number to call her mother who was notified of daughter's condition @1032. FD Engine arrival @1033 report given and pt also became more responsive, eyes opened and stated clearly that she was feeling better. Pt color also improved. Pt denied any allergies, PMH or hx of seizure activity. Pt only reported a syncope many years ago. Ambulance arrival @1036, report provided to emergency staff and pt taken to ambulance for further evaluation @1039. Pt returned to vaccine clinic @1052, having declined ambulance transport. When asked about events, pt stated that upon sitting down she felt a sudden onset of moderate nausea and reached for her water bottle in her bookbag, pt states she could not recall or hear anything until she was moved to wheelchair, and did not recall how she came to be in the observation area (based on this information, suspected time unconscious was approx 6-12 seconds). Pt was educated regarding the many causes of syncope and the necessity for further evaluation in the Emergency department. Pt discouraged from driving herself from the clinic and was able to obtain ride from her roommate. Pt urged again to obtain a ride to the hospital for further evaluation, understanding verbalized and agreed with plan of care. |
| 1105952 | 3/16/2021 | GA | 23 | M | 3/16/2021 | 3/16/2021 | patient fainted after vaccination |

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| 1106180 | 3/16/2021 | | | F | | 3/4/2021 | <p> Syncope; Flushing; Blurred vision; Felt like is going to pass out; A spontaneous report was received from a pharmacist concerning a 67-year-old, female patient, and experienced syncope, flushing, blurred vision (vision blurred) and felt like she is going to pass out (presyncope). The patient's medical history, was diabetes type 2, high blood pressure and anxiety. Concomitant medications reported included non specified medications to diabetes type 2, high blood pressure and to anxiety. On 04 Mar 2021, prior to the onset of the events, the patient received the second of two planned doses of mRNA-1273 (Lot number: 016M20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On an unspecified date, the patient experienced syncope, she was flushing and had blurred vision. She felt like she is going to pass out. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. The outcome of the events, syncope, flushing, blurred vision (vision blurred) and felt like she is going to pass out (presyncope) were considered as unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. </p> |

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| 1101910 | 3/15/2021 | NY | 64 | F | 3/1/2021 | 3/3/2021 | To give context to the adverse event, in early November 2020 I was diagnosed with Bell's Palsy of unknown origin on the left side of my face. I was tested for COVID-19 and it came back negative. It resolved itself in about a month. About 8 hours after receiving the COVID-19 vaccine on 3/9/21 (about 6:30 p.m., I started to feel a slight headache. Because I had just had the vaccine, I was trying to avoid taking any pain medication, so I did not take anything for it. The headache got worse throughout the evening, and by 10 p.m. I would describe it as a moderate headache. It was primarily concentrated on the left side of my head towards the front, on my forehead and above the eyebrow. I went to bed without taking any pain medication. About 3 hours later, at about 1 p.m., I woke up, and the headache was much more intense. It felt like all the nerves around the left side of my face, including the nerve along my jaw line leading to the 7th cranial nerve that causes Bell's Palsy, were throbbing. I grew concerned about getting Bell's Palsy again, so at that time I took one ibuprofen Advil. After taking it, the headache subsided, although I continued to have a dull headache throughout the night and the next day. Patient received the vaccine Monday March 1st around 2:30pm. Patient began to feel arm soreness around 5pm, woke up at 3am the following morning with a severe headache and spent the next day resting. Wednesday morning March 3rd, the patient reported extreme fatigue, dizziness and feeling "woozy". As she was walking around the store, around 8:30am, patient had to request help as she almost fainted. Patient went home quickly after, reported dizziness until 3pm. Patient's friend who is a nurse came to her home to check her vitals, confirmed they were normal and encouraged fluids/rest. After resting further Wednesday/Thursday, patient returned to work Friday morning and has been fine since. Patient did not take any medications prior/during/after incident. |
| 1101893 | 3/15/2021 | IL | 58 | F | 3/12/2021 | 3/13/2021 | - dizziness, nausea, throwing up, and passed out for approximately 2-3 minutes approximately 17 hours following vaccine - headache, muscle and joint pain, chills, feeling tired, weak, and unwell from 8 hours following vaccine until 48 hours following vaccine |

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| 1101794 | 3/15/2021 | VA | 45 | M | 3/13/2021 | 3/13/2021 | Felt extremely warm, started feeling lightheaded, started sweating profusely, vision started blacking out, got very close to blacking out and fainting. I was seated at the time, waiting the 15 minutes for observation after the shot, symptoms happened about 10 minutes into the waiting period. I was given some cold water right away, over the next 10 minutes my vision started coming back and I stopped sweating. Was told I looked flush when they first came over but was looking much better after another 10 mins. I stayed an additional 30 minutes for observation after the event and had friends come take me home and get my car. I'm still feeling very slightly light headed and somewhat tired 2 days later, but otherwise feeling great. |
| 1101758 | 3/15/2021 | IL | | M | 3/11/2021 | 3/11/2021 | LIGHTHEADED, POST VACCINE 10 MINS. HAS FAINTED BEFORE AS A CHILD MIXTURE OF NERVES AND IT AS WARM INSIDE TENT |
| 1101737 | 3/15/2021 | IN | 56 | M | 3/11/2021 | 3/11/2021 | Pt felt lightheaded once in parking lot after receiving vaccine around noon. Beeped horn at 12:10pm. Fainted and reports possible stiffening of limbs/seizure activity. Hx of fainting with needles. Pt was pale and lightheaded when nurse arrived to car at 12:11pm. 911 called immediately due to possible seizure. BP 90/50, unable to obtain pulse and O2 sats. Ambulance on scene at 12:17pm and patient transported to hospital via ambulance at 12:30pm. Pt was feeling better and responsive when he left scene. |
| 1101581 | 3/15/2021 | MO | 72 | M | 3/13/2021 | 3/13/2021 | BEFORE THE TIME WAS UP WAITING TO BE RELEASED AFTER THE SHOT. I STARTED TO SWEATING , JUST THOUGH IT WAS WARM IN BUILDING. SO THEY SAID MY TIME WAS UP THAT I COULD LEAVE. MADE IT TO MY CAR OK AND SETTING BEHIND THE WHEEL , I TOOK A FEW SHIPS OF WATER . THEN I TOLD MY WIFE I WAS FEELING LIKE I WAS GOING TO GET SICK. I TOLD HER GO GET SOME HELP AND SHE WENT BACK IN AND GOT SOME NURSES AND THEY CAME RUNNING, BUT THE TIME THEY GOT BACK I WAS ALL READY PASSED OUT . THEN I THREW UP THEY SAID . I DON'T REMEMBER. THEY CALLED AN AMBULANCE THEY GOT THERE AND TOOK ME TO THE HOSPITAL EMERGENCY |

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| 1101516 | 3/15/2021 | KS | 18 | M | 3/12/2021 | 3/12/2021 | Patient Passed out a few minutes after he received his vaccine and was walking to observation. was with patient and claims it is not unusual for the patient to pass out from needle fear. Patient was monitored by staff and had no other issues. Patient rested and drank fluids for thirty minutes and left. was fairly certain it was his fear of needles that made him pass out. |
| 1101933 | 3/15/2021 | NC | 82 | F | 3/6/2021 | 3/7/2021 | March 7, 2021 at about 6:30 p.m. I had two spells where I had no control over my body. I fell and could not get up. I had no strength and was unable to get up. Each time it only lasted a few seconds or minutes. It was sort of like I fainted but stronger. I had spent most of the day resting as I had a very bad headache but that was about gone when I had the two spells. I had also had a small patch of hives (fever and swelling) about the size of my hand at the site of the shot. That lasted about a week after each shot. I thought this was something I should report. Thanks. |
| 1101566 | 3/15/2021 | NY | 22 | F | 2/25/2021 | 2/25/2021 | Extreme dizziness and fainting after standing up for a prolonged period of time 12 hours after the second dose of the vaccine. |
| 1101702 | 3/15/2021 | | 27 | F | 3/15/2021 | 3/15/2021 | Patient with syncope a few minutes after vaccination. Able to keep patient upright in chair until able to get in wheelchair. After a minute or two, patient was alert again. Given juice. Vitals stable. Able to discharge home with boyfriend. |
| 1101951 | 3/15/2021 | | 42 | M | 3/15/2021 | 3/15/2021 | presyncope, nausea, evaluated by EMS, refusal to transport. |
| 1101969 | 3/15/2021 | IN | 29 | F | 3/13/2021 | 3/15/2021 | Patient fainted shortly after receiving the vaccination. She was seated in the post observation area. It occurred approximately 3 minutes after receiving the vaccination. Patient stated that she started feeling dizzy and then remembered waking up. She woke up quickly and EMS arrived to assess the patient. |
| 1102089 | 3/15/2021 | GA | 36 | M | 3/15/2021 | 3/15/2021 | Vasovagal syncope. Felt better after laying down for a while and then slowly drinking water and eating granola bar. |

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| 1102213 | 3/15/2021 | IL | 45 | M | 3/12/2021 | 3/13/2021 | High fever/ chills to increased 104.6 on 2nd day , not controlled by 400 g of ibuprofen and 500 mf of Tylenol. Finally additional 500.mg was taken in 4 hrs span to break the fever. Severe body aches and inability to sleep. Next day was better qith fever only raging to 100 deg. 4rh day, Monday went to work feeling very weak. Passed out suddenly an hour into work, luckily passed out sitting in chair. 911 was called, all things normal , except weakness, aching, dizziness, Declined er transfer. |
| 1102231 | 3/15/2021 | WI | 88 | F | 3/11/2021 | 3/12/2021 | pt got to feeling really sick w/ headache, nausea, light headed and fever of 100.9. Pts son called ambulance. Pt passed out when EMTs were treating her. Pt was taken to hospital ER on 3/12/2021. They did blood work, covid test (negative) and CT. She was given fentanyl then admitted to the 2nd floor room for observation and given an IV. DX was reaction for Covid Vax. She was discharged on 3/14/2021 to FU w/ PCP within 1 week. |
| 1102255 | 3/15/2021 | TX | 59 | F | 3/15/2021 | 3/15/2021 | PATIENT FAINTED DURING IMMUNIZATION, NO TREATMENT, PATIENT WOKE UP IN 2 MINUTES AND REFUSED EPI-PEN AND AMBULANCE SERVICE |
| 1102264 | 3/15/2021 | MN | 20 | F | 3/15/2021 | 3/15/2021 | PATIENT STATED FELT DIZZY AND FAINTED AT TIME OF ADMINISTRATION. THE PATIENT WAS RESPONSIVE WITHIN 1 MINUTE AFTER FALLING TO FLOOR AND WALKED OVER TO POST-IMMUNIZATION AREA FOR OBSERVATION. SHE STATED THAT SHE FELT FINE AND DID HAVE A BIT OF A SORE ARM AROUND THE ADMINISTRATION SITE. SHE STATED THAT IT FELT LIKE HALF OF THE PAIN OF A TETANUS SHOT. SHE DID TAKE A GLASS OF WATER AND STATED THAT SHE HAD RECENTLY EATEN. 911 WAS CALLED AND THE PATIENT EVALUATED AND WALKED OUT OF STORE. NO MEDICATIONS ADMINISTERED A TIME OF EVENT. |

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| 1102333 | 3/15/2021 | MD | 69 | F | 3/1/2021 | 3/2/2021 | day 2 (3/2/2021) left arm swelling and red over the inject site; painful to raise arm overhead. day 3 - fatigue/chills - arm better, little pink inject area; swelling down. day 4 nausea/regurgitation/loose stools. day 5 called doc Thursday still weak- Dr said symptoms are among those possible; Advised I likely have more severe symptoms for 2nd shot; get gatorade; Imodium, BRAT diet foods, etc. Mon 3/8 had 3 near fainting spells. (3/8 pm -red painful rash on left arm inject site. Lasted till 3/15 Mon COVID ARM?) Checked BP and Pulse/Oxy. Called Doc/video visit; Thought my BP/O2/Pulse numbers OK/ Ordered blood work. 3/11/2021 8:40am did blood/urine tests/ Made follow up appt for 3/16 with GP. |
| 1102344 | 3/15/2021 | VA | 23 | F | 3/15/2021 | 3/15/2021 | PATIENT FAINTED IMMEDIATELY AFTER VACCINE ADMINISTRATION. BP WAS ELEVATED INITIALLY AND PATIENT WAS MONITORED AND REQUIRED NO FURTHER INTERVENTION. |
| 1101508 | 3/15/2021 | GA | 29 | F | 3/12/2021 | 3/13/2021 | On the day following my second dose, I woke up with a headache around 6am (expected this may happen and took Tylenol). A little before noon my partner and I got in the car to run an errand. In the car I started to feel worse and I fainted. I was out for about 30 seconds according to my partner. I came to and had my vitals checked at an urgent care center (all vitals WNL). During this episode in the car I think I also had chills. The onslaught of symptoms in the car lasted only about an hour before resolving. I continued to have a off and on headache for the rest of the day but other symptoms resolved. By Sunday I was pretty much back to normal; any headache symptoms were pretty much resolved. I am not sure if the fainting episode was related to vaccine or not. I have had fainting episodes in the past (2-3x at dentist office and 1x at optometrist when having eye pressure checked). |

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| 1100264 | 3/15/2021 | | | F | 2/23/2021 | 2/24/2021 | passed out on the floor; fainted; A spontaneous report was received from a female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and who fainted and passed out on the floor. The patient's medical history was not provided. Concomitant medications included a blood pressure pill and a thyroid pill. On 23 Feb 2021, the patient received the second of two planned doses of mRNA-1273 (Lot number: unknown) intramuscularly in the right arm for prophylaxis of COVID-19 infection. The details of the administration of the first dose were not provided. On 24-Feb-2021, after being awake for 30 minutes, the patient passed out on the floor and fainted. Treatment information was unknown. Action taken with study drug was not applicable as the patient had already received both scheduled doses. The outcome of the events, fainting and passed out on the floor, was resolved on 24 Feb 2021.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |
| 1102324 | 3/15/2021 | VA | 23 | F | 3/15/2021 | 3/15/2021 | PATIENT FAINTED IMMEDIATELY AFTER VACCINE ADMINISTRATION. BP WAS INITIALLY ELEVATED BUT PATIENT WAS MONITORED AND PATIENT DID NOT NEED ADDITIONAL INTERVENTION. |
| 1100789 | 3/15/2021 | NY | 44 | M | 3/14/2021 | 3/14/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Patient was feeling paralyzed. However, we can clearly see the patient moving all his extremities-Mild, Systemic: Headache-Mild, Systemic: Weakness-Mild |

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| 1102345 | 3/15/2021 | VA | 33 | F | 2/20/2021 | 2/20/2021 | 1/23/2021 - The first Moderna vaccine. I had flu like symptoms, which included fatigue, muscles aches, muscle spasms, joint aches, chills, and shortness of breath for 2-3 days afterward. 2/20/2021 - The second Moderna vaccine. The side effects were much worse, including muscle aches, abdominal pain, back pain, headache, nausea, chills, fatigue, and shortness of breath. I also found myself limping. 2/21, 2/22, 2/23 - I rested and stayed home from work. Most of my symptoms had improved by the evening of the 23rd, and I felt like the shortness of breath was also improving if I took it easy. 2/24 - I went to work where the shortness of breath became much worse after working for a couple of hours. I began to get dizzy, and my hands and feet were cold and tingling. The school nurse checked my temperature (which was normal) and oxygen levels (99%). I was sent home and told to take another day or two off. I was fine if I was sitting still and doing nothing, but talking caused me to become winded. Walking and exertion of any kind caused me to become winded. Once winded, it would take 15 minutes of sitting still to get my breathing back under control. Then I would be hit by a wave of fatigue. Also, when my breathing was bad, I walked with a limp. 2/25 - I went to the shortness of breath was still bad. They were concerned. They took a chest x-ray (which came back clear), did blood work (which was normal), and gave me a Rapid Covid test (which was negative). My oxygen levels were at 99%. They prescribed a 6 day pack of MethylPREDNISolon. If I was not better by Saturday, they wanted me to return. They also did a PCR test (this came back negative on 2/28). 2/26 - The steroid did not help, and by the evening, I was worse. I went to the ER. The doctors there were concerned about a pulmonary embolism. They did blood work (which was normal), a chest x-ray (which came back clear), and an EKG (which was normal). My vitals were good, though my blood pressure was high for me (113/64). The doctor told me to continue the steroid pack and prescribed an albuterol inhaler. I was directed to contact a pulmonary specialist on 3/1 if symptoms did not improve. The doctor wrote a note for me to work from home through 3/5. 3/1 - The shortness of breath did not improve. I almost passed out while driving after I picked up my two small children from school. I could not catch my breath in the car and started |

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to get lightheaded. When I parked, I stayed in the car huffing and puffing for several minutes. I was seeing spot, was dizzy, and my hands and feet were tingling. When I climbed out of the car, my legs buckled beneath me. I was able to grab onto the car and not fall. I had some really bad breathing episodes between 3/1-and 3/3. At these times, the breathing was so rough, that I couldn't even talk. It would take 30 minutes or more of sitting still for me to be able to bring my breathing under control. 3/3 - Appointment with Pulmonary Specialist. I had an appointment. He ruled out asthma, as the inhaler and steroid were both ineffective. He considered anxiety, but the problem was clearly not a panic or anxiety attack. (I have experienced those before and know the difference.) He ruled that out. He ran a pulmonary function test (which was normal) and a CT scan with contrast (which was normal). The doctor wrote a note for me to work from home through 3/10. 3/4 and on - My breathing was better some days than others. The less energy I exerted, the better I did. If I did too much one day, my breathing would be worse the next day. 3/7 - Ajoyv injection. I was past due for this monthly injection. Once injected, I had an allergic reaction to it for the first time ever (this was the 7th time I used it). A few minutes after the injection, the injection area had a rash and was itching like crazy. I put ice on it and took benadryl. It was fine by the next morning. 3/9 - Appointment #2 with Pulmonary Specialist. The specialist was not sure what the problem was with my breathing. I was the first patient with these vaccine side effects that he had seen. He scheduled more tests and said he wanted to read more literature. He wrote a note for me to work from home through 4/6.

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| 1100260 | 3/15/2021 | AZ | 38 | F | 1/22/2021 | 1/22/2021 | back pain; difficulty breathing; heart racing; heart hurting; felt like she would pass out; A spontaneous report was received from a consumer who was also a 38-years-old, female patient, who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced heart racing (palpitations), heart hurting (angina pectoris), difficulty breathing (dyspnea), felt like she would pass out (presyncope) and back pain. The patient's medical history was not provided. Concomitant product use was not provided. On 22 Jan 2021, the patient received the first of two planned doses of mRNA-1273 on (Batch# 043L20A) (route of administration unknown) for prophylaxis of COVID-19 infection. On 22 Jan 2021, after three weeks post vaccination, the patient reported still having symptoms of her heart racing and hurting, difficulty breathing, felt as if she was going to pass out, and about a week of back pain. On 12 Feb 2021, the patient went to the emergency room (ER) for heart symptoms. She reported everything was fine at the ER. The patient was to have second dose on 16 Feb 2021 and inquired on whether to have the second dose if experiencing all of these symptoms. No treatment information was provided.. Action taken with mRNA-1273 in response to the events was unknown. The outcome of the events was unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |

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| 1100232 | 3/15/2021 | TX | 64 | F | 1/2/2021 | 2/21/2021 | Fainted; Sweating; Vision was blurry; It went "black"; Whole skin feels cold; Felt something weird on her body; vision was sparkly; Chills; A spontaneous report was received from a Consumer concerning a 65-years-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced events felt something weird on her body, sweating, chills, vision was blurry, vision was sparkly, it went black, she fainted, whole skin feels cold, just feels weird. The patient's medical history was not provided. Products known to have been used by patient, with in two weeks prior to the event, included levothyroxine, lisinopril, amlodipine, omeprazole, atorvastatin, baby-aspirin, lisinopril hydrochlorothiazide. On 2-Jan-2021, patient received the first of two planned doses of mRNA-1273 (lot/batch: 037K20A) intramuscularly at right arm . On 28-Jan -2021, prior to the onset of the events the patient received their second of two planned doses of mRNA-1273 (lot/batch: 010M20A) intramuscularly at right arm for prophylaxis of COVID-19 infection. On 21-Feb-2021, the patient experienced the events felt something weird on her body. sweating, chills, vision was blurry, vision was sparkly, it went black, she fainted, whole skin feels cold, just feels weird. Treatment information was not provided. The patient received both scheduled dose of mRNA-1273; therefore, action taken with the drug in response to the event is not applicable The outcome of events, felt something weird on her body, sweating, chills, vision was blurry, vision was sparkly, it went black, she fainted, whole skin feels cold, just feels weird were considered unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |

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| 1100267 | 3/15/2021 | | | F | 3/3/2021 | 3/3/2021 | chills; fatigue; heat from head; sweating; Passed out; A spontaneous report was received from a 51- year old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and who experienced heat from head, sweating, passing out, chills and fatigue. The patient's medical history was not provided. No concomitant product use was reported. On 03-Mar-2021, the patient received the first of two planned doses of mRNA-1273 (Lot number: 001211a) intramuscularly for prophylaxis of COVID-19 infection. On 03-Mar-2021, 4.5 hours after the administration of the vaccine the felt heat from head and was sweating following which the patient passed out. On 04-Mar-2021, it was reported the patient was feeling better despite of experiencing chills and fatigue. Treatment information was not provided. Action taken with mRNA-1273 was unknown. The outcome of the events was unknown; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |

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| 1100284 | 3/15/2021 | MI | | F | 1/28/2021 | 1/29/2021 | sore arm/arms were quite sore; injection site pain; extreme fatigue/exhaustion; a little headache; chills; muscle pains which makes them a little achy overall; feel like they have Covid all over again; achy; feel lousy; sleepy all afternoon and stated that she sat down and just passed out, caller clarified that she went to sleep/very drowsy; issues with breathing and shortness of breath; This is a spontaneous report from a contactable consumer (patient herself) via Medical information team. A 77-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Lot number: EL3248) intramuscularly on 28Jan2021 at single dose in left arm for COVID-19 immunization. Medical history included Covid (she had Covid already). Concomitant medication was none. Patient received the 1st dose of the vaccine yesterday afternoon. Today patient experienced a sore arm, injection site pain, extreme fatigue, a little headache, chills, and muscle pains which makes them a little achy overall on 29Jan2021. she received the vaccine yesterday and stated that she felt like she has Covid all over again on 29Jan2021. She stated that she had Covid already and stated that they have chills and are achy in 2021. Caller said that she was also having issues with breathing and shortness of breath in 2021. Caller said that she was also having that Covid exhaustion. Their arms were quite sore too from the shot, but she did not expect to feel lousy in 2021. patient have been sleepy all afternoon and stated that she sat down and just passed out, caller clarified that she went to sleep in 2021. Yesterday they were ok, but she felt sleepy. She started feeling very drowsy after the shot and they were fine all night. Caller said that since they have slept all afternoon they have perked up a little bit. She does not feel the chills anymore, she turned the furnace up a little bit. Achy: She said that it has improved as her back does not hurt as badly. patient said that this was her first dose of the Covid-19 vaccine. The outcome of event chills was recovered on 29Jan2021, for fatigue, COVID-19 and ache was recovering and for other events was unknown. No follow-up attempts are possible. No further information is expected. |

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| 1100396 | 3/15/2021 | | 24 | F | 2/5/2021 | 2/6/2021 | Passed Out; upset stomach; Dry heaving; Stomach Cramps; Chills; Fever; This is a spontaneous report from a non-contactable consumer (patient). A 24-year-old female patient (not pregnant) received bnt162b2 (lot number unknown), via an unspecified route of administration, at Left arm, on 05Feb2021 16:15 at SINGLE DOSE for COVID-19 immunisation. The patient medical history was not reported. There were no concomitant medications. No covid prior vaccination. No covid tested post vaccination. No other vaccine in four weeks. The patient experienced woke up out of her sleep, upset stomach. Dry heaving. Stomach Cramps. Chills. Fever. Passed Out. Adverse event started on 06Feb2021 12:00 AM. No treatment AE. The outcome of the event was recovered in Feb2021. No follow-up attempts are possible; information about lot/batch number cannot be obtained. |

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| 1100471 | 3/15/2021 | SC | 70 | F | 2/1/2021 | | <p>syncope; afib; afib; soreness, redness, and pain at injection site/left arm pain/under arm pain; soreness, redness, and pain at injection site; her blood pressure was really high and kept going up and down like a roller coaster; She was taken to the ER and began feeling sick to stomach in ambulance; headache; felt her ears vibrating; Breast, arm and clavicle starting hurting two weeks and one day after the injection; Breast, arm and clavicle starting hurting two weeks and one day after the injection; Breast, arm and clavicle starting hurting two weeks and one day after the injection; She is anxious about getting the second vaccine; Enlargement of lymph nodes; increased heart rate; This is a spontaneous report from a contactable Nurse reported for self. This 70-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 01Feb2021 on Arm left at single dose (Lot # EL9262, Expiration: May2021) for covid-19 immunisation. Medical history included Atrial fibrillation from Jan2020. Had 2nd dose appointment scheduled but canceled appointment. Concomitant medications included apixaban (ELIQUIS) from 07Feb2021 at 5mg twice a day by mouth (provided SN100089537925, LOT 1771228, EXP: May2023, NDC: 0003-0894-21) for Atrial fibrillation. History vaccine included a Tetanus shot 40 years ago (1981) for immunisation and reacted terrible to it. She reports having and experienced soreness, redness, and pain at injection site. She reports getting a mammogram sometime after receiving the vaccine. They saw a spot they are going to recheck and saw swollen lymph nodes on the left side/ Enlargement of lymph nodes, which is the same side she received her vaccine. She was told it was most likely due to the vaccine. Six days later she suddenly felt sick, near syncope, couldn't catch her breath. It got so bad she thought she was dying and called EMS. Leads confirmed afib, her blood pressure was really high and kept going up and down like a roller coaster. She was taken to the ER and began feeling sick to stomach in ambulance. IN the ER she received 1000 ml of fluids and additional metoprolol in addition to dose she took that evening at home. She was sent home to follow up with her Cardiologist the following Monday. He wasn't sure if it was due to vaccine and started her on twice daily eliquis and increased her toprolol immediate release to twice daily. The following Friday night she got</p> |

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a headache and felt her ears vibrating. Her home EKG was fine, but blood pressure was high again and stayed up for hours. Took additional toprolol. Came down after 5 hours. Breast, arm and clavicle starting hurting two weeks and one day after the injection. She is anxious about getting the second vaccine. Asked PCP if she needed an antigen test to see if she needed a second dose of the vaccine. She says she got her first dose 01Feb, then on Wednesday, 03Feb she went and got a mammogram which had already been planned. She says that they saw enlarged lymph nodes to her left breast, under arm, and clavicle which they said are due to vaccine, but they also said they saw something else so they wanted to do a repeat mammogram three months later. She says it took two weeks, but suddenly her left breast and under arm were killing her, caller did not clarify this statement. She says she talked to her doctor who said don't worry it might take a while to go down. She says that the other thing is she has known atrial fibrillation that was diagnosed a year ago, and most of the time it is quick and doesn't last long, sometimes she doesn't know she is having it. She says 6 days after the first dose she started to feel ill, she had been in bed reading so she got up to get some water and suddenly felt like something was wrong and like she was going to pass out, she couldn't breathe, so she called EMS. She says her atrial fibrillation is not unusual, but she has never had it to where she couldn't breath. She says that the rate they estimated was 350, and her only other documented that was high like that was 150. She says that they treated her and she went home, and when she saw her cardiologist they said they don't know if the vaccine had to do with this, and to report it. She says a week later, on Friday a week ago, she started feeling funny standing while she was working on the computer in the middle of the afternoon, she felt like her ears were vibrating, which was very unusual, and she didn't know what was wrong so she looked at her Cardia app, and her heart was in normal sinus, and she checked her blood pressure which for her was sky high, up to 190/100 which her blood pressure is usually very low. She provided a second blood pressure that call handler was unable to capture and caller did not clarify as she no longer had her log with her. She says for hours her blood pressure (BP) went up and down, which was a similar or

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same thing as what happened that night she went to the ER with her atrial fibrillation, her BP would go up and down like riding a wave. She says needless to say, she has two questions: she says she doesn't know if there have been reports of that vaccine making A-fib worse, she is scared to get her second dose which she was supposed to get Monday a week ago, but put off primarily before the second thing with BP, she thought she would wait because she could hardly move her left arm so she put it off until the next Wednesday, She says that her second dose is now scheduled for 03Mar, so 4 weeks between doses, and she is a little afraid to get it because she doesn't know if her response was over the top or caused the other things, going to the ER with A-fib was terrifying, and she doesn't want that to happen again. She says people say that she has got to get her second dose because she won't be protected, so she would also like to know if it is possible for her to get antigens early on. She says that she had a tetanus shot 40 years ago, and had a horrible reaction after it, then years later they did a titer for tetanus and they said she would likely never need a tetanus shot again since she had built up such a high level and would never need it again. She says is it possible that she had enough immunity that she wouldn't need the second dose, or would there be an antigen test that could tell her if she would need a second dose, if so what is that test? She says she is afraid the next dose will kill her. AE treatment included says that when she went to the ER it was about 12:30AM when she arrived, they did not admit her. She says on the way to the ER in the EMS truck they gave her Cardiozyme to get her blood pressure going down and gave her 1000 cc fluids, and Metoprolol, another dose. She says that the Cardiozyme was IV push in the ambulance, she doesn't have the information to provide for all of the heart stuff they gave her, NDC/LOT/EXP: Unknown for Metoprolol or Cardiozyme. She clarifies that she takes Metoprolol normally every day that they have had her on that is extended release and she takes it at night. She says she had taken that at 09:30PM, and by the time she got there to the ER after midnight a little, they after gave her another to see if it would bring her heart rate down. She says that they kept her there a couple of hours, until her heart rate was normal, though her BP was up a bit. She says that they told her they could admit her but she said

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she would rather go home if they thought it was safe, and she went home. She says that her sister came home and stayed with her, whose husband is a cardiothoracic surgeon. Metoprolol: Caller says that the Metoprolol she is taking is in a pharmacy bottle that says use by 08Feb2022, it does not have an official label, the NDC or LOT are not on there. She says that they gave her 60 to take of regular Metoprolol, not extended release, which is 25mg to take twice a day by mouth, so 60 tabs and she would need to get refills as it is a months worth. Metoprolol extended release NDC/LOT/EXP not provided when queried. She clarifies that the not extended release is called Toprol/Metoprolol Tartrate 25mg. Caller says that her swelling lymph node limited the use of her arm, she can't pick up anything or lift her self up while moving in the bed, she is miserable, it hurts to put pressure on her arm and she can hold her arm up and move it around she can do anything with not holding anything, she feels a tightness there, even when she breathes or coughs. She says her left arm was sore initially for 3-4 days after getting the shot but the soreness left. She says she was told on 03Feb that she had swollen lymph nodes, which was two days after the shot, but she couldn't feel them then, she couldn't tell, and had no pain. She says it was two weeks later that happened, it was so odd that it was two weeks before it was hurting then got progressively worse. Caller says that Tuesday a week ago she thought she must have done weights with her arms since her muscles were sore, but it was only on one side and she hadn't done any exercise since after she went to the ER she was being careful what she did, and she thought she strained her arm and realized what it was, it has gotten progressively worse over the last week. She says last night she started looking up remedies, she has been putting ice on it, and the clinic said use warm, and she rubbed castor oil on it last night in the shower then this morning she massaged her arm with castor oil and put a warm wash cloth over it. She says that castor oil has anti inflammatory properties. She says she has not noticed a difference yet, but she has only done it two times. She says it also said she can take Aleve or Ibuprofen, they told her at the ER, they also started her on Eliquis the night she was there, which she had never been on, they didn't consider her A-f fib bad enough. She says that is what has her concerned, she got the shot then 6 days

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later A-fib made her feel like she couldn't breathe. She says also her BP and heart rate going back up made her sick to her stomach that subsided when her BP was coming down but then it started going back up again, when she went to the ER that Saturday night on the 6th but by the time she got there it was the 7th. Outcome of the events was unknown.; Sender's Comments: The possibility that suspect drug may have contributed to the reported event cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer drug is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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| 1100477 | 3/15/2021 | TX | 64 | F | 2/24/2021 | 2/24/2021 | dehydration; slight fever (99); chills; passed out in floor; sweating; Broke a tooth; Dizzy; Diarrhea; Super tired and went to bed by 8pm after COVID-19 vaccine; Arm was sore; This is a spontaneous report from a contactable consumer (patient). A 64-year-old female patient received the 1st dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), via an unspecified route of administration, on 24Feb2021 at 15:00, at single dose, for COVID-19 immunisation. Medical history and concomitant medications were none. Patient did not have known allergies. Patient did not receive any other vaccine the same day and in four weeks. Patient did not have COVID-19 prior to vaccination. The patient experienced passed out in floor (medically significant) on 24Feb2021 at 10:30 PM, diarrhea (disability) on 24Feb2021, broke a tooth (medically significant) on 24Feb2021 at 10:30 PM, dehydration (disability) on 25Feb2021 12:00 AM, slight fever (99) (disability) on 25Feb2021 at 12:00 AM, chills (disability) on 24Feb2021 at 10:30 PM, super tired and went to bed by 08:00 PM after COVID-19 vaccine (non-serious) on 24Feb2021, arm was sore (non-serious) on 24Feb2021, sweating (non-serious) on 24Feb2021 at 10:30 PM, dizzy (non-serious) on 24Feb2021. No therapeutic measures were taken as a result of the events. Patient stated that all side effects resolved completely by 25Feb2021 evening, except for broke a tooth. Patient did not tested positive for COVID-19 post vaccination. The information on the Lot/Batch number has been requested. |

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| 1100563 | 3/15/2021 | NC | 74 | F | 2/25/2021 | | watery eyes; runny nose; slight headache; This is a spontaneous report from a contactable consumer. A 74-year-old female patient received the 2nd dose of bnt162b2 (BNT162B2) at single dose on 25Feb2021 for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient received the 1st dose of bnt162b2 (BNT162B2) on 01Feb2021 for COVID-19 immunisation and she experienced she passed out and fell to the floor before daylight and dizziness on 01Feb2021. The patient experienced watery eyes, runny nose and slight headache in 2021. No treatment was received. No admission to hospital due to the events. The outcome of events was recovered in 2021, she was fine now. Information about lot/batch number has been requested. |
| 1100271 | 3/15/2021 | WI | 82 | F | 2/8/2021 | 2/10/2021 | Lost control of muscles; ended up blacking out; could not move; could not talk; A spontaneous report was received from a Consumer concerning about a 82 years old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced Paralysis, Syncope, Mobility decreased and Aphasia. The patient's medical history was provided as diabetes, dementia as current illness. Relevant concomitant medication was reported as blood thinner for blood clots. On 08 FEB 2021, prior to the onset of event, the patient received their first dose of two planned doses of mRNA-1273 (lot/batch: unknown) for prophylaxis of COVID-19 infection. On 10 FEB 2021, the patient experienced Paralysis, Syncope, Mobility decreased and Aphasia. Due to these events patient's required hospitalization and on oxygen. Laboratory details was not provided. Treatment information was not provided. Action taken with mRNA-1273 in response to the events was unknown. The outcome of the event's Paralysis, Syncope, Mobility decreased, and Aphasia was as unknown.; Reporter's Comments: The events were consistent with increased risk of cerebrovascular complications associated with elderly age of patient. Company assessed the events to be unlikely related to company product. |

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| 1100786 | 3/15/2021 | CA | 26 | F | 3/14/2021 | 3/14/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Shakiness-Mild, Systemic: Weakness-Mild, Additional Details: patient has a history of fainting after vaccine administration |
| 1101476 | 3/15/2021 | PA | 33 | M | 3/15/2021 | 3/15/2021 | Patient was standing and felt dizzy/light headed and fainted in the store roughly 3 minutes after vaccination. |
| 1100791 | 3/15/2021 | NY | 23 | M | 3/13/2021 | 3/13/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild |
| 1100814 | 3/15/2021 | CA | 30 | F | 3/12/2021 | 3/12/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild |

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| 1101151 | 3/15/2021 | IA | 92 | F | 2/19/2021 | 2/21/2021 | Sore arm; Passed out; loss sense of time for 36 hr; so weak to get up; Vomiting for several time; A spontaneous report was received from a consumer, who was a 92 year-old, female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced sore arm, lose the sense of time, vomiting for several time, so weak to get up and passed out. The patient's medical history included cancer, restless leg syndrome, allergies to shellfish and currently living in hospice. Concomitant products included rivaroxaban, digoxin, diltiazem, omeprazole, pramipexole, vitamin D3, budesonide and paracetamol prn. On 19 Feb 2021, the patient received the first of two planned doses of mRNA-1273 (Lot number: 004M20A) intramuscularly for prophylaxis of COVID-19 infection. On an unknown date after receiving the vaccine, the patient experienced sore arm. One night, she lost the sense of time for 36 hours. She got up in the middle of night and went to bathroom and was vomiting for several time. She then got back to bed with waste basket and was so weak to get up. She called the nursing home next door and she believed that they may have called 911 but was not full sure if they did or did not. The next day morning, one of the neighbors came to check on her at 11 am. When the neighbor tried to wake her up, she was passed out therefore the nursing home called 911 again. Patient believed that nurse gave her a shot to stop vomiting but do not clearly remember. She was not planning on getting the second dose of the vaccine. No treatment information was reported. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events, sore arm and so weak to get up, were unknown. The outcome of the events, lose the sense of time and passed out, were considered resolved on 22 Feb 2021.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |

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| 1101158 | 3/15/2021 | CA | 49 | F | 1/25/2021 | | almost fainted; low blood pressure; sore arm; shaking (chills); A spontaneous report was received from a forty-nine-years old female consumer, who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced low blood pressure, almost fainted, sore arm and shaking (chills). The patient's medical history was not provided. No relevant concomitant medications were reported. The patient received the first of the two planned doses of mRNA-1273 on 25-Jan-2021 (Batch# 041L20A) intramuscularly for prophylaxis of COVID-19 infection. Approximately 12 hours later , she experienced low blood pressure, almost fainted, had sore arm and had shaking (chills). No treatment information was provided. Action taken with mRNA-1273 in response to the events was not reported The outcome of the events was reported; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events 12 hours after vaccination, a causal relationship cannot be excluded. Further information has been requested |
| 1101217 | 3/15/2021 | IL | 78 | F | 3/12/2021 | 3/12/2021 | Injection hit blood vessel, bleeding, dark blue bruise. Intense Swelling down arm to elbow, deep redness and itching Friday 3-12-21 to today?s date 3-15-21 continues. 3-13-21 fainted after shower, 3-14-21 some dizziness during day. No dizziness as of 3-15-21. Swelling down some, Itching continues. |
| 1101245 | 3/15/2021 | FL | 44 | M | 3/12/2021 | 3/14/2021 | Sudden onset of severe dizziness (causing nausea), balance/standing/ walking issues. Complete weakness. Total loss of color/hue in complexion. Difficulty communicating. Feeling of things shutting down or not continuing to ?work.? Got to bed and passed out for over 10 hours. Woke up feeling mostly better. |
| 1101253 | 3/15/2021 | TX | 35 | F | 2/25/2021 | 3/4/2021 | A week after I fainted, dizziness, blurred vision. |
| 1101423 | 3/15/2021 | FL | 84 | F | 2/12/2021 | 2/13/2021 | I passed out the next day and had to be taken to Bethesda East ER. |

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| 1101426 | 3/15/2021 | | 28 | F | 3/12/2021 | 3/13/2021 | ~24 hours after vaccination, individual was in the shower and passed out. Patient remembers getting in the shower, and woke up on the floor of the shower. Patient does not know for how long, probably not more than an hour. Patient had not eaten that day. Afterward, patient had a headache for about a day. Patient has been well since Sunday. Patient did not feel need to seek care in ED or doctor's office. Patient came to office to file a report. Scheduled an appointment with provider on Thursday. |
| 1100703 | 3/15/2021 | VA | 20 | F | 3/13/2021 | 3/14/2021 | Pt presented to the medical department after a single episode of syncope that occurred the day after receiving her vaccine. Upon evaluation, she stated that she had not eaten for an entire day prior to her episode of syncope. She also reported diffuse body aches and a headache. She was given a shot of toradol and 2L of IVF and her symptoms improved. |
| 1103429 | 3/15/2021 | AR | 67 | F | 3/6/2021 | 3/7/2021 | Patient said she passed out 3 times the next day, has felt dizzy all week, and her blood sugar has been elevated. |
| 1103088 | 3/15/2021 | TN | 58 | F | 3/10/2021 | 3/11/2021 | Patient awoke in the night with severe shaking, chills. Reports back and chest pain-began vomiting, then fainted and hit her head on toilet. Did not seek medical attention. Refuses second vaccine. |

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| 1103100 | 3/15/2021 | LA | 66 | F | 3/11/2021 | 3/12/2021 | Woke up around 2 am with stomach cramps, loose bowels, nausea, chills, sweating, dizziness, sore left arm, very shaky feeling. Went to bathroom for bowel movement, had trash can in front of me in case of vomiting. Apparently passed out and fell off toilet. Woke up on floor, on my right side, with very cold chills and sweating. Finished going to bathroom. Noticed small cut on forehead, with dried blood, probably from hitting my head on trash can I was holding. Went back to bed. Still dizzy, chills, sweating, stomach cramps, nausea, sore arm, and aching all over. These symptoms persisted for hours. Finally fell asleep, woke up around 7:30 am, still dizzy, stomach cramps. Took temperature, normal, took blood Additional information for Item 18: pressure, also normal. Called office of primary care doctor, not open on Friday, declined appointment with another doctor, left detailed message, and was told they would contact me on Monday. Went back to sleep, woke around 11:15 am, still nauseous and stomach cramps and dizzy. Went back to sleep until around 2:30 pm. Woke up feeling better, still sore left arm, sore stomach, achy and very tired. |
| 1103157 | 3/15/2021 | MD | 55 | F | 3/12/2021 | 3/13/2021 | chest pain and nearsyncope 3/13 |
| 1103182 | 3/15/2021 | CA | 21 | M | 3/12/2021 | 3/13/2021 | I almost fainted the night after my shot. I had vaped cannabis prior at around 1:00am, and probably re-dosed at around 3:00AM, before falling asleep at around 4:30AM. I had a harder than normal time falling asleep that night, and I didn't sleep very well. At around 6:00AM I woke up and walked to the bathroom, feeling pain in my anal region. As I started to sweat profusely, I recognized that I was likely about to faint, so I pre-emptively lied down on the floor of the bathroom until I felt well enough to stand up. I don't remember exactly how long I was on the floor but most likely a few minutes. I then had a bowel movement, still feeling pain in my anal region but to a lesser degree, and then drank some water and went back to sleep at around 6:30AM. |

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| 1103238 | 3/15/2021 | IN | 51 | F | 3/15/2021 | 3/15/2021 | Lost consciousness and hit the floor from a seated position. Most likely vasovagal syncope which I have experienced previously. Dizziness and vertigo passed in about 15 minute and I safely left. 6 hours later I am experiencing some lightheadedness. |
| 1103259 | 3/15/2021 | | 33 | U | 3/9/2021 | 3/12/2021 | H/A,fever. HA, nausea, vomiting and chills since she got Moderna #2 3days ago. Takes tylenol,motrin and zofran q6hrs without relief. Pt is having periodic palpitations with near syncope, but no dyspnea/hemoptysis/pleurisy. VAERS data has shown several cases of otherwise unexplained embolic events in young healthy recipients of Pfizer and/or MODERNA COVID vaccines. Will evaluate for PE with Dimer. Another possible etiology is intermittent idiopathic tachydysrhythmias, which have also been frequently described in young healthy COVID vaccine recipients. For this reason, the patient will likely benefit from admission to telemetry bed overnight. Case discussed with Doctor (MOD) for admission- he will evalua |
| 1103266 | 3/15/2021 | NY | 69 | M | 3/13/2021 | 3/15/2021 | aches and pains, passed out and fell to floor, aches and pains gone |
| 1103289 | 3/15/2021 | AZ | 71 | M | 2/3/2021 | 2/15/2021 | Lightheadedness Shortness of Breath near syncope, Very sleepy 4 trips to ER at 2 different hospitals. One admission for 2 days and one admission for 5 days Symptoms still appearing upon discharge |
| 1103084 | 3/15/2021 | MI | 62 | M | 3/12/2021 | 3/12/2021 | Severe Vasovagal reaction with syncope. He has a past history of the same but assumed he had outgrown it based on recent experiences. |

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| 1103351 | 3/15/2021 | MI | 57 | M | 3/10/2021 | 3/10/2021 | <p>PRESENTING PROBLEM: Syncope and collapse [R55] HOSPITAL COURSE: History of Present Illness: 57-year-old man known to me for bilateral lung transplant for bronchoalveolar cell carcinoma complicated by bilateral pleural effusions of unknown etiology and mild decrease in pulmonary mechanics, DVT on Eliquis who came to the Emergency Room 3/12/21 with a chief complaint of near syncope. Patient and woke up in the early morning hours of 3/12/21 to use the restroom. While urinating, he became very dizzy and nauseated and had a sense like he needed to lay down to rest. Other than nausea he did not have any other symptoms. He returned to his bed and fell upon his wife and had decreased level of consciousness but without total loss of consciousness (he was able to hear his wife talking to him but was unable to respond). This lasted about a minute and slowly he came back to his senses. After this he felt quite cold and did have some shaking but is not clear whether these were true rigors. He did not have any preceding fevers nor did he have any fevers in the emergency room. After about 5-10 minutes he was feeling back to his normal self but want to come into the hospital to get checked out. He has never had anything like this before. The patient has had chest pressure since his COVID vaccine which he had on Wednesday. This is been intermittent, mostly positional and better with laying on his side and leaning forward, worse with recumbency. It is not pleuritic in nature. No associated shortness of breath. No other fevers chills sweats. No sick contacts. Evaluation in the emergency room was done and a CT scan was done and no pulmonary embolus was found. No parenchymal abnormalities. The patient's pleural effusions remain, and her mildly worsened, personally reviewed. Baseline labs were unremarkable for anemia, kidney injury. EKG personally reviewed, normal sinus rhythm. High sensitivity troponin was done and negative. Family otherwise feels well, no sick contacts, eating well no nausea vomiting diarrhea blood in his stool. Pt admitted for observation. Continued to feel well VSS, ekg stable, ECHO without acute findings (see below), UA neg, cardiac monitoring uneventful, orthostatics negative, walking in halls and eating well. Appears to have had vaso vagal episode. Will be getting routine head imaging in the coming month with cancer history See below testing Care plan upon discharge > To call if any return</p> |

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of symptoms > To hold metformin until Monday due to recent dye load > Blood cultures Pending, low clinical suspicion > To change H2 blocker to PPI due to GERD on 3 month esophagram > Follow up in clinic when return from break > Dr discussing with pulmonary team most recent CT (see below) and treatment plan moving forward Brief exam: awake, alert, oriented, not in any distress. PERRL, EMOI, tongue midline. Upper and lower extremities at full strength 5/5 in the arms, hands, dorsi flex and flexion at the ankles, knees and legs. Sensation not tested. Brief history and medical decision making: s/p bilateral lung transplant for bronchoalveolar cell carcinoma complicated by bilateral loculated pleural effusion, DVT on eliquis presenting post syncopal event. Syncopal event without evidence of seizure like activity, fast recovery, and no sudden changes consistent with an acute cardiac event. Thus symptoms were likely due to vasovagal event possibly post COVID_19 related side effect (headache, achy muscles, not feeling well overall). He has no neurologic deficit, CTA thorax without PE, negative EKG, troponin and echocardiogram. He is not on antihypertensives and blood pressures have been normal. Given his initial diagnosis of BAC, there may be concern for metastatic disease, though symptoms have not persisted and he has no focal deficit. He also received contrast for his CTA today, thus will defer further imaging for now. Syncope: - defer 2nd dose of COVID-19 vaccine as its effectiveness in transplant patient is not established and patient potentially had an adverse event. - oral hydration encouraged - monitor for additional ongoing neurologic symptoms such as headaches, vision changes, neck stiffness, fevers, night sweats, weight loss, weakness or paraesthesias - patient advised to avoid driving until further evaluation - consider MRI brain with and without contrast if any symptoms persist or reoccur Complex loculated pleural effusion

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| 1103280 | 3/15/2021 | SC | 48 | M | 3/15/2021 | 3/15/2021 | Patient received first dose of his Moderna COVID 19 vaccine and was seated in the waiting area around 11:45am. Around 11:49am patient had fainted and fallen to the floor slumped over onto the adjacent chair. 911 was called, and patient regained consciousness after a minute and was responsive and stated no issues other than dizziness. Patients BP was checked and documented, EMS arrived and also did a thorough exam of the patient and found him stable. Patient stayed in seating area to wait for spouse who came to escort him home around 12:40. |
| 1103442 | 3/15/2021 | CA | 74 | M | 2/27/2021 | 3/1/2021 | Periods of dizziness for 4 hours followed by patient unable to stand, almost passed out, lasted most of day and for two days after feeling of not being connected to surroundings |
| 1103448 | 3/15/2021 | IL | 54 | M | 3/15/2021 | 3/15/2021 | Patient fainted a few minutes after receiving vaccine. He stated he had a history of doing this with past vaccinations. 911 was called. Patient declined treatment and left store approximately 30 minutes later. |
| 1103449 | 3/15/2021 | NY | 62 | F | 3/13/2021 | 3/13/2021 | Patient received covid-19 vaccine at off-site clinic. As she was walking up to the post vaccination waiting area after receiving the vaccine, she suffered what appeared to be an anxiety attack and fainted. She awoke quickly and was monitored by pharmacy staff. She maintained good blood pressure and was fine afterwards. |
| 1103468 | 3/15/2021 | FL | 66 | F | 3/8/2021 | 3/9/2021 | First started with nausea, slept because was very tired, this is now 10 hrs after vaccine. Went outside after nap for short walk with husband, started sweating, came in house was getting sick to stomach. Started vomiting, dry heaving then passed out hit chin and fell hit head on tile floor. continued with dry heaves, got chills. We called for ambulance EMT to check vitals. Decided not to go to hospital, to wait it out. Vials were ok just blood pressure was up. |

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| 1103473 | 3/15/2021 | OH | 81 | F | 2/12/2021 | 2/19/2021 | 1-19-21 patient fainted after ONLY having rubber band wrapped around upper right arm. After 2 doctors & several nurses failed to revive her quickly, ambulance was called & patient was taken to emergency. After venous blood draw, another blood draw was ordered because doctors were not satisfied w/results. After THREE FAILED attempts to get satisfactory arterial blood draw from one wrist, TWO MORE attempts were done to OTHER wrist! Patient had to ask for a BASIC drink of water after 5 hours of NO nursing care attention. Then...after 7 hours we had to ask for food, since this was already 5PM & patient hadn't eaten until prior evening. After NO care/attention for over 9 hours, patient & spouse left emergency room. |
| 1103487 | 3/15/2021 | CA | 23 | M | 3/13/2021 | 3/13/2021 | My son had the shot and 3 hours later passed out on the bathroom floor. I called 911 and paramedics evaluated him, all vitals were normal and he felt ok 5 minutes later. |
| 1103528 | 3/15/2021 | NV | 19 | F | 3/15/2021 | 3/15/2021 | AFTER RECEIVING VACCINE PT. FELT LIGHT HEADED, SHE SAT DOWN AND APPROACHED PHARMACY AND ASKED IF SHE SHOULD FEEL COLD AND SWEATY. SHE THEN PASSED OUT AND GINGERLY FELL TO THE FLOOR. PHARMACIST RAN OUT TO ASSIST, ELEVATED LEGS AND SPOKE TO HER, SHE WAS SEMICONSCIOUS. PHARMACY WAS INSTRUCTED TO GRAB ICE PACK AND QUICKLY DID. ICE WAS APPLIED TO PT. WRIST AND SHE IMMEDIATELY REGAINED CONSCIOUSNESS. PT. WAS INSTRUCTED TO REMAIN ON FLOOR AND CONTINUED CONVERSATION TO MEASURE ALERTNESS. AFTER A FEW MINUTES SHE SAID SHE FELT FINE. PHARMACIST AND ASSISTED HER TO CHAIR, AND SHE REMAINED FOR 20 MORE MINUTES. DISCUSSED IF SHE HAD ANY INJURIED FROM FALL. SHE SAID SHE FELT FINE. PTS LEFT WITH INSTRUCTIONS TO CONTACT PHARMACY OR SEEK MEDICAL HELP IF ANY REOCCURRENCE. |

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| 1103504 | 3/15/2021 | CA | 32 | F | 3/15/2021 | 3/15/2021 | Pt received 1st dose at 6:10PM. Was sitting in observation area for approximately 10 minutes when patient fainted in her seat slumped over. Patient did not respond to questions. EMS called. Patient was transported to the observation tent and was placed on cot in supine position with legs elevated. Initial vital signs BP 150/91, HR 127, 99% Room air, Temp 97.3 F. Patient regained consciousness and was able to respond to questions. Repeat vital signs 5 minutes later were BP 133/83, HR 117. EMS arrived on the scene and patient was advised to go to the hospital for further evaluation. Patient was transported via EMS. |
| 1102497 | 3/15/2021 | IL | 61 | F | 3/13/2021 | 3/13/2021 | Severe chills, fever highest 101.4°, Pulse ran 80-100, fell to do that I think I fainted Blood pressure 93/49,94/41,99/50,77/46,92/44, |
| 1103338 | 3/15/2021 | CA | 43 | F | 3/15/2021 | 3/15/2021 | Patient received the vaccine and went to sit down in the chair. Patient stated she started feeling nauseous and light headed so asked if she can wait outside for some fresh air. When she went outside, she sat on the edge of the stairs and fell backwards and passed out. The store manager was there to catch her before her head hit the pavement. Patient wasn't alert for about 2 minutes. Pharmacist came out and assessed the patient and she was communicative. She was in and out but was able to tell us her name, DOB and where she was. We sat her up, gave her some water, and waited with her. She requested not to call the ambulance. I checked her pulse at 1:15pm and it was 92. I checked her pulse again at 1:30pm and it went down to 72. Patient was fully alert and speaking in full sentences by 1:35pm. She called her mom and was able to stand up without feeling dizzy. She walked to the car with assistance and was driven home by her mother. |

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| 1102521 | 3/15/2021 | OK | 56 | M | 3/12/2021 | 3/12/2021 | Client received Moderna vaccine and walked to the monitoring area. A few minutes into his 15 minutes of monitoring he passed out fell and his head on the floor. Blood pressure 79/40 Pulse 39. He awakened and was able to sit up with help take a few drinks of soda. States he had not ate breakfast. He then stated he started to feel dizziness and wanted to lay back flat on the floor. Blood pressure rechecked and increased to 110/70 with a heart rate on 69. EMSA called and transported him to Medical Center. Followed up with client today and he states they evaluated him in the ER, gave him something to eat and sent him home. States only symptom he has currently is arm soreness. |
| 1102509 | 3/15/2021 | | 89 | F | 3/15/2021 | 3/15/2021 | Patient was transported to hospital. She was diaphoretic, nauseas and almost passed out. She just had a pacemaker put in 3 months ago. EKG was done by paramedics and they immediately recommended transport to the hospital. |
| 1103297 | 3/15/2021 | AZ | 55 | M | 3/14/2021 | 3/14/2021 | Within 30 seconds of getting the shot, I passed out. EMTS immediately administered first aid to me, and had me wait quite a while before letting me leave. They insisted that just because I passed out, please come back for 2nd dose April 5 at 7:30am. |
| 1102520 | 3/15/2021 | CA | 68 | F | 1/8/2021 | 1/8/2021 | I initially felt fine after the injection. Approximately 15 minutes after receiving the vaccine I felt pain in my left arm then felt nausea, light -headedness ,dizziness nearly syncope. I did not pass out. I recovered with in 10-15minutes. I had no respiratory symptoms and no rash or swelling. I was taken to the ER and released shortly after. I had no other symptoms aside from a mildly sore arm for a day. I have had no subsequent symptoms. |
| 1103083 | 3/15/2021 | KY | 70 | F | 3/12/2021 | 3/15/2021 | Had nausea, vomiting, diarrhea, and then I passed out and hit my head, shoulder, and arm resulting in multiple bruising. |

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| 1102547 | 3/15/2021 | MI | 64 | F | 3/13/2021 | 3/14/2021 | Janssen COVID vaccine was administered on 3/13/21- patient was screened twice and denied receiving any vaccines in the past 2 weeks. after administration it was noted today (3/15/21) that the patient received the Moderna COVID vaccine (one dose) on 3/4/21. I attempted to reach out to patient to discuss and noted that she is admitted to Hospital for a NSTEMI. Per chart notes patient reported symptoms of fever, nausea, malaise on 3/13/21 after vaccination. The next day 3/14/21 developed syncope and chest pain. Patient reported to emergency room and was admitted with NSTEMI |
| 1102595 | 3/15/2021 | IL | 28 | F | 3/15/2021 | 3/15/2021 | Dizziness, ringing in ears, stated felt like passing out and fainted many times before with flu vaccine and blood drawing 63/45 12:25 81/57, 57, 16, 90/62 100% room air |
| 1102611 | 3/15/2021 | WI | 22 | F | 3/15/2021 | 3/15/2021 | patient was nervous about the injection but still got it. she said she was okay but sat down to make sure, then fell off her chair and fainted. patient woke up shortly after and paramedics evaluated her for concussion |
| 1102641 | 3/15/2021 | | 17 | F | 3/12/2021 | 3/13/2021 | Hard heart rate, sweating, nausea, fainting |
| 1102642 | 3/15/2021 | KS | 83 | F | 2/19/2021 | 2/20/2021 | within 24 hours; near syncope, brain fog, fatigue/weakness, exac of underlying anxiety secondary to symptoms; these have been episodic. Brought to ER The Four Paramedics that came to take her to the ER stated they were overwhelmed with calls for post covid vaccine problems and that ALL of their vehicles were out on calls many due to this. Agressive workup including CT, EKG, Cardiac monitoring, CTA neck and Brain, Carotid and peripheral dopplers and vascular surgeon consultation revealed nothing. Told it temporally had to be assoc with the vaccine?? I am reporting so that this can be evaluated for confirmation. |

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| 1102707 | 3/15/2021 | NY | 39 | F | 2/3/2021 | 2/3/2021 | Around 1PM on 2/3/21 after receiving the second vaccine I started getting a headache and was extremely tired. Around 5PM I started having chills, cold sweats, muscle soreness, nausea, and vomiting. My arm was so sore i could not lift it al all. At some point around 9PM I passed out on my bathroom floor. My 6 year old found me and thought I had died and called her father crying hysterically. I think I was passed out for a few hours before I came too, as my child had the phone on speaker and her and my husband were both yelling at me to wake up. I crawled back to bed and went to sleep. The next morning 2/4/21, I could hardly move to get my daughter ready for school, I had to call out of work. I was still having chills, cold sweats, muscle soreness, nausea, and vomiting, headache, and I could hardly move my left arm. on 2/5/21 I was still very tired, still had nausea, and a headache. 2/6/21 - 2/7/21 I still had a slight headache. on 2/8/21 I felt better and went to work. |
| 1102816 | 3/15/2021 | IL | 35 | M | 3/15/2021 | 3/15/2021 | Patient fainted/fell and developed a rash on both arms 15 minutes after administration. Patient hit his nose as he fell. We gave the patient an icepack and administered oral Benadryl 20 minutes after injecting the vaccine. Patient went to the ER. The ER stated that his nose was cosmetic and that the rash was a bruise instead. |
| 1103052 | 3/15/2021 | PA | 27 | F | 3/11/2021 | 3/15/2021 | Began feeling sick after injection. Low fever, fatigue for day of injection and day after. Day 3 felt normal, but day 4 began feeling sick again with no appetite, nausea and chills. At 5:30 I passed out and remained unconscious until my mother found me on the floor and then had a seizure lasting about 2 minutes. I was unconscious for at least 30 minutes. I have had seizures in the past, but never anything close to this. |

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| 1102518 | 3/15/2021 | GA | 58 | M | 3/4/2021 | 3/12/2021 | Per MD Clinical Note 3/14/21, "Further discussion with his daughter today-patient has not been able to walk and has had unclear mentation for approximately 8 years after an alcohol related decline. Was in a nursing home until he moved into his parent's house. His mother actually passed away and December and his stepfather has been trying to take care of him since. Patient may periodically stand but is a house where he is pretty much confined to his bedroom and bathroom. Patient received his COVID-19 vaccine at the prescription shop 03/04/2021 and since then he has had a steady decline starting with aches and pains to increased weakness and confusion and then collapse which brought him to the emergency room. Assessment and plan Syncope with altered mental status/toxic metabolic encephalopathy Acute on chronic respiratory failure with hypercapnia Sepsis Supratherapeutic Coumadin level INR greater than 9 Anemia Small hemoperitoneum Hypotension Chronic pain syndrome COPD UTI Enteritis Subsegmental atelectatic changes with nodule left lower lobe the-recheck 3 months Cirrhosis Nicotine dependence CHF-chronic diastolic Functional quadriplegia One week post COVID-19 vaccination Agitation Other: GI bleed, PAD, hypothyroidism, history of DVT left leg, neuropathy, depression, BPH, CAD, subdural hematoma, acquired thyroid disease, GERD, Wernicke -continue to trend the LFTs downward. Is on Precedex currently to allow him to further recover. He was using accessory muscles and poor inspiratory effort today but maintaining his oxygenation. BiPAP was reinstated to avoid CO2 retention. One possibility is that the patient consumed a significant amount of Tylenol due to the discomfort exacerbated with the cirrhosis. LFTs are trending upward still. -hypercapnia patient consume both the benzodiazepine and morphine supported initially for the 1st 36 hours with BiPAP. Has had periods where he is off and answers appropriately. -consider rescanning in a.m. To further evaluate the hemoperitoneum. Continue broad-spectrum antibiotics and hemoglobins. Patient is NPO until further delineation Patient is a functional quadriplegic year and at home is fairly dependent on his stepfather for a total care family seeking long-term care which may mentally benefit the patient with broadening his activities -blood cultures pending. " Per |

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| | | | | | | <p>Clinical note 3/13/21, "Assessment and plan Syncope with altered mental status/toxic metabolic encephalopathy Acute on chronic respiratory failure with hypercapnia Sepsis Supratherapeutic Coumadin level INR greater than 9 Anemia Small hemoperitoneum Hypotension Chronic pain syndrome COPD UTI Enteritis Subsegmental atelectatic changes with nodule left lower lobe the-recheck 3 months Cirrhosis Nicotine dependence CHF-chronic diastolic Functional quadriplegia Other: GI bleed, PAD, hypothyroidism, history of DVT left leg, neuropathy, depression, BPH, CAD, subdural hematoma, acquired thyroid disease, GERD -patient is more awake and waking a hourly on BiPAP will remove 1 fully alert and functioning will use BiPAP overnight. Nicoderm avoid tobacco. NPO unless ammonia level is elevated. Continue empiric antibiotics. Last evening required to units packed RBC. If hypotensive and or increase in anemia will rescanned. Monitor for DTs and withdraws. Was advised by the nursing staff patient is following orders. Functional quadriplegic rotation every 2 hours had bed at 20-30 degrees to avoid aspiration. Patient and his family confirm DNR status. Long-term placement required as his stepfather is unable to care for him without assistance. Anticipate restarting diet in a.m.. One fully alert will ascertain if this was delivered or accidental. Drug screen was positive for both benzos and morphine. He has been and prescribed the morphine. The dual combination liver failure patient with depression likely ill-advised ~~~</p> |
| 1102872 | 3/15/2021 | | 51 M | 3/15/2021 | 3/15/2021 | Diaphoretic, syncope, unresponsive, evaluated by EMS, transported to ER |
| 1103054 | 3/15/2021 | PA | 30 F | 3/7/2021 | 3/7/2021 | Pt had episode of syncope following vaccination. After walking to observation area, pt felt briefly dizzy and fell backwards, hitting head on floor. No observed open wounds/blood, sensation intact, pt alert & oriented. Did not move pt, remained laying on ground until Emergency Response Team transported to ED. |
| 1102994 | 3/15/2021 | KY | 31 F | 3/13/2021 | 3/14/2021 | The patient reported that following the vaccine she felt nauseous throughout the night. She got up and felt nauseous and reported shortly after that she passed out for approximately 10 seconds. |

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| 1102976 | 3/15/2021 | IL | 32 | F | 3/12/2021 | 3/12/2021 | Shaking/ chills starting at 6pm- lasted for a few hours Woke up 6:30am and started feeling unwell about 20min later and passed out while getting out of the shower. Came to shortly after with a bloody nose (I fell). I have never passed out before. |
| 1102946 | 3/15/2021 | TN | 69 | F | 3/9/2021 | | BLURRED VISION AND ALMOST FAINTED THEN RASH BEGAN IN TORSO AND BREAST AREA. NEXT DAY THE RIGHT EYE GOT REALLY SWOLLEN ALMOST SHUT |
| 1102945 | 3/15/2021 | NJ | 35 | F | 3/13/2021 | 3/14/2021 | Extremely sore arm within hours, by 10 began to fever, woke up around 3:30 a.m with a fever of 102.5, felt overwhelmingly nauseated and fainted in my bathroom, husband described my speech as extremely incoherent, clammy and sweaty, needed assistance getting back to bed, claimed I hadn't hit my head (I actually think I did lightly- my arm seems to have taken the brunt of it evidenced by a giant bruise, no bruising on head), drank two bottles of Gatorade and continued drinking water, continued to run fever until 3/15 sometime extremely early in morning, fever was accompanied by chills, joint and muscle aches, and headache. Fever always maintained predominantly above 102, dropped to 101 before it broke and went down. |

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| 1102911 | 3/15/2021 | CA | 50 | F | 3/15/2021 | 3/15/2021 | Patient at chair for 10 minutes when she began to flag the attention of medical staff, she complaint of dizziness stating "I feel like I'm going to faint". Patient was asked if she have eaten, she responded "yes". Patient states a history of vasovagal syncope causing her to faint. Patient was asked if she need to lay down, she responded "yes". Patient taken to east portion of the room, provide privacy and vital taken. @3:17 Temp. 98.6, O2 98%, HR 82, B/P (L/A) 125/90, patient continues to lay on the ground for 11 minutes before sitting up in a criss/crossed leg position. At this point patient complaint of increase dizziness, patient was allowed to sit in this position for an additional seven minutes before being moved to a chair allowing both feet to be planted on the ground while the rest of the body in an upright position, patient started to feel better while in this position. last vital: T-98.6, O2 98%, HR 85, B/P 140/95. It was decided that the co-worker would take the patient home as the patient stated "I am too dizzy and do not feel well enough to drive". Patient left her Hyundai Santé vehicle in the parking lot to be retrieved at a later time. Patient help to a wheelchair, taken to check out, then wheeled out by three staff to the vehicle of the co-worker, to leave. |
| 1102885 | 3/15/2021 | MS | | M | 3/15/2021 | 3/15/2021 | Patient left the immunization area and returned immediately. He was disoriented and briefly passed out. He regained consciousness and was sweating. We placed a cold compress behind his neck and call 911. The paramedics arrived and did an assessment. The Patient refused to go to the hospital. |

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| 1103066 | 3/15/2021 | CA | 71 | M | 3/12/2021 | 3/12/2021 | Approximately 20 mins after he received covid vaccine, patient got up and began walking with his cane and assistance from his nephew. Patient stopped walking and said "my legs aren't working" and then began to slowly fall. Patient assisted to the floor by his nephew. Dr. notified by MA. Vital signs taken and monitored. Patient remained alert and able to answer questions. Patient denies dizziness, pain, SOB, or any other discomfort. Per nephew, "something feels off about him". BP went to 70s/40s with HR 60s. Notified Dr. and he assessed patient. Patient advised to go to the ED for syncope episode. Nephew agreed with plan and felt comfortable taking pt to the ED now. Patient discharged via wheelchair at 1645. |

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| 1097912 | 3/14/2021 | TX | 28 | F | 3/8/2021 | 3/8/2021 | <p>Symptoms: Fainting, Unconsciousness (repeatedly), Profusive Sweating, Low Blood Pressure (60 over unknown number), Nausea, Dizziness, Unable to stabilize quickly, not able to get an IV, extreme thirst</p> <p>Signs: Immediately felt unwell within 5 minutes of the vaccine. Time Course: Injection (1st dose - Pfizer) at 4:00pm. Adverse Reaction at 4:05/4:10 (est.) Released at 5:00pm (est.) Description of Incident: On March 8th, at 4:00 pm, I received my first dose of the covid vaccine. Within 5 to 7 minutes, I felt unwell while sitting in the waiting area. I walked towards a worker to inform them that I was feeling unwell and that I was going to pass out. I became unresponsive and laid on the ground. My husband was with me at the time. I was unconscious for a bit and when I regained consciousness, my legs were being raised. I regained consciousness and was able to recall my name, DOB, and address. After I was done recalling my information, I began to lose consciousness again. They brought a wheelchair and took me to the medical room. As I moved from the wheelchair to the bed, I began to lose consciousness again. They told me to lay down. I overheard a woman ask my husband if I had diabetes or heart problems. He answered "No.". She explained to him that my body did not know how to accept the vaccine and was trying to regulate back to normal. She explained that my body was going through "homeostasis" (?). While I laid on the bed, some workers took my blood pressure and tried to start an IV. One of them made a comment and said I was extremely dehydrated. This was odd to hear because I normally drink 3 to 4 liters of water daily. During this entire medical event, I felt the water pushing out through my pores. I was drenched in sweat. He tried to start an IV on my left arm and was unsuccessful. He tried to start an IV on my right hand, which was also unsuccessful. He stated they were unable to start IV liquids because my veins kept popping/collapsing. My blood pressure was reading 60. They checked it again, still at 60. I laid in the bed and basically waited it out. After a few minutes, they checked my blood pressure at it was at 120. They said that was good and I was good to go. No report was given to me nor my husband about the event that occurred. Even after they agreed to let me use a wheelchair (due to feeling weak), one was not provided to me. They basically stated that I was "good to go", after doing a</p> |

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| | | | | | series of hand squeezes and walking a few steps upright. I am currently trying to obtain a copy of the report I saw the gentleman fill out at the time. I was given Zofran to help with my nausea, it was placed under my tongue. After going home, I felt weak, tired and somewhat lightheaded. My husband drove me home and I got some rest. I set an appointment with my doctor on Friday March 12th to determine what happened to me during my vaccine and to record the incident. After describing the incident, she determined that it was anaphylaxis. She recommended for me not to get my second dose due to the anaphylactic shock I experienced with the first dose. She was shocked to learn that they did not transport me to the hospital or provided an Epi Pen injection. When asked why I didn't drive myself to the hospital, I let her know that they told me I was 'good?'. They did not explain what had occurred to me, no mention of anaphylaxis was explained. I was not aware that is what had occurred. The incident occurred from 4:00pm (injection time) to 5:00pm (left location). | | |
| 1098804 | 3/14/2021 | MO | 72 | M | 3/13/2021 | 3/13/2021 | Patient had a syncopal event approximately 20 minutes following his first dose of vaccine. The patient's wife reports that the patient has similar events with previous injections. As the injection was given at a vaccination clinic, patient was evaluated by onsite healthcare professionals while EMS was called. Patient was transferred to local ED for observation and was released home late the same day with a discharge diagnosis of syncope. |
| 1098555 | 3/14/2021 | PA | 50 | F | 3/14/2021 | 3/14/2021 | Patient developed signs of syncope about 5 minutes after vaccine given - 7:50 dose and 7:55am she felt warm, dizzy and had blurry vision and a dry throat. We supplied ice packs and she felt symptoms subside by 8:11am. At 8:18am she felt a wave of symptoms back and had an itchy throat - she was given 50mg of oral benadryl and felt better - leaving the pharmacy with her husband at 835am. I called patient at 1:18pm 3/14/21 and she had just gotten home from the ER where she was treated with iv fluids, benadryl and steroids per husband |

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| 1098745 | 3/14/2021 | AZ | 47 | F | 3/9/2021 | 3/9/2021 | Four hours post vaccine I had muscle and joint pain throughout my entire body and I took 600 mg Advil. Four hours after that I repeated the 600 mg dose of Advil and went to bed. I felt feverish and my pain did not diminish despite the medication. At approximately 2 am I got up to try and cool myself off. I fainted in my bathroom and fell, hitting my head on the tub, although I did not know this at the time. I thought I just laid down. I was unable to get up. For the next 2 hours I slowly inched myself from the bathroom into the hallway and towards my bed. I was very cold and in severe pain. When I reached my bed I finally warmed up and fell asleep. I was unable to get up out of the bed, except to raise myself on my right elbow to drink a mouthful of water, until approximately 4 pm the following day. This was 28 hours after the vaccine. No medications helped my pain, it just slowly subsided on it's own. For the next 24 hours I was able to get up and use the bathroom and drink some water and juice but I could not eat or perform any function. I could not even sit up in bed. When I was able to start eating again I had diarrhea for 24 hours. It has been 5 complete days since the vaccine. I am still winded while performing simple cleaning tasks. I need about 2 hours of rest in bed (twice yesterday) just to get through a day with nothing in it. I did not expect the level of immobility/illness, unalleviated pain or the seriousness of my second vaccine reaction. |
| 1098735 | 3/14/2021 | NY | 50 | F | 2/10/2021 | 2/10/2021 | Developed scratchy throat and then itchy rash at approximately 15 minutes post dose. Patient given 50 mg oral Benadryl and monitored for over 30 minutes. Patient has a history of epi pen usage due to history of allergies to sulfa, flaxseed and environmental triggers. She has received flu vaccine in the past with minimal reactions. Given oral benadryl 50mg x 1 and monitored for at least an additional 30 minutes. Per pt on my chart in March: tingling of the tongue was mild. The right ear and right side of my head was intense with pressure and it did feel like it wanted to explode. After the Benadryl it started to subside. It lasted about 50 minutes. The rash were not like hives. The rash was on my neck , arms and face. It lasted about 2 days and was a mild case. Not over body. No fainting, no low grade fever. |

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| 1098666 | 3/14/2021 | DE | 31 | M | 3/14/2021 | 3/14/2021 | Administered COVID-19 Moderna vaccine to patient. Patient immediately fainted for about 15 seconds, then woke up and began immediately shaking entire body and gripping fists tightly. Both pharmacist and person accompanying patient called 911. Patient was awake and sitting down while 911 was on the way. While waiting for 911 to arrive, patient vomited into a bucket. Emergency medical services then arrived and took patient out on a stretcher. |
| 1098828 | 3/14/2021 | IN | 65 | F | 3/10/2021 | 3/11/2021 | Dizziness, passed out, nausea, severe headache, Body aches, fever of 101.6 on the second day On the third day fever of 101.1 off and on during the day, body aches, headache and extreme fatigue Fourth day-extreme sore throat, extreme mucus, headache and continued fatigue Fifth day, headache and fatigue , on and off dizziness |
| 1098657 | 3/14/2021 | IL | 65 | F | 3/14/2021 | 3/14/2021 | Dizziness, shortness of breath, near syncope. |
| 1098606 | 3/14/2021 | CT | 55 | M | 3/14/2021 | 3/14/2021 | Systemic: Allergic: Anaphylaxis-Severe, Systemic: Allergic: Difficulty Breathing-Medium, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Medium, Systemic: Chills-Medium, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Medium, Systemic: Shakiness-Medium, Systemic: Weakness-Severe, Additional Details: note: pt stated no allergies on form and when asked verbally by immunizer. at the 7 minute mark he began to exhibit weakness and started falling off his chair. seemed like he was going to pass out. his breathing seemed labored. we position pt on floor, rph admin epipen to left outer thigh. 911 called. ems responded. pt felt better after epipen. bp, hr normal. pt taken to er by ems |
| 1098416 | 3/14/2021 | KS | 30 | F | 2/5/2021 | 2/5/2021 | Starting around 11pm patient experienced mild fever, aches, chills. Overnight, fever increased, and pt had moderate/severe chills, aches, discomfort. Pt took Tylenol and ibuprofen overnight and fever after medication was approx. 101F. The next morning, pt experienced syncope and vomiting. Nausea, dizziness, fatigue, aches, low grade fever (99.4F) and mild chills continued for approx 36-48 hours. |

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| 1098344 | 3/14/2021 | NJ | 39 | F | 3/13/2021 | 3/13/2021 | 1130 Post vaccination reports feeling light headed w/dizziness and episode of syncope; vitals assessed BP 100/56 P98 O2 sat 99% RA Medical monitoring x 30 min, feet elevated. Maintains alert answering questions, reports hx "low blood pressure and "fainting with blood draws". Declines po hydration, snack / crackers provided reports "feeling better" : BP 113/87 P65 12pm Released from facility home w/self |
| 1098242 | 3/14/2021 | MI | 92 | F | 3/10/2021 | 3/10/2021 | Approximately 4 hours after receiving the Moderna COVID-19 vaccine (left-arm), my mother began to have moderate pain in her left arm, particularly in the left shoulder area. The pain continued to increase throughout the afternoon, until it became so severe (10 on a 10-point pain scale) by 8:30 pm on 3/10/21 , that she could no longer lift her arm. She took 500 mg of Tylenol to attempt to relive the pain and went to bed early. At 2:45 am on 3/11/21, she needed to go to the restroom, and I (daughter) had to assist her to get out of bed, as she had no use of her left arm due to severe pain in that arm. While seated on the toilet, she indicated that her arm was extremely painful and she felt that she was going to pass out and felt nauseated. Within a minute, she lost consciousness and I called emergency services. EMT arrived within 5 minutes and stated that her blood pressure was extremely low and she needed to be placed on the floor. They placed her on a gurney and took her to the ambulance, where they started an IV and took her to her local hospital. I followed shortly thereafter, where she was taken to the ER. She was admitted to the hospital for observation and given Ativan (she refused any opioids) She was ultimately diagnosed with vasovagal syncope due to the pain in her left arm. Two days later, the pain has subsided. |
| 1098213 | 3/14/2021 | IN | 31 | F | 3/14/2021 | 3/14/2021 | Patient felt lightheaded, nauseated, hot and sweaty and appeared pale. She states she has a history of fainting with blood draws and vaccines. VS improved over 25 mins, patient left via own car. |
| 1097924 | 3/14/2021 | IL | 26 | F | 2/19/2021 | 2/21/2021 | Syncope, hypothermia, shock, hypotension, arrhythmia, diarrhea, vomiting |

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| 1097911 | 3/14/2021 | NC | 52 | F | 3/12/2021 | 3/13/2021 | I had a sudden syncope episode with LOC as I walked to my bedroom. Didn't wake up until my head hit door jam and I was on the floor. |
| 1097900 | 3/14/2021 | CA | 66 | F | 3/12/2021 | 3/12/2021 | Fainting spell (had it in line too, before receiving vaccine) - given juice and crackers. |
| 1099267 | 3/14/2021 | IN | 78 | F | 3/14/2021 | 3/14/2021 | Patient fainted 1 hour and 15 minutes after receiving 2nd Moderna vaccine. Paramedics were called but patient felt well enough to go home instead of going to the hospital. |
| 1098874 | 3/14/2021 | | 69 | M | 3/10/2021 | 3/11/2021 | Passed out in doctors office weak lightheaded dizzy brought to urgent care dept on first floor transported to er at hospital. I was very out of it really weak , because of my stents they were afraid I may have had a heart attack stayed in er for about a day for tests and observation had echoes radioactive isotope stress test blood tests ekg all came back normal . I have been improving each day since vaccine dose almost back to normal still some arm pain but only if I press injection site |
| 1098007 | 3/14/2021 | MA | 35 | M | 3/13/2021 | 3/13/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Headache-Medium, Systemic: Weakness-Medium |

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| 1099323 | 3/14/2021 | TN | 39 | M | 3/14/2021 | 3/14/2021 | BEFORE GIVING THE JANSSEN COVID VACCINE (LOT # 1805025 EXP 5/25/21), THE PATIENT HAD STATED THAT THE LAST FEW TIMES HE GOT A SHOT OR HAD A BLOOD DRAW HE GOT REALLY SICK AND EVEN PASSED OUT. THE VACCINE WAS GIVEN WITHOUT INCIDENT AND PATIENT SAID HE FELT OK. HE TRADED PLACES WITH HIS GIRLFRIEND AND SAT IN A CHAIR IN THE EXAM ROOM. IT WAS NOT UNTIL AFTER I HAD ALREADY GIVEN HIS GIRLFRIEND HER VACCINE THAT HE SAID THAT HE WAS FEELING FUNNY. HIS COLORING CHANGED AND HE WAS DIAPHORETIC. I GOT A PAPERTOWEL WITH COOL WATER ON IT AND PLACED ON HIS NECK AND ANOTHER ONE FOR HIS FOREHEAD. AFTER A MINUTE OR SO, HE DID PASS OUT WHILE IN THE CHAIR. HE WAS OUT FOR ABOUT 30 SECONDS AND THEN CAME BACK TO AND WAS ALERT AND ORIENTED X 4 BUT STILL FELT VERY WEAK. I GAVE HIM A WATER TO SIP ON. HIS GIRLFRIEND STAYED AT HIS SIDE THE WHOLE TIME. HIS O2 WAS 100% AND HIS PULSE 53. HE SAID THAT HE HAD EATEN SHORTLY BEFORE COMING TO GET HIS VACCINE BUT THEN LATER ASKED FOR AN APPLE BECAUSE HE WAS ON A CLEANSE DIET AND REALLY HAD NOT EATTEN MUCH. THE PCT WENT TO GET HIM AN APPLE. AFTER EATING THE APPLE AND SITTING FOR AN ADDITIONAL 20 MIN HE FELT WELL ENOUGH TO LEAVE. STILL WITH HIS GIRLFRIEND AND HIS GIRLFRIEND COMMITTED TO DRIVING HIM SO HE DID NOT HAVE TO. HE LEFT WITH NO ASSISTANCE. |

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| 1099155 | 3/14/2021 | PA | 58 | F | 3/14/2021 | 3/14/2021 | While patient was sitting in chair waiting her 15 minute monitoring period in post- immunization waiting area patient fainted. Patient did not fall down or was she injured by fainting. Patient slowly rolled off chair and patients friend helped lower her to floor where patient regained her awareness . Pharmacist raced quickly to be by patient's side to monitor her vitals and to see if an allergic/ anaphylactic reaction had occurred. No symptoms of an allergic reaction or anaphylaxis was observed by pharmacist. Patient quickly regained her awareness and stated that fainting is common to her when routine blood work, injections, giving blood, etc.. Patient stated that fainting is something that has occurred several times in her past. No signs of allergic reaction, redness, hives, facial swelling, cardiovascular collapse were observed by pharmacist while closely monitoring her vitals after 911 was called. EMTs and paramedics arrived quickly and after closely examining patient and talking with her it was decided by Paramedics that patient fainted due to an emotional response by patient and there was no allergic reaction or anaphylaxis to report, nor any injury sustained by patient after fainting. Patient was quickly back to normal, and she verbally declined ambulance. Patient stated that she felt fine and that she was going to do some shopping and return home to relax. |
| 1098906 | 3/14/2021 | CA | 20 | M | 3/14/2021 | 3/14/2021 | Patient passed out or fell asleep. Once approached he woke up and was shaking for a bit. He had no issues breathing, no hives, or rash. Upon awakening he was given some water and quickly recovered. After a few minutes the patient seemed normal. We observed him for about another 30 minutes and he continued to be fine. |
| 1099450 | 3/14/2021 | PA | 66 | F | 3/9/2021 | 3/10/2021 | Passed out and fell face-first on a tile floor. Teeth cut inside lip requiring many stitches. Glasses cut across my nose. Hit left cheek bone - bruised. Bloody nose. Bruise and cut on right shoulder where I must have hit the counter on the way down. Sore forehead. Headache. |
| 1099387 | 3/14/2021 | VA | 31 | F | 3/11/2021 | 3/11/2021 | Passed out at home 3 times. Heart racing. Severe leg weakness. Leg gives out after walking for a fe minutes. |
| 1099352 | 3/14/2021 | AZ | 65 | M | 3/14/2021 | 3/14/2021 | Fainted 3 minutes after vaccine given, felt warm |

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| 1099312 | 3/14/2021 | NE | 75 | F | 3/11/2021 | 3/12/2021 | Approximately 12 hours after receiving the vaccine, began feeling different with headache, body ache and chills. Upon arising in the morning at about 7:45 AM was not feeling well. Set down at the dining room table with my husband to take my temperature. While still sitting at the table my husband caught me as I was passing out/fainting. Bellevue paramedics were called and transported me to the hospital. I was alert during this time. I was transported to the Bellevue Nebraska Medical Center emergency room. After being checked out in the ER, I was admitted to the hospital for overnight observation. Released from the hospital about noon the next day. There were no adverse findings. |
| 1099282 | 3/14/2021 | PA | 25 | M | 3/2/2021 | 3/3/2021 | Severe vomiting, diarrhea, dehydration. Passed out and ambulance called. |
| 1099272 | 3/14/2021 | TN | 30 | F | 3/13/2021 | 3/14/2021 | I woke up around 5:30 with a high fever. I went to the restroom and on the way back I passed out and was unresponsive for a few seconds (10-20 seconds). I have since been running a fever, breaking out in a sweat, had a severe migraine, and body aches and joint aches. It has been over 24 hours since the vaccine and am still having side effects. |
| 1098994 | 3/14/2021 | NC | 67 | F | 3/11/2021 | 3/12/2021 | Seizure and passed out. |
| 1099135 | 3/14/2021 | LA | 42 | F | 3/11/2021 | 3/11/2021 | 3pm: Immediate body-wide, internal feeling that can only be described as "intoxication." Felt loopy & woozy -- not lightheaded or dizzy. Felt as if I were floating to chair. Sat for 20mins, legs weak, odd sensation across shoulder blades & cervical spine. "Slow" & woozy for duration of evening. Physically moved slow, cognitively slowed down, inability to focus. Internal body-wide sensation difficult to define. All very similar to immediate effects I have from alcohol. Passed out (sleep) 9hrs later & woke 100% fine at 8am. |
| 1099123 | 3/14/2021 | OK | 33 | F | 3/14/2021 | 3/14/2021 | Approximately 5 minutes after administration patient fainted briefly, after a few seconds she regained consciousness and was fine. We put a cold compress on the back of her neck and observed her |

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| 1099105 | 3/14/2021 | MA | 59 | M | 3/14/2021 | 3/14/2021 | PATIENT GIVEN VACCINE AFTER ALL PROCEDURAL ITEMS WERE COMPLETED AND WAS LEFT SEATED IN A CHAIR ASSIGNED FOR COVID 19 MONITORING . PATIENT STARTED SNORING/GURGLING AND I LOOKED OVER TO SEE IF PATIENT WAS CATUALLY SNORING . PATIENT WIFE CALLED HIM BY NAME HE DID NOT ASWER RIGHT AWAY, I RAN TO TO ATTEND TO HIM AND I NOTICE HE WAS PALE , SWEATLY AND CLAMY ALSO WARM TO TOUCH. I CALLED HIS NAME HE ASWERED I THEN TOOK HIS PULSE WHICH WAS NORMAL AND GAVE HIM SOME WATER TO SIP AND ALSO GAVE PATIENT A CANDY WITH MENTHOL THEN HE STARTED GAINING BACK COLOR . HE FELT WEAK BUT STARTED FELLING BETTER. HE SEEM TO HAVE DIZZY ,LIGHTED HEAD SPELLS RIGHT AFTER VACCINE WAS ADMINISTERED. I MONITORED PATIENT FOR 45 MINS HE WAS ABLE TO GET UP AND WALK AND SAID HE FELT BETTER. ITS SEEM LIKE IT WAS MORE OF A FAINTING SPELL BUT BECAUSE HE WAS SEATED AND BEING MONITORED HIS RECOVERY WAS GOOD. PATIENT GOT UUP AND WALK AROUND AFTER RECOVERY AND I TOKK HIS NUMBER SO THAT I CAN FOLLOWUP AFTER CLOSING |

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| 1099097 | 3/14/2021 | FL | 52 | F | 3/3/2021 | 3/4/2021 | This is a report after my 2nd vaccine. I received my 1st vaccine on 2/10/21 [Lot # EL9265]. Both vaccines gave me a reaction, and both around the same time the next morning. My reaction to my 1st vaccine included slight fever, aches, and chills. Both doses were administered around 3:30pm and reaction was approximately 10:30-11am the next morning. On this 2nd dose, roughly 40 minutes after waking from sleep, I became mildly nauseas. I sensed I would vomit, so I sat down on the commode with a bucket in front. I started getting the sweats, got very cold, and my arms starting shaking. I started to feel the room spin, saw big black dots, and after banging on the wall to alert my husband something was happening, I fainted and passed out cold. My husband saw me fall face down, and after waking me, I was in a panic, did not know where I was, or how I was on the floor. I passed out a 2nd time, at which point, my husband was able to get me to the car and he took me to the local hospital. I was incoherent on the car ride, moaning, and not knowing what was happening. My eyes remained closed until I was wheeled into the emergency area and they asked me my name. I was taken to a private room, where they hooked up a blood pressure cuff, an oxygenator on my finger, and took several viles of blood. I was then taken to the cat scan room for a brain scan, and several hours later, was given a chest xray. I remained in the room for approx 6 hours, where I was becoming more and more aware of where I was. I had not eaten/drank anything, except a cup of water. I had not used the lavatory. The PA came to me hours later stating all my tests came back negative, and they could not determine what happened, xrays and blood tests were good, and cat scan was good. He said that while they couldn't determine what happened, they would recommend a stay, so they can do more extensive testing. I contacted my husband via cell, told him what they said, and after another 1 1/2 hours, I made the decision to release myself as I was feeling more like myself again, albeit tired. I went home that evening, ate a small dinner, went to bed, and by 12 Noon the next day, I was fine again. |
| 1099058 | 3/14/2021 | FL | 36 | F | 3/13/2021 | 3/14/2021 | Blurred vision and fainting that last about 3 minutes. |

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| 1099260 | 3/14/2021 | VA | 42 | M | 3/14/2021 | 3/14/2021 | Patient passed out immediately after being administered the vaccine as he walked to the observation zone of the ware house. He was caught from behind by pharmacy technician on duty. He was able to respond to questions about his name, where he was and what he was there for. His blood pressure reading was showing "out" on the wrist cuff. Five minutes later the blood pressure was 127/68. Thirty minutes later his BP was 160/84. He called his dad who picked him up |
| 1099375 | 3/14/2021 | IL | 36 | M | 3/12/2021 | 3/12/2021 | Patient became very pale and sweaty and was close to passing out. Patient moved from the bench where he was sitting down to the floor. I came to check on him and gave him water and orange juice to drink. I checked his blood pressure twice, approximately 2 minutes apart. The first blood pressure reading was 73/46mmHg and a heart rate of 46bpm. The second reading was 110/74mmHg and HR 66bpm. After the second BP reading, patient stated that he was feeling better. This was just likely vasovagal syncope. Patient remained on the floor because it was a cooler location for approximately 15 minutes and was feeling better and went home with his father-in-law and mother-in-law. |
| 1098942 | 3/14/2021 | TX | 34 | M | 3/13/2021 | 3/13/2021 | Janssen COVID-19 Vaccine EUA 34 y.o. male with GERD who presents with syncope and question of PEA arrest. He went for COVID 19 J&J vaccine on 3/13/2021. A few minutes after getting the vaccine he started feeling nauseated. His lips became gray. He went unresponsive and was taken out of the car. He had agonal respirations. He had 90 seconds of chest compressions and returned to his normal state of health. He was seen in ED where labs were remarkable for mild hyperkalemia (serum potassium 5.5). Given worrisome syncope, chest compression he was admitted for observation. He did well overnight, No arrhythmias of telemetry and was discharged with Holter monitor. |
| 1096758 | 3/13/2021 | TN | 32 | M | 3/13/2021 | 3/13/2021 | Patient received vaccine and then became light headed and passed out. He states he does this with shots. Improved on his own within couple of minutes and needed no further treatment. |

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| 1096803 | 3/13/2021 | | 71 | F | 2/1/2021 | 2/1/2021 | Pulmonary embolism, Patient began becoming short of breath shortly after receiving her first vaccine, and then became worse with her second one. She presented with syncope and was found to have multilobar embolic burden as noted above with evidence of right-sided heart strain |
| 1096817 | 3/13/2021 | | 22 | F | 3/13/2021 | 3/13/2021 | Patient stated she passes out after shots, so RN got her a wheelchair to sit in while the shot was being administered. The vaccine was administered and she felt fine. While sitting for another minute she passed out in the wheelchair and the RN called for help. The patient came too. The patient was assessed by paramedics on scene and stayed an extra 30 minutes. She knew she blacked out and she went home with her mother. |
| 1096866 | 3/13/2021 | NC | 52 | F | 3/13/2021 | 3/13/2021 | Syncope 15 minutes following vaccine. EpiPen administered. Subsequent ER visit. |
| 1096885 | 3/13/2021 | | 22 | F | 3/12/2021 | 3/12/2021 | syncope, hx of syncope with immunizations |
| 1096889 | 3/13/2021 | OH | 30 | F | 3/13/2021 | 3/13/2021 | Patient in 1st trimester of pregnancy, 5 minutes after vaccine was administered patient fainted and fell off of chair. Patient came to but 911 ER squad was called. Squad said patients blood pressure dropped. Blood pressure came back and patient felt better. Squad monitored patient. Patient felt better and went home. |
| 1096897 | 3/13/2021 | MI | 46 | F | 3/12/2021 | 3/13/2021 | vasovagal syncope(faint) at 3 am. that triggered a small seizure (eyes open, arm suspended in bent position mid-air, lasted around 30 seconds). Extreme headache followed for hours after. |
| 1096937 | 3/13/2021 | IL | 29 | M | 3/13/2021 | 3/13/2021 | Fainted during the mandatory 15 minute evaluation period post vaccination. Sat with patient who returned to and refused medical transport and color returned was with wife who will watch him today. Recommended a meal with rapid, intermediate, and long acting carbohydrates. Reported once started drinking water again he felt better. Monitored patient for additional 20 minutes to observe. Stood up without assistance but was carefully monitored. Then left with wife for lunch since hungry. |

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| 1096740 | 3/13/2021 | TN | 40 | M | 3/12/2021 | 3/12/2021 | Patient after couple of minutes post vaccination, passed out. BP was 68/32, HR58 |
| 1096264 | 3/13/2021 | NY | 34 | F | 3/12/2021 | 3/12/2021 | Pt was sitting in the observation area for 15 mins following Covid -19 vaccination where witnessed syncopal episode occurred, Pt is approximately 35 weeks gestation. Pt reported feeling nauseous. Pt noted to be slumped over, lost consciousness, with jerking notions in the upper extremities. Episode lasted approximately 15-20 seconds. Pt regained consciousness and asked if she passed out. initial VS 84/57, HR 60, rr 16, and O2 sat 98% on RA. Follow-up VS 89/58, 60, 18, and O2 sat 99%. Pt denied itching, dyspnea, rash, and SOB sensation. No allergic reaction symptoms observed. EMS called to the scene, and assessed VS 103/58, HR 74. Pt interactive, A&O with husband at her side. Pt reports continued light headed sensation. Pt transferred to the hospital via EMS for further evaluation of syncopal episode and pregnancy. |
| 1097028 | 3/13/2021 | | 27 | F | 3/12/2021 | 3/12/2021 | she recieved shot without reaction. she stood up and moved over the waiting area to sit for 15 mintues. after 3 to 4 minutes of talking with her mother (mom left to go get water from front of store). she said out loud "I think I'm going to faint." I rushe out of the pharmacy to help. Her eyes rolled back and she fainted, the she convulsed for 5 top 10 seconds. she woke up 30 seconds later (mom returned by this time). 9-1-1 was called and ambulance came to check vitals and she left on her own accord. |
| 1096942 | 3/13/2021 | RI | 33 | M | 3/12/2021 | 3/12/2021 | Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Severe, Systemic: Hypotension-Severe, Additional Details: Patient had short fainting spell post vaccination while seated, immunizer was a registered nurse who provided immediate care, checked blood pressure, 100/60 then 125/90 10 minutes later, patient was upright and responsive after being assisted. after observation period left on own ability with mother. left message with pcp office post event, spoke with patient following morning, no issues feeling fine. |

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| 1096930 | 3/13/2021 | MO | 67 | F | 3/3/2021 | 3/4/2021 | Mild dizziness after shot. But I passed out the next day after feeling extremely dizzy & nauseous. Then my husband also got dizzy & nauseous the following day. I thought it might be my meds but the only thing we both take is Levothyroxine. We were dehydrated?? |
| 1096686 | 3/13/2021 | NV | 31 | F | 3/9/2021 | 3/12/2021 | Immediately passed out and hit head. Days later, right eye is puffy and droopy. |
| 1096613 | 3/13/2021 | IN | 28 | F | 3/11/2021 | 3/11/2021 | 6 hrs after vaccine: low grade fever; 9 hrs after vaccine: fever, severe chills, moderate to severe body aches, inability to sleep; 15 hrs after vaccine: symptoms continued, fainted while walking back to bed after urinating, unconscious for about 1 minute; 21 hrs after vaccine: fever broke, no remaining symptoms whatsoever |
| 1096465 | 3/13/2021 | MN | 62 | F | 3/10/2021 | 3/10/2021 | The actual injection itself was so painful that I almost passed out. It hurts so badly while the needle was in my arm and when she took it out it was worse. I was in such pain that I began to sweat profusely and apparently I turned white and began dry heaving. This was all within a minute or so. I really thought I was going to pass out. A woman with a tag that said pharmacist came rushing over. She got a reclining chair with wheels, they help me into it and then took me to a recovery room. After a few more minutes of sweating and dry heaving I began feeling better. The pharmacist got me some paper towels so I could dry myself off as I was drenched in sweat. I asked her for a bottle of water. I waited the 15 minutes and came home. They never checked my vital signs. Once I got home, I laid down and slept for 15 hours. I was fine the next day and my arm was never sore. Could the shot have hit a nerve? I've never felt such acute pain. |
| 1096452 | 3/13/2021 | IN | 62 | F | 3/11/2021 | 3/12/2021 | Nauseous chills sweats headache and passed out |
| 1096376 | 3/13/2021 | NC | 23 | F | 3/10/2021 | 3/10/2021 | Patient became diaphoretic and passed out within minutes of receiving vaccination. She woke within seconds. Returned to baseline within 15 minutes. Patient stated this has happened before with blood draws and other vaccinations. She was released into the care of her driver/sister after returning to baseline. |

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| 1096355 | 3/13/2021 | PA | 60 | F | 3/1/2021 | 3/12/2021 | Patient was sitting in chair when she alerted Medic she was feeling dizzy and lightheaded. Patient had syncope episode lasting approximately 45 seconds. Patient did not strike her head and was placed in recovery position on the floor by two medics. EMS was called to facility. EMS cleared patient to return home with spouse. |
| 1096316 | 3/13/2021 | CA | 43 | M | 3/8/2021 | 3/8/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient did experience fainting with Janssen, though important to note that patient said he has fainted before in past with vaccinations. He said he is fearful of them and it is more \"mental\" and does not attribute it to the vaccine itself. |
| 1096314 | 3/13/2021 | OH | 43 | F | 3/10/2021 | 3/11/2021 | 9 hours after the shot I felt very nauseous. After getting out of bed, my legs felt wobbly and I passed out. |
| 1096301 | 3/13/2021 | FL | 38 | M | 3/12/2021 | 3/12/2021 | Systemic: Fainting / Unresponsive-Medium, Additional Details: Patient fainted, was given EPI then came back, EMTs came and said it was a vagal response. Patient recovered, but was taken to ER by ambulance because EPI was given. |
| 1096254 | 3/13/2021 | MN | 68 | F | 3/12/2021 | 3/12/2021 | Chills, fainting |
| 1096170 | 3/13/2021 | NE | 58 | F | 2/19/2021 | 2/19/2021 | Heart rate sudden increase to 115, dizzy, weak, almost fainted while seated. Lasted 5 minutes. |
| 1096311 | 3/13/2021 | SC | 27 | F | 3/12/2021 | 3/12/2021 | Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Exhaustion / Lethargy-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Seizure-Mild, Systemic: Shakiness-Mild, Additional Details: Patient became rigid, unresponsive, fixed eyes, dilated pupils, shaking (seizure-like movements), when patient was moved to floor, she became alert and oriented. Dizziness, shakiness, body slower to respond than normal...took some time to get back to normal. EMS called for monitoring and support. |

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| 1097059 | 3/13/2021 | CA | 77 | F | 3/12/2021 | 3/12/2021 | Was monitored for 30 mins and felt lightheaded and weak at the exit table. I was put in wheelchair, moved to a cot, and Paramedics were called. I was weak, couldn't stand without help and I felt drugged. I was taken to ER for monitoring and testing for reasons why this occurred. Continued to feel passed out for 2 hours. Tests for heart attack, diabetes and anemia were negative Diagnoses was Vasovagal attack - sent home after 8 hours monitoring |
| 1096310 | 3/13/2021 | CA | 20 | F | 3/10/2021 | 3/10/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild |
| 1097655 | 3/13/2021 | TN | 64 | F | 3/13/2021 | 3/13/2021 | pt was vomiting, near syncope, tremors, laid pt down and put her in trending burg, pt responded well BP was 112/62 911 was called. pt recovered and was able to verbalize how she was feeling and was transported to ER for further evaluation. |
| 1096306 | 3/13/2021 | CA | 26 | M | 3/11/2021 | 3/11/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Hypotension-Severe, Systemic: Visual Changes/Disturbances-Medium, Additional Details: Patient has history of fainting with IVs but never to vaccinations. He said he gets stomach aches with sugar derivatives. First BP taken was 107/93 with a low pulse. 5 minutes later it was 165/93 pulse 99. We called the paramedics and they came within 5 to 10 minutes. Patient stabilized after. |
| 1097061 | 3/13/2021 | NC | 27 | M | 3/13/2021 | 3/13/2021 | PATIENT FAINTED ABOUT FIVE MINUTES AFTER GETTING THE VACCINE. HE CAME TO AFTER ABOUT 30 SECONDS. CALLED PARAMEDICS AND HE WAS ATTENDED TO. HE DID NOT HAVE ANY OTHER REACTION. PT MENTIONED THAT HE HAD NOT HAD ANY FOOD SINCE MORNING AND HAS HISTORY OF SYNCOPE AFTER BLOOD DRAW. |
| 1097822 | 3/13/2021 | NY | 59 | F | 3/12/2021 | 3/13/2021 | During the night following the vaccination, I had chills, muscle aches and a headaceh. I got up to go the bathroom and on the way back to bed I fainted and hit head on the floor. |

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| 1097694 | 3/13/2021 | | 53 | M | 3/11/2021 | 3/11/2021 | Hand tremors 9 hours after injection lasting for one hour. Fever starting approx. 12 hours after injection. Possible contribution to fainting event approx. 15 hours after injection. Muscular aches in neck and shoulders starting approx. 17 hours after injection. |
| 1097663 | 3/13/2021 | VA | 29 | F | 3/13/2021 | 3/13/2021 | brief vasovagal syncope followed by nausea and vomiting x 3 hrs. |
| 1097635 | 3/13/2021 | KY | 80 | F | 3/12/2021 | 3/13/2021 | Nausea, fever, fainted, chills. |
| 1097849 | 3/13/2021 | MS | 44 | F | 3/4/2021 | 3/4/2021 | SOB, throat tightness 5 minutes after vaccination 4 mg decadron, epi and benadryl given IM on scene transferred to Emergency room via ambulance C/) SOB, itching and swelling at the back of her throat and in her neck. No hives. No syncope. Described as moderate and later mild. No radiation, no vomiting, no wheezing. Patient discharged from ED at 09:30 am |
| 1097597 | 3/13/2021 | IL | 24 | F | 3/13/2021 | 3/13/2021 | Patient felt light headed and stated felt like fainting. She stated she was nervous about getting shots. Monitored patient blood pressure 125/75 pulse 76 and five minutes later 123/81 pulse 80. Patient waited 15 minutes after vaccination and stated was fine and did not want further intervention then left with family. |
| 1097587 | 3/13/2021 | TX | 29 | M | 3/13/2021 | 3/13/2021 | pt received vaccine and went to waiting area. 5 minutes after in the waiting area, pt had a self reported panic attack/fainting spell. pt did not fully lose consciousness. pt has a history of panic attacks/fainting spells, especially with needle sticks. Paramedics assisted on scene but pt was not transported to hospital. pt left under his own power |
| 1097550 | 3/13/2021 | MN | 38 | M | 3/13/2021 | 3/13/2021 | Shortly after patient received vaccination he went to get up. He didn't look well, so I asked him to sit back down. Then as I was about to tell him to lie down on the floor, it appeared to me as if he fainted in the chair. We were able to lie the patient flat on the floor and raise legs on a chair. He stated he immediately felt better. He also stated he never lost consciousness and that he had bad anxiety and that this has happened before due to his anxiety in the past. They checked out the patient and the patient walked out on his own accord and did not leave with the paramedics. |

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| 1097536 | 3/13/2021 | NY | 31 | M | 3/13/2021 | 3/13/2021 | Patient has a fear of needles, which was not mentioned initially. The patient got the vaccine and was told to have a seat outside the immunization room for 15 minutes at least to ensure no side effects. The patient wanted to get something in the store. Pharmacist was immunizing the next patient already. Patient knocked on the door and stated he didn't feel good and was dizzy. I told him to take a seat I was going to get him some water. As he was about to sit down he passed out and hit the door with his head. EMS was called and patient was taken to hospital. The patient woke up 30 seconds after and was dizzy. He felt better after about 5 minutes. |
| 1097504 | 3/13/2021 | CA | 20 | F | 3/13/2021 | 3/13/2021 | Pt 20 y/o female found ambulatory at vaccination site. c/c weak/dizzy, borderline hypotensive. Pt received her first dose of Moderna COVID-019 vaccine at approximately 1040hrs. Pt was monitored for 15 minutes in a designated area. Upon standing up pt became lightheaded and dizzy. Pt sat down and notified staff of feeling weak and dizzy. Responder was notified and responded to pt. Pt denied any chest pain or shortness of breath. Minor nausea but no vomiting. Pt had equal grips and pushes, no headache, blurred vision or tinnitus. Abdomen was soft and non tender on palpation. No hives, rash or redness noted. Pt was given 500cc of NS via IV, 20g in L AC. Pt was positive orthostatic and was laid down supine on a blanket. Last LPM 30 days ago. Gravida 0, Para 0. Pt states she has had syncopal episodes during menstrual period. Pt denied any food intake this morning. Pt was transported by Hospital. Vital signs improved with administration of NS. Vital Signs: BP 106/52, HR96, SPO2 99%. (1052hrs) BP 118/76, HR 68, SPO2 99% Hx: Syncope during menstruation, Anxiety, borderline hypotensive. Allergies: NKDA Medicine: None |
| 1097493 | 3/13/2021 | TX | 22 | F | 3/13/2021 | 3/13/2021 | PATIENT FAINTED |

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| 1097443 | 3/13/2021 | AZ | 49 | F | 3/11/2021 | 3/12/2021 | 02/12/2021- 12:36am woke up with chills that went on for about 1 hour. About 7am woke up went to the restroom and almost fainted (lightheaded, nausea, black vision, cold sweat). Blood pressure was 84 over 44. In the afternoon had muscular pain and a low grade fever of 100F for about 2 hours. A little sore at the injection site but all symptoms disappeared on day two 03/13/2021 |
| 1097203 | 3/13/2021 | LA | 22 | M | 3/13/2021 | 3/13/2021 | patient fainted after vaccination |
| 1097436 | 3/13/2021 | IA | 83 | F | 3/13/2021 | 3/13/2021 | Patient had severe diarrhea within 30 minutes of getting the shot and passed out |
| 1097110 | 3/13/2021 | KS | 27 | F | 3/12/2021 | 3/12/2021 | Passed out 5 minutes after injection |
| 1097134 | 3/13/2021 | FL | 23 | M | 3/13/2021 | 3/13/2021 | Patient was given the vaccine and seemed fine. He was talking and then just fell out of the chair and fainted. He was unconscious for about 15-20 seconds and came to. He was disoriented and complained of tingling in his hands. EMT was called non-emergency since the patient had regained consciousness. He still appeared disoriented for several minutes. Patient said he hadn't eaten since breakfast. He was given crackers and water. EMT arrived and took vitals. Patient appeared fine, just a bit shaky. |
| 1097095 | 3/13/2021 | MO | 28 | F | 3/10/2021 | 3/11/2021 | Felt absolutely fine after 2nd injection. 10:30AM the next day I started like I had the flu and felt extremely ill out of nowhere. 10:35 am I passed out sitting down at work. I woke up and immediately passed out again. My coworkers said I shook like I was having a seizure as I went down both times. Ems was called and checked vitals. Everything was perfect. Ems wanted me to go to hospital but I refused due to cost |

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| 1097204 | 3/13/2021 | CA | 38 | M | 3/10/2021 | 3/10/2021 | ADMINISTERED VACCINE AND PT. PT WAS SEATED ON A CHAIR AND COMFORTABLE. 1 OR 2 MINUTES LATER AFTER RECEIVING THE VACCINE PATIENT FAINTED. WE CALLED 911 BUT WHILE ON THE CALL WITH DISPATCH PT CAME TO "WOKE UP". PT WAS OUT FOR ABOUT 1 MIN OR LESS. WE ASKED PT IF NEEDED AND AMBULANCE HE SAID NO. SAID THIS HAPPEN A FEW WEEKS AGO WHEN PT HAD BLOOD DRAWN AT CLINIC. WAS DIAGNOSED WITH A POSSIBLE VASOVAGAL SYNCOPE. PT STAYED, SEATED. WE GAVE HIM WATER AND FOOD. HE FELT COMFORTABLE AND FINE. HE DID NOT NEED TRANSPORTATION. AFTER ABOUT AN HOUR OF MONITORING HE WENT HOME ON HIS OWN. |
| 1097242 | 3/13/2021 | MI | | M | 3/13/2021 | 3/13/2021 | Pt is a 59 year old male who presented to the community center for Moderna vaccination. After receiving an intramuscular shot at his left arm he began to feel numbness and heaviness in his left arm, 3-4 minutes post injection. Pt stated he had associated light headedness and fatigue. Pts vitals were taken with 140/90 BP, HR 84, SPO2 97-98 %. Pts vitals were retaken and he became tachycardia with HR ranging from 130-125. PT stated his symptoms worsened and the paramedics were called at that time. PT received 125mg solumedrol to upper outer quadrant of left gluteal area. Paramedics arrived on scene within 10 minutes of onset of symptoms. Physical - General - Anxious , sweating Cardiac - Tachycardia, no murmurs, rubs, or gallops. Resp - clear to auscultation B/L ABD - soft non-tender, non distended, bs + in all 4 quadrants. Presyncope rule out cardiogenic vs. neurogenic causes, pt was taken to the emergency room via paramedics secondary to what was described in the HPI. Pt was taken to hospital. |
| 1097392 | 3/13/2021 | TX | 38 | M | 2/10/2021 | 3/11/2021 | Fainting, possible seizure, unconsciousness, severe chills, nausea, aches/flu like symptoms |
| 1097433 | 3/13/2021 | CA | 57 | F | 3/8/2021 | 3/12/2021 | I started feeling weird after dinner. I passed out or had a seizure. And then went to the hospital. When I arrived I could barely move my body at all. I had to be undressed by nurses and picked up to get in bed. After three hours I was able to move again and went home. |

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| 1097259 | 3/13/2021 | GA | 79 | M | 3/13/2021 | 3/13/2021 | patient's wife reported that he passed out in a restaurant about an hour after he left the pharmacy and received his vaccine. He started to feel bad and stood up from his seat to use the restroom and fainted. The staff called and ambulance but he refused to go to the hospital. Patient's wife reports the EMT's did check him over and said his vitals were okay and appeared fine. His wife then met him and took him home to rest. |
| 1097364 | 3/13/2021 | IN | 59 | F | 3/6/2021 | 3/6/2021 | Immediately Saturday: spacey and throat feels strange; afternoon: body is cold/tired. Sunday: felt great! lots of energy until during a walk at 3pm started to feel spacey (hands feel weird) and spiked a short term fever. Tired and cold. Monday: tired, bottom of lungs burning like I inhaled campfire smoke for a week straight, stumbling over words. Tues: tired, more burning lungs but sensation moving to mid chest (NOT heartburn), feeling like I needed to cough but nothing in lungs, still tired, still struggling with full sentences, irritable. Weds: felt hot but temp was below normal, lungs burning. Took Covid test (negative), incredibly tired, got the spacey feeling and hands felt weird-lasting 30 mins. Thurs: tired, irritable, left side hurt, started having to clear my throat every 20-30 minutes, cold. Fri: still tired, felt like I needed to cough but didn't reduce the pressure in chest/burnin/aching. Slept 14 hours. Sat: woke up feeling awful. Short of breath, clearing throat all day. Went to urgent clinic. Lab/chest x-ray and EKG all negative. Dr:"Nothing we can do for you. This vaccine is too new and you are likely having a reaction. Come see us if it gets worse." I almost cried. When he had me take 4-6 deep breaths to check my lungs with his stethoscope I almost passed out. Now I'm home stuck on the couch under an electric blanket feeling like crap with no relief in sight. Hoping no one else has this ever. |
| 1097340 | 3/13/2021 | | 56 | M | 3/13/2021 | 3/13/2021 | Syncope. Evaluated by EMS-Cleared |
| 1097328 | 3/13/2021 | NJ | 66 | F | 3/8/2021 | 3/9/2021 | Fever, chills, Migraine like headache, dizzy upon first arising from bed., Loud ringing in ear and extreme bright light, feeling of fainting, quick nauseous feeling. |

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| 1097323 | 3/13/2021 | AL | 50 | F | 1/6/2021 | 1/6/2021 | Almost passed out after injection. Had immediate disorientation, head pressure, ear ringing, and slight hearing loss. I stayed 1 hour after at facility . The next day disorientation was better. The head pressure was better after 2 weeks. The hearing loss has slightly improved. The ear ringing worsened significantly and is still going on now, 9 weeks later. It has improved some now after seeing an ENT ear specialist. I have been taking medicine to try to help the ear ringing for about 7 weeks. The severity of the ear ringing has gone from an 8 out of 10 in loudness to about a 2. It is not gone and may never go away. |

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| 1094194 | 3/12/2021 | MD | 42 | F | 3/7/2021 | 3/8/2021 | Immediately after receiving the vaccine, I felt pretty good. Just some soreness in arm and a minor headache an hour later. I took Tylenol and symptoms were bearable the rest of the day. By around 6 or 7p that night, I experienced full body pain and chills, similar to the flu. I also had some chest pain and tightness but attributed that to the overall body pain. I was also very winded and short of breath. I called my Primary Care Doctor to report this, and she said this was a normal reaction and it meant my immune system was working. It continued into the next day, and I took my temperature and had a 102 fever. I slept most of the day and was unable to work. I also had a severe headache. The next day, on Day 3, my flu symptoms were getting better; however, I felt dizzy and short of breath. I also fainted . This is the first time this has ever happened to me. I have never fainted in my life. My symptoms seemed to resolve after eating and drinking, so I figured it may have been dehydration. On Day 4, I was concerned because I was having shortness of breath and chest pain, along with dizziness. I could not take a deep breath without having pain. I called my Primary Care Doctor, and she told me she was concerned I might have covid and to go to the ER. I do not believe I have covid. No one in my household has these symptoms except for me. I believe it is from this vaccine. My chest pain/shortness of breath seemed to go away. for a bit so I did not go to ER. I'm on Day 5 now, and the chest pain/shortness of breath has come back, so I decided to report this because I do not listed on the list of common side effects for the Johnson and Johnson vaccine. I joined a J&J social media group where others are also reporting these symptoms, so I decided to report to Vaers. I also have had night sweats every day since taking the vaccine and my blood pressure is lower since taking the vaccine. |

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| 1093826 | 3/12/2021 | TX | 76 | M | 3/11/2021 | 3/11/2021 | 3 - 4 hours after dose (Dose approx 1030 am reaction 2-230 pm) Light headed then dizzy blood pressure dropped to As low as 85 over 48 then appeared to have a small seizure and passed out. He recovered before ambulance arrived and blood pressure returned to 112 over 68. Then higher when EMT took it after arrival. Today (1day later) he has a bit of a sore neck and is still a little tired. Blood pressure 133 over 70 which is slightly higher than is normal. |
| 1093889 | 3/12/2021 | KY | 23 | F | 3/12/2021 | 3/1/2021 | Upon checking out patient passed out landing on floor. Transferred care to Urgent Clinic per stretcher by MD and nurse |
| 1094010 | 3/12/2021 | MN | 26 | M | 3/11/2021 | 3/11/2021 | 5-7? after vaccine, had a fainting episode- fell out of his chair, hit forehead on the floor. Vitals taken immediately after the event and again 10? after event. Vitals stable both times. Patient lay in a cot and drank water to recover. Felt well after 35? and left clinic. |
| 1094019 | 3/12/2021 | ID | 33 | F | 3/12/2021 | 3/12/2021 | Patient got lightheaded and dizzy about 15 minutes after vaccination. She showed syncope and lightheadedness. We laid her down and stated started to fill better. She state up and about a minute or two needed to rest again. We contacted paramedics and the arrived in 15 minutes and were able to take over from there. |
| 1094082 | 3/12/2021 | MT | 31 | F | 3/10/2021 | 3/12/2021 | I felt as though I was going to vomit so i got up to go to the bathroom-on my way I fainted, falling into closet door breaking it & leaving hole in wall. My arm pain & body aches were severe. low grade temp & HA as well |
| 1094089 | 3/12/2021 | MO | 28 | M | 3/11/2021 | 3/11/2021 | Very brief vasovagal response (syncope) lasting less than 5 seconds. Patient stated he has this response even when discussing vaccines and advised us prior to vaccination that syncope was likely. Following episode he was given a cool cloth and water. He was able to move to our post vaccine waiting area in less than 15 minutes. On a follow up phone call, patient stated his only side effect was a sore arm.. |
| 1094105 | 3/12/2021 | NC | 21 | F | 3/11/2021 | 3/11/2021 | patient fainted for a few seconds 3 times in a row after receiving vaccine during her 15 minute observation time. after the 3rd time she was ok. |

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| 1094181 | 3/12/2021 | NY | 29 | M | 1/20/2021 | 1/20/2021 | Client c/o dizziness, weakness and near syncope. VS at 1137: 120/60, 82 HR, 16R, A&Ox3. 1145 no change and ambulance called. 1210 client refused medical advice. |
| 1093984 | 3/12/2021 | FL | 83 | M | 3/10/2021 | 3/10/2021 | On day of Wednesday day of Moderna vaccine shot, felt good all day, got ready for bed at 9 PM. Felt very warm and took my temperature it was 99.7. Not too bad. My hands and feet were very cold. Put socks on my feet and climbed in bed. Feeling ok. Woke up around 4 AM my tee shirt is soaking wet, had to pee. Got out of bed and walked to bathroom no problem. Sat down and then my wife said she heard a loud noise in bathroom. She comes to check on me and I?m sitting on toilet passed out, I?m leaning to my right against the shower door. She?s hollering and talks to me to wake up and shakes me and eventually I wake up, get up and walk to the bed no problem. Then I feel the urge to vomit. Go through a series of dry heaves, lay on my back and feel urge to vomit again. Wife tells me to lay on my side, not on my back, that works and I fall asleep. Woke up Thursday at 8 AM, wife is in the kitchen, I make the bed get dressed and feel ok. Walk out to the kitchen and wife is amazed I?m OK. She proceeds to tell me about my passing out in the bath room. I have no recollection that occurred. Had some tea and toast, drinking water to rehydrate and felt better. Walked outside, got leaves out of the pool. Feeling better. No further reaction, just a little tired the rest of the day. Had light lunch, soup. Took a nap at 3 PM woke refreshed and had normal dinner with a glass of wine. Today Friday had normal breakfast and feel completely normal. All in all not a bad reaction. |

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| 1094315 | 3/12/2021 | CA | 33 | F | 1/15/2021 | 1/15/2021 | Within 5 minutes, I felt burning sensation in my chest; in 10 minutes - I started getting chills and within 15 minutes chills were a lot worse. They placed me on a gurney, and the chills started getting so bad I was shaking and out of control and I was really cold. After about 25-30 minutes after I felt like my blood pressure dropped and I actually passed out and once I passed out I don't know how long I was out for. Maybe less than a minute, I couldn't breathe and I was hyperventilating and they put a oxygen mask on me. They took me to ER (Hospital) and I recognized I was in there when I "woke up" - they were trying to get an IV in me but I was shaking so much it took several attempts. They gave me several medications because I was nauseated as I wanted to vomit and they gave me anaphylactic medications. I was having chest pains. I fell asleep. They were going to admit me but I kind of refused to be admitted and they let me go with Zofran, prednisone and one other medication. One of coworker took me home. I slept the rest of the day and night. The next day, Really fatigued and chest pain was semi getting better. Breathing - was pretty okay after that. By day 3, I was fine. |
| 1094392 | 3/12/2021 | CA | 27 | M | 3/12/2021 | 3/12/2021 | After receiving the Johnson & Johnson vaccination at approx 0855 the patient told the vaccinating nurse that he was "feeling dizzy." Pt then fainted and was lowered to the floor and positioned on his side; he was pale and diaphoretic initially but resolved before he was sat up. He then opened his eyes and stated that he was "feeling ok." Patient then confirmed that he has fainted twice before while receiving bloodwork or vaccines. Pt refused emergency services. Pt advised to call 911 or seek medical attention for any concerns after leaving facility. Pt verbalized understanding. Pt vital signs are as follows BP 136/58, R 18, P 84, O2 sats 98% on room air. Pt alert and denies any pain or discomfort. Denies any further concerns. Pt left facility at 0900. |
| 1094435 | 3/12/2021 | TX | 60 | M | 3/12/2021 | 3/12/2021 | Patient reports feeling lightheaded, dizzy. Passed out a couple times. Presents sweating, flushing, and clammy skin. Patient reports having veso vagal previously. EMs preformed EKG and results were normal. Refused EMS transport |

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| 1094490 | 3/12/2021 | OK | 66 | F | 2/24/2021 | 3/10/2021 | Patient was vaccinated with her second dose on Wednesday, February 24th. A family member contacted us to let us know she was sitting in a casino exactly one week later and passed out, going into cardiac arrest. The patient did pass away. |
| 1094515 | 3/12/2021 | IL | 41 | F | 2/12/2021 | 2/13/2021 | Other than the normal symptoms of chills, body aches, feeling run down...the day after I had the second dose, I experienced a fainting episode and collapsed on the floor. |
| 1094583 | 3/12/2021 | AZ | 79 | F | 3/8/2021 | 3/9/2021 | I became progressively more sleepy the afternoon after the vaccination, as expected. I did get up and make dinner, then went to bed at 9:15 p.m. on March 8th and slept until 9:15 a.m. March 9th. I felt unstable walking into the bathroom to urinate, and even more unstable waking into the kitchen to take my meds. I passed out and woke up on the floor. I was weak but managed to pull myself up holding on to the kitchen range. I headed for the living room sofa and passed out again, waking up on the floor by the sofa. I'm guessing I was unconscious about 2 minutes each time, but don't really know. I lay down on the sofa and called a neighbor. He thought I should call 911, and they came and drove me to ER. They did an EKG, chest x-ray, and CAT scan of my brain, and drew blood. All results were normal. I returned home that same day (March 9) and had little energy, and ate lightly. When I was getting in bed about 10:30 p.m. I let my head drop on the pillow and the room started to whirl around me for about six seconds. Sometimes when I roll over in bed during the night there is a pause before it feels like the room gives one spin. My scalp is very tender in the large area where I hit it twice when passing out. I'm taking it easy again today, but do feel a little stronger. I am normally exceptionally healthy for my age, and work, traveling to destinations to research and photograph my articles. Both the travel and article take stamina, and I thrive on the work. |

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| 1094532 | 3/12/2021 | KY | 41 | M | 3/11/2021 | 3/12/2021 | Upon waking this morning pt reports L arm numbness, tingling and flaccidity. pt walked to kitchen and he began feeling sweaty and hot, the next thing he awoke laying in the floor after passing out . Pt was incontinent of urine during event. He now reports some mild shortness of breath but no acute distress or known injuries from syncope episode. pt advised to go to the ER. Pt's states his wife is on her way home and will drive him to the ER. |
| 1094557 | 3/12/2021 | TX | 57 | F | 3/11/2021 | 3/12/2021 | She fainted and was out between 5-10 minutes. This has never happened before, she's healthy, nothing unusual except getting vaccine yesterday. |
| 1093812 | 3/12/2021 | MA | 67 | F | 3/11/2021 | 3/12/2021 | Vaccine was Thur 3/11 at noon. Slight headache and pain at site of injection. Friday morning, was very dizzy. Had walked into kitchen to get the thermometer. My temp was 99. I got very dizzy and passed out for a second or two. When I hit my head on a cabinet handle I came to. At first I thought I was in my bed and couldn't figure out what I had hit my head on. There was blood coming from the wound. My husband came to help me. We stopped the bleeding after a few minutes and I began icing my head. I was still very dizzy and had an urge to use the bathroom. I was afraid to get up. With my husband's help, I crawled to bathroom and he helped my onto toilet. I had diarrhea. At that point I was able to walk with help to my bed. I have had a mild to moderate headache since I had the vaccine. |
| 1093495 | 3/12/2021 | NJ | 21 | F | 3/11/2021 | 3/11/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Additional Details: Pt fainted while seated. emergency services were called. she recovered quickly. we gave some candy and water. her bp was normal and osat was normal. mother drove her home |

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| 1094519 | 3/12/2021 | AL | 64 | M | 3/5/2021 | 3/6/2021 | About 21 hrs after shot I experienced significant dizziness and almost fainted. I have continued to experience slight dizziness from time to time but only severe when lying down, rolling over while lying down, looking straight up, and sometimes bending over. 5 days after shot I decided to check blood pressure and it was repeatedly around 175/100. I went to local doctor and he prescribed additional BP meds. BP now good (126/80) but I still experience dizziness from time to time. Yesterday when BP high I also had constant headache and some nausea. Today(3/12), almost week after shot I still experience dizziness to a minor degree off and on, but still somewhat severe when lying down, looking up, and bending over |
| 1093524 | 3/12/2021 | FL | 26 | M | 3/10/2021 | 3/10/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Hypotension-Mild, Additional Details: Patient fainted, unfortunately did fall, however despite some bruises was ok. Waited for family to come to get him and was able to leave under his own power. Ambulance was called and he was checked, no issues found and did not leave with ambulance. |

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| 1093317 | 3/12/2021 | VA | 25 | F | 1/20/2021 | 1/20/2021 | <p>Felt very tired; loss of consciousness with fainting; Felt like her throat was closing; Chills; A spontaneous report was received from a consumer concerning a 25-years-old patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced loss of consciousness, felt like her throat was closing, chills and felt very tired. The patient's medical history was not provided. No relevant concomitant medications were reported. Laboratory data was Prolong QT interval on ECG reported. On 20 Jan 2021, approximately same day prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: unknown) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 20 Jan 2021, 5 minutes after vaccination, the patient felt like her throat was closing, chills, lightheaded and fainted. In the ER the work up for syncope revealed prolonged qt interval on ECG. Treatment included Benadryl, Magnesium, fluids. The patient was discharged on the same day but she still feels tired having brain fog. Action taken with mRNA-1273 in response to the events was not reported. The outcome of events were not reported; Reporter's Comments: Very limited information regarding this event/s has been provided at this time. Further information has been requested.</p> |

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| 1093323 | 3/12/2021 | NY | | F | 2/26/2021 | 2/27/2021 | Lightheaded; passed out; Lymph knot under armpit; A spontaneous report was received from a consumer for a 67-year-old female patient who experienced light headedness and passed out. She also had lymph knots under her armpit. The patient's medical history was not reported. No concomitant product use was reported. On 26 Feb 2021, the patient received their first of two planned doses of mRNA-1273 (Lot number: 011A21A) intramuscularly for prophylaxis of COVID-19 infection. On 27 Feb 2021, next day after receiving the vaccine, the patient felt lightheaded and passed out and was hospitalized. She also experienced lymph knots under her armpit. Action taken with mRNA-1273 with respect to the events was not reported. The outcome of the events was not reported. The reporter did not provide the causality assessment for the events.; Reporter's Comments: Based on the current available information which shows a strong temporal association between the use of the product and the start date of the reported event, a causal relationship with the event cannot be excluded. Axillary lymphadenopathy is consistent with the known safety profile of the mRNA-1273 |

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| 1093333 | 3/12/2021 | FL | | F | | 1/28/2021 | I fell and must have passed out; I fell and must have passed out; painful, large red swollen arm at injection site (size of half a baseball in height and about 6 inches down my arm); painful, large red swollen arm at injection site (size of half a baseball in height and about 6 inches down my arm); Body pain; severe headache; fever (100/sweating); chills (shaking with temp drop- 97.2; normal 97.6); vomiting; loose stools; Lost 6 lbs; abrasion on her right side forehead; dizzy; weak; fever (100/sweating); nausea; This is a spontaneous report from a contactable consumer (patient). A 68-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number unknown) via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunisation, at 68 years old. Medical history included Metastatic breast cancer, thyroid, glaucoma, osteo arthritis, neuropathy, sulfa allergy, Fish/shellfish allergy, penicillin allergy, MS (Multiple sclerosis), and Phenothiazines allergy. No other vaccines in four weeks were received. The patient is not pregnant at the time of vaccination. The patient did not have COVID prior vaccination. The patient was not tested for COVID post vaccination. Concomitant medications included amlodipine, levothyroxine sodium (SYNTHROID), gabapentin, timolol, and cyanocobalamin (B12), therapy dates and indications unspecified, in two weeks. The patient previously took Cytoxan, cipro, Demerol and experienced allergies. On 28Jan2021 20:00 (also reported as about 8 hours), the patient experienced body pain; severe headache; fever (100/sweating); chills (shaking with temp drop- 97.2; normal 97.6); Nausea; vomiting; loose stools; painful, large red swollen arm at injection site (investigation: size of half a baseball in height and about 6 inches down her arm); dizzy; weak; and she fell and must have passed out. Woke up on floor with abrasion on her right-side forehead. The patient also reported she lost 6 lbs. The events lasted from Thursday evening to Sunday morning. Treatment for the adverse events included BENARDRYL. Outcome of the events was recovered on 29Jan2021. The patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number EL9267) via an unspecified route of administration (right arm) on 18Feb2021 09:30 for COVID-19 immunisation. Information on the lot/batch |

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| | | | | | | | number has been requested. |
| 1093413 | 3/12/2021 | WA | 53 | F | 3/11/2021 | 3/11/2021 | Patient complained tingling on her fingers, toes, chill about to be fainted. Rashes appeared on her neck. Gave her 50mg liquid diphenhydramine at 5:05pm. About 10 min later, she said she felt better, and her rash seems to calm down, but her tingling on her extremities didn't improve much. Call 911. EMT suggested her to call home and said she may have anxiety related. Check with her again tonight at 9:13pm. She said she is a lot better. Recommend her to check with her PCP |
| 1093422 | 3/12/2021 | CA | 42 | F | 3/4/2021 | 3/5/2021 | Extreme neck pain, difficulty moving neck, gout like symptoms in feet, extreme fatigue, shakiness, flu like symptoms, swollen red knuckles on left hand that were stiff and painful, fainted, dizziness, vision disturbances |
| 1093442 | 3/12/2021 | CA | 33 | F | 3/9/2021 | 3/9/2021 | 33yo F having intermittent palpitations causing near syncope, dizziness causing gait instability, and nausea/vomiting and headache. This is day 3 of these symptoms and she states they have not improved at all. |
| 1093459 | 3/12/2021 | CA | 68 | F | 3/4/2021 | 3/4/2021 | 2/4/21: First Moderna - left arm. Sore arm. 5 to 8 days later, rash on arm, under forearm, hand area. 20 days later, rash on chest and neck. 3/4/21: Second Moderna-right arm. Sore arm, body aches, chills. 3/5/21: fainting (2), dizziness, fatigue, diarrhea, body aches. Stayed in bed. Drank liquids, ate crackers and rice. Low blood pressure: 103/57; pulse 48. 3/6/21 - 3/7/21: Fatigue; low blood pressure: 114/63; 60. 100/61; 82. 106/65; 71. 110/64; 59. Slept 11 to 12 hrs. 3/7/21 - 3/8/21: Basically back to normal. BP normal avg 118/78; 75. |

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| 1093460 | 3/12/2021 | CA | 22 | M | 3/11/2021 | 3/12/2021 | <p>On Thursday, March 11th, 2021 approximately 3:10 pm, Patient received his first dose of Moderna Vaccine (Lot number: 003A21A) in his left deltoid Patient received the Moderna Vaccine. After which he sat in the designated medical observation area for 15 minutes. Approximately five minutes later around 3:15 pm, Patient experienced syncope, fell out of his chair, hit the left side of his forehead on the ground. Due to the fall, he experienced a mild abrasion on the left side of his forehead, which led to bleeding. The Physician?s Assistant rushed to aid Patient who was lying on the ground in a supine position. Emergency Medical Services (EMS) - Fire Department and ambulance were called immediately and approximately five minutes later EMS arrived. During the time frame prior to EMS arrival, the Physician?s Assistant asked numerous questions to Patient to assess his condition. She asked Patient if he could breathe and he responded ?yes?. She asked Patient if he was short of breath and he responded ?no?. She asked Patient if he felt like his throat was closing and he responded ?no?. At this point, an Epinephrine pen was not used. Patient was alert and the Orient x 4 questions were asked [(1) Who are you? (2) Where are you? (3) What is the date and time? (4) What just happened to you?]. Patient also denied head pain, neck pain, nausea or chest pain. Staff performed a limited neuro-exam and was deemed within normal limits. Patients Glasgow Coma Scale score was 15 Patient mentioned that he has a phobia of needles and something like this has happened before when he was ?young?. Patient initially did not want an ambulance to be called. It was explained to him that it might be in his best interest to call EMS due to syncope and abrasion on his forehead due to the fall. Patient also mentioned that he only consumed two cookies and coffee for that day. When the EMS arrived (about 5 firefighters), they interviewed him and performed a blood pressure test. His sitting blood pressure was 130/82. One of the firefighters assessed his spine and Patient denied cervical, thoracic, and lumbar tenderness or pain. The firefighter assessed Patient's glucose level, which was a bit difficult to obtain in the first initial efforts, with the glucometer reading ?error?. The firefighters eventually were able to obtain a reading on Patient's glucose and it read 86. Patient was able to stand on his own, and a second blood pressure test was performed;</p> |

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| 1094571 | 3/12/2021 | RI | 64 | F | 3/9/2021 | 3/12/2021 | <p>his standing blood pressure reading was 145/89. EMS gave Patient gauze to address his head wound Patient initially refused to go to the hospital, but per EMS protocol, fluids needed to be administered. Patient entered the ambulance and was taken to the hospital by EMS.</p> <p>64 yo female with hx bipolar disorder on multiple psych meds, Htn, here for same day visit. Pt reports got her second covid vaccine on 3/9/2021 in the left arm, Pfizer. Yesterday (3/10/21) woke up with severe right knee pain, felt like she could not bear weight/ws going to fall. She went to son's apartment who is in same building and then went to lie down in bedroom. Because she drinks a lot of water, she had to get up to go to bathroom to urinate. She was about to sit down on toilet, when she felt both her legs go numb as well as her arms and her vision was blurred. She tried to grab the tub but fell forward on the floor. She states she urinated on the floor. She was on the floor for about 30 mins until her son got her up and back to bed. Later in the day she needed to urinate again and when she got up, she felt unsteady and fell on the bureau bruising the left arm. Since she feels a bit unsteady with gait and used a walker to come hre today. She denies feeling dizzy before her falls. She denies striking her head. She denies convulsions or hx of seizure disorder. She reports no new meds, only recent change an increase in her alprazolam dose. She does report a headache day after her vaccine.'She denies vomiting or diarrhea or antecedent illness. No longer has headache. She denies positional changes Of note she is on propranolol (prescribed by psych) as well as lisinopril-hydrochlorothiazide for HTN 64 yo female with bipolar disorder on multiple psych meds, htn on propranolol 20 mg bid and lisinopril-hydrochlorothiazide, s/p recent Pfizer covid vaccine, s/p presyncope episode after experiencing severe right knee pain and attempted micturition. Pt felt like her sight was affected and experienced numbness/weakness in legs and arms causing a fall. Did not hit head. The history is most suggestive of a vagovagal episode.</p> |

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| 1093507 | 3/12/2021 | CT | 61 | F | 3/11/2021 | 3/11/2021 | Systemic: Confusion-Severe, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Hypotension-Mild, Systemic: Visual Changes/Disturbances-Medium, Systemic: Weakness-Medium |
| 1094698 | 3/12/2021 | MD | 82 | F | 3/5/2021 | 3/6/2021 | Flu like symptoms including but not limited to fever, aches, sweating, dizziness. Resulted in fainting and falling, proceeded to faint multiple times - lost all bodily functions, eyes rolled in back of head multiple times and 911. Did get back to ability to get home but now repeats herself more than before and seemed to have lost some mental capacity till Wednesday March 10 / she now is better but scared to do anything on her own as fearing issues again |
| 1093782 | 3/12/2021 | MD | 75 | F | 3/4/2021 | 3/7/2021 | On 3/7 the patient presented to the ED after having 3 episodes of presyncopal staring events in the past week, and reports having them over the past year and a half. Reason for admission: syncope and collapse. Per, EUA all hospitalizations must be report after recently receiving a vaccine. This patient has had a history of syncope and this hospitalization does not seem to be related to the vaccine. |
| 1093525 | 3/12/2021 | AL | 30 | F | 3/11/2021 | 3/11/2021 | Systemic: Fainting / Unresponsive-Severe, Additional Details: Patient fainted immediately after injection. Immunizer (RN) administered epinephrine and the patient arose from her fainting state with no issues. Patient stated that she always faints from every needle stick (did not inform the immunizer beforehand). Patient was monitored for 30 minutes before leaving. |
| 1093533 | 3/12/2021 | NY | 51 | F | 3/11/2021 | 3/11/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Mild, Systemic: Nausea-Medium, Systemic: Shakiness-Medium, Additional Details: Patient stated she had only eaten a bagel and a lemon tart today, shortly after giving her 2 apple juice boxes and a few bites of vanilla ice cream paramedics checked her blood glucose and found it to be 88. Because she bumped her head when she fell, she was escorted to an emergency room. |

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| 1093537 | 3/12/2021 | CA | 26 | F | 3/11/2021 | 3/11/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Nausea-Mild, Systemic: Seizure-Mild, Systemic: Tingling (specify: facial area, extremities)-Mild, Systemic: Vomiting-Mild, Additional Details: Within 10mins of vaccine, pt seem to have a mild seizure for less than 30sec. Pt had no hx of seizures, on no current medication. Pt recovered, and within 1-2mins she passed out. She was warm. She woke up within 1min, then started to vomit. Called emergency services. She felt better after throwing up. When ambulance arrived, she started to have tingling sensation on her finger tips. States she felt better. EMT advised her to go to the ER. Pt decided to go to ER to get checked up. Let with ambulance. |
| 1093538 | 3/12/2021 | NY | 58 | F | 3/11/2021 | 3/11/2021 | Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Additional Details: pt complained of feeling hot, then lost consciousness while seated for approx 10 sec, pt was given cold cloths and ice pack, given water to sip, and monitored for 30 min. when pt felt recovered, she left, and was followed up by phone call approx 1 hr later, experiencing no further adverse effects |
| 1093541 | 3/12/2021 | TX | 20 | M | 3/11/2021 | 3/11/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Nausea-Mild, Systemic: Tingling (specify: facial area, extremities)-Mild, Systemic: Tinnitus-Mild, Systemic: Visual Changes/Disturbances-Mild, Additional Details: Pt nearly fainted/passed out. Had some tunnel vision/nausea/loss of hearing. Recovered after water and sitting for 15 minutes. Had some numb/tingling hands/arms. |
| 1093544 | 3/12/2021 | FL | 21 | M | 3/11/2021 | 3/11/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Hypotension-Mild, Additional Details: Patient prone to fainting, sweaty, pale face. Laid patient down, lifted knees. Mother was with patient, denied emergency care. Patient recovered and was able to walk out of pharmacy unassisted after event. |
| 1093592 | 3/12/2021 | PA | 48 | F | 3/11/2021 | 3/11/2021 | Patient experience brief episode of syncope - blurry vision, dizziness and sweating that was treated with ice packs. Began at 4:50pm and resolved at 4:58pm |

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| 1093642 | 3/12/2021 | NC | 42 | F | 3/9/2021 | 3/9/2021 | Fever >102; chills; dizziness - lasted 6 hours loss of consciousness - passed out about 2AM for just about 30 seconds swollen lymph node under right arm - persisting on day 3 post injection brain fog - lasted 2 days |
| 1093654 | 3/12/2021 | PA | 19 | F | 1/14/2021 | 1/14/2021 | Syncope/Collapse 20 minutes after receiving the vaccine I was in AFIB and had a heart rate of 150, hospitalized overnight. Been dealing with high HR ever since, which has hindered my ability to run and train at my normal level. Had to wear a heart monitor for two weeks. Followed up with my cardiologist; have to get an echocardiogram done and then an electrophysiology test/heart cath done in the near future. |
| 1093687 | 3/12/2021 | PA | 45 | F | 3/11/2021 | 3/11/2021 | At approximately 1607, observes found patient having a syncope episode. The observation team went over to the patient and safely moved the patient to the floor. The patient was placed on 1.5L oxygen via nonrebreather. The staff paramedic was able arouse the patient with a sternal rub. After arousal the patient did not complain of any difficulty breathing or pain any place. The patient was assisted to chair. The patient was able to answer all orientation questions appropriately at 1612. EMS arrived to the location at 1620. The patient was assisted to the ambulance and care was transferred to EMS. |
| 1093504 | 3/12/2021 | NC | 37 | M | 3/9/2021 | 3/9/2021 | Patient became lightheaded, diaphoretic and passed out minutes after receiving vaccine. Woke within seconds. Patient was evaluated by medical professional. BP normal and all symptoms resolved with 10minutes. Kept in nurses offices for approx 45 minutes for observation and was released to his care. |

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| 1095867 | 3/12/2021 | CA | 81 | F | 2/23/2021 | 2/23/2021 | She had no issues with the 1st dose in the series. She did not have any symptoms but acknowledged feeling anxious about the side effects prior to arrival for vaccine. After the 2nd dose, she experienced chest pain, jaw pain, body numbness and tingling, and nausea. She did not have vomiting, shortness of breath, syncope, or headache. She was hypertensive on the cardiac monitor and EKG with T wave inversion in lead III, otherwise unremarkable. Heart rate stable, alert and oriented, cardiopulmonary exam benign. She was sent to the ER for further workup, but did not seem to have any allergic reaction to the vaccine. It is unknown what occurred at ER, as she either went to a separate health system or did not go at all. |
| 1095500 | 3/12/2021 | DC | 24 | F | 3/12/2021 | 3/12/2021 | Patient notified administering pharmacist that she has a history of fainting after receiving flu shots. Two other pharmacists came in preparation to assist if needed. After the pharmacist administered the covid vaccine, the patient fainted for 1 second, regained consciousness. She refused medical treatment. Patient was breathing so Epinephrine was not administered. Patient was sweating and ice packs, water, and crackers were provided to her. She sat in a chair with her legs elevated for 1 hour with pharmacists closely monitoring her. |
| 1095521 | 3/12/2021 | NC | 47 | F | 3/12/2021 | 3/12/2021 | Patient warned staff that she was not good with shots and had a history of syncope. She also marked this on her VAR form. She was very nervous and crying in the chair. She received the vaccine promptly and remained in the chair for a few minutes before getting up to sit in the auditorium bleachers. after about 20 or more minutes someone shouted that saw her fall in the bleachers, she was face down between the benches. She was conscious and responding, breathing normally, with normal pulse when we examined her. She got up slowly and recovered without needed further medical attention. |
| 1095546 | 3/12/2021 | CA | 42 | M | 3/12/2021 | 3/12/2021 | Fainting, sweating, blood sugar dropped, unresponsive. |

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| 1095577 | 3/12/2021 | DC | 20 | F | 3/12/2021 | 3/12/2021 | Patient did not report any allergic reaction to any vaccine or medications when asked during consultation prior to administration. The pharmacist had administered the vaccine and patient was sent to the waiting area to wait the mandatory 15-20 minutes after receiving the shot. Patient was seated and after 5 minutes, patient disclosed with another patient in the waiting area that she was not feeling well. After a few min she lost consciousness for less than a minute, her eyes rolled back. Epinephrine was not administered. When she became conscious, she refused medical treatment. Patient was nauseous and vomited a few times. A pharmacist checked vitals and all were within normal limits and a neuro check was also performed which was normal. Patient was given water, gingerale, raw ginger, and ginger tablets for the nausea. Patient was also given saltine crackers. Patient's aunt arrived at the scene. Patient reported feeling chills and weakness. Patient did not feel comfortable standing/leaving. Pharmacist stayed with the patient for 90 min until patient was stable and walked the patient to the aunts car. At the end of the event patient reported having vasovagal syncope and has a history of fainting at the site of blood, too much stress, and anxiety, but never after vaccines.She reported she did not eat anything in the morning and just drank coffee. |
| 1095578 | 3/12/2021 | TX | 28 | F | 3/12/2021 | 3/12/2021 | Patient immediately got lightheaded after receiving the vaccine. About 5-10 minutes after she fainted but regained consciousness. Patient was nauseous, her ears were ringing, and felt extremely hot. 911 was called and patient was taken to the hospital. |
| 1095597 | 3/12/2021 | WV | 66 | F | 3/8/2021 | 3/10/2021 | After 1 hour of light housework she walked approximately 200 yards to her daughter?s house to retrieve her dog. She bent over a couple times to pick up the dog then she became dizzy and passed out and fell to the ground. This has never happened before taking this shot. |
| 1095627 | 3/12/2021 | MI | 53 | F | 3/9/2021 | 3/9/2021 | 5-10 minutes after shot felt warm and passed out on third day (3/11/21) extreme fatigue, diaria, vomiting |

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| 1095640 | 3/12/2021 | WA | 47 | F | 3/12/2021 | 3/12/2021 | near syncope, hypotension, shaking. Lasted 20 minutes in clinic with stable BP, HR, and SpO2 mostly >96%. Dipped to 88% a few times. no respiratory symptoms, rash, or throat swelling. transferred from clinic to ED via ambulance |
| 1095709 | 3/12/2021 | CA | 38 | F | 3/9/2021 | 3/10/2021 | Most concerning reaction was: on Wed., 3/10/21, at approx. 9:30am, I fainted. I had just had a couple bites of food then felt really warm and nauseous. I fainted at table, then my spouse didn't know when he came downstairs, he thought my head was just resting at the table. He asked if I wanted to walk to the couch to rest, and as he helped me do so, I fainted and he caught me and carried me to the couch. Recovered within 1 minute but my hearing was fuzzy for a couple more minutes, sounded like static in my ears. Other reactions were: Standard ones I read could happen- Fever of 100.1 that lasted less than a day, chills, aches, warm feeling and fatigue. |
| 1095471 | 3/12/2021 | NM | 24 | M | 3/11/2021 | 3/11/2021 | 5 minutes after receiving vaccine felt lightheaded, dizzy Passed out with brief LOC No SOB, chest pain Resolved after lying down, oral hydration |
| 1095814 | 3/12/2021 | MN | 71 | M | 3/10/2021 | 3/10/2021 | 15 minutes after vaccine had flushing, syncope and then nausea vomiting. |
| 1096065 | 3/12/2021 | TX | 49 | F | 3/12/2021 | 3/12/2021 | PT PASSED OUT FOR LESS THAN 20 SECONDS, EMS CAME. NOT TREATMENT RECOMMENDED BY THE EMS |
| 1095972 | 3/12/2021 | NJ | 36 | M | 3/12/2021 | 3/12/2021 | fainted, in and out once, lifted legs and rubbed chest and patient returned to normal in under a minute |
| 1095995 | 3/12/2021 | TX | 30 | M | 2/23/2021 | 2/24/2021 | Spell of fainting or convulsive syncope resulting in dislocation of left shoulder and fracture of humoral right head. Seeing neurologist but recommended by internal medicine doctor to report event as it is possible it contributed or caused the episode. |
| 1096008 | 3/12/2021 | NC | 36 | F | 3/12/2021 | 3/12/2021 | I had hives on site. They administered 50mg of Benadryl and I was able to go home. Once at home, I did experience syncope, nausea, and headache. I still have hives and feel unwell but am otherwise okay. I haven't gone back to see anyone. |

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| 1094732 | 3/12/2021 | GA | 66 | F | 2/4/2021 | 2/5/2021 | Patient reports waking up around 3 AM on 3/5/2021 with fever, aches, headache, and chills. Reports taking Tylenol and feeling better around 10 or 11 AM. Then around 1:30 PM (24 hours later) patient reports being in kitchen preparing a sandwich and started to not feel well. Patient sat in chair to take blood pressure, while taking blood pressure patient passed out. Patient reports waking to grand-daughter rubbing back and she stated, "I passed out didn't I". Patient letting health care provider know. Patient reports having A-FIB 9/2/2021 was feeling sick, headache, and chest discomfort. Reports going to ER Monday September 7, 2020 after being tested for COVID-19. Reports Negative results for COVID-19. Reports passing out and having a 5 day stay in the hospital. |
| 1096086 | 3/12/2021 | CA | 65 | F | 3/12/2021 | 3/12/2021 | PATIENT FAINTED AND BECAME UNRESPONSIVE BUT BREATHING WITH PULSE, PARAMEDICS ARRIVED WITHIN FEW MINUTES, PATIENT CALLED FEW HOURS LATER TO INFORM US THAT SHE IS OK AND HER ADVERSE REACTION WAS DUE TO HYPOTENSION. |
| 1094539 | 3/12/2021 | MN | 71 | M | 3/10/2021 | 3/10/2021 | Patient received the vaccine around 10 am on 3-10-21. He mentioned to the vaccinator that he had a large anxiety of needles. After receiving the vaccine the patient went to the recovery area for the required 15 minutes. About 10 minutes later his breathing rapidly increased - eventually turning to large gasps of air. The patient then briefly passed out but then quickly woke up. He then started vomiting for the next 10 minutes. Eventually he recovered enough to walk with the help of his wife. The wife stated that he has had episodes like this from other vaccines and blood draws. He has never vomited from the episodes, however. |
| 1096114 | 3/12/2021 | LA | 33 | F | 3/12/2021 | 3/12/2021 | Fainting a minute after vaccination and going unconscious. Lasted a minute and was taken to the emergency room. Had low blood pressure for 3 minutes |

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| 1096144 | 3/12/2021 | PA | 61 | F | 3/12/2021 | 3/12/2021 | Patient reported prior to administration of vaccine significant history of syncope episodes with previous vaccine injections. Placed in wheelchair prior to administration of vaccine. After vaccine given patient experienced lightheadedness and feeling hot within 1 to 2 minutes placed on cot no respiratory distress or anaphylaxis occurred symptoms persisted EMS on site now feeling better EMS recalled back to site and transported to local hospital. |
| 1096147 | 3/12/2021 | WV | 77 | M | 3/11/2021 | 3/12/2021 | Spouse reported that patient had been feeling achy, tired and fevered most of day and had spent day in bed. When he got up, he fainted face down on bed. EMT arrived and rolled him over. Oxygen level was at 88, fever of 99.9. Since a diabetic, finger stick done (171) Patient given oxygen and IV fluids before transport and he started to feel better. Transported to Hospital - unknown if admitted. |
| 1095795 | 3/12/2021 | NJ | 20 | F | 3/12/2021 | 3/12/2021 | Patient was flushed, could not hear, was feeling nausea, and fainted for few seconds. I administered Epi 0.3mg and called 911. Paramedics arrived and patient was taken to the hospital. |
| 1094827 | 3/12/2021 | TX | 58 | F | 3/9/2021 | 3/10/2021 | At 12:30 am awoke and felt thirsty and achy in my right arm. I had been feeling chills off and on for a couple of hours. I got out of bed and went to the kitchen, drank a small amount of water and located the bottle of Tylenol. While I was attempting to open the safety seal on the Tylenol I suddenly felt very dizzy and immediately passed out. I awoke on the floor moments later and passed out a second time. After awaking the second time, I remained still and waited a few minutes for the dizziness to go away. I then carefully crawled back to bed without standing. I continued to fill chills throughout the night and the next day (3/10/2021), as well as fatigue. The following day (3/11/2021) the symptoms all seemed to disappear, except for bumps and bruises I sustained in the fall. |
| 1096109 | 3/12/2021 | MO | 68 | F | 2/18/2021 | 2/20/2021 | Diarrhea (usually 4+ times per day) began on 2/20/2021, and continues to today (3/12/2021). Fainted 2/26/2021. To Urgent Care and then ER 2/27/2021. Suspected dehydration. |

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| 1095470 | 3/12/2021 | MN | 60 | M | 3/10/2021 | 3/10/2021 | 08:10 vaccine administered 08:14 dizzy, light headed, room spinning. Sat down 08:25 felt lump in throat, contacted clinic nurse in waiting area. Uncomfortable but never to the point of difficulty breathing. ~08:30, BP 128/99 (I think) Systolic up only a bit. Diastolic very high for me sent to urgent care part of clinic. Monitored BP, oxygen, did EKG (normal), symptoms started easing ~ 09:40. Sent home. Attending PA though it might just be a Vaso-Vagal response, but, after hundreds upon hundred of needles, I've never had such a response, and, my symptoms did not involve a low BP, fainting or nausea, rather I remained conscious, had throat constriction with increased BP and a narrowed pulse pressure range. |
| 1094737 | 3/12/2021 | NY | 24 | M | 3/12/2021 | 3/12/2021 | Immediately after vaccination, patient felt dizzy, lightheaded, and nauseous. Immediately laid down. Observed to be pale and diaphoretic. No loss of consciousness, alert and oriented throughout. Patient reported that he has previously had fainting episodes associated with blood draws but not previously with injections. Patient was evaluated by staff and EMS. After 5-10 minutes lying down, felt better and was able to ambulate. Vaccination occurred at 1:35 pm; BP at 1:40 pm (lying down): 90/62. BP at 1:50 pm (sitting up): 110/78, HR 70, SpO2 100%. Patient felt better and refused transport to ED for further evaluation. |
| 1094817 | 3/12/2021 | GA | 50 | F | 3/8/2021 | 3/9/2021 | On day of shot, I was fine, more tired than usual by bed time. Next morning I was extremely weak and fatigued not able to get out of bed for two hours. I went downstairs to get water, blacked out and completely fainted. I got out of bed around 10:25 or so, went downstairs very slowly, saw clock when I was able to get up around 10:47. I don't believe I was passed out for long. Woke up on kitchen floor, arm bruised. Thankfully head was not injured, apparently fell with arm supporting head (assumption since no head injury). Advised by nurse to come to dr. office, they tested blood pressure, top number was 82 (did the tilt test for orthostatic hypotension). EKG was normal and other blood tests were normal. Was diagnosed with dehydration and low BP. I habitually drink water and even if I did potentially skip a day, I should not faint. |

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| 1094839 | 3/12/2021 | OH | 20 | F | 3/10/2021 | 3/12/2021 | Immediately following vaccine administration patient experienced shakiness, black out feeling, sweats, nausea, and faintness. We tried ammonia inhalants to keep her from fainting and also gave her some water to drink. Nurse practioner checked her blood pressure and was low 85/40's x 3. Patient refused blood sugar check by pharmacist b/c she didn't want "any more needles." We called 911 and local medic and ambulance was sent. Patient was transported to local hospital to help with her hypotensive event. |
| 1094872 | 3/12/2021 | TN | 43 | M | 3/6/2021 | 3/6/2021 | Patient passed out immediately , pale Patient regained consciousness within a minute. No further issues. |
| 1094881 | 3/12/2021 | NC | 33 | M | 3/12/2021 | 3/12/2021 | 33 yo M with NKA, history of fainting in the past and anxiety about vaccines and needles was in the drive through clinic to receive COVID-19 Janssen vaccine on 3/12. After receiving the vaccine at 0943 (lot # 1802070) in right deltoid, the patient began to feel anxious. He had been or was watching EMS working with another patient who had experienced an ADR. He began to feel "floaty" and noted he was blinking uncontrollably. He reported some tunnel vision/blurred vision. He states he recalled a nurse rubbing on his chest and placing a cold pack on his neck and at this point he began to feel better. He states he was trying to "fight" the feeling and was tensing up his extremities but denied convulsions or any loss |
| 1094886 | 3/12/2021 | TX | 60 | M | 3/9/2021 | 3/11/2021 | Patient was at work when he had blurry vision and an episode of syncope. |
| 1094928 | 3/12/2021 | PA | 38 | F | 3/11/2021 | 3/11/2021 | Quick episode of syncope after injection. Recovered without complication. |
| 1095020 | 3/12/2021 | AL | 66 | M | 3/1/2021 | 3/5/2021 | Passed out then was brain dead . Death |
| 1095043 | 3/12/2021 | TX | 28 | M | 3/11/2021 | 3/11/2021 | Dizziness, passed out |
| 1095398 | 3/12/2021 | NY | 23 | F | 3/12/2021 | | Patient stated that she had a history of syncope with previous vaccinations due to anxiety. Staff observed patient for 30 minutes after vaccine was administered taking vitals every ten minutes. Vitals were stable and patient left after thirty minutes without incident. |

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| 1095193 | 3/12/2021 | NV | 24 | F | 2/19/2021 | 2/19/2021 | Anaphylaxis - Throat swelled almost completely closed, wheezing, lightheadedness (nearly passed out), throat/neck and injection site were very itchy and swollen, face/eyes swelled up, turned very pale all over, heart palpitations, etc. The next day - severe, horribly painful burning sensation all throughout my body. Even clothing lightly touching my skin felt like hot razors cutting in to me. Residual swelling of the face/ arm. Migraine. For two weeks after - Very large, hard lump under my skin at the injection site. It was about the size of my hand and was very painful. After a few weeks it went away. Treatment-large amounts of benadryl. The pharmacist wanted to use an epipen and send me to the hospital, but I refused because I could still get some air in (doctor later told me that my reaction was so severe I should have gone to the hospital). I had to keep taking large amounts of benadryl for the next few days to keep the reaction down a bit. |
| 1095195 | 3/12/2021 | ID | 54 | F | 3/12/2021 | 3/12/2021 | Patient was advised to wait in store for 15 minutes after receiving vaccine. She walked from the pharmacy to the meat department and fainted in front of the meat department. The store staff came to get the pharmacy staff and called 911. Patient was laying on the floor and reported she was "just having a hot flash". She was conscious and aware with no difficulty breathing. EMS arrived on the scene and patient refused service. An EpiPen was not administered |
| 1095225 | 3/12/2021 | MO | 72 | F | 3/11/2021 | 3/12/2021 | muscle stiffness during morning walk, nausea while eating cereal, stood up and fainted some nausea while on floor for 2.5 hours sleeping three hours later |
| 1095230 | 3/12/2021 | PA | | F | 3/12/2021 | 3/12/2021 | PATIENT FAINTED AND FELL ON THE FLOOR |
| 1095342 | 3/12/2021 | CA | 34 | F | 3/12/2021 | 3/12/2021 | 34-year-old woman with no significant past medical history presents with syncope event after receiving a COVID-19 vaccination prior to arrival. Patient describes lightheadedness and eventually falling forward. She did sustain facial abrasions to her forehead, bridge of the nose, and right zygomatic arch region. Complains of mild headache with without any nausea. |

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| 1095345 | 3/12/2021 | CA | 25 | M | 3/12/2021 | 3/12/2021 | Pt was in seated position in a chair and slumped over to right side and fell to floor. Pt appeared to twitch slowly for about 20 seconds. Pt was brought to seated position on floor. Appeared pale and diaphoretic. Pt verbalized he did not realize he fainted and loss consciousness for about 20-50 seconds. BP: 67/27. HR: 36. MDP doctor called over to assess situation. 2nd set of vitals taken. BP 51/27. HR 41. Pt given water. States he feels dizzy and light headed. Vision is "weird." Sees colors more vibrantly. The Dr. recommends pt go to ED. Pt transported via wheelchair by the Dr and clinic NP with Anaphylaxis kit. In ED, pt's BP was 86/60. Blood Sugar 91. Pt admitted for fluid hydration and monitoring. |
| 1095421 | 3/12/2021 | CA | 43 | M | 3/12/2021 | 3/12/2021 | MDM-43-year-old man presents wit syncope versus near-syncope. Differential diagnosis includes vasovagal reaction versus dehydration versus anxiety versus arrhythmia. |
| 1095366 | 3/12/2021 | NY | 71 | F | 2/19/2021 | 2/20/2021 | 8 am the following morning after the vaccine, I became very flushed and hot and don't remember leaving my seat at the breakfast table. I found myself on the floor on the other side of the table. I had fainted which has never happened to me in my lifetime. I was drenched in sweat, and nauseous, and a headache began and lasted the day. I spent the day resting and was fine the following day. I do have an occasional hot flash, even at 71 years old. I was alert, oriented, and had a bruise on my shoulder. I had now reoccurring issues . |
| 1095411 | 3/12/2021 | CA | 34 | F | 3/12/2021 | 3/12/2021 | 34-year-old woman with no significant past medical history presents with syncope event after receiving a COVID-19 vaccination prior to arrival. Patient describes lightheadedness and eventually falling forward. She did sustain facial abrasions to her forehead, bridge of the nose, and right zygomatic arch region. Complains of mild headache with without any nausea. |
| 1094795 | 3/12/2021 | LA | 33 | F | 3/12/2021 | 3/12/2021 | 33 year old female patient fainted on-site after receiving a vaccine around 10:16 am, roughly 3 minutes after receiving the vaccine. Her partner was able to catch her from falling to the ground and on-site EMS was brought over to do further assessment. EMS provided fluids on-site and then transported via EMS to local hospital. Patient reported fainting after vaccines in the past. |

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| 1095119 | 3/12/2021 | AZ | 80 | M | 3/11/2021 | 3/11/2021 | Evening: chills fever Morning: fever, Nausea, fainted, Resting comfortably now |
| 1091465 | 3/11/2021 | CO | 66 | M | 2/26/2021 | 3/1/2021 | 66-year-old gentleman who received his first COVID injection on Friday. His family member feels that since this time he has had some drooping of the left eyelid and then today while they were making love he had a several minute episode of vertigo. He states that may be lasted 1 to 2 minutes. His wife states he was "unresponsive" when I asked what she meant by that she states his eyes were closed and his eyes were open and he stared. She states this lasted for 4 to 5 seconds. He denies headache, double vision, blurred vision, tinnitus, focal neurologic complaints. He denies neck pain, back pain, chest pain abdominal pain, syncope, near syncope, abdominal pain, extremity pain. He has no history of CVA/TIA. He denies any history of trauma. |
| 1091444 | 3/11/2021 | MO | 73 | F | 2/11/2021 | 2/12/2021 | Client's spouse reported almost 24 hours after vaccination episode syncope around 12:00 p.m. the next day (02/12/2021). |
| 1091439 | 3/11/2021 | SC | 78 | F | 2/25/2021 | 2/26/2021 | fell/passed out (unknown) at home, taken by ambulance to local hospital, small bleed noted on CT scan, transferred to tertiary care center, f/u scan after 6 hours unchanged. Sent home. next morning unresponsive, transported back to tertiary care center. required ventilation en route.. massive cerebral hemorrhage noted on CT scan in different area. due to advanced dementia and unresponsiveness life support removed around 9pm that night. passed away at 9am on 3/1. |
| 1091486 | 3/11/2021 | | 71 | F | 3/7/2021 | 3/7/2021 | Dizziness, passed out and fell backwards onto tile floor. (FIRST TIME EVER) Stopped bleeding from cut on back of head. Severe headache for 3 days. Occasional nausea and lightheadedness. |

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| 1091343 | 3/11/2021 | MN | 71 | M | 2/18/2021 | 2/19/2021 | Pt woke up at 7. Cleaned up brushed his teeth and came upstairs from the basement to the kitchen. Poured a cup of coffee and sat down on living room chair four feet from me. He slumped over. I went to him and tried to wake him but he had passed out. Could not tell if he was breathing. I called 911. Put phone on speaker. I was told to lay him in the floor and start chest compressions. I did this for about 4 minutes when he made some noise. The first sheriff arrived after 8 minutes and by then PT had started to come around. He rolled over on his side and spoke to the sheriff. A couple minutes after that the ambulance arrived and the EMTs took over. They got him up and in the chair. Checked his pulse, blood sugar, blood pressure and did two EKGs. Everything was normal. He of course did not remember what happened but was very coherent. His conversation was very normal. They stayed with him about 30 minutes and he chose not to go to the hospital. He was out about 10 minutes. He has since been to the doctor and checked out fine. |
| 1091980 | 3/11/2021 | OH | 62 | F | 3/8/2021 | 3/9/2021 | started vomiting at 1:30 and I felt really dizzy and confused. My roommate found me on the floor passed out. I am not sure how long I was passed out. I woke up and I was talking gibberish. I was aware that nothing I said was making sense. I went to bed and slept almost 24 hours. I woke up feeling wiped out but I wasn't confused and I was talking normal again. Right arm hurt and is numb. (right side of my body typically is kind of numb but the right arm seemed more so numb after the vaccine) |
| 1091333 | 3/11/2021 | MN | 27 | F | 2/25/2021 | 2/25/2021 | Client received vaccination after reporting she felt anxious. After vaccination she lowered herself to the ground because she felt lightheaded and lost consciousness for 20-30 seconds. Episode witnessed by nurse and she reported that client did not hit her head. Upon regaining consciousness was responding and vitals were within normal limits. She stated she had history of fainting following blood draws and other vaccinations but did not tell vaccinating nurse this. EMS called. Client refused transport. She was monitored another 30 minutes and left after fluids and a snack. |

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| 1091376 | 3/11/2021 | TX | 49 | F | 3/4/2021 | 3/4/2021 | 1:25PM, a 49 year old received her second dose of Moderna vaccine 0.5ml at 1:23PM. 2 minutes later patient started fainting x anxiety attacks, dizziness, diaphoretic and weakness, rolling of eyes and feeling if warmth. Patient never lost consciousness and no respiratory distress exhibited. Patient and family denies any health issues like diabetes, HTN, etc. Vital signs recorded BP 141/124, 50 pulse, 22 respirations. Paramedics called. Continued to far patient for air. 20 minutes later, paramedics arrived, patient was more alert before their arrival. They assessed patients vital signs recoded and within normal. BP 118/74, HR 59, O2 Sat 100%, lung sounds clear. Patient refused further treatment by refusing to go to the hospital. |
| 1091642 | 3/11/2021 | | 86 | F | 3/10/2021 | 3/10/2021 | PMH dementia, HTN & syncope who experienced a syncopal episode during the post vaccine observation. Episode like historical syncopal event s with feeling overheated when over tired or worried. Transferred to ED, Labs, EKG within pt's norm's. Given IV Fluid and discharged to home. |
| 1091683 | 3/11/2021 | TX | 26 | M | 3/10/2021 | 3/10/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Exhaustion / Lethargy-Medium, Systemic: Fainting / Unresponsive-Mild, Systemic: COLD TO TOUCH AND SWEATING, DIFFICULTY HEARING-Mild, Systemic: Flushed / Sweating-Medium |
| 1091813 | 3/11/2021 | OH | 62 | F | 3/10/2021 | 3/10/2021 | Patient arrived to the outpatient vaccine clinic for her scheduled appointment. Immediately after receiving the vaccine, the patient felt chest pain, dizziness, and passed out. She had swelling of the tongue, lips, eyes, and throat. Patient was admitted to the hospital and treated for anaphylaxis with epinephrine, benadryl, famotidine, methylprednisolone, Duoneb and tylenol. Patient is currently still in the hospital but her condition is stable. |

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| 1091964 | 3/11/2021 | WI | 45 | F | 3/10/2021 | 3/11/2021 | Pt reports that 5 min after receiving the vaccination yesterday, she felt dizzy, lightheaded, "jaw tension and tightness." Symptoms lasted approximately 10 minutes. She also reports that for a split second she could not open her mouth due to jaw tightness, but reports that she has not had any further issues with this. She did not notify any of the immunization clinic staff about any of these symptoms. This morning when patient was at work, she noticed that she had some circumoral numbness and tingling with chin numbness and mild tongue swelling and numbness. The symptoms started at approximately 1030 this morning and are still occurring. "It feels like I just went to the dentist." Patient denies difficulty swallowing her secretions, but she does feel like there is possibly a "mild compression" in her esophagus. Denies any new foods or fluids, itching, shortness of breath, wheezing, voice changes, nausea/vomiting, syncope. She has not taken any over-the-counter medications for her symptoms. |
| 1092076 | 3/11/2021 | | 33 | M | 3/11/2021 | 3/11/2021 | pre syncope episode, diaphoretic, dizziness, felt as if he was going to pass out. Evaluated by EMS-Cleared |
| 1092101 | 3/11/2021 | TX | 19 | F | 3/11/2021 | 3/11/2021 | patient experienced tiredness and fainted for a few seconds after injection, a few seconds of twitching occurred before waking up. Paramedics were called, once arrived, patient was evaluated and denied transport. |
| 1091276 | 3/11/2021 | TX | 37 | F | 3/11/2021 | 3/11/2021 | Passed out, confused, loopy like they Drunk. |
| 1090400 | 3/11/2021 | FL | 19 | M | 3/9/2021 | 3/9/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Shakiness-Mild, Additional Details: THE PATIENT RECEIVED THE VACCINE AND WAS SEATED IN THE WAITING AREA . AFTER A FEW MINUTES, THE PATIENT BEGAN TO FAINT. THE PHARMACIST AND TECHNICIAN HELPED HIM TO THE FLOOR. HE STATED THAT THIS HAS HAPPENED TO HIM BEFORE WHEN HE HAD BLOOD DRAWN. HE ALSO CALLED HIS MOTHER AND SHE CONFIRMED THAT HE HAS A HISTORY OF SYNCOPE WHEN RECEIVING SHOTS. THE PATIENT DID NOT GO TO THE HOSPITAL, BUT HAD A FRIEND COME TO GET HIM. HE WAS CALLED LATER THAT NIGHT AND STATED THAT EVERYTHING WAS BACK TO NORMAL. |

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| 1091822 | 3/11/2021 | CA | 50 | F | 3/11/2021 | 3/11/2021 | Patient was observed in observation area. Patient was sitting in a chair and fainted to the ground. Patient did not notify RN?s in observation that she was feeling faint, lightheaded or had any symptoms. Code was called for EMS to patient side and safety measures were taken. |
| 1090561 | 3/11/2021 | | 46 | F | 3/10/2021 | 3/10/2021 | Dizziness, syncope, evaluated by EMS-transported to nearest ER |
| 1092183 | 3/11/2021 | MI | 59 | F | 3/9/2021 | 3/9/2021 | Patient had dizziness after receiving vaccine. Evaluated by clinic staff - then reporting throat tightness and reported having left shoulder pain for the prior 1.5 hours. patient was sent to the ED by EMS. The pt states that she had her first covid vaccine injection today and less than 30 minutes after her vaccine she developed acute central chest pain radiating to her left shoulder. She was given a full dose asa and 1 SL nitro by EMS. She states her chest pain was a 9/10 and it was pressure and tightness. She had associated lightheadedness. She states her pain is much worse than her typical chest pain she gets at home and takes nitro for. She states she is unsure if it is exertional, it is not worsened by deep breathing or palpation. She denies syncope, facial swelling, diaphoresis, n/v, abdominal pain, and hx of allergic reactions from vaccines. |
| 1093380 | 3/11/2021 | CA | 17 | F | 3/11/2021 | 3/11/2021 | PATIENT BECAME DIZZY AND PASSED OUT ABOUT 10 MINUTES AFTER RECEIVING HER VACCINE. WHEN SHE REGAINED CONSCIOUSNESS, SHE SAID THAT SHE COULDN'T HEAR OR SEE ANYTHING AND SHE ALSO WANTED TO VOMIT. WE CALLED EMERGENCY SERVICES. EMERGENCY SERVICES CAME WITHIN 10 MINUTES AND SHE SAID THAT SHE WAS FEELING BETTER; BOTH SIGHT AND HEARING IS NORMAL AGAIN. THEY RECOMMENDED SHE REMAINED SEATED FOR A LITTLE BIT MORE BEFORE LEAVING, BUT DECLARED THAT SHE WAS OK. |

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| 1090218 | 3/11/2021 | NY | 67 | F | 2/17/2021 | 2/17/2021 | <p>syncope; feeling of heat rising into throat; feeling of heat rising into throat; lightheaded; chills; mild pain at injection site; This is a spontaneous report from a contactable pharmacist reported for self. This 67-year-old female patient (no pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 17Feb2021 13:45 PM on Arm left via Intramuscular at single dose (Lot # EL9269) for covid-19 immunisation. Medical history included Osteoporosis, known allergies: Sulfa, flu vaccine for immunisation. No COVID prior vaccination. Concomitant medications included alendronate sodium (FOSAMAX), ergocalciferol (VITAMIN D), calcium, magnesium, biotin, bifidobacterium lactis (PROBIOTIC). No other vaccine in four weeks. Past similar reaction from Flu vaccine 8 years ago (2013) for immunisation and treated in ED, had no problems with any other vaccine such as HepB (Hepatitis B), DTAP, pneumococcal 23, Shingrix all for immunization. On 17Feb2021 14:15 PM, feeling of heat rising into throat, then lightheaded- EMT on-site monitored BP, heart, oxygen then administered IV Benadryl and zofran - signed out in 2hr, developed chills and syncope for next 4 days and mild pain at injection site. Self treated with Tylenol/ advised by MD to not get 2nd dose. Events resulted in emergency room/department or urgent care. Treatments were received for the events. Treatment included IV Benadryl and IV Zofran. Outcome of the events was recovering.;</p> <p>Sender's Comments: Based on a temporal association, a causal relationship between the events of feeling of heat rising into throat, lightheaded and syncope, and BNT162B2 cannot be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p> |

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| 1090178 | 3/11/2021 | MI | 48 | F | 12/31/2020 | 1/8/2021 | Overwhelming weakness; Blood pressure was elevated to 160/100 bpm; Brain fog; Thought was going to pass out, thought she was going to die; Pre-syncope episode; Systolic blood pressure of 180; Rigors in her chest; Neuro effects; A spontaneous report was received from a nurse who was also a 48-years-old, female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and who experienced brain fog, pre-syncope episode, systolic blood pressure of 180, rigors in her chest, neuro effects, blood pressure was elevated to 160/100 bpm, overwhelming weakness and thought was going to pass out, thought she was going to die. The patient's medical history was not provided. Concomitant product use was not provided by the reporter. On 31 Dec 2021, approximately 9 days prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 (Batch number: 026L20A) intramuscularly in the left deltoid for prophylaxis of COVID-19 infection. The patient had some brain fog off and on after receiving vaccine. About the 8th day on 08 Jan 2021, had a pre-syncope episode with systolic blood pressure of 180, thought patient was going to pass out and had rigors in patient's chest. Patient's husband called emergency medical service and went to the hospital where patient works, patient was evaluated in emergency room. The next day, patient rested at home. The following day, on 10 Jan 2021, patient went to work but couldn't think due to brain fog and neuro effects. After work, went back down to the emergency. Patient was admitted to the hospital and kept overnight. Consulted the neurologist. Neurologist stated it sounded like it was side effects from the immune response to the vaccine. Discharged the 11 Jan 2021 with no treatment besides follow-up with primary care doctor. Patient followed up with patient's primary care (cannot remember what date). The patient reported experiencing more pre-syncope episodes at home and at work. Patient's blood pressure was elevated to 160/100 bpm. Most recently had a syncope episode on 21 Jan 2021 where patient reported overwhelming weakness and had to sit down because patient "thought patient was going to die". After, made an appointment with the cardiologist. Had more test done. After taking medications patient felt a little bit better but had in head where doesn't feel right, feels little pings in head. Patient stated that patient missed forty hours of work because |

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didn't feel so could work. Relevant laboratory tests included computed tomography scan of chest and brain, an Magnetic resonance imaging of the brain was performed results unspecified. Did bloodwork which showed her vitamin D level was low. Treatment for the event included fluids unspecified, vitamin D supplement for vitamin d deficiency, Toprol 25mg once a day to stop the pre-syncope episode and lisinopril 5mg once a day for blood pressure Action taken with mRNA-1273 in response to the events was not provided. The outcome of the events was unknown.; Reporter's Comments: Very limited information regarding the events has been provided at this time. Further information has been requested.

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| 1090225 | 3/11/2021 | MI | 35 | F | 2/5/2021 | 2/5/2021 | was going to pass out/Loss of consciousness; was going to pass out/Loss of consciousness/hx of passing out remote in distant past; started to feel very strange/No hearing or vision loss, just a general strange and uncomfortable feeling.; deep dreaming, then awoke feeling poorly; deep dreaming, then awoke feeling poorly; shaking; chills; BNT162B2 used in a Breastfeeding Mother; BNT162B2 used in a Breastfeeding Mother; This is a spontaneous report from a contactable physician (patient), this physician reported information for both mother and fetus/baby. This is the maternal report. Only this case is serious. A 35-year-old female patient (not pregnant at the time of vaccination) received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) intramuscular into left arm on 05Feb2021 09:00 at single dose for COVID-19 immunization in workplace clinic. Medical history included hx of passing out remote in distant past. No allergies to medications, food, or other products. concomitant medications were none (no other medications the patient received within 2 weeks of vaccination). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. patient previously took the first dose of BNT162B2 on unspecified date at single dose for covid-19 immunization. About 17 hours after vaccine, at 3am (06Feb2021 03:00), while up feeding her infant and sitting in a chair in the dark, she started to feel very strange, kind of like she was going to pass out (hx of passing out remote in distant past). No hearing or vision loss, just a general strange and uncomfortable feeling. Tried to call for help. Lost consciousness for a few seconds and had deep dreaming, then awoke feeling poorly. Set child back to bed, went to bed myself, had shaking chills for maybe 30 minutes following. No sweats, no normal symptoms related to vasovagal syncope. Just a general uncomfortable strange sensation as the prodrome. Prior to vaccination, was the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. No treatment received for the events. Patient was recovered from the events on unspecified date. It was reported as non-serious report. Seriousness criteria results in death, life threatening, caused/prolonged hospitalization, disabling/incapacitating and congenital anomaly/birth defect were all no. Information on the |

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| | | | | | | | lot/batch number has been requested.; Sender's Comments: Based on the available information, the Company considers the reported event loss of consciousness recurrence is unrelated to BNT162B2 vaccine but more likely an inter-current medical condition in this subject with medical history of passing out remote in distant past. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate..Linked Report(s) : US-PFIZER INC-2021240721 mother/baby case |
| 1090424 | 3/11/2021 | CA | 22 | F | 3/10/2021 | 3/10/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Mild, Systemic: Weakness-Severe |
| 1090432 | 3/11/2021 | TX | 34 | F | 3/9/2021 | 3/10/2021 | Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Nausea-Medium, Systemic: Shakiness-Mild, Systemic: Weakness-Medium, Additional Details: 1:19PM: Pt expressed anxiety, received vaccination, c/o of panic attack and sad down by the chair. 3 secs later, looked flaccid, unresponsive, discolored, jerked briefly, bladder incontinent, loud sound, no difficulty breathing, no allergic reaction. RPH open airway, layed on side, head raised and called 911. Pt immediated had a deep breath and became responsive, alert/oriented x3. Ambulance, SaO2 97%.Pt later didn't see the need to urgent care, husband insisted, transported out by ambulance. |
| 1090548 | 3/11/2021 | | 31 | M | 3/10/2021 | 3/10/2021 | Nausea, syncope episode, evaualed by EMS-refused transport. Cleared. |

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| 1091227 | 3/11/2021 | MO | 63 | M | 3/10/2021 | 3/10/2021 | Patient passed out after receiving janssen covid-19 vaccine. There was no injection site reaction, no wheezing, or rash/hives. Patient had vision loss, dilated pupils, sweaty, unable focus or respond to use questions being asked, and was having trouble hearing-said he had ringing in his ears. We were able to lay him on the floor without injuries-he did not fall. I was fanning him and we were talking to him. He got a little worse but then got better. When he was better, he said that he had passed out before when having blood taken. He did not mention this to me before the vaccine was administered. I do not feel that the Janssen COVID shot was the cause, I think he just passes out from injections or needles. We did call 911 when he was getting worse. By the time they got here, he was better but they did check him. |
| 1090582 | 3/11/2021 | NC | 50 | F | 3/7/2021 | 3/7/2021 | SOON AFTER VACCINATION PATIENT EXPERIENCED CHILLS, SYNCOPE AND BRADYCARDIA. EMS ON SITE. PATIENT TRANSPORTED TO ER. |
| 1090621 | 3/11/2021 | NC | 20 | M | 3/7/2021 | 3/7/2021 | MINUTES AFTER VACCINATION PATIENT EXPERIENCED BRADYCARDIA, SYNCOPE AND HYPOTENSION. EMS ON SITE. PATIENT TRANSPORTED TO ER. |
| 1090639 | 3/11/2021 | VA | 38 | M | 1/14/2021 | 1/14/2021 | I passed out while sitting in the observation area shortly after receiving my shot (10-15 minutes). I was initially able to walk from the area where the injection was administered about 50 yards to the observation area. Sat down & shortly thereafter could feel myself getting woozy. I laid my head back & closed my eyes hoping to avoid it. I was given two epinephrine shots the second of which woke me up. Several medical staff were around me when I opened my eyes. I was taken to the patient wing and checked into my own room for observation for a few more hours. Blood was drawn and sent off for a Triptase test which came back negative a couple days later. After being kept under observation for a few hours I was release around noon. I have a history of problems with shots/needles. Haven't actually passed out from it in over 20 years, but it is a known problem. |
| 1090679 | 3/11/2021 | KY | 23 | F | 3/9/2021 | 3/9/2021 | Syncope, nausea Refused Benadryl PO Pepcid, 20 mg given @ 0910 |

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| 1090947 | 3/11/2021 | LA | 34 | F | 3/5/2021 | 3/6/2021 | Subject woke up to use the bathroom and passed out while on the toilet. She called my name immediately prior to the event. She fell prostrate on the floor resulting in facial bruising/cuts. Subject regained consciousness one minute later. She was able to work the next day and had chills for the next 2 days. |
| 1091139 | 3/11/2021 | IA | 29 | F | 3/9/2021 | 3/9/2021 | Vasovagal syncope a few minutes after vaccination. Fever of 101.8F 24h after vaccination (3/10/2021). Fever is continuing today (3/11/2021), but is lower at 100.4F. Tingling fingers on hand from vaccination arm (left), swelling from vaccination injection site, headache, and neck pain all developed on 3/10/2021. Headache and neck pain could be due to head trauma from vasovagal syncope. Tingling fingers were not observed on 3/11/2021. *I have had vasovagal syncope in the past, but never with vaccines. It always occurs when I see my own blood. |
| 1091174 | 3/11/2021 | IL | 30 | F | 3/11/2021 | 3/11/2021 | Patient was waiting in required observation area after her COVID-19 vaccination and suddenly passed out, fell out of chair, lost consciousness, and hit forehead on the floor. Rapid response call was initiated and patient was sent to ED. |
| 1090435 | 3/11/2021 | AZ | 64 | M | 3/10/2021 | 3/10/2021 | Site: Bruising at Injection Site-Medium, Site: Swelling at Injection Site-Medium, Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Medium, Systemic: Hypotension-Medium, Systemic: Nausea-Mild, Additional Details: Paramedics and Firefighters came out. Gave him 1 liter of normal saline. His heart rate was in the 30's. They stabilized the patient and took him to hospital. |
| 1092891 | 3/11/2021 | WA | 18 | M | 3/11/2021 | 3/11/2021 | pt fainted after receiving his 1st dose of Pfizer. He fell out of his chair and hit head on the ground. He fainted 1-2 more times after initial collapse. EMS came and he reported being fine after about 10 minutes after the incident. Patient admitted to not eating anything before his shot. He was fine and when follow up call occurred, indicated he wanted to get his 2nd dose in three weeks and we will take precautions and eat food and sit on a carpeted floor against a wall in case he faints again. |

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| 1092577 | 3/11/2021 | MN | 39 | F | 3/10/2021 | 3/11/2021 | Vasovagal syncope event 18 hrs post injection. Severe headache Muscle pain and weakness Slight swelling in injected arm and hand |
| 1092630 | 3/11/2021 | LA | 52 | M | 3/10/2021 | 3/10/2021 | 5min following administration of vaccine pt passed out. Within moments pt became responsive. Pt was pale and diaphoretic. Bp 76/54. HR 84. Pt was taken to hospital by ambulance. Pt was d/c from hospital 2hrs later. Pt states he received iv fluids and ekg wnl. Pt states he feels much better. |
| 1092649 | 3/11/2021 | WI | 94 | F | 2/23/2021 | 2/25/2021 | Red pruritic rash at the injection site Two days following vaccination, she had an episode of syncope with fall, head trauma, rhabdomyolysis that resulted in hospitalization |
| 1092735 | 3/11/2021 | CA | 29 | F | 3/11/2021 | 3/11/2021 | Approximately 3 to 4 minutes after receiving vaccine, patient stated she was not feeling good and patient turned red and fainted. She was sitting in chair so mom stood behind her with an ice pack behind neck and holding patient head while dad stood in front of patient. Her body became limp and mom was shaking her body on right side in attempt to wake patient up. Her eyes opened but was still unresponsive and she was breathing heavily for 30-40 seconds. After placing patient on floor and elevating her legs, patient stated she felt better but still feels nauseated. Paramedics were called. |
| 1092740 | 3/11/2021 | CA | 42 | M | 3/11/2021 | 3/11/2021 | 42 yo male without h/o reaction to prior vaccinations or medical problems here for first covid vaccination. approx 9 min after vaccination with dizziness but no headache, no syncope no altered mental status no shortness of breath no wheezing no palpitation no chest pain no stridor no dysphonia no globus no rash no flushing no hives no angioedema. sx resolved with hydration. pt admitted to poor intake and anxiety.. pt discharged home alert and oriented. |
| 1093031 | 3/11/2021 | CA | 31 | F | 3/11/2021 | 3/11/2021 | Patient felt dizzy, fainted, nauseous and tingling sensation all over her body. Allowed to rest with feet higher than her head, 911 called, water given. Refused to go to the hospital. Her friend took her home with no symptoms. |

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| 1092564 | 3/11/2021 | | 30 | F | 3/11/2021 | 3/11/2021 | Client fainted, and became unconscious. Client assisted to floor, and EMS called. Feet elevated, cold packs placed on extremity, and VS initiated. Client A&Ox3, and concious. EMS arrived, VS initated, Blood Glucose, and EKG initated. EMS discharged client. |
| 1092869 | 3/11/2021 | NC | 40 | M | 3/11/2021 | 3/11/2021 | Patient passed out about 5 minutes after vaccine, did not respond to stimulus, 911 called, pt woke up after about 10 seconds, blood pressure 110/58. Pt was awake for about 5 minutes then pass out again, this time was longer with no response to stimulus, patient was moved to the floor from a chair where he woke back up. EMS arrived and monitored patient. |
| 1092787 | 3/11/2021 | GA | 57 | F | 3/6/2021 | 3/6/2021 | Fatigue, fever, arm pain at injection site, muscle & joint pain, loss of taste & smell, diarrhea, severe low blood pressure. Fainted 2x, and wacky heart rhythms. |
| 1092896 | 3/11/2021 | TX | 35 | F | 3/11/2021 | 3/11/2021 | PATIENT FAINTED AFTER ADMINISTRATION OF MODERNA COVID VACCINE. PATIENT HAD REPORTED HISTORY OF FAINTING ON PATIENT CONSENT FORM. |
| 1092898 | 3/11/2021 | TN | 32 | M | 3/11/2021 | 3/11/2021 | Patient walked away from vaccination room and passed out and fell backwards to the floor. The patient regained consciousness in about 30 seconds. After sitting on the floor for about 30 minutes the patient got up and continued to walk around for a few minutes |
| 1092971 | 3/11/2021 | OH | 36 | F | 3/3/2021 | 3/4/2021 | Dizziness, almost syncope, vomiting, nausea |
| 1092989 | 3/11/2021 | NY | 35 | F | 3/11/2021 | 3/11/2021 | syncope |
| 1092997 | 3/11/2021 | NY | 19 | F | 3/11/2021 | 3/11/2021 | after administering vaccine patient fainted and was found on the floor of observation area. She was conscious when i ran to her.She said she usually feels nausea after vaccines and feels like this was just her normal reaction. She refused an ambulance and felt like she was ok. We gave her ice water and and ice pack as she bruised her head when she fainted. We continued to monitor her and she kept refusing medical assistance. She had a friend come to drive her home. |

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| 1092188 | 3/11/2021 | MD | 72 | F | 3/1/2021 | 3/1/2021 | 3 minutes after the vaccine was administered I had a Complement Immune System Pathway reaction. I have been dizzy every since. I have had intestinal issue. the next day I almost fainted and my heart was racing. I went to the ER with palpitations dizziness and elevated blood pressure. EKG (dr said it was normal but I retrieved the report which says inferior infarction and abnormal ECG) and blood pressure(138/83) readings taken. |
| 1092808 | 3/11/2021 | IL | 19 | F | 3/1/2021 | | Day of: Arm pain, 2am fever 101.7, March 2 -chills, body aches, headache, loss of appetite. 9am fainted, Mar 4th started with left sided weakness Mar 5 taken to ER for increased weakness Diagnosed with encephalitis in the hippocampus area related to vaccine |
| 1092288 | 3/11/2021 | TX | 52 | M | 2/13/2021 | 2/14/2021 | I have taken the 2nd Moderna Shot that morning. During my sleep i felt bad and i was sweaty middle of the night i headed to restroom. And i have fainted. My wife called 9-1-1 when i was awake, i have noticed my sweat. they did EKG and checked my blood pressure 85/95 95 was too low, my tpical is 80/120. EKG was clean. they took me to the ER . Dr . treated me. Two times EKG has conducted all clean, IV connected. Multiple lab tests have been conducted. My diagnosis was poisoning by vaccine. |

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| 1092202 | 3/11/2021 | CA | 17 | F | 3/11/2021 | 3/11/2021 | Written by the patient and guardian: " 8-10 minutes after shot, complaints of light head an throat closing up. Removed mask for fresh air, no relief. Went to get up for water, immediately for light headed, pale face, checked-out look in eyes. Body went limp, set 17yo in chair, still was light headed and lethargic. Laid 17yo down on floor, administered water. Vision came back dizziness went away. remained seated for another 15minutes. Continued hydrating w/ water, other symptoms diminished." From Dr.: "Witnessed patient pass out in chair, within 10-20s was helping caregiver lower patient to the floor and patient had come to. Increasingly alert. Endorses above narrative, as well as not having eaten or drinking much today, "maybe an apple". She does not have a history of vasovagal syncope. Patient Pulse at 65, normal breathing, no distress, no signs of injury. Overall episode appears to be vasovagal syncope. Patient asked to drink water and remain at the vaccine center an additional 15-20 minutes for observation. After 15 min patient feeling back at baseline. No further medical intervention. |
| 1092238 | 3/11/2021 | OH | 76 | F | 3/11/2021 | 3/11/2021 | Pt fainted and remained dizzy. |
| 1092867 | 3/11/2021 | MO | 67 | F | 3/3/2021 | 3/4/2021 | Fainted 20 hours after shot |
| 1092560 | 3/11/2021 | CA | 33 | F | 1/5/2021 | 1/8/2021 | Day of injection after I left the vaccination site I started to have a really bad headache and then sore arm (left arm where the injection was). Then about 7 hours after the injection I started to have a really bad stomach ache and cramps with nausea. This last all night long into the next day where it slowly went away. I was incredibly fatigued and the headache would not break. Then on the 3rd day Thursday January 7 I was feeling okay but not 100% myself. Then Friday January 08 I woke up and knew something was incredibly wrong because my stomach hurt way worse then before, i was so lethargic that I was falling asleep at my desk at work, I was shaking uncontrollably, blurred vision, diarrhea with blood in stool and one close episode of fainting. So at the point I ended up in the ER missing the rest of my work day. My symptoms didn't get better until the following Monday |

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| 1092258 | 3/11/2021 | CA | 25 | M | 2/2/2021 | 2/4/2021 | Moderna COVID-19 Vaccine EUA The day after I received the 2nd dose of the vaccine I had a headache. That same night I ran a fever and woke up the next morning feeling ok. I was taking a shower and it was reported to me by my fiancé I had passed out, started to seize, my eyes rolled to the back of my head. A few minutes later I woke up on the floor and asked what had happened. I was not sure what had happened. I felt fine when I woke up. When first responders arrived they asked me if I knew who I was, the date, the president, where I lived to all I was able to answer correctly. I went to the ER and they did a ECG, blood test, urine test, chest x-ray, CT of my head and they said everything came back normal. I was prescribed Keppra and have an MRI scheduled in the coming week. |
| 1092287 | 3/11/2021 | IA | 29 | F | 3/9/2021 | 3/9/2021 | patient given vaccine and during the 15 minutes wait afterward, patient fainted and hit head on floor. Provider on sit attended to patient and advised patient to go to emergency room. |
| 1092314 | 3/11/2021 | CA | 30 | F | 3/10/2021 | 3/10/2021 | Lightheaded (syncope). 25 weeks pregnant. BPs 92/66 (pulse 72), 95/68 (pulse 75). Given apple juice. |
| 1092324 | 3/11/2021 | | | F | 1/4/2021 | 1/5/2021 | 1/5/2021 0718 Pt received 2nd COVID vaccine 1/4/21. Oral temp 100.6, near syncope, muscle aches and head aches. Per EMS NSR, denies SOB, and chest pain. 500 ml bolus received in route. In ED, Pt c/o nausea. Pt anxious, sweating and uncomfortable. 0855 Pt resting comfortably, reports decrease in pain/body aches 4/10. 1043 Discharge disposition: home. Accompanied By: self. Mode: walk. |

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| 1092392 | 3/11/2021 | NE | 27 | F | 3/11/2021 | 3/11/2021 | Patient was found unconscious laying back in her chair shortly after receiving her Covid-19 vaccine. Patient was awoken with a light shake on the shoulder, but not to noise. The patient stated they had difficulty hearing, along with nausea and light headedness. The patient denied any other symptoms, including difficulty breathing, abdominal pain, and body soreness. Nothing was administered on the pharmacy's end. The paramedics arrived shortly after and took the patient as she was going in and out of consciousness. Patient was contacted after the incident, in which she said that she was told she had vasovagal syncope. The patient is fine now. |
| 1092527 | 3/11/2021 | FL | 48 | F | 3/11/2021 | 3/11/2021 | fainting, pale , sweating |
| 1092497 | 3/11/2021 | MO | 39 | M | 3/11/2021 | 3/11/2021 | Patient passed out for 30-45 seconds shortly after receiving the shot. He recovered with low BP (62/31) shortly after EMS was contacted. After monitoring, patient recovered BP to 112/61 under supervision. He left with parents afterward. |
| 1092279 | 3/11/2021 | MD | 26 | M | 3/10/2021 | 3/10/2021 | About 30 minutes after dose he passed out and had a seizure that lasted 10 -15 seconds. This happened a couple times. He went to hospital had low blood pressure and oxygen. He stabilized and was released. He has a follow up appointment with his primary care doctor. |

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| 1092402 | 3/11/2021 | LA | 16 | M | 3/10/2021 | 3/10/2021 | Summary: Syncopal episodes x 2 16 yo patient received his Covid-19 vaccine and as he was going to sit down in observation, he leaned on his mom and passed out. His mother gently lowered him to the ground (@ 1804). Patient's mother stated he just passed out and that this was his first injection ever in his life. Patient was immediately assessed by multiple nurses. Patient did not fall or hit his head or injure any part of his body. Patient took less than 60 seconds to respond to verbal commands and comprehend what had happened. Patient's legs were immediately raised and vital signs were obtained. He was diaphoretic and pale but both were dissapating. Patient denied difficulty breathing, pain, discomfort. Patient was moved to a reclined chair. Patient and family at side (mother and father) agreed to be monitored. At 1828, Patient complained of feeling "a star" on the left side of his chest. Patient was unable to describe this further. I asked if he was feeling anxious and he said yes. I instructed patient to take several deep breaths in through his nose and out through his mouth. After doing this 3 times, patient stated he did not feel anything funny in his chest anymore. At 1835, while still seated in a reclined chair, patient passed out again. He was pale and diaphoretic. A few team members saw him jerk/twitch and it was questionable if he was having a seizure. The jerking did not last but a few seconds. 911 was called @ 1826. Patient was transferred to a wheelchair and put in the ambulance @ 1841. Vitals were obtained throughout and charted. Pulse ox saturation levels were not below 96%. Immediately after the patient passed out the second time, his pulse was measured at 38 bpm and his lips displayed slight cyanosis. His pulse quickly rose to 52 bpm, within less than 10 seconds. One minute later his pulse was up to 68 bpm. |
| 1092372 | 3/11/2021 | CA | 38 | F | 3/3/2021 | 3/3/2021 | Fainted two times, fast heart rate, dizzy, light headed Sought treatment from doctor. |
| 1092371 | 3/11/2021 | CA | 66 | M | 3/11/2021 | 3/11/2021 | Syncope, flushing, chest pain, pressure - taken to the ED |

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| 1092366 | 3/11/2021 | AZ | 37 | M | 3/5/2021 | 3/5/2021 | while receiving his vaccine at the pharmacy pt started to feel lightheaded after his first moderna shot, passed out for 2 minutes, EMS told him his bp was very low and he seemed to be dehydrate which he know he was. He was told he probably stood up too quickly. Denies palpitations, cp, SOB or other associated symptoms. |
| 1092339 | 3/11/2021 | NY | 51 | F | 3/11/2021 | 3/11/2021 | After getting vaccinated and escorted to waiting area patient fainted out of chair and hit head on floor. She was briefly unconscious and pale for a few minutes after coming back to consciousness. She remained on the floor feeling dizzy, shaky, and nauseous until she was taken to the hospital by paramedics. |
| 1088721 | 3/10/2021 | CA | 87 | M | 3/3/2021 | 3/3/2021 | Moderna COVID-19 Vaccine EUA Leaning over to pick something off the floor, I fainted and fell to the floor. Unconscious a few seconds. Recovered immediately. No treatment. A friend has had the same reaction, so I thought this should be reported. |
| 1088037 | 3/10/2021 | PA | 32 | F | 3/6/2021 | 3/7/2021 | Patient reported typically side effects the night of vaccination, chills and mild fever. Patient took Acetaminophen the night of 3/6/2021. On 3/7/2021 she stated that she woke up feeling fine. While shopping on 3/7/2021 she had a syncopal episode in the grocery store and stated she passed out. No injuries reported. She left the store and stated that she felt very light headed again later in the day but did not pass out. |
| 1087665 | 3/10/2021 | CO | 51 | M | 3/7/2021 | 3/7/2021 | 3 hours post vaccine, patient passed out and lost consciousness, demonstrating seizure like activity |
| 1088336 | 3/10/2021 | CA | 37 | F | 2/26/2021 | 2/26/2021 | Major dizziness , passed out, brain fog, major headaches, fatigue, I get tired easy, major nausea, nose bleeds, right ear pain, unable to poop (until this date 3/11/21), lots of gases, burping, farting. Rash on my arm on 8th day with chest pain, armpit pain and arm pain. |

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| 1087780 | 3/10/2021 | NY | 19 | M | 3/10/2021 | 3/10/2021 | After receiving first dose and in the observation room, patient was feeling light headed and nauseated. Patient passed out briefly for 2-3 seconds and slumped in his chair. EMT was with the patient at all times. After syncope episode, patient was alert and oriented. Patient was brought to tent in the supine position and was stable. Patient was still alert and oriented and given juice. Dr. looked patient over and determined to be vasovagal episode. Patient fine 20 minutes post episode. Patient was monitored until sister came to pick him up. Dr. recommended for patient get vaccine recumbant in 3 wks for second dose. |
| 1087829 | 3/10/2021 | MD | 26 | F | 3/10/2021 | 3/10/2021 | Patient received her first dose of the Moderna vaccine. Shortly after (within seconds) she described feeling nauseous. Staff reported her slumping over in a chair. Prior to the vaccination she informed the vaccinator she has had episodes of fainting with vaccination in the past notably to Gardasil.The vaccinator who was a physician lowered her to the ground in a trendelenburg position with her legs up in a chair. Patient quickly regained consciousness with a pulse of 65. She appeared pale, diaphoretic, but alert and oriented x4. She was provided with a cold pack, apple juice and crackers. She was helped into a wheelchair , taken to the post vaccination area and observed for 30 mins by this writer who is a nurse. She called a friend to drive her home. |
| 1087834 | 3/10/2021 | FL | 29 | M | 3/10/2021 | 3/10/2021 | diaphoric, pale, decreasing LOC immediately after injection. Did not fully lose consciousness. EMS immediately at patient side along with NP and RN staff. O2 Sat on RA 98. VSS. EKD- NSR. Blood suger 118. Patient stated he had not eaten breakfast or had a lot to drink. He also stated he has fainted in the past when at a medical facility. BP 188/70/hr 84 |
| 1087942 | 3/10/2021 | AK | 64 | F | 2/9/2021 | 2/10/2021 | No signs or symptoms ahead of time. While standing at the counter feeding my dogs I passed out on the kitchen floor. The rest of the day I had chills. |
| 1087749 | 3/10/2021 | NJ | 28 | M | 1/30/2021 | 1/31/2021 | fatigue eventually leading to pre-syncope |
| 1088070 | 3/10/2021 | OR | 26 | F | 3/5/2021 | 3/5/2021 | Patient had a syncopal episode approximately 10 minutes after injection. She briefly passed out. She was gently lowered to the floor. She had no injury. |

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| 1088088 | 3/10/2021 | VA | 68 | M | 3/9/2021 | 3/10/2021 | Strong pain in the arm during the middle of the night. While getting up to get an ice pack, I felt nauseous and fainted, apparently from the pain. I stayed on the floor for some minutes in quite a bit of pain and then it subsided all at once. |
| 1088097 | 3/10/2021 | IL | 70 | F | 3/5/2021 | 3/6/2021 | After my second vaccination shot on 3/5/21 I started with a low grade fever on 3/6/21. On 3/7/21 after getting up I started feeling funny while going to the restroom. I laid on the floor for a while and then proceeded to the couch. I passed out on the couch. Upon waking up I was sweating very bad. My clothes were wet. |
| 1088118 | 3/10/2021 | GA | 52 | F | 2/11/2021 | 2/18/2021 | 1 week after dose 2 of the COVID-19 vaccine, the patient experienced swelling, burning, itching, and redness over the injection site in the left upper arm. Then over a few days, experienced a burning, itching, and tingling sensation over the left face, left arm, and left leg. The left side of her face became mildly swollen and itchy. She has since noticed swelling over the palms and soles. No shortness of breath or difficulty swallowing. No fever/chills. No pre-syncope/syncope. |
| 1088120 | 3/10/2021 | CO | 78 | F | 2/20/2021 | 2/21/2021 | Called nurse line 4 days after 2nd Moderna vaccine, SOB, fainting, can't eat, dry cough, nose bleeds since shot. Advised to go to ED, patient refused as she feels a bit better today. Called again the following day with same symptoms - again advised to go to ED and quarantine for flu/covid-like symptoms. Patient agreed to come to ED, found to have bilateral PEs and RLE DVTs. Covid/flu negative. LUE red/swollen at injection site - no cellulitis. Admitted overnight and d/c'd home the following day. |
| 1088173 | 3/10/2021 | KY | 26 | F | 3/9/2021 | 3/9/2021 | 5 hours after being given the shot, uncontrollable tremors began. Muscles began tensing up, tunnel vision started, extreme dizziness, vomiting, severe weakness in muscles, and fainting. These lasted for about 2 hours before decreasing in severity but continued to be present until about 10:30pm, 13 and a half hours after receiving the shot. Nothing was done to treat the symptoms. As of 12:30pm on 3/10, some minor symptoms are still present, such as muscle weakness and pain, severe migraine, and dizziness. |

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| 1087612 | 3/10/2021 | PA | 72 | F | 3/8/2021 | 3/8/2021 | in less than a minute I had a vasovagal syncope response and my blood pressure got so high that the machine couldn't take it--in the 200's/100 something. I was taken to the ER and monitored for a few hours and labs. BP came down slowly, but not perfect. I was released around 7pm. Event happened at 3:46pm. The next day I had chills first, then I had a slight fever, a terrible headache in the back of my head, dizziness and night sweats. By the 2nd day after I am feeling better. |
| 1088138 | 3/10/2021 | CA | 50 | F | 3/6/2021 | 3/6/2021 | Syncope. Vasovagal episode, felt lightheaded. Loss of consciousness < 10 seconds while sitting. Prior history of vasovagal episodes with needles. Vital signs within normal limits. |
| 1087248 | 3/10/2021 | AZ | 44 | F | 1/31/2021 | 1/31/2021 | Within 1-2 minutes of receiving the vaccine in my right arm (while sitting in the passenger seat of our car), my husband pulled forward in the lot, and I immediately felt a wave of heat come from my chest, up through my neck and into my face. I started sweating, got light-headed, very nauseous, and the left side of my face (everything under my cheekbone) felt "tingly". When we parked, I opened the car door, we opened the windows I drank water, and did some deep breathing. If I had been standing up after the shot, I think I would have fainted. I'm not sure what that reaction was.....I have had similar reactions when I've had my triptan-class injection medication or even the triptan medication in pill form. In those instances, I think my blood pressure dropped because of the vasodilation . I am not scared of shots, needles, or getting blood drawn at all. It wasn't fear and I had eaten plenty that morning as well as drank a lot of water. As far as the numbless/tingly feeling in my face, I do have damage to my trigeminal nerve that occurred during my craniotomy in 2016, so that area doesn't ever feel 100% normal, however the change to a more intense "tingliness" after the injection was pronounced and lasted about 3-4 days. |

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| 1087144 | 3/10/2021 | TX | 39 | F | | | <p>felt almost like fainting; felt like she was drowning especially when going to sleep; chest tightness/felt tightness in her chest; She couldn't take a deep breath.; This is a spontaneous report from a contactable physician. A 39-years-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) , via an unspecified route of administration on an unspecified date at single dose for covid-19 immunisation. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient received the 1st dose of the PFIZER-BIONTECH COVID-19 VACCINE and experienced chest tightness. Patient started to experience this symptom the day after she got the 1st dose - Experiencing chest tightness/feeling of drowning especially when laying down to bed daily - No history of cough, fever, anxiety, depression. The patient got the shot during the first 10 to 15 minutes she felt almost like fainting, but she didn't. Patient was keep for 15 to 20 minutes after receiving the vaccine to monitor. The feeling didn't last long. The first ten days after the vaccine the patient felt tightness in her chest for no reason. In the patient's medical history, there is no history of asthma or reactive airway disease or anxiety or depression. For a total of 10 days the patient felt like she was drowning especially when going to sleep. She couldn't take a deep breath. She didn't have to seek medical attention or go to the ER. The outcome of events was unknown. Information on lot number/batch number has been requested.</p> |

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| 1086865 | 3/10/2021 | CA | 54 | F | 1/26/2021 | 1/26/2021 | Fainting episode; Arm soreness; A spontaneous report was received from a Consumer concerning a 55-years-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced events fainting episode, arm soreness. The patient's medical history was not provided. Concomitant medications reported were Tysabri for drug use for unknown indication. On 26 Jan 2021, prior to the onset of the events the patient received their first of two planned doses of mRNA-1273 (lot batch: 042L20A) intramuscularly for prophylaxis of COVID-19 infection. On 26 Jan 2021, the patient experienced the events arm soreness. On 27 Jan 2021, the patient experienced fainting episode. No treatment medication was provided. Action taken with mRNA-1273 in response to the events was not reported. On 27 Jan 2021, the outcome of events fainting episode was resolved. The outcome of events arm soreness was not reported.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the onset date of the events, a causal relationship cannot be excluded. |
| 1088353 | 3/10/2021 | AR | 31 | F | 3/9/2021 | 3/9/2021 | Left arm went numb about 4 hours after injection and remained numb for 12 hours. Severe muscle aches began 4 hours after injection. Extreme dizziness and nausea. Fever, chills, vomiting started 10 hours post injection. Fainting upon standing. Severe chest pain started 12 hours post injection. All symptoms are continuing except for the numbness in the left arm. |

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| 1086878 | 3/10/2021 | | | F | 2/26/2021 | 2/26/2021 | Passed out; Nausea; Fever; Chills; A spontaneous report was received from an other healthcare professional for a female patient of an unspecified age who received Moderna's COVID-19 vaccine (mRNA-1273) and who experienced fever, chills, nausea and passed out for a short duration. The patient's medical history was not provided. No concomitant product use was reported. On 26 Feb 2021, the patient received their second of two planned doses of mRNA-1273 (Lot number: unknown) intramuscularly for prophylaxis of COVID-19 infection. After receiving the vaccine, the patient had experienced chills and fever overnight. On 27-Feb-2021, the patient developed nausea and reportedly passed out for a short duration while coming out of shower which was followed by a second episode of passing out while dressing. As per the patient this could be related to dehydration and low blood pressure in general. The patient was feeling fine at the time of this report. Treatment information was unknown. Action taken with mRNA-1273 was not applicable. The outcome of the events, fever, chills, nausea and passed out for a short duration, were considered as recovered.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded.; Sender's Comments: MOD-2021-029837:Same reporter, Male patient |

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| 1086886 | 3/10/2021 | TX | 39 | M | 1/23/2021 | 1/25/2021 | My blood pressure, which normally runs low, dipped very low (85/55); I had pretty severe brain fog. I never blacked out, but I was concerned I might.; This is a spontaneous report from a contactable consumer reporting for himself. A 39-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EL3246), via an unspecified route of administration on 23Jan2021 on right arm at single dose for COVID-19 immunization. Facility type vaccine was at hospital. Medical history included small fiber neuropathy, dysautonomia/vasovagal syncope, ineffective esophageal motility disorder, migraine, GERD, allergic to preservatives in many eye drops, but never a vaccine; allergic to dust mites. Concomitant medications included nadolol, midodrine, esomeprazole magnesium (NEXIUM), amitriptyline and other unspecified medications. The patient stated "My blood pressure, which normally runs low (I have dysautonomia/vasovagal syncope) dipped very low (85/55) and I had pretty severe brain fog. I never blacked out, but I was concerned I might." The reported events happened on 25Jan2021 18:00, and resulted in Doctor or other healthcare professional office/clinic visit. No treatment was received for the events. The outcome of the events were resolved in 2021. |

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| 1086896 | 3/10/2021 | NM | 30 | F | 2/19/2021 | 2/19/2021 | <p>syncopal episode; itching; fullness; feeling funny; This is a spontaneous report from a contactable pharmacist. A 30-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN6198), intramuscular on 19Feb2021 14:15 at single dose for COVID-19 immunisation. Medical history included manual vacuum aspiration (MVA), traumatic brain injury (TBI) from 2007 to an unknown date, vagovasal and hypotension post TBI, Celiac disease, allergy to milk products, diagnosed with COVID-19 from Aug2020 to an unknown date prior to vaccination. It was unknown if the patient was pregnant at the time of vaccination. Concomitant medication included famotidine, methylphenidate, fludrocortisone, omeprazole, desvenlafaxine succinate (PRISTIQ), brexpiprazole (REXULTI), and folic acid. The patient was previously vaccinated with the first dose of bnt162b2 (lot number: EL3246) at the age of 30-year-old, intramuscularly for COVID-19 immunisation on 19Jan2021 at 14:15 and experienced heart flutters and "fell faint" (fainted). The patient also previously took ibuprofen and experienced allergies. After approximately 5 minutes after the patient had the second dose of vaccine (19Feb2021 14:20), the patient had syncopal episode, itching/ fullness. Covering physician present and assessed with EMS on Duty: VS: 110/80-BP, 18-RR, 96-HR, SaO2-98% on RA, CBG: 138. Patient awakened and reported "feeling funny" on 19Feb2021, but was A &Ox4, MAEW x4 with equal strength, Lungs Clear to auscultation. At 14:20 the patient was given Benadryl liquid PO given along with 8oz of water. Patient able to drink without issues. At 15:00, EMS called for ER transport to due prolonged recovery. The events resulted in emergency room/department or urgent care. The outcome of the events was unknown.; Sender's Comments: Based on the very close temporal association, there was a reasonable possibility that the vaccination with BNT162B2 played a contributory role in triggering the onset of the reported events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified</p> |

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| 1086877 | 3/10/2021 CO | 94 M | 1/22/2021 | 2/10/2021 | <p>to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p> <p>low grade UTI; collapse; been kind of weak; A spontaneous report was received from a consumer, who was the caregiver of a 94-year-old male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced urinary tract infection (UTI), collapse (syncope), and weak (asthenia). The patient's medical history was provided. Concomitant product use was not provided. On 22 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (batch number 029L20A) intramuscularly in the left deltoid for prophylaxis of COVID-19 infection. The patient was hospitalized for a UTI from 10 Feb 2021 to 12 Feb 2021. The reporter stated, "after that, he's been kind of weak and everything". The reporter indicated it was a "low grade" UTI and the patient didn't show any symptoms but then stated "it actually had him collapse and he did that in between the two vaccines and spent two days in the hospital." On 17 Feb 2021, the patient received his second of two planned doses of mRNA-1273 (batch number 012M20A) intramuscularly in the left deltoid for prophylaxis of COVID-19 infection. The patient received both planned doses of mRNA-1273; therefore, the action with mRNA-1273 in response to the events was not applicable. Treatment for the UTI included nitrofluorine. The outcome of the events were unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded</p> |
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| 1087212 | 3/10/2021 | CA | 18 | F | 3/8/2021 | 3/8/2021 | At 1405, Patient was sitting in observation room after receiving first dose of Pfizer. Patient slide down from the chair to the floor and was assisted by her grandmother as well. I immediately went to the patient aide, and she awoke quickly to my voice. I asked the patient for her name and she stated her name. I asked her DOB and she identified her DOB. I asked her if she had any allergies and she denied. I asked the patient if she had any medical conditions, and she denied. I asked the patient if she has ever fainted before and she stated "yes", she has an extreme fear of needles. I also asked the patient if she had eaten anything and she stated, yes, we just had lunch. While I was asking the patient these questions, I assessed the Patient pulse and it was 110, and respiratory was 16. I then asked the patient to focus on her breathing and took the patient Vital Signs. 138/58, HR 78, Resp 16.Auscultated anterior fields, lungs were clear, no advantageous sounds heard. The patient remained on the floor while asking the questions and assessing the patient. The charge nurse and the LVN, placed the patients feet up on the chair. I then asked the patient how she felt and she stated she was fine, I assisted the patient to a sitting position and asked her how she felt and she stated fine, and then we went to a standing position and she stated she was fine. I then assisted the patient to the chair, provided water and also a cool ice pack. Patient continued to have normal conversation with myself and her grandmother. A few minutes later, the patient appear to look like she was going to vomit, I then immediately provided the trash can to the patient. I also assisted the patient with cleaning the patients hands and right arm, where vomit was. Provided Clean hand wipes, and hand sanitizer. The patient remained stable, and 30 minutes later walked to the car with her grandmother and went home. |
| 1087569 | 3/10/2021 | PA | 73 | F | 2/22/2021 | 2/23/2021 | Pt felt dizzy and started shaking, and then fainted. awoke on the floor had been passed out for greater than 30 minutes per patient. |

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| 1087258 | 3/10/2021 | AZ | 30 | F | 3/3/2021 | 3/3/2021 | Vasovagal syncope, onset 1 hour after vaccine administration. Resolved in ~15 minutes, upon lying down. Sudden lightheadedness, seeing stars; tunnel hearing, then tinnitus; leaned forward and lightheadedness continued to worsen, so I laid the car seat back; suddenly felt hot and started sweating profusely; slight nausea; bradycardia (which I never have - I am on a prescription stimulant, and usually run >80 when seated). Called roommate to pick me up and take me back to the vaccine site to check with paramedics there before continuing home. |
| 1087278 | 3/10/2021 | NY | 24 | F | 3/10/2021 | 3/10/2021 | After patient was vaccinated, she stood up and had loss of consciousness, falling backwards onto floor and +hit back of her head. She does report history of syncope after injections. BP 96/58, P48, R17, O2=98%. Alert and oriented. No deformity. Moving all extremities. Denies headache, nausea. She was on stretcher and after 15 minutes felt better. |
| 1087315 | 3/10/2021 | CA | 29 | F | 3/9/2021 | 3/9/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Pt was escorted to waiting area and sat in chair. Within 5 mins of sitting down, pt's head fell backwards and hit the wall behind her slightly, slipped out of the chair and fell on floor. Pt got up as soon as she was on the floor. The incident transpired in less than one minute and she regained consciousness. Pt was given water and said she felt \"the blood rushing back\" and felt \"much better\". Had pt stay around for > 30 minutes and was picked up by friend. Per pt, she was not hurt |
| 1087321 | 3/10/2021 | NY | 26 | F | 3/9/2021 | 3/9/2021 | Syncope after getting vaccine. BP 95/60, P 100, O2sat 96%. Improved after 2 minutes but monitored for 20 minutes. |
| 1087332 | 3/10/2021 | NY | 30 | F | 3/10/2021 | 3/10/2021 | Syncope and fell on her hands and knees. No head trauma. No other injuries. BP 110/77, 85, O2 sat 96%. She was observed for 35 minutes. She felt better and went home. |

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| 1087490 | 3/10/2021 | OH | 48 | F | 3/9/2021 | 3/9/2021 | At 11:30pm on 3/9/2021 over 12 hours after my 1st COVID-19 vaccine , I awakened from my bed and went into my bathroom to urinate. As I was using the restroom, I noticed my arm where I got the vaccine was very sore, and raised it slightly. Immediately after raising my arm, I became very dizzy and passed out, fell off of the toilet and hit the left side of my temple and eye on the marble ledge of my shower. As I came to, my whole body had chills and I was shaking. I applied a cold compress and took 2 Tylenol. I alternated between sweating and chills for the rest of the night. The next morning I had a headache and felt fatigued, but the dizziness had subsided and I rested. |
| 1087562 | 3/10/2021 | NC | 47 | F | 3/5/2021 | 3/6/2021 | Received vaccine at 825 am, low grade temp, chills, body aches, temp never over 100.4, at approximately 1:00am woke up to use restroom, felt lightheaded, nauseated. Passed out, hit head and had tonic-clonic seizure. No history of syncope or seizures. Transported to ER by EMS. given fluids, completed labwork and CT head, given concussion protocol. Discharged and arrived home by 5:00am. |

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| 1087129 | 3/10/2021 | CA | 68 | F | 1/28/2021 | 1/28/2021 | got dizzy and almost passed out; got dizzy and almost passed out; had slight pain at injection site/awoke with moderate pain (5/10); This is a spontaneous report from a contactable consumer (patient). A 68-year-old female patient (no pregnancy) received the first dose of BNT162B2 (Pfizer-BIONTECH Covid-19 Vaccine, lot number: EL9262), via an unspecified route of administration at the site of left arm at 12:45 on 28Jan2021 at single dose for COVID-19 immunisation. Medical history reported as none. There were no concomitant medications. Clinical course: patient was vaccinated about 12:45 pm with no ill effects. When she went to bed, she had slight pain at injection site. She awoke with moderate pain (5/10) about 1 am. She got up to get some paracetamol (TYLENOL). On the way to the kitchen, she got dizzy and almost passed out. She found a chair and rested. She went back to bed (with no paracetamol). No other problems. No other vaccine received in four weeks. No other medications received in two weeks. No treatment received for adverse event. No covid prior vaccination. No covid tested post vaccination. No known allergies. Adverse reactions did not result any serious consequences. The outcome of events was recovered on an unspecified date. |
| 1089545 | 3/10/2021 | TX | 57 | M | 3/9/2021 | 3/10/2021 | patient passed out today ,, around 28 hours after getting covid janssen vaccine.. also patient has headache, fever,chills |
| 1089276 | 3/10/2021 | NJ | 59 | F | 3/10/2021 | 3/10/2021 | Patient fainted in and out three times due to anxiety of needles |

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| 1089308 | 3/10/2021 | PA | 25 | F | 3/10/2021 | 3/10/2021 | Pt contact initiated. On scene to for a 25 y/o female pt with a chief complaint of syncope. Pt was sitting upright in chair in no apparent distress. Pt demeanor is calm. GCS 15, Aox4. Pt stated she felt dizzy and had a syncopal episode. Pt fell on floor from sitting position. Pt found on floor prone. Pt rolled over to right lateral recumbent position. Pt hit head and has approximately 1 cm abrasion on right anterior face. Controlled bleeding with gauze and bandage. Airway is patent. Speech is clear and even with no noted slur or abnormality. Breathing is non labored and regular with adequate chest rise. Radial pulses with steady rate and rhythm. Skin is intact, warm, and dry. Eyes PERRL. No JVD, tracheal deviation, or peripheral edema. Negative DCAPBTLS other than noted. Pt is able to ambulate. Gait is steady. Pt denies headache or blurred vision, shortness of breath or difficulty breathing, nausea or vomiting, chest pain, dizziness, tingling or numbness in extremities, or any other complaints at this time other than noted. |
| 1089316 | 3/10/2021 | CA | 27 | M | 3/9/2021 | 3/9/2021 | Presyncope - prior history. BP 108/53 (pulse 50). |
| 1089360 | 3/10/2021 | MO | 28 | F | 3/10/2021 | 3/10/2021 | Patient fainted 5 minutes after immunization. Patient hit head upon falling out of chair. Pt regained consciousness immediately. Ambulance was called due to hitting head. Patient refused treatment by ambulance. Patient felt passing out was due to low blood sugar. She drank 7-up and was helped cleaning up blood and given band aid. |
| 1089389 | 3/10/2021 | CA | 45 | F | 3/10/2021 | 3/10/2021 | Client had a vasovagal reaction x 3 seconds within 5 minutes post vaccination. Hx of fainting with blood draws and vaccination during her college years. client stated tingly on left upper chest for just a few seconds. denies chest pain, shortness of breath or dizziness. Client vitals were take at 15:26 with spo2 97, pr 54, BP 147/62, vital #2 at 15:31 spo2 98, pr 67, BP 140/85, vitals #3 15:48 spo2 98, pr 71, bp 150/88. Client was advised to go to an urgent care/ emergency room for further monitoring. Client's son will be transporting. |
| 1089466 | 3/10/2021 | FL | 69 | F | 2/28/2021 | 2/28/2021 | Got home Felt nauseous. Went into the bathroom and passed out and fainted and hit her head as she passed out |

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| 1089205 | 3/10/2021 | CA | 21 | M | 3/10/2021 | 3/10/2021 | Patient began reporting numbness and tingling in his left arm several minutes after vaccination. These symptoms persisted for 30 minutes without worsening or lessening. He did not have any SOB, syncope or other symptoms. Physical exam WNL. Pt was instructed to seek ER care for worsening symptoms. His mother was present with him today and will keep an eye on him as well. |
| 1089476 | 3/10/2021 | MO | 24 | F | 3/10/2021 | 3/10/2021 | Pt fainted in waiting area after her vaccine. She was fine after I tended to her. It was about 5 min after her vaccination. After talking to her, it was determined that she has anxiety and she has fainted with blood draws in the past. |
| 1089709 | 3/10/2021 | AZ | 64 | M | 3/10/2021 | 3/10/2021 | After receiving the vaccine with in minutes the patients left arm began to swell and bruise. He began to become pale and his eyes rolled back into his head and passed out. He woke up a min later and had SOB. Very pale and almost threw up. Paramedics and Firefighters were called. The eveulated the patients and gave him a liter of sodium choride. His Heart Rate was in the 30's. After several min and a liter of fluid, patient was alert. Once stable he was transported to Hospital. |
| 1089572 | 3/10/2021 | NV | 18 | F | 3/10/2021 | 3/10/2021 | Pt fainted after vaccine |
| 1089621 | 3/10/2021 | CA | 30 | F | 3/4/2021 | 3/4/2021 | Vasovagal, syncope episode. Client walked to observation area receiving vaccine. Sat for about 5 minutes and started feeling dizzy, had about "80-90" vision, felt like vision was narrowed and leaned back. Found self on side in nurses lap. Nurse in observation area assisted client to ground from chair, controlling the fall. Report per client of history of vasovagal reaction with injections or any needle based procedure. |
| 1089650 | 3/10/2021 | IA | 45 | M | 3/10/2021 | 3/10/2021 | patient was sitting after the shot in the waiting area for 15 min after the shot and one of his college who is sitting near by called me and said he passed out twice but when I went with the nurse he was ok and he said he did not. but his friend said no he did. we kept watch him closely for one hour. no symptoms observed. no sob , we offer him epipen or bendryl but he refused. I asked to call his family dr of pcp he said he does not have one. I called the patient on his sell phone after 6 hr of incident and he said he had no issue after that |

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| 1089785 | 3/10/2021 | CA | 64 | F | 2/24/2021 | 3/4/2021 | Became incredibly ill on March 4, 2021, still sick, fluctuating fevers 100-104, body aches, dizziness, weakness, unbalanced, sweating, unable to get out of bed to days, almost passed out on March 6th. Day 7, dizzy head, dry mouth, recent tickle cough at back of tongue making it hard to breathe or talk without coughing spasm, slightly more strength today, but still feel incredibly weak and don't know how long to get back my normal self. No congestion or lung problems. |
| 1086931 | 3/10/2021 | MA | 75 | F | 2/10/2021 | 2/11/2021 | Shingles in the ear; Passed out; Couldn't mover her arm, head, legs, chest, felt paralyzed; Felt weak; A spontaneous report was received from a consumer concerning a female patient of 75 year old, who was received Moderna's COVID-19 vaccine(mRNA-1273) and experienced loss of consciousness, paralysis, weakness and shingles in the ear. The patients medical history, as provided by the reporter, included myasthenia gravis. Concomitant medications reported included lidocaine patch and prednisone. On 10 feb 2021, prior to the onset of events, the patient received their first of two planned dose of mRNA-1273(Lot number:010M20A) intramuscularly on an unknown arm for prophylaxis of COVID-19 infection. On 11 feb 2021, one day after vaccination, patient experienced loss of consciousness, paralysis and weakness. The event loss of consciousness and paralysis was also considered to be medically significant. On 16 feb 2021, patient experienced shingles in the ear. Treatment for the events included acyclovir and ice. Action taken with mRNA-1273 in response to the event was not reported. The outcome for the events loss of consciousness, paralysis, weakness and shingles in the ear were considered as unknown.; Reporter's Comments: Based on the current available information, a strong temporal association between the use of the product and the start date of the events, a causal relationship with the events cannot be excluded. |
| 1090288 | 3/10/2021 | CA | 23 | F | 3/10/2021 | 3/10/2021 | Syncope - fainted in observation area. Laceration above left eyebrow (2 cm x 2 cm) and on bottom lip. BPs 111/79 (pulse 104), 113/81 (pulse 98), O2 sat 100%. |

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| 1088370 | 3/10/2021 | MD | 28 | M | 3/10/2021 | 3/10/2021 | client felt flushed 10 mins after vaccine client fainted fell face down received a laceration on the left side of the forehead was pale and diaphoretic v/s 133/84 72 pox 96 r 20-22 after fall PATIENT WAS ALERT AND OX3 stated he felt ok legs were elevated . patient stated he had a similar episode after having a tattoo EMS was called vs 124/100 78 pox 96% RA patient refused to go to ER or urgent care offered water and rested for 30 mins left ambulatory without any c/o |
| 1089469 | 3/10/2021 | CA | 60 | F | 3/7/2021 | 3/7/2021 | acute chest tightness, chest pressure, SOB, severe cough, tachypneic, throat closing feeling hoarse voice, presyncope but epipen administered on site of vaccination location to avert syncope or cardiovascular collapse promptly. Symptoms occurred within 10 minutes of vaccine administration . Vaccine given 12:18 pm or 12:25 pm and symptoms within 10 minutes since in ER 12:30 pm but had received epipen en route before ER arrival since medical building was next to ER |
| 1088460 | 3/10/2021 | NJ | 26 | M | 3/9/2021 | 3/9/2021 | Systemic: Fainting / Unresponsive-Severe, Additional Details: Patient remembered sitting down in a chair for observation, then slumped forward while on his phone. He did not remember falling over and was alert and oriented right away. Emergency services were called as he sustained an injury during his fall. |
| 1090281 | 3/10/2021 | CA | 17 | F | 3/10/2021 | 3/10/2021 | Syncopal, BP 104/61 (pulse 100), O2 sat 100%. Given water and rested 45 minutes. Final BP 129/86. |
| 1089189 | 3/10/2021 | TX | 51 | M | 3/10/2021 | 3/10/2021 | Patient described feeling lightheaded and dizzy. Passed out for a moment and recovered. Patient received 2 bags of saline |
| 1088419 | 3/10/2021 | GA | 21 | F | 3/10/2021 | 3/10/2021 | Pt sitting in observation area after Pfizer vaccination. Felt hot, got up and then eased to the floor and laid down. Hx of vasovagal syncope with injections and blood draws. No LOC. Vitals taken at time- HR remained 70s-110, BP at first in 90s/60s. Pt laid down with feet up, cool compress, able to converse easily. Eased to sitting position, then to sitting in chair and then standing. BP when leaving was 110s/80s, patient reported feeling fine. This was comparable to all previous syncopal events with blood draws/ vaccinations. |

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| 1088469 | 3/10/2021 | | 60 | F | 3/9/2021 | 3/9/2021 | pt became flush and had trouble breathing and fainted |
| 1088413 | 3/10/2021 | NH | 76 | M | 3/10/2021 | 3/10/2021 | The patient transferred from Hospital's COVID-19 Vaccine Clinic to Emergency Department and evaluated by the provider for near syncope event post vaccination. |

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| 1088508 | 3/10/2021 | MI | 67 | M | 2/23/2021 | 2/24/2021 | diarrhea; 12 hours after injection - fainted in bathroom/fainted 2nd time; wooziness when trying to walk/just felt woozy; headache; chills; This is a spontaneous report from contactable consumers (patient and wife). This 67-year-old male patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EN6202) in right arm on 23Feb2021 05:00pm at single dose for COVID-19 immunisation. Medical history included high cholesterol, acid reflux (esophageal). The patient had no known allergies. Concomitant medications in two weeks included atorvastatin for high cholesterol, ongoing omeprazole for acid reflux (esophageal), and ongoing multivitamins (1 tablet a day for men over 50 by mouth as supplementation therapy). The patient did not receive other vaccine in four weeks. The patient previously received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EM9810) at the age of 67-year on 02Feb2021 at 05:00PM in left arm at single dose for COVID-19 immunisation, had no reaction with the first dose, had no issues in the waiting period or while shopping afterwards; received influenza vaccine (FLU) and pneumonia shot for immunization on an unknown date a couple of months ago. The patient did not have COVID prior vaccination, COVID was not tested post vaccination. The patient received second dose of the Covid-19 Vaccine, then on 24Feb2021, fainted twice 12 hours after receiving the second dose, fainted in the morning of 24Feb2021 around 05:20, he got up because he had diarrhea and that was when he first fainted in the bathroom. He also had chills and a headache in the morning of 24Feb2021 at 05:15, but she reported that he did not have a fever. Temperature was normal on 24Feb2021. The patient reported that he just felt woozy, wooziness when trying to walk/just felt woozy in the morning of 24Feb2021 at 05:15. She said that he fainted for a second time just minutes after he fainted the first time when the reporter was helping the patient get back from the bathroom to the bedroom, the patient collapsed on the floor and reporter got him up. He developed the diarrhea around 05:30 in the morning of 24Feb2021. He took some ibuprofen to treat the headache. It was unknown if the treatment received for the other events. He has been resting since he had the diarrhea. Outcome of the events faint and diarrhea was unknown, wooziness |

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| 1088523 | 3/10/2021 | KY | 26 | F | 3/9/2021 | 3/9/2021 | when trying to walk/just felt woozy was recovering, while other events was recovered on 24Feb2021. Pt reported that approximately five hours after vaccination, she experienced uncontrollable tremors, fainting, vomiting, chest pain and tightness. Today, extremely fatigued and has some chest tightness. She has a history of chest tightness. Did not seek emergency care last night, but called physician this morning who was not in office and referred to local health dept. Advised that it would be best to consult with local emergency facility and if anything worsens she needs emergency care. |
| 1088542 | 3/10/2021 | NV | 71 | F | 3/2/2021 | 3/2/2021 | About 6 hours after the vaccine she felt really, really sleepy. Then she laid down and then her left hand started stinging all over. Both legs started getting a strange warm sensation, the size of a pea that kept getting warmer. She was not able to get up or open her eyes, doesn't know if she passed out but apparently went to sleep and slept for 3 hours and woke up and went to bed. She then had toe cramps on her left foot, then got up and walked around the bed and laid down again and fell asleep until the morning. She did not feel normal until 3/5/21. On Sunday, 3/7/21 had nausea, took something for that and the next day she was fine. |
| 1089033 | 3/10/2021 | CT | 44 | F | 3/10/2021 | 3/10/2021 | Patient received her first Moderna COVID-19 vaccine and fainted within 1-2 minutes. She was sitting and fell to the floor. Vital signs remained stable as follows: 12:40pm BP 94/50, pulse oximeter - 97% and HR - 91 laying down 12:43pm BP110/78, pulse oximeter - 98% and HR 97 sitting 12:51pm BP 114/84, pulse oximeter - 98% and HR - 91 standing Patient was responsive after fainting and reported history of syncope. She was accompanied to Health Office at the school by wheelchair and family was called to pick her up. |
| 1088663 | 3/10/2021 | KY | 31 | F | 3/9/2021 | 3/10/2021 | Chills during the night and in the morning when got up from bed had symptoms of orthostatic hypotension' headache neckache and while using bathroom my head was spinning when got up to go to bed I fainted and fell down on the floor which I dont remember until I got up myself and found my son crying next to me i was sweating |

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| 1088849 | 3/10/2021 | FL | 57 | M | 3/9/2021 | 3/9/2021 | <p>Around 5 pm patient got his first dose of the Moderna Covid-19 vaccine, and after 5 mins,he passed out while he was sitting in the observation area,his wife was with him, once that incident had been noticed, I ran quickly to him but when I reached him he started to wake up again, I brought the emergency kit , a bottle of water, also I asked pharmacy tech to call store manager to come over. I asked patient what happened and he stated that suddenly he felt dizzy and that he was anxious about the vaccine from the beginning and excited to get it at the same time, then I measured the blood pressure it was 125/61 with pulse of 45/min.I offered him and his wife to call 911 but they declined it. I asked him to go back to my consultation area so he could lie down on the floor and raise his legs up so we can bring back the blood pressure up, he did that, and he went with me over there and laid down on the floor and we raised his legs up, later I measured his blood pressure again, and it was 113/71 with pulse 51/minute, I offered again to call 911 but he refused and he said that he was feeling better. I left him about 10 more minutes,then he started to get up and sit by the chair and I re-measured the blood pressure and it was 121/76 with pulse of 54/minute, he started to drink water. He stated he felt better than he was about 20 minutes ago, then they left once their driver came to pick them up.</p> |

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| 1088946 | 3/10/2021 | KS | 67 | F | 2/10/2021 | 2/10/2021 | <p>Progress Notes Expand All Collapse All COVID VACCINE CLINIC 2/10/2021 Subjective PT. is a 67 y.o. female who was seen at COVID Vaccine Clinic today for her second dose of the COVID 19 vaccination. She was given the Moderna vaccination in the left deltoid muscle. During her 15 minute waiting period after the injection, the patient began to experience lightheadedness and neck pain. She denied rash, hives, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, facial swelling, lip swelling and tongue swelling. This provider was notified of patient reaction and she was then assessed in the emergency bay area. Monitored patient for severe reaction symptoms, including but not limited to blood pressure abnormality , chest pain, hypotension, rapid progression of symptoms, respiratory distress and tongue swelling. Medical history includes htn, hld. Takes low dose 10 mg po daily Lisinopril. Last ov with pcp in October, bp normotensive. Review of Systems Constitutional: Negative for chills, diaphoresis, fatigue and fever. HENT: Negative for drooling, facial swelling, sore throat and trouble swallowing. Eyes: Negative for itching. Respiratory: Negative for cough, choking, chest tightness, shortness of breath, wheezing and stridor. Cardiovascular: Negative for chest pain and palpitations. Gastrointestinal: Negative for abdominal pain, nausea and vomiting. Musculoskeletal: Positive for myalgias (neck/upper shoulder pain). Skin: Negative for color change, pallor and rash. Neurological: Positive for headaches (pressure behind eyes). Negative for dizziness, syncope, facial asymmetry, speech difficulty, weakness and light-headedness. Psychiatric/Behavioral: Negative for agitation and confusion. The patient is not nervous/anxious. Previous Reactions: none</p> <p>Objective Vitals Vitals: 02/10/21 1108 02/10/21 1111 02/10/21 1153 BP: (!) 199/96 (!) 164/103 (!) 162/80 Pulse: 90 84 74 SpO2: 97% 96% Blood Sugar 99 collected at 1111 Blood Sugar 99 collected at 1145 Physical Exam Vitals reviewed. Constitutional: General: She is not in acute distress. Appearance: She is not ill-appearing or diaphoretic. HENT: Mouth/Throat: Mouth: Mucous membranes are moist. Pharynx: Oropharynx is clear. Eyes: Extraocular Movements: Extraocular movements intact. Conjunctiva/sclera: Conjunctivae normal.</p> |

VAERS_ID RECVD STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

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| | | | | | | | <p>Pupils: Pupils are equal, round, and reactive to light. Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Heart sounds: Normal heart sounds. Pulmonary: Effort: Pulmonary effort is normal. Breath sounds: Normal breath sounds and air entry. Musculoskeletal: Cervical back: No swelling. Comments: ttp over upper trapezius. No cervical spine tenderness. Skin: General: Skin is warm. Coloration: Skin is not pale. Findings: No rash. Neurological: General: No focal deficit present. Mental Status: She is alert and oriented to person, place, and time. Psychiatric: Mood and Affect: Mood normal. Thought Content: Thought content normal. Judgment: Judgment normal. Assessment/Plan Treatment included: water, snacks and tylenol Follow up response to treatment: good. Patient discharge: Stable to go home and follow up with PCP. Differential Diagnosis: Vaccine-Related Anxiety (include misc mental health) Directed to closely follow up with her primary care provider on her blood pressure. She's aware of what to watch for and when to go to ED. Pt denied wheelchair. She was accompanied out to front assistant. Dr. at bedside as well. Electronically Signed 2/10/2021 11:54 AM</p> |
| 1088981 | 3/10/2021 | NY | 25 | M | 3/10/2021 | 3/10/2021 | Syncope, headache, dizziness, feeling of "burning up~~ |
| 1089014 | 3/10/2021 | IL | 26 | M | 3/10/2021 | 3/10/2021 | <p>Patient was sitting down for a few minutes after their vaccine and then got up to tell the pharmacy staff he wasn't feeling well. He walked back to the waiting room and fell onto the bench. I went out to sit with him and held onto him as he passed out/lost consciousness for approximately 20 seconds. We gave him water and called 911. The paramedics arrived and checked his vitals. He was fine after that and stayed for about a half an hour before he left.</p> |
| 1089149 | 3/10/2021 | | 21 | M | 3/10/2021 | 3/10/2021 | <p>Pt became lightheaded, nauseous and sweaty with 2-3 minutes of receiving the vaccine. He stood up to alert us he was feeling lightheaded and then fainted. We applied an ice pack because the patient was hot. No sign of reaction at the injection site, nor did the patient state he had trouble breathing. Over a period of 30 minutes, the patient recovered and did not lose consciousness again. Patient left under their own power.</p> |

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| 1089177 | 3/10/2021 | AK | 20 | M | 3/10/2021 | 3/10/2021 | Light-headed, fading vision, caused fainting post vaccine. Patient fell to the floor and had come back within seconds. Patient was evaluated in place for 1 minute and recovered. Patient was escorted to a chair and talked with a watcher for 15 minutes. |
| 1088606 | 3/10/2021 | NM | 38 | M | 3/9/2021 | 3/9/2021 | ?Pfizer-BioNTech COVID-19 Vaccine EUA" 5 minutes after administration of Pfizer COVID vaccine, patient passed out for less than a minute. Patient was alert, knew where he was and what had just happen. He stated he was not experiencing chest pain, shortness of breath, no rash observed. Patient stated he tends to pass out at the site of needles or when he was blood drawn. 10 minutes after passing patient begin to feel lightheaded, skin tone become very pale and patient stated he was hot. Patient passed out a 2nd time and experience 2 body jerk movements for less than a minute. Epi Pen was administered to the patient. Paramedics were called to the scene. Patient become alert and patient stated he need to vomit. Patient vomited profusely. Vitals were taken: BP 100/60mmhg, O2 stat 97%, Temperature 96.5F. Paramedics arrived at scene. Paramedics spoke with patient let him know his vitals were stable and if he would like to be taken down to the ER. Patient declined stated he was feeling much better. On 3.10 patient was contacted and he stated he was feeling great, just experiencing soreness at the site on Pfizer vaccine and Epi pen administration site. |
| 1085023 | 3/9/2021 | IN | 53 | F | 3/7/2021 | 3/7/2021 | Started with chills about 12 hours after the shot, headaches, nausea, light-headedness (nearly passed out), dry-heaving, fatigue (slept on and off for 24 hours) Symptoms lasted about 36 hours and then I felt fine again. |
| 1084843 | 3/9/2021 | MD | 35 | F | 2/18/2021 | 2/18/2021 | Pt with tongue swelling, throat "closing" and near syncope/tunnel vision within 2 hours of receiving dose 1 of Moderna COVID vaccine. Treated with "antihistamines" at hospital. Pt states that she had a similar reaction 3-4 years ago when she received the MMR vaccine. Symptoms: Angioneurotic edema(T783), DIZZINESS AND GIDDINESS(R42). |

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| 1084780 | 3/9/2021 | NJ | 42 | F | 3/9/2021 | 3/9/2021 | Patient experienced an episode of syncope and fainted twice during observation period. Offered oxygen and called 911 and EMS arrived. Patient evaluated by EMS and was recommended to go to ER with EMS but she declined. Patient was counseled on anticipated side effects. She was recommended to follow up with PCP and describe what took place and what she experienced. The timespan that this took place was 20 minutes and she improved and able to speak with assistance. Her husband was present. |
| 1084612 | 3/9/2021 | OH | 65 | F | 3/8/2021 | 3/8/2021 | Patient received Janseen COVID vaccine. The first 1/2 of the vaccine was given easily IM to the left deltoid and then the patient complained of severe arm pain, tensed her muscles, and the last 0.25ml was difficult to inject. Then the patient became hypotensive 90/45, dizzy, and felt like she was going to pass out. She was laid in the supine position, given a cool cloth for her forehead and monitored for approx. 45 minutes. Her blood pressure remained 90/60, 96/56 at discharge. Her heart rate ranged from 55-65, regular. Her son came to take her home as we did not feel comfortable with the patient driving. The patient was continuously monitored by the NPs and APCT. She ambulated without difficulty and was discharged home. She was given information for V-safe to report her reaction and advised to follow up in the ER for any SOB, difficulty breathing, difficulty swallowing, syncope, CP, etc. |
| 1085131 | 3/9/2021 | NJ | 18 | M | 3/8/2021 | 3/8/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Additional Details: Pt fainted in waiting area shortly after vaccine administration. Quickly became responsive, talkative, and aware. Had patient lie down, elevated feet, gave pt water and potato chips to increase salt intake/ raise bp. Monitored patient for additional 30 minutes. Pt indicated he was feeling much better and left with family members with instructions to monitor him and have pt rest for remainder of the day. Tried to follow up with patient on 3/9, but phone number was out of service. |
| 1084522 | 3/9/2021 | NJ | 88 | M | 3/5/2021 | 3/5/2021 | i stood and Fainted,i passed out for 1/2 an hour |
| 1084709 | 3/9/2021 | NY | 71 | M | 3/6/2021 | 3/8/2021 | atrial fibrillation, hypotension, syncope, possible seizure |

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| 1085028 | 3/9/2021 | NJ | 34 | F | 3/9/2021 | 3/9/2021 | Patient and husband arrived to received covid-19 vaccine together, 12:30 pm and 12:45 pm appointments. I informed patients that if they wanted to, they can both enter room together. Both patients were counseled on side effects/ what to expect. Patient was administered the Moderna COVID-19 Vaccine first in left arm. Upon vaccination, patient's arm began to bleed from injection site. I informed patient I would clean her arm, and attempted to hold gauze in place myself. Patient stated she would hold the gauze instead. After applying bandaid and cleaning area, I began process to vaccinate her husband. While vaccinating husband, patient stated she felt dizzy/faint. Patient sat in chair. Husband stated she is prone to fainting spells. I offered EMS services. Husband refused. I elevated patient's legs with other chair. Patient started to become non-responsive. I stated I would use an epi-pen. Patient's husband refused epipen. Informed technician, to contact 911. Informed technician to contact front end manager. Patient continued to be non-responsive. Asked husband if I should get patient juice. Ran to get patient orange juice and straw. Husband wet patient with water. Patient started drinking orange juice through straw. Felt better. Started becoming responsive. Patient and husband waited for EMS. Refused EMS services. |
| 1085250 | 3/9/2021 | MS | 40 | M | 3/9/2021 | 3/9/2021 | seconds after administration patient started losing consciousness. he stated he previously experienced vasovagal syncope after flu shots. he went in and out consciousness several times over the next 5 minutes. he lost color in face and eyes closed when head dropped. his body was stabilized and kept alert with verbal and physical tests. cold compress was applied behind neck and BP monitor placed on arm. he had normal BP/pulse. skin color gradually improved as well as mental acuity. patient could stand after approx 10m and was observed for additional 30m. his phone was used to call his wife and someone came to assist getting home. said felt fine after full observation time and seemed to have made full recovery. |

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| 1085128 | 3/9/2021 | MA | 53 | F | 3/6/2021 | 3/7/2021 | Apart from the expected side effects (soreness of injection site, muscle ache and fatigue, which all started the night after the injection, I experienced severe dizziness associated with vertigo (up and down motion of room), nausea, profuse sweating and near syncope around 7:15 AM the day after the injection. Symptoms lasted about 3-4 hours before they gradually subsided. There was no arrhythmia at the time of the near syncope, I was unable to check blood pressure, as I had to stay on the ground to avoid a fall. Fatigue and a sense of disequilibrium persisted for an additional 48 hours before resolving. |
| 1085196 | 3/9/2021 | OH | 69 | F | 2/9/2021 | 2/9/2021 | Feeling faint; Light headed; Fatigue; Diarrhea; Nausea; Vomited; Sore arm; A spontaneous report was received from a consumer concerning a 69-Years old, female patient who experienced the events syncope, dizziness, pain in extremity, diarrhoea, nausea, vomiting and fatigue. The patient's medical history was not provided. Products known to have been used by the patient, within two weeks prior to the event, included metformin for diabetes type 2, valsartan 25mg for high blood pressure and paroxetine for anxiety and depression. On 09 Feb 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot/batch: 031M20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 09 Feb 2021, the patient experienced sore arm. On 11 Feb 2021, the patient felt very bad had nausea and vomited. The patient also experience diarrhea on the same day. On 12 Feb 2021, the patient woke up with feeling faint and lightheaded. The patient reported that she cannot put anything in their mouth and experienced fatigue. The event syncope was considered to be serious with seriousness criteria - medically significant and all other events were non-serious. Action taken with mRNA-1273 in response to the events was not unknown. The outcome of the events syncope, dizziness, pain in extremity, diarrhoea, nausea, vomiting and fatigue was unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded. |

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| 1084513 | 3/9/2021 | MD | 28 | M | 3/9/2021 | 3/9/2021 | diaphoresis, hypotention, bradycardia, dizzy. likely vasovagal/presyncope 2/2 seeing blood after admin of vaccine |
| 1083952 | 3/9/2021 | CA | 24 | F | 3/8/2021 | 3/8/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: Hypotension-Medium |
| 1085051 | 3/9/2021 | CO | 36 | F | 1/27/2021 | 1/27/2021 | Passed out approximately an hour after vaccine administration after waiting in the facility for over 30 mins, while driving. Stopped breathing, broke bones in 8 different places in my face requiring surgery. Still recovering. |
| 1084422 | 3/9/2021 | CA | 27 | F | 3/7/2021 | 3/7/2021 | Exactly 14 minutes after injection, felt dizzy and nauseous. Fainted, had convulsive syncope for 1 minute, lost voluntary control of bodily function (urinated), woke up, and vomited multiple times. Vomiting lasted from 10:35am - 1:10pm. Also had diarrhea twice in between vomiting, and was shaking occasionally. |
| 1084375 | 3/9/2021 | AZ | 59 | F | 3/8/2021 | 3/8/2021 | I got dizzy approximately 15 minutes after receiving the vaccine. I went home and passed out for approximately two hours and have been very tired ever since. I had chills a few hours after receiving the vaccine. I still feel tired despite sleeping very well and feel groggy. |
| 1084347 | 3/9/2021 | VI | 31 | F | 3/3/2021 | 3/3/2021 | Within 4-5 minutes after receiving the vaccine the recipient became Hypotension and Diaphoretic . blood Pressure 78/59 and HR 89. She was given oxygen, and bolus of IV fluids in ambulance. BP improved to 112/76. She was taken to the ER and after additional tests, she was discharged around 9pm with diagnosis of Vasovagal Syncope. |
| 1084343 | 3/9/2021 | ID | 83 | F | 3/4/2021 | 3/6/2021 | Rigors and pre-syncope with fall and right hip fracture |

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| 1084273 | 3/9/2021 | VA | 61 | F | 3/5/2021 | 3/5/2021 | Within in 30 minutes of administration she felt nasal stuffiness that lasted 1-2 hours. 10 hours after administration she developed fatigue but could not sleep. 12 hours after administration she developed severe chills that made her teeth chatter beyond control x 2 hours. She also reported severe joint and muscle pain. Saturday she felt nausea, aching and fatigue. Sunday (40 hours after vaccine was given) she developed syncope and fell hitting her head. Her B/P at that time was 89/49. Her b/p was checked numerous times after that and stayed low for about 24 hours. She missed work d/t this on Monday 3/8/21. |
| 1084216 | 3/9/2021 | MO | 31 | F | 3/5/2021 | 3/5/2021 | ~~light headed, dizzy and then vision began to go out" No syncope, no numbness or tingling, able to self ambulate, no other symptoms noted. patient is pregnant but unknown of gestation, previous births, etc. |
| 1084135 | 3/9/2021 | SC | 28 | F | 3/8/2021 | 3/8/2021 | Loss of consciousness, irregular heart palpitations, nausea. Loss of consciousness lasted less than one minute, recovery took about twenty minutes to become stable to leave the facility; lingering ?wooziness? throughout the day. This reaction was more likely due to vasovagal syncope than the vaccine. Patient has a history of vasovagal syncope. Arm soreness, fatigue, and headache presented the following day. |
| 1083973 | 3/9/2021 | | 79 | F | 3/8/2021 | 3/8/2021 | 15 monitoring status. Syncope episode after release from Monitoring (outside). Escorted back to monitoring area in w/c. Evaluated by Paramedics. SaO2 98% P 110 BP 142/84. 2:50PM feels "normal" hold until 3 and re-evaluate. 3:05mstands w/o dizziness. W/c escort to car. Home |

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| 1083948 | 3/9/2021 | TX | 22 | M | 3/8/2021 | 3/8/2021 | Site: Pain at Injection Site-Mild, Systemic: Dizziness / Lightheadness-Medium, Systemic: Hypotension-Medium, Systemic: Nausea-Medium, Systemic: Shakiness-Medium, Systemic: Tinnitus-Medium, Systemic: Visual Changes/Disturbances-Medium, Additional Details: Near fainting episode. Pt did not lose consciousness but blacked out (visual disturbances, tinnitus/temporary hearing loss, nausea) occurred within 2-3 minutes of administration. First attempt to read BP was low (~80/60). Pt is an athlete, so I waited until after water was consumed to take BP again. 2nd reading was ~106/65. Pt felt better after drinking water and after sitting for 15 minutes under observation. |
| 1083945 | 3/9/2021 | CA | 25 | F | 3/8/2021 | 3/8/2021 | Site: Pain at Injection Site-Mild, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Mild, Systemic: Hypotension-Mild, Systemic: Nausea-Mild, Systemic: Weakness-Mild, Additional Details: Patient described feeling nauseas about 10- 15 minutes after vaccination then patient fainted. Patient regained alertness a couple minutes after fainting but was still weak and unable to get up. Paramedics came and patient was found to be hypotensive after 15-20 minutes patients blood pressure restored and she was at full alertness and paramedics signed her release. |
| 1083942 | 3/9/2021 | CA | 24 | F | 3/8/2021 | 3/8/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Medium, Systemic: Hypotension-Mild, Additional Details: Patient fainted 10 minutes after administration of Janssen vaccine. Patient was unconscious for about 15 seconds before regaining consciousness. 911 was called and EMT arrived on scene to monitor's patients blood pressure and blood sugar. Patient still reported lightheadedness so was taken to hospital by EMT/ambulance. |

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| 1083928 | 3/9/2021 | TX | 40 | F | 3/4/2021 | 3/5/2021 | I thought my lopes were tingling immediately, but thought it may just be psychological. Several hours later, my arms and hands were tingling and numb, followed by some chest pains momentarily. Eight hires after the shot, I got up to use the restroom, in distress of the tingling and numbness. I was sitting on the toilet and seem to be going in and out of consciousness. I stood up, washed my hands... and woke up on the bathroom floor. I had clearly passed out, hit my head and lost some time. |

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| 1083750 | 3/9/2021 | KY | 71 | M | 2/21/2021 | 2/22/2021 | passed out; This will drive me nuts all day; I don't feel comfortable walking in my own house; I got up this morning with the feeling of vertigo; getting little worse, worse than they were; This is a spontaneous report from a contactable Consumer. A 71-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, NDC number of Covid-19 Vaccine: 592671000-1, Expiry Date of Covid-19 Vaccine: 31May2021, Lot: EL9267), via an unspecified route of administration on 21Feb2021 13:24 at single dose for covid-19 immunisation. The patient medical history were none. Concomitant drug received. Patient stated, "Yes, I am on Inhalation Pump so, I take it went for one when I need it, I just had that was just little while ago, it wasn't (Incomplete sentence). The patient stated, "I got my second shot (Covid-19 Vaccine by Pfizer) Sunday about 1:30(13:24 PM) it says on the piece of paper, and I was fine all day Sunday, Monday(22Feb2021), I got up this morning with the feeling of vertigo, which I have had in the years of the past okay, all day, got out of shower from the bathroom out here and get some coffee, and I sat down I went to get up and the vertigo hit and I almost fall over, now I went into the shower and I dropped the wash cloth on the floor, so I went down to pick it up and again almost passed out, almost immediately, and I sat and I get in the kitchen for some toast and I said well let me see what happens here and sat down eating some toast and when I got up to put dirty dishes in the sink, I almost again passed out, now I just got up to get the check I have to write to the gentleman right here who is working for me and just before that I got the same thing now I don't like it, how are these supposed to last, is what I want to know because I can't, this will drive me nuts all day, I can't go anywhere, I can't drive anywhere, yeah I don't feel comfortable walking in my own house. Right now, I have to say I am feeling them getting little worse, worse than they were." No treatment. Outcome was not recovered. |
| 1085566 | 3/9/2021 | NY | 35 | M | 3/9/2021 | 3/9/2021 | after 30 minutes of receiving his Dose 2 of Pfizer COVID 19 vaccine. Patient c/o palpitations and tightness of his throat. Denies any SOB/Chest pain/Pruritus/syncope. Able to tolerate clear liquids with c/o of dysphagia unresolving " my throat is feeling like it is tightening up. ~~ |

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| 1084058 | 3/9/2021 | CT | 36 | F | 3/6/2021 | 3/6/2021 | Post vaccination feeling of breath doom, walking to door to get fresh air. Syncope, fell to floor. No head injury. Post vaccination syncope, brief generalized tonic-clonic movement followed by emesis. Blood glucose 114, BP 120/80, HR90, O2 Sat 96%. |
| 1086361 | 3/9/2021 | TX | 24 | F | 3/9/2021 | 3/9/2021 | Patient came in for Janssen COVID vaccine that was scheduled electronically online. All appropriate prescreening was done and patient had no previous allergies or issues. Patient was instructed to sit in one of the chairs designated for post vaccine observation for 15 minutes after her vaccine. Within a minute or so patient felt light headed and like she might pass out. She notified the technician who was right there and he notified me. I assisted her to a sitting position on the floor from her chair and I was able to ease her back to a lying down position from there with her head on the floor and feet elevated above heart on a chair. Patient was able to talk the whole time. She told us at that point when she was younger she was scared of shots and had fainted when having them, but thought she was past that and did not mention it during screening. She said she was surprised to feel this way because she was so excited about getting her COVID vaccine. She had not eaten much today (a small snack) and had rushed here for her appointment without getting food. I checked her blood pressure while she was lying down and it was 94/63 and pulse of 75. She said she normally had lower end of normal blood pressure. She was pale when I started checking her, but her color began to return to normal within minutes. After 5 minutes she felt well enough to sit up and we got her a granola bar and water. She remained this way for 5 minutes and felt good, so we moved her to sitting in a chair and got her a pepperoni and cheese snack tray from the cafe. She ate this and waited for 10minutes and felt good. We walked her to her car and she felt fine. I called to verify she got home fine and she did. |
| 1085502 | 3/9/2021 | TN | 58 | F | 3/5/2021 | 3/5/2021 | Near syncope. Pt asked for help as she felt faint and the feeling worsened over the next two minutes. Had pt recline in her automobile. Called EMS and they arrived at 10:10am and evaluated her. She recovered quickly and by 10:30am was able to leave the facility by herself. |

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| 1085561 | 3/9/2021 | CT | 61 | F | 3/9/2021 | 3/9/2021 | tingling sensation left arm, light headed, body extremely weak-could not get up, almost passed out, could barely speak, stomach nausea. EMT arrived checked blood pressure with finger (she did not tell us first result when I was extremely weak and felt like was about to pass out and had blurred vision-husband said I was barely responsive and couldn't move to get up), EMT then said would take BP again and while putting on arm cuff I vomited 2 times. After vomiting I felt immediately somewhat better. EMT took blood pressure and she said it was normal. EMT took blood sugar and she said it was normal All less than 15 minutes after shot. We then waited at EMT direction for another 15 minutes. We left the clinic and parked just outside till 10:30. I am now feeling better, just tired. |
| 1086511 | 3/9/2021 | MD | 29 | M | 3/9/2021 | 3/9/2021 | vasovagal syncope or seizure? After receiving the drive-through vaccine, we drove into a parking space to sit and make sure I was ok. Within 5-10 minutes, I was sitting in the car and sending a text and with no warning whatsoever mid-text lost consciousness, profuse sweating, wheezing, lost color in my skin, was making unintelligible noises, and eventually woke up about a minute later but couldn't speak or comprehend those speaking to me (according to my wife who was terrified). I was not nervous, stressed, or scared of receiving a vaccine. I regained the ability to speak about a minute later and my wife had summoned the staff on the scene who instructed me to lie back and breathe without a mask. I drank some liquids. A nurse was called over and offered to take my vital signs but I decided I felt ok enough not to. Eventually my normal skin color and came back and sweating stopped after about 5 minutes. We sat for a few extra minutes and once I felt it was past me, my wife drove us home. |

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| 1086495 | 3/9/2021 | FL | 68 | F | 3/9/2021 | 3/9/2021 | Patient had an episode of syncope 6 minutes after vaccination while seated in a chair. Arousal was difficult, carotid pulse was difficult to discern. Once conscious, patient seemed like they were going to fall in and out of consciousness, so we kept speaking to her and asking her questions to keep her conscious. Patient began grabbing right upper abdominal quadrant and complaining of pain. She requested ice because she was feeling hot and her abdomen was hurting, ice was provided. AED was connected and 911 was called, no shock was suggested by AED. EMT arrived and took vitals and blood sugar. They found no issues with vitals, but suggested that she go to Hospital for further assessment. She was taken out on a stretcher, but it is unknown to me what resulted after she left the building. |
| 1086386 | 3/9/2021 | TX | 43 | F | 2/25/2021 | 3/5/2021 | On day 8 I got Covid Arm at the injection site. Lasted for 3 days. On 3/7/21 6:30am I woke up for work and had terrible chest pain. It knocked me back a few steps. Examined my chest and only experienced the pain when I moved a certain way. Thought I had pulled a muscle. Went to work feeling exhausted and my eyes burned. Came home early from work and passed out. Noticed that when I lay down my hands swell. Next morning I work up fine. No pulled muscle. No pain. Never experienced anything like it. I started my monthly cycle that morning. It is over a week early. |
| 1086372 | 3/9/2021 | | 34 | M | 3/9/2021 | 3/9/2021 | Patient entered to observation after receiving the covid vaccine. started to report feeling dizzy and fainted. patient began to keel over, and was escorted by two nurses on the floor. Patient did not hit his head, and no sustain injury on the way down. Patient was placed on supine position with legs elevated. Peep breathing exercises encouraged. Vitals were initiated and recorder. Patient had a syncopal episode, responded to sternal rub. Patient lost consciousness again and once again responded to sternal rub. Vitals were initiated and EMS was activated. Patient vitals were stable with one orthostatic hypotension. Patient reported feeling better and refused to go to the hospital with EMS. Patient was escorted out of building visibly looking better, no pale noted, left site at 1:30 PM. |

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| 1086342 | 3/9/2021 | CA | 27 | F | 3/9/2021 | 3/9/2021 | pt stated to the nurse that she feels like she will pass out. She lost consciousness soon after for about 10-15 seconds. Afterwards, she woke up and was alert and oriented. Vital signs within normal limits. Dr assessed, pt stated she has history of syncope with needle procedures. |
| 1086333 | 3/9/2021 | NJ | 22 | M | 3/9/2021 | 3/9/2021 | Patient fainted after receiving vaccine. Regained consciousness shortly after and began throwing up |
| 1086309 | 3/9/2021 | NV | 31 | F | 3/9/2021 | 3/9/2021 | Patient fainted about 5 minutes after receiving the vaccine. She was in the monitoring area and fell over and hit her head on the ground. I went to her aid and monitored her until the paramedics showed up. She was unconscious for a 10-15 seconds with her eyes open before regaining consciousness. She was not having breathing problems or other symptoms of anaphylaxis so i did not administer an epi-pen or benadryl to her. I rolled her on her side in case she became nauseas. Then the paramedics arrived and attended to her. |
| 1086219 | 3/9/2021 | TX | 28 | F | 3/9/2021 | 3/9/2021 | Patient fainted about 2 minutes after receiving vaccine. She experience nausea, dizziness , and a moment of confusion. Patient stated at pharmacy for 1 hour after episode. She was given water and crackers but refused other medical attention. Patient denied shortness of breath: difficulty breathing. Checked patients blood pressure. It was 144/74. Patient left pharmacy after 1 hour. She called when she make it home. She said she was still a little dizzy and nauseous. She had vomited. I asked patient if she was alone or if someone was there with her. She stated her sister is a nurse and was with her. Will follow up with patient on 3/10/21 |
| 1086201 | 3/9/2021 | GA | 23 | F | 3/9/2021 | 3/9/2021 | patient became lethargic and briefly passed out 1 minute after receiving vaccine. Patient did not have swelling or breathing problems so an epinephrine pen was not needed. Patient became sweaty and had muscle rigidity of her hands and arms. Patient had rapid heart rate and extreme exhaustion. Ambulance was called and patient care was passed off to the EMTs and the hospital. |
| 1086197 | 3/9/2021 | TX | 23 | F | 3/8/2021 | 3/8/2021 | At 10:44am, Fainting, drastic drop in blood pressure, blurred vision, numb hands. That evening, chills and vomiting. |

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| 1086108 | 3/9/2021 | CA | 20 | M | 3/9/2021 | 3/9/2021 | After vaccine was administered patient stated feeling a little dizzy and then patient fainted out of chair and came back to for a few seconds, hten passed out again and came back seconds after. Patient was then transported to the Emergency Room where EKG was done. Diagnosed with Syncope, Vasovagal. |
| 1085699 | 3/9/2021 | NC | 33 | M | 3/5/2021 | 3/13/2021 | Client begin to feel numbness and tingling to right hand and fingers shortly after receiving vaccine. While being assessed by this nurse, client experienced syncope episode for approximately 10 seconds and was immediately alert and oriented to self, person, place and time after syncope episode. Client became clammy and diaphoretic. 911 was called and client was assisted to triage area for further assessment. BP 164/96, HR 74. Client was cleared per EMT, able to walk out of clinic withou assistance and drive self home. |
| 1085581 | 3/9/2021 | CT | 60 | M | 3/9/2021 | 3/9/2021 | Syncope. Did not fully pass out, but felt a wave of tightness, followed by paleness (tech said color drained), followed by lightheadedness. |
| 1086378 | 3/9/2021 | NC | 26 | M | 3/4/2021 | 3/4/2021 | Vision blurring, cold sweat, racing heart rate, flushing and syncope 5 minutes post-injection. EKG showed ventricular arrhythmia which converted to normal sinus rhythm with regaining consciousness approximately 5 minutes later. |
| 1086051 | 3/9/2021 | IL | 51 | F | 3/9/2021 | 3/9/2021 | Patient has a history of fainting after vaccination. Patient told us prior to vaccination. Patient did not pass out but needed to lay down and put her legs on a chair. She was a give a ice pack for her forehead. She recovered after 5 to 10 minutes and reported back to work without any problems. |

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| 1085624 | 3/9/2021 | OH | 84 | F | 3/9/2021 | 3/9/2021 | Patient entered lobby after 1st Moderna vaccine accommodated by daughter for monitoring. This nurse asked patient three times during monitoring if she felt fine. Patient responds yes each time. Once 15 minutes patient was released with daughter and walked to car with walker. At 1410 this nurse was called out to car to assess patient due to n/v. Vitals were obtained T-99.0, B/P 148/96, R-18 regular and at ease, P- 96, O2-96 at room air. Dr. consulted and this nurse was instructed to patient into office to be evaluated by provider. With stand by assist from 3 LPN's patient walked into building with walker. Once entering lobby patient fainted and was assisted slowly to ground with one nurse behind her and one on each side. Patient awoke 30 seconds later. Physician came to scene of accident, vitals were obtained B/P- 140/88, O2-97% at 3 L of oxygen, P-92, no Temp obtained, squad called and in route. On scene approx. 1420 squad arrived. Paramedics took over care at that point. This has been reported to CDC |
| 1085631 | 3/9/2021 | FL | 29 | F | 3/9/2021 | 3/9/2021 | Patient developed syncope after 13 minutes. Patient regained after one second. Patient was able to leave pharmacy on her own. |
| 1085595 | 3/9/2021 | TX | 68 | F | 3/6/2021 | 3/7/2021 | Vasovagal Syncope Sudden drop in blood pressure. occurred day after vaccination 9:00pm Called my cardiologist. Encouraged to monitor and keep them informed reduce blood pressure meds until stable. Discontinue chlorthalidone until BP is stable Blood pressure seems to be stable today (3-9-10). Still slight headache and mild dizzy spells |

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| 1085760 | 3/9/2021 | WI | 82 | F | 3/3/2021 | 3/3/2021 | On the first evening I had a fever and joint pains which resolves by the next morning, On 02/03/2021 I had diarrhea on awakening and about two hours later, after doing morning chores including carrying and lifting 4 gallons of water, I fainted, which included having another episode of diarrhea while I was out. I was seen by emergency medical personnel, had an EKG, and then my children, with whom I live, took me to see my primary care provider who ordered some basic blood tests: a CBC and panel. All blood tests were normal as well as the EKG, I assume. We think the faint was perhaps triggered by the diarrhea and exertion of chores in addition to the vaccine's effect. Since then I have had fatigue. |
| 1085815 | 3/9/2021 | ID | 87 | F | 2/9/2021 | 2/16/2021 | Pt experienced syncope and collapse, was admitted for pericardial effusion without cardiac tamponade. Treated for suspected inflammatory pericardial effusion with colchicine 0.6 mg daily for 3 months, ibuprofen 600 mg 3 times daily for two weeks. Patient was discharged home from hospital in good condition 2 days after admission, scheduled for follow-up with cardiology. Additionally pt was treated for a scalp laceration from collapse with staples to posterior scalp. |
| 1085844 | 3/9/2021 | | 60 | F | 3/9/2021 | 3/9/2021 | Syncope, difficulty focusing- Evaluated by EMS- Transported to Emergency room/department or urgent care. |
| 1085910 | 3/9/2021 | | 21 | F | 3/8/2021 | 3/8/2021 | 4 hours after vaccine I experienced vasovagal (passed out), for the rest of the day after I experienced fever, chills, fatigue, body aches |
| 1085917 | 3/9/2021 | CO | 60 | F | 3/7/2021 | 3/8/2021 | Horrendous headache starting 13 1/2 hrs later. Then nausea, and I passed out. Came to and had extreme chills. After the 24 hr mark, just tired and had to stay in bed. Today 3/9, all good. |

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| 1085923 | 3/9/2021 | | 78 | M | 2/28/2021 | 3/1/2021 | While eating breakfast the next morning after my shot, I got dizzy/light-headed and fainted, falling to the floor. I was "out" for ~2 minutes, according to my MD wife. After 2-3 minutes, I felt fine and went and played tennis 15 Minutes later. I don't think that I have never fainted in my life time. I take no prescriptions for anything. I do still have a sore shoulder from the fall, since I was sitting in a "Bar stool" at a counter at the time of the fall. |

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| 1086027 | 3/9/2021 | | 79 | F | 2/19/2021 | 2/1/2021 | <p>Passed out; Things were going downhill; Dizzy; Injection site was painful; Fatigued; Muscle pain; Joint pain; Nausea without vomiting; Low grade fever; A bit of an ache in injection arm; A spontaneous report was received from a consumer concerning a 79-year-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced the following: things were going downhill, injection site was painful, fatigued, muscle pain, joint pain, nausea without vomiting, low grade fever, dizzy, passed out, and a bit of an ache in her injection arm. The patient's medical history was not provided. No concomitant medications were reported. On 19-Feb-2021, prior to the onset of the events, the patient received their second of two planned doses of mRNA-1273 (lot/batch: 032L20a) intramuscularly for prophylaxis of COVID-19 infection. On 19-Feb-2021, the patient received the vaccine around noon and by the evening she could tell things were going downhill. She went to bed early, and throughout the night the injection site was painful, she was fatigued, she had muscle pain, joint pain, nausea without vomiting, and a low grade fever. The patient got up at night to go to the bathroom and got dizzy and passed out. She said she was passed out for barely a minute and when she came too she laid there for a bit before she went back to bed with her husband's help. All day on Saturday 20-Feb-2021 the patient was in bed but by that evening she was able to get up and walk out of the bedroom. On Sunday night 21-Feb-2021, she was able walk up stairs without huffing and puffing and felt much better. The patient states they have recovered from it all except sometimes when doing yoga, they can feel a bit of an ache in the injection arm. No treatment information was provided. The patient received both scheduled doses of mRNA-1273 prior to the event(s); therefore, action taken with the drug in response to the event(s) is not applicable. The outcome of the events things were going downhill, injection site was painful, fatigued, muscle pain, joint pain, nausea without vomiting, low grade fever, dizzy, and passed out, were considered recovered/resolved. The outcome of the event, ache in injection arm, was unknown.; Reporter's Comments: This case concerns a 79 Y/O F with a serious unexpected event of loss of consciousness along with NS unexpected dizziness, feeling abnormal, pain in extremity, and NS expected fever, fatigue, myalgia,</p> |

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| 1086037 | 3/9/2021 | TX | | M | | 2/26/2021 | arthralgia, nausea, vaccination site pain. Event onset the same day as second dose mRNA-1273. Events resolved except arm pain. Based on current available information and temporal association between use of the product and the start date of the event, a causal relationship cannot be excluded. |
| 1081146 | 3/8/2021 | CT | 77 | F | 2/17/2021 | 2/18/2021 | Passed out for a few minutes; Nausea; 24 hours of fever; A spontaneous report was received from a consumer concerning a male patient of unspecified age, who received Moderna's COVID-19 Vaccine (mRNA-1273). The patient's medical history included immunodeficiency, cancer and gall bladder removal (not specified). Concomitant product use was not provided by the reporter. The patient received their first of two planned doses of mRNA-1273 (Batch number not provided) on an unspecified date. On an unspecified date, prior to the onset of the symptoms, the patient received their second of two planned doses of mRNA-1273 (Batch number not provided) via an unknown route for prophylaxis of COVID-19 infection. The patient had fever for twenty-four hours. On 26 Feb 2021, while on outing with patient's friend's patient had 2 beers. Later patient reported nausea and passed out for few minutes. However, patient drove back to home. Treatment information was not provided. The patient received both scheduled doses of mRNA-1273 prior to the events; therefore, action taken with the drug in response to the events is not applicable. The event, fever was considered recovered/resolved on an unspecified date, and the events passing out and nausea were considered recovered/resolved on 26 Feb 2021.; Reporter's Comments: Very limited information regarding this event/s has been provided at this time. Further information has been requested. |
| | | | | | | | lightheadedness/presyncope, palpitations, racing heart, premature ventricular contractions with bigeminy, atrial tachycardia, fever 101, chills, myalgias, arthralgias, headache, right arm pain |

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| 1081452 | 3/8/2021 | | 62 | M | 3/8/2021 | 3/8/2021 | 64-year-old male with a history of hypertension, melanoma, vasovagal events from previous needles presenting to the emergency department today for vasovagal episode. Patient was across the street receiving his first dose of Covid vaccine. At that time patient had a syncopal episode. According to EMS they indicate that nursing there was unable to feel pulse and began CPR. They did multiple rounds of compressions and patient woke up. They are bringing patient in today for further evaluation of syncope versus cardiac arrest. Patient does endorse that he has chest wall pain from where they were doing compressions. |
| 1081214 | 3/8/2021 | IN | 60 | F | 2/26/2021 | 2/27/2021 | Fever greater than 104° for 24 hours. Syncope for 24 hours following that. |
| 1081276 | 3/8/2021 | MA | 32 | F | 2/23/2021 | 2/23/2021 | Patient neglected to tell the nurse administering COVID vaccine that she has fainted in the past. After getting the vaccine she seemed fine and walked over to the observation area. She suddenly stated she felt dizzy to a companion then collapsed onto the floor striking her forehead. She was unconscious briefly and a little dusky around her mouth. She awakened upon stimulation and was evaluated. Her vital signs were reassuring but a growing hematoma on her forehead prompted ac referral to the ED by ambulance. She was seen there and discharged without imaging. She had some fatigue, headache and vertigo for several days. |
| 1081298 | 3/8/2021 | | 79 | F | 2/28/2021 | 2/28/2021 | The patient had near-syncope and confusion about 2 minutes after receiving a vaccine. She is diabetic and hadn't eaten at all yet and thought it was more of a metabolic derangement. She was sent to the ER. |

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| 1081311 | 3/8/2021 | OR | 38 | F | 2/27/2021 | 2/28/2021 | Patient experienced three episodes of syncope between 1000-1100 on Sunday, 2/28 after receiving the vaccine on Saturday, 2/27 at approximately 1810. Loss of responsiveness ranged from approximately three to twenty seconds. Two of the three episodes were witnessed. Episode one occurred when patient attempted to sit up after waking. Episodes two and three occurred while attempting to change position from sitting to standing. Episodes were preceded by flushing, diaphoresis, graying/blackening vision, and tremulousness. Patient had not experienced syncope prior to these events. Patient recovered at home with increased fluids and rest on Sunday, 2/28 and outpatient infusion of normal saline at a naturopathic clinic on Monday, 3/1. Patient experience no further episodes of syncope as of 3/8 but did have multiple episodes of near-syncope in the week following vaccination. Syncope started at approximately 10 am on Sunday after having received the vaccine on Saturday at approximately 6:10 pm. |
| 1081435 | 3/8/2021 | MO | 52 | F | 3/8/2021 | 3/8/2021 | patient passed out, she was clammy and sweating. She stated that it was the same feeling that ct dye gives. We called the ambulance and the paramedics checked her an her husband out. He was feeling nauseated and lightheaded after she started feeling better. |
| 1081167 | 3/8/2021 | VA | 41 | M | 3/6/2021 | 3/7/2021 | Woke up around 5:30AM having to go to the bathroom. Went to Flush the toilet and passed out on the floor. My wife found me unresponsive but breathing on the floor. My wife called 911 and was at the hospital around 6:15AM. |
| 1081468 | 3/8/2021 | VA | 43 | F | 2/27/2021 | 2/27/2021 | Flushing, palpitations, urticaria on chest, near syncope, chest tightness, BP 170/100 Pulse 130 Resp 18. 1:50 pm 50mg Benedryl po. Pt then felt worse. Transported to ER. |

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| 1081560 | 3/8/2021 | AZ | 44 | F | 12/22/2020 | 1/1/2021 | I stood up from a sitting position after smoking a cigarette and got a headrush that traveled through whole body , and then I fainted for a few seconds. After the first event, I never fainted again but had several headrush like dizzy spells over the next few weeks. These spells would last for 1-2 minutes, originally only occurred after smoking a cigarette, but then began to happen when I would stand from a sitting position when not smoking, and I would need to sit back down until the headrush passed. This reaction occurred periodically up until one week before my second shot (01/23/2021), and I have not experiences it since, not even after my booster shot. I understand it may not be related, however, I have been smoking for 30-years and have never experienced a reaction such as this one before. |
| 1081606 | 3/8/2021 | CT | 60 | F | 3/7/2021 | 3/8/2021 | Site: Pain at Injection Site-Medium, Systemic: Allergic: Difficulty Breathing-Medium, Systemic: Fainting / Unresponsive-Medium |
| 1081739 | 3/8/2021 | | 75 | F | 2/20/2021 | 2/20/2021 | Fainting; Aches; Extreme Nausea; Chills; A spontaneous report was received from a consumer, concerning a 75-year old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced extreme nausea, chills, aches and fainting. The patient's medical history, as provided by the reporter, included COVID-19 infection on last March. Concomitant medications reported included atorvastatin and levothyroxine sodium. On 20Feb2021, approximately 4 hours prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (batch number:015M20A) for prophylaxis of COVID-19 infection. On 20Feb2021, the patient experienced extreme nausea, chills, aches and fainting. Treatment for events included ondansetron and paracetamol. Action taken with mRNA-1273 in response to the events were unknown. The outcome of the events, extreme nausea, chills, aches were considered recovering/resolving. The outcome of the event, fainting, was considered recovered/resolved on an unknown date.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the onset date of the reported events, a causal relationship cannot be excluded. |

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|-----------------|-----------------|--------------|----------------|------------|-----------------|-------------------|---|
| 1081918 | 3/8/2021 | TX | 31 | M | 3/1/2021 | 3/1/2021 | I was called by COVID vaccine observation staff at approximately 11:57AM to respond to patient who was reported to be diaphoretic, pale, and retching 15-20 minutes after having received one dose of Moderna COVID vaccine. Vital signs before my arrival were: 11:55AM BP 97/52 HR 75 Patient states history of diabetes, hypertension, anxiety, panic attacks, and pulmonary embolism and is on Xanax prn, Xarelto, an ace-receptor antagonist and an insulin pump. States consumed about 12oz of water and a pop tart in the morning. Physical assessment: Alert oriented to person, place, time and situation. Gait normal Firm bilateral hand grips Radial pulse 2+ bilaterally EOMS intact and PERRLA Lung sounds clear in all lobes S1 and S2 auscultated. Advised patient to consume 2L of water before leaving clinic. Advised to stay additional 30 minutes for observation with blood pressure to be repeated at 5 minute intervals until blood pressure turns to normal range. 12:05PM BP 162/94 HR 95 12:10PM BP 134/51 HR 100 Gave emergency warnings to go to ER if experiences additional adverse reactions after returning home (shortness of breath, chest pain, etc.) Diagnosis: Vasovagal syncope in response to vaccine |
| 1081921 | 3/8/2021 | FL | 22 | F | 3/6/2021 | 3/6/2021 | Shortly after being given the vaccine the person had an episode of near-syncope where she felt light-headed and was not feeling well. She has had a history of this occurring in the past after an injection before (unknown if vaccination or other IM injection) and blood draws. She did not have any loss of consciousness, but she became pale and diaphoretic and felt like she could pass out if she would stand consistent with a vasovagal event. She initially had an elevated pulse at 113 which came down to 65 and her blood pressure was initially 110/60 and then 98/62 on recheck. Patient was placed supine on a cot and then her legs were elevated to help her symptoms. She did have some improvement in her symptoms prior to transport to the ER via EMS at her request. |
| 1081014 | 3/8/2021 | WI | 40 | F | 3/5/2021 | 3/5/2021 | Near syncope (multiple events); vomiting (multiple events); chills; headache Onset approx. 12 hours following vaccine. Rapid onset with little to no warning, lasting approx. 2-3 hours. |

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| 1080372 | 3/8/2021 | MA | 42 | F | 2/7/2021 | 2/7/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Tingling (specify: facial area, extremities)-Medium, Systemic: Vomiting-Severe, Additional Details: Approximately 5 minutes after administration of moderna vaccine, pt reported feeling hot to observer. RN came out to check pt and pt then rolled eyes to left and back and passed out in chair. RN helped pt to sit upright in chair as was about to fall off chair. After 10 seconds patient able to talk with patient. She stated she still felt tingling in arms but cooling down. Had additional tingling/warm and vomiting episode. Paramedics called. Pt refused transport, parent going to drive to ER. |

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| 1081746 | 3/8/2021 | OH | 70 | F | 2/12/2021 | 2/12/2021 | <p>began to pass out; because every time I tried to lift my head, I would start blacking out again; dizzy; diaphoresis; fell against the wall; violent high abdominal pain; n having multiple, large formed bowel movements; shaking; chills; nausea; fatigue; This is a spontaneous report from a contactable consumer. This 70-year-old female consumer (patient) received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, lot number EM9809) , via an unspecified route of administration on 12Feb2021 at 09:45 (at the age of 70years old) at single dose for covid-19 immunisation. Medical history included hypersensitive to latex, allergies to levaquin, ddavp, CT scan dye, codeine, fentanyl, primary immune deficiency, myasthenia gravis, Sjogren's, autonomic neuropathy, myelodysplastic syndrome, von Willebrand's, Barrett's esophagus on unknown date and unknown if ongoing and received Pfizer Covid vaccine (dose 1, Lot: EL9261) on 22Jan2021 at 2:45am on left arm. Prior to the vaccination, the patient was not diagnosed with COVID-19. Relevant concomitant medication was not provided. At approximately 9:50 AM on 12Feb2021, the patient received second Pfizer Covid-19 vaccine in left arm at Administration facility. The patient waited the 15 minutes post injection. At approximately 10:19AM, the patient left site & drove to her home without issues. At home approximately at 11:20am, she had violent high abdominal pain like she never had before. she proceeded to the commode and began having multiple, large formed bowel movements then began to pass out. She began to have diaphoresis and violent shaking and chills. She had passed out on commode and fell against the wall. She later managed to pull pants up and crawl with head hanging down stated that because every time she tried to lift her head, she would start blacking out again. This continued until after approximately 20 minutes. She managed to pull herself up to the couch and raise legs high above heart and head and let head hang off couch to restore blood pressure. The patient mentioned that shot triggered something with her autonomic nervous system. On 22Feb2021, she was still with nausea, fatigue and dizziness. The outcome of events was not recovered. No treatment was received for events. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Since the vaccination, the patient had not been tested for COVID-</p> |

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| 1080526 | 3/8/2021 | OH | 35 | F | 2/8/2021 | 2/25/2021 | Initially tasted metal, numb mouth, flushing, later resulting in all flu like symptoms (severe chilling, fever, body aches, headaches and GI issues.) GI issues persisted for the next 3 weeks and on Thursday evening, 2/25/2021 at about 6:30 pm. I was sitting on floor with children and almost passed out. I felt very faint, dizzy, and instantly started chilling. I had a fever of 102.8 and could not get warm. My husband was going to call paramedics, but I encouraged him not to. Discovered my right breast was red and inflamed/ swollen as well as all of my lymph nodes in my right arm pit. I could not reach my right arm forward. I noticed around 12:06 AM after not being able to get warm or break fever. I messaged my primary care clinic when I noticed the breast swelling, redness, pain, and lymph node swelling. I continually felt like I was going to faint/pass out and was very dizzy all night long. I was also extremely fatigued. The did a telemedicine appointment the next morning and diagnosed me with mastitis and prescribed me antibiotics. I am a breastfeeding mother and all of these symptoms came on suddenly and severely on the same side that I got the vaccine shot. I have been breastfeeding for over 7 months and my supply has been dwindling to nothing so I have no problems with engorgement or blocked milk ducts. Before this baby I had just got done breastfeeding a baby for 11 months with no issues of the like. |

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| 1082870 | 3/8/2021 | NC | 68 | F | 1/25/2021 | 1/25/2021 | <p>Allergic reaction; Tongue felt full; Did not feel well; Puffiness; Trouble swallowing; rash; Swollen glands; Blood pressure high/ changes in blood pressure; Felt faintness; Feeling hot; Fluid accumulation; Turned a dark, pinkish color/ flushed; Changes in heart rate/ heart was racing; A spontaneous report was received from a health care professional concerning a 68-years-old, female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced allergic reaction/ hypersensitivity, feeling hot, fluid retention, flushing, presyncope, heart rate abnormal, swelling face, tongue felt full/ swollen tongue, hypertension, dysphagia, not feeling well/ malaise, rash, and lymphadenopathy. The patient's medical history, as provided by the reporter, included anaphylaxis to Keflex, lisinopril and sulfa drugs. Concomitant medications reported included HCTZ, diltiazem, rosuvastatin, isosorbide mono, metoprolol and pepcid. On 25 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: unknown) intramuscularly for prophylaxis of COVID-19 infection. On the same day patient experienced allergic reactions, feeling hot, fluid retention, flushing, presyncope, high blood pressure, swollen glands. On 26 Jan 2021, the patient was taken into the hospital and kept there for 6 hours. On 29 Jan 2021, the patient still had faintness. Her heart was racing and she did not feel well. On 04 Feb 2021, her tongue felt full and something did not feel right. The patient's vital signs included blood pressure 190/98 and later 140/80. Treatment details included Benadryl, EpiPen, Ativan, Solumedrol, steroids, and Tylenol. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events, feeling hot, fluid retention, lymphadenopathy, and rash were considered recovered/resolved on an unknown date. The outcome of the events, flushing, and presyncope, was considered not recovered/not resolved. The outcome of the events, allergic reaction, hypertension, heart rate abnormal, swelling face, swollen tongue, malaise, and dysphagia, was not provided.; Reporter's Comments: This case concerns a 68 Y/O F who had serious unexpected hypersensitivity along with unexpected BP high, heart rate abnormal, presyncope, dysphagia, face swelling, swollen tongue, flushing, feeling hot, malaise, fluid retention, and expected rash,</p> |

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| | | | | | | | lymphadenopathy. Event onset the same day as first dose mRNA-1273. Treated with Benadryl, EpiPen, steroids. Based on current available information and temporal association between use of the product and the start date of the event, a causal relationship cannot be excluded. |
| 1080297 | 3/8/2021 | | 48 | M | 2/26/2021 | 2/27/2021 | Got up to use bathroom in middle of night, got lightheaded and fainted. Wife woke me up and I was on floor of bathroom. Not sure how long. Went to bed with racing heart, cold sweats. Symptoms subsided after about 30 minutes in bed. Went back to sleep. Woke up sore all over body, rash on torso. Sore and tired all day. Symptoms persisted for about 36 hours. |
| 1080378 | 3/8/2021 | VA | 61 | F | 3/7/2021 | 3/8/2021 | Work up at 12:30 a.m. very hot and nauseous. When I tried to stand up I fainted. When I came to I crawled to the bathroom and vomited several times. Continued to run fever for about an hour or so. Then headache began. As of 7:00 I still feel nauseous and have a slight headache. |
| 1080383 | 3/8/2021 | CA | 23 | F | 3/7/2021 | 3/7/2021 | Site: Redness at Injection Site-Mild, Site: Swelling at Injection Site-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Headache-Mild, Systemic: Nausea-Mild |
| 1080385 | 3/8/2021 | CA | 23 | F | 3/7/2021 | 3/7/2021 | Site: Pain at Injection Site-Mild, Systemic: Fainting / Unresponsive-Medium, Additional Details: PARAMEDIC TOOK THE PATIENT |
| 1080396 | 3/8/2021 | MA | 30 | F | 3/6/2021 | 3/6/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe |
| 1080382 | 3/8/2021 | MA | 19 | F | 3/7/2021 | 3/7/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Visual Changes/Disturbances-Mild, Additional Details: Patient fainted from seated position. Hit left side of head from this distance. Patient regained consciousness within a few moments and legs were elevated while laying on back. Reported vision tunneling occurred before fainting (once she came to). Patient was pale but regained color 15+ minutes later. Patient answered all questions 2 paramedic crews had/checked her BP/O2 sats etc. Declined hospital and signed off with father present who was called in. Father drove her home. |

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| 1080483 | 3/8/2021 | MI | 49 | F | 3/4/2021 | 3/5/2021 | <p>Pt came to ED on 3/6/21 with allergic reaction symptoms (diaphoresis, facial swelling, nausea, vomiting, urticarial rash, tachycardia) due to 2nd dose of Moderna COVID-19 vaccination. This Moderna COVID-19 vaccine 2nd dose was received on 3/4/21 at Health Dept (Lot# 030A21A). On 3/6/21, "a 49y/o F with a past medical history of migraines and hypothyroidism who presents to the emergency department for syncope. Patient states she believes she is having an allergic reaction to the moderna COVID-19 vaccine. She received the vaccine two days ago and last night began to notice a few hives on her body. This morning she woke up with more hives diffusely throughout the body and swelling to the face and lips. She presented to urgent care for this and while at the urgent care, she began to feel lightheaded, nauseated and had a syncopal episode while sitting in the chair. She denies hitting her head. After she woke up, she vomited after. Her mother states she was diaphoretic and pale during this episode. She was given benadryl and solumedrol at the urgent care. Paramedic was called and patient was brought in for evaluation of the syncopal episode. Patient denies any chest pain or difficulty breathing. She denies any throat swelling. She has had some diarrhea with this. No abdominal pain. She denies recent fevers or chills. She denies prior cardiac hx. No significant family history. Non-smoker. Labs are notable for mildly elevated liver enzymes. D-dimer is elevated so CTA chest was obtained and is negative for PE. Patient was given solumedrol and benadryl prior to arrival. Symptoms improved during ED stay. No uvular swelling or oral involvement. Airway is patent. Patient advised to follow up with her PCP for re-evaluation and repeat labs. Rx for prednisone and pepcid. Continue benadryl." Pt was given NS 1000 mL IV x1, diphenhydramine 25 mg IV x1, and famotidine 20 mg IV x1 while in SCH ED. Pt did already received diphenhydramine and methylprednisolone at the Urgent Care. Allergy added to patient chart for Covid-19 MRNA vaccine. Then, on 3/7/21, patient did return to ED with continuing reaction (new upper lip swelling). Dr noted: "Presentation c/w allergic reaction to Moderna vaccine. New upper lip swelling, but lower lip swelling and urticaria have resolved. No airway compromise or acute bronchospasm. Discussed option of switching from Benadryl to Zyrtec, if overly sedating. Continue</p> |

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| | | | | | | | Prednisone. Consider Pepcid twice daily. Discussed angioedema, with possibility of improvement without repeated exposure. Dose of Pepcid given in ED. Comfortable with plan to release.~~ |
| 1080770 | 3/8/2021 | WI | 52 | F | 3/5/2021 | 3/5/2021 | Within minutes after vaccine, became dizzy, shaky, stated felt nasal congestion, reported she has blood pressure, then passed out. Called for Paramedics and assisted to floor, elevated legs, monitored symptoms, no swelling noted, continued to breathe normally throughout with 100% oxygenation and came back to consciousness within a minute. Paramedics responded. Stable, pt agreed to be transported to local ER for further evaluation. |
| 1080592 | 3/8/2021 | NY | 26 | F | 3/5/2021 | 3/5/2021 | Patient fainted 2 minutes after receiving the Pfizer vaccine and had 10 second witnessed seizure. |
| 1080710 | 3/8/2021 | TX | 29 | F | 2/12/2021 | 3/4/2021 | Syncope episode with convulsions Underwent cardiovascular and brain scanning and imaging Treated with Keppra x 3 days Determined to be a non-seizure event |
| 1080756 | 3/8/2021 | | 40 | M | 3/1/2021 | 3/4/2021 | Loss of consciousness Client was said to have passed out while sitting at the waiting area about 5 minutes after vaccination. He was brought to the First Aid area on a wheelchair. Client was noted to having urinary incontinence immediately he arrived at the First Aid area. His head was repositioned and ice pack applied to his forehead and client recuperated and started talking. Duration of witnessed episode lasted for 15 seconds . Patient claimed having similar episodes with last episode occurring 6 years ago while at work. Vital signs was taken, monitored for additional 30 minutes and was driven home by his significant other. Vital signs recorded Temp: 96.9deg. F; BP: 102/62 MAP: 76; H.Rate: 78; Oxygen sat: 97%. (Vasovagal syncope). Neurologic: Loss of consciousness (Comment: Patient had Vasovagal reaction with patient having urinary incontinence, lasting for 15 seconds 5 minutes after vaccination. Patient claimed having similar episodes 6 years ago.) |

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| 1080759 | 3/8/2021 | NY | 67 | F | 3/7/2021 | 3/7/2021 | About ten minutes after the shot, my heart suddenly started pounding, I was panting, and I got very hot. Then tingling went all over my body, even in my lips. At one point, I felt close to fainting. The pharmacist lady gave me cold water (I asked for it), and I just sat there for quite a while. Gradually my heart rate came down, and I got cold, but the tingling kept going, and I felt somewhat weak. Since I didn't want any epinephrine (it affects my heart), and I didn't think I was so bad that I needed an ambulance, after being there nearly an hour my husband drove me home. There I took some liquid Benadryl, and that seemed to help with the tingling. I just took it easy after that. Considering my reaction to the first dose, I will NOT be getting the second one. I don't need to consult with a doctor to decide that. It was somewhat frightening because I didn't know how bad it was going to get. |
| 1080763 | 3/8/2021 | KY | 73 | F | 3/2/2021 | 3/2/2021 | Pt developed vomiting, syncope, urinary incontinence the evening of 3-2-21 at 9:00pm. She continued to vomit through the night and had 1 syncope episode when trying to get up. on the morning of 3-3-21, pt was ambulating with assistance to the restroom and had a syncope episode, confusion and fell and hit her head on a chair. 911 was called and pt was transported to ER, pt was found to be dehydrated and had elevated blood sugar (< 300) per daughter.) admitted overnight for observation. |
| 1081948 | 3/8/2021 | NY | 20 | F | 3/8/2021 | 3/8/2021 | Pt states after receiving the vaccine she started feeling faint. Pt fainted and fell from a standing position. Pt was unconscious for approx. 30 seconds. Pt was seated in a wheelchair and moved to the observation area. Pt denies any head, neck, or back pain. Pt states she is feeling better and would like to leave. Pt didn't require transport to the hospital. |
| 1080459 | 3/8/2021 | NJ | 44 | F | 3/6/2021 | 3/6/2021 | At 11pm I started feeling chills and was having cold sweats. Around 1 am I went to the next room to check my temperature and almost fainted. I sat on the floor and started vomiting. I kept gagging nonstop for several minutes. During that time I urinated on myself, I felt strong stomach aches, headache, and my body felt extremely fatigued. I was dizzy and sweating. All these symptoms came back again a few minutes later. I do not remember how long everything lasted. I woke up the next day with a slightly upset stomach and headache. |

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| 1083346 | 3/8/2021 | UT | 45 | F | 3/4/2021 | 3/4/2021 | Became flushed , rapid HR, nausea and syncope. Employee taken to ED where she was stable and received IV fluids and Zofran, monitored and discharged to home. |
| 1082989 | 3/8/2021 | TX | 53 | M | 3/8/2021 | 3/8/2021 | Reports he fainted for few minutes. History of same symptom to injection or venipuncture Refused to go to ER, refusal form signed |
| 1082997 | 3/8/2021 | KY | 66 | M | 3/8/2021 | 3/8/2021 | Approximately ten minutes following vaccination patient decided to check his blood pressure at the automated machine because he didn't feel well. Patient passed out sitting at the machine and lost control of his bladder. Patient's eyes were open and he was making snoring noises. Upon checking pulse, it was faint. Patient was breathing. Team moved patient to lying position on the floor. Pulse became more prominent and patient woke up. EMS arrived and took patient to local hospital for precautionary testing. Patient discharge home 2 hours later. |
| 1083071 | 3/8/2021 | ID | 19 | F | 3/8/2021 | 3/8/2021 | Patient received the Janssen Vaccine Covid-19 injection and immediately afterwards asked for a trash can. She immediately passed out and fell forward. She hit her head on the wall and received a cut. We called the paramedics and she was transported to the emergency room at the local hospital. |
| 1083182 | 3/8/2021 | GA | 28 | F | 3/8/2021 | 3/8/2021 | patient stated she was fine after vaccine, then after a few minutes she stated she felt dizzy. before pharmacist could get back around counter to patient, she fainted and slid out of her chair. patient was alert moments after landing on the floor. patient was laid out on floor and vitals monitored. once vitals returned to normal and patient felt better, she was given water and a banana. EMT arrived and evaluated patient. patient was taken to hospital per EMT suggestion. time frame: 17:26-17:52 |
| 1083234 | 3/8/2021 | NC | 23 | F | 1/14/2021 | 1/14/2021 | pt felt dizzy and almost passed out and couldnt walk bp went up felt like something was sitting on my chest passed out and coworkers called 911 she could hear them talk but couldnt respond nausea |
| 1082822 | 3/8/2021 | NC | 31 | F | 3/6/2021 | 3/6/2021 | Severe cold and shivering. Severe light-headedness, fainted, body aches, headache |

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| 1083341 | 3/8/2021 | CT | 46 | M | 3/6/2021 | 3/6/2021 | Vasovagal Syncope - seated talking immediately after vaccine. Suddenly stopped and fell off chair onto gym floor. Regained consciousness after 30 - 60 seconds and was light headed and was diaphoretic. No SOB, swelling, itching, hives, difficulty speaking or swallowing, hoarse voice, palpitations, CP, headache. AO x 3. No hives or rash. Ambulance called but patient declined export. Driven home by a friend. Advised to call 911 if further symptoms. |
| 1083200 | 3/8/2021 | WI | 75 | M | 3/8/2021 | 3/8/2021 | patient waited the 15 minutes sitting on a chair. He got up to make a second appt and passed out when he was being helped. He fell and there was a loud thump. When I ran out he was laying on his back and his eyes were open and looked glazed over. He started talking as soon as I addressed him. We called 911 because I was concerned of a head injury. We elevated his feet and had him wait until help came. He was able to get up and walk out with the policeman and had the paramedics look at him. I don't believe he went with them to the hospital. |
| 1083364 | 3/8/2021 | FL | 19 | F | 3/8/2021 | 3/8/2021 | Patient felt dizzy and clammy just after receiving injection. Patient was very nervous about receiving shot. Conditioning started getting worse with chills and almost fainting. Called 911 and patient was taken to ER along with her mother for treatment. Patient was alert and talking at all times. Followed up with later in the day and she indicated doctor treated patient and released from unspecified hospital. Mother said patient is doing fine. |
| 1083405 | 3/8/2021 | NC | 29 | M | 3/8/2021 | 3/8/2021 | Patient received his vaccine while sitting down at 5:50 pm, when he got up to move to waiting area he passed out and hit his head against the floor. We called 911, he woke and we had him just sit in room until they arrived. They arrived and took him out on the Guenery. |
| 1083449 | 3/8/2021 | MD | 52 | F | 3/1/2021 | 3/1/2021 | First and second day severe injection site pain. Third day heart ache. On the forth and fifth day severe diarrhea, vomiting, fainting, headache, body ache, joint pain, exhaustion. After that only body and joint ache and fatigue. |

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| 1083512 | 3/8/2021 | NY | 71 | F | 2/23/2021 | 2/23/2021 | For 2 days after vaccine occasionally felt dizzy with fluttering heart. On and off. Then subsided A week after got hot flashes. Then subsided During the second week I had an episode when I felt like fainting, Throughout the week I am increasingly tired to a level of total exhaustion and bewilderment. I have extreme reservations about taking the second shot as I never felt so extremely exhausted |
| 1083540 | 3/8/2021 | MD | 57 | F | 3/6/2021 | 3/7/2021 | Feels fatigue and like she's about to have a panic attack before fainting....has happened twice and had convulsions once. |
| 1081998 | 3/8/2021 | MO | 50 | F | 3/7/2021 | 3/8/2021 | Fainting, nausea, weakness, dizziness, headache, and chills |
| 1083314 | 3/8/2021 | CT | 50 | F | 3/6/2021 | 3/6/2021 | Vaso Vagal Syncope. Felt warm and dizzy. Previous episodes after vaccines, blood draws, family events. No itching, hives, SOB, tongue or mouth swelling, palpitations. Supine on floor for several minutes and symptoms resolved. Walked around with no return of symptoms. Released to go home. Advised to seek treatment if symptoms return. Lungs CTAB, no hives. BP WNL after resting. |
| 1082260 | 3/8/2021 | NH | 57 | F | 3/6/2021 | 3/6/2021 | Passed out within 10 minutes of getting the shot Went into a seizure An EpiPen was administered within a few minutes Transported to the hospital via ambulance and monitored at the hospital for about an hour after that. |
| 1082014 | 3/8/2021 | MN | 31 | F | 3/5/2021 | 3/6/2021 | Mild headache and nausea set in shortly after the injection on Friday, but went away after rest and eating/drinking. My arm was sore for the entire evening. I woke up around 2am Saturday morning and became dizzy. I fell to the floor and passed out for a short period of time. When I woke, I was extremely nauseous to the point of nearly vomiting. I had chills and fever. I could hardly move due to weakness - I needed help getting back into bed. When I woke the next morning, I had 100.3 fever, I had a headache and my entire body was sore. My fever went away late Saturday afternoon, but I still felt mildly nauseous. It is Monday and I still have mild nausea and light-headedness. My arm is only slightly sore. |

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| 1083287 | 3/8/2021 | VA | 51 | F | 2/23/2021 | 2/24/2021 | I felt fine after the vaccine. That night, I had a sore injection site, but no other symptoms. I woke up at 1:15 a.m., felt okay, walked to the bathroom, and suddenly felt extremely nauseous and thought I might vomit. After walking a few steps, I fainted unexpectedly and got a concussion from the fall. Note: I had hit my head earlier that day on something while standing up, but that had not caused any symptoms. |
| 1082164 | 3/8/2021 | NM | 75 | F | 3/8/2021 | 3/8/2021 | Patient started to experience dizziness almost immediately after receiving immunization. She did eventually experience syncope after being put into a reclining position. |
| 1082809 | 3/8/2021 | TX | 32 | F | 3/8/2021 | 3/8/2021 | Client seated in observation Client lost consciousness (passed out) and fell out of her chair Client fell onto the floor on the left side hitting the side of her head (left temple area) Witness nearby reports the client had a seizure first prior to falling out of the chair Seizure activity was not witnessed by the nurse Client was assisted into a wheelchair and evaluated further in a private area by EMT EMT was present. EMT assessed client and vitals were taken at 9:36 : O Sat 99%, Pulse 53, BP 112/56 Client was able to report that she felt flushed and hot. Client is visibly sweating Client states that she felt like her heart was racing and that she was dizzy Client reports that she has no history of seizures. Client was offered water Nurse called for an ambulance (EMS) and spoke with dispatch Client drove herself and has no one with her The client?s status given included details regarding client?s vehicle Client voiced concern about the cost of an ambulance but decides that she would like to be taken to hospital which is in network with her insurance At 9:43 Client reports that she feels ?heat inside her head? and is feeling very dizzy A 9:46 EMS arrives on site At 9:49 Client was transported via stretcher |
| 1082289 | 3/8/2021 | PA | 30 | M | 3/6/2021 | 3/6/2021 | Minor syncope without head trauma: pt slumped in chair and the chief pharmacist (myself) was alerted. Pt was assisted to another room and laid on the floor until symptoms passed (roughly 15 minutes). Pt was monitored for an additional 30 minutes before leaving the vaccination site. |

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| 1082318 | 3/8/2021 | NJ | 77 | F | 3/5/2021 | 3/5/2021 | <p>IMMUNIZATION CLINIC NOTES: 77 y.o. female presented to Elementary School for second dose of COVID-19 vaccine. No known allergies. Patient reports history of hypertension, being treated with amlodipine. No history of asthma, COPD, use of inhaler for any conditions, or recent respiratory illness. Patient is a non-smoker. First dose of vaccine, Lot # 039K20A, administered on 2/6/2021 and patient reported no immediate symptoms during observation period after first dose. Second dose of vaccine, Lot# 013A21A, was administered on 3/5/2021 at 10:52AM to the left deltoid. Approximately 5 minutes after receiving second dose, patient reported feeling anxious and feeling like her blood pressure was increasing. Patient taken to EMS observation area. Patient observed by EMS. Nurse assessed patient at 11:23AM. Patient was alert and oriented x 4. Manual blood pressure was 196/86. Pulse, manually palpated, was 86 and strong. SpO2 99% on room air. Patient with flushing. No generalized hives. No itching. No swelling of face, lips, or eyes. Left deltoid injection site without erythema or swelling. Skin warm and dry. Lungs auscultated and inspiratory wheeze noted in all lung fields. No shortness of breath. No cough. No nasal congestion. No change in voice. No sensation of throat closing. No stridor. No dizziness or syncope. No GI symptoms. Patient experiencing skin and respiratory symptoms. RN was asked to assess patient's respiratory symptoms and also noted bilateral wheeze. Patient's symptoms post-vaccination involved more than one body system, skin and respiratory. Reviewed symptoms and standing order procedures with patient. Standing order for Medical Management of Vaccine Reactions in Adults in a Community Setting was followed. Patient was assisted to stretcher by EMS. 0.3mg epinephrine auto injector, Lot # G191202X Exp. 4/2021, was administered to the right outer thigh on 3/5/2021 at 11:39AM by RN. Patient was then transported by EMS to Medical Center. EMERGENCY DEPARTMENT COURSE AND TREATMENT NOTE: Patient's condition remained stable during Emergency Department evaluation. Decision made to obtain prior medical records. (+)Prior records reviewed. There is low suspicion for an allergic reaction given symptoms. Patient is well appearing with a normal exam. Plan to monitor. 03/05/2021 13:13 Patient remains well appearing will discharge home.</p> |

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| 1082421 | 3/8/2021 | NJ | 20 | F | 3/5/2021 | 3/5/2021 | Adverse event: Vasovagal syncope , nausea 2 minutes after injection , treatment - supine leg elevation -- ice - water , outcome : patient felt better after 15 minutes , left pharmacy observation after 30 minutes after injection |
| 1082496 | 3/8/2021 | NJ | 46 | F | 3/6/2021 | 3/6/2021 | Adverse Event: Vasovagal syncope 2- 3 minutes after injection , treatment: supine , legs raise, ice back of head , water Outcomes: after 911 evaluation by EMT patient left the pharmacy |
| 1082620 | 3/8/2021 | NJ | 58 | F | 3/5/2021 | 3/5/2021 | During the post-vaccination observation period, vaccine recipient complained of vertigo and some mid-sternal chest pain. They were seen by EMS and the cardiac monitor showed abnormal rhythm. They were transported to emergency department Medical Center. They reported chest pressure and near syncope. During reexamination, there was no chest pain or palpitations. They were discharged to home. Registered 03/05/2021 11:37 AM, Discharged 03/05/2021 4:38 PM. |

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| 1082635 | 3/8/2021 | NJ | 57 | M | 3/7/2021 | 3/7/2021 | Patient received his first Moderna covid vaccine shot at about 4:00pm on 3/7/2021 and proceedd to the post-vaccination observation area for his 15 minute observation period. About 10 minutes after his shot, patient alerted the an observation staff member that he was starting to feel hot. Staff member alert the pharmacist who had given him his shot and the pharmacist came over. Patient told the pharmacist he feels like he is burning up. Pharmacist took hi temperature an it in the 98 rang (can't remember the exact temp but was 98. something) Patient then then told the pharmacist that he feels like he is getting an aura of a coming seizure. The pharmacist applied an intant ice pack to the back of the patient neck and provided a bottle of cold water. Pharmacist stayed next to him talking to him and asking how he was doing and kept a hand on him in case he had a full blown seizure. Patient was awake but looked pale and seemed like he was going to faint. Stayed like that for about 10 minutes. after about 10 minutes patient "came back". He looked back to normal and felt fine. During the process he called his wife to come get him and he was fine when she aroungs a few minutes later. Patient, wife, and pharmacist chatted for about 15 minutes before wife took him home. Patient said based on his history that it was a petit mal seizure. |
| 1082642 | 3/8/2021 | NC | 20 | F | 3/5/2021 | 3/5/2021 | Syncope or seizure 10 hours after vaccine, preceded about about 1 hour of aches, chills, and feverish feeling. Resulted in fall to floor, hitting head and injuring shoulder. EMTs reported hypertension, tachycardia, trembling, some EKG abnormality, and low-grade fever. Transported to emergency room where CT scan, CBC, and additional labs and monitoring were performed. Released when scans and labs were normal (after monitoring.) |

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| 1082656 | 3/8/2021 | CA | 56 | F | 3/3/2021 | 3/4/2021 | Moderna COVID-19 Vaccine EUA In the midnight of my 2nd shot, my whole body felt freezing cold, and I was trembling, teeth were clinching, I almost passed out. I could not take shower. I turned on all heaters and 3 heat pads in my bed, and I put 4 comforters on top of me, wearing my down coat in my bed, and tried to sleep. I was afraid to not able to wake up in the morning if I fall into sleep, so I made myself wake up every 15-20 min, to get up and drink hot water. I woke up about 25 times in the whole night to go to the bathroom to pee and flush out medicine, and I kept drinking hot water each time. In the morning, I started to feel better. That is said, I also felt right head a kind of pain , it is around my ears, I say. It lasted about 5 days including today, still felt a little bit, but a lot of better than before. |
| 1082675 | 3/8/2021 | | 70 | F | 2/12/2021 | 2/18/2021 | Patient received first Pfizer COVID-19 vaccine on 1/20/2021 and second dose on 2/12/2021. Patient had minor symptoms such as body aches with both vaccine doses which resolved. Patient then stated she started to experience headache, nausea, and body aches, decreased oral intake, and chill starting on 2/18/2021. On 2/20/2021 patient had several loss of consciousness episodes. Patient presented to the Emergency Department on 2/21/2021 with a chief complaint of syncope, nausea, and vomiting and subsequently admitted to the hospital for potential sepsis, syncope, hyponatremia, dehydration, lactic acidosis. (Continued on second page) |
| 1082702 | 3/8/2021 | NY | 26 | F | 3/7/2021 | 3/8/2021 | I am feeling extremely dizzy, any time I move my head the room spins and my ears get hot. I feel achy all over my body and very very cold. As the day has gone on the dizziness has gotten worse. At times it feels like I?m going to faint. (I haven?t yet fainted) I have not tried any treatment yet hoping it doesn?t last longer then today. |

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| 1082585 | 3/8/2021 | ID | 40 | F | 1/29/2021 | 1/29/2021 | Lightheaded following COVID -19 vaccine. Injection at 12:15 pm Vital Signs: B/P: 142/82 HR: 71 Resp.: 16 O2Sat: 95% Skin Signs: Warm and dry Circulation: Cap refill <2sec Resp.: Breath Sounds Clear Bilaterally Treatment: Pt assisted to cot. Requested to remain in sitting position. C/O dizziness and vertigo with head movements. Denies nausea , No flushing, skin p/w/d. Repeat Assessment: 12:45 pm Vitals: B/P: 132/82 HR: 74 Resp.: 16 O2Sat: 98% Skin Signs: Warm and dry Circulation: Cap refill <2sec Respiratory: Breath sounds bilaterally Treatment: Remains in seated position- Offered fluids- refused. Repeat Assessment: 13:02 pm Vital Signs: B/P: 122/88 HR: 73 Resp.: 16 Skin signs: Warn and dry Circulation: Cap refill <2sec Resp.: Breath Sounds clear bilaterally Treatment: Lightheaded, states "easier to focus eyes." No syncope, No increased light or vertigo with movement of head. 13:20 pm Pt released via wheelchair to vehicle to home with a friend. ALOx3, skin p/w/d. No further c/o dizziness . F/U Call: 2/4/2021 Fine after returning home. Woke up in the middle of night fell in BR x2 (no head injury) sweating, fevers, syncope, weakness, vertigo "spinning" disoriented felt delirious with 2nd fall in BR. Extremely nauseated. |
| 1082022 | 3/8/2021 | UT | 18 | M | 3/8/2021 | 3/8/2021 | About 3 minutes after patient received immunization, he fainted and had a seizure. Patient was with his parents and he told them he felt like he was going to faint, so his parents stabilized him before it happened. Patient seized for about 10 seconds and then came to alertness. He was made comfortable and given juice and a granola bar after a while because patient had not yet eaten this morning. I monitored patient for about 45 minutes before I felt patient was stable and feeling well enough to leave. Patient left with his parents monitoring him. |
| 1078758 | 3/7/2021 | IN | 54 | M | 3/6/2021 | 3/7/2021 | Felt nauseous when trying to urinate, then was sweaty, fainted and fell. |
| 1079086 | 3/7/2021 | NY | 68 | F | 3/6/2021 | 3/7/2021 | Very very sick with stomach ache, nausea, diarrhea-- but most important nearly fainting at more than one moment-- having to choose between finishing going to the bathroom & lying down SO I WOULDN'T FAINT!! |

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| 1079026 | 3/7/2021 | VA | 64 | F | 3/4/2021 | 3/4/2021 | swollen gland armpit night of 2nd vaccine, fatigue next day, chills and hot flashes evening, while sleeping tried? to get to bathroom directly connected to bedroom to splash cold water on face, couldn't locate faucet or light switch, woke up on the floor. I know I passed out as I have bruise on butt where I hit the night table. Do not know if I was dreaming, then tried to get up or I had fallen while getting up. |
| 1078992 | 3/7/2021 | WI | 24 | M | 3/7/2021 | 3/7/2021 | VAR form was reviewed with patient prior to vaccinating. It was noted that he has a history of syncopal episodes with vaccines. Patient was advised to sit for 15 minutes after receiving the vaccine so we could observe him. After receiving the vaccine, patient was escorted to observation chair. Immunizer advised registration technician that patient had a history of fainting, so to keep a watchful eye on him. Patient said I need to get some ice and stood up before we were able to advise him to sit and we would assist him. Upon standing, patient had syncopal episode. Patient did not have loss of consciousness and denied any injury from the fall. Patient was assisted back to the observation chair and monitored for the next 15 minutes. |
| 1078983 | 3/7/2021 | | 35 | F | 3/6/2021 | 3/6/2021 | Pounding headache about 10-11 hours after vaccine administration. Took 1000mg Tylenol Extra Strength which did not help. Chills about 12-13 hours after vaccine administration, lasting several hours. High fever (102.8) about 17 hours after vaccine administration (took additional 1000mg Tylenol at 2am) and fever was gone by 8am. Muscle/shoulder extreme tightness on right side (same arm receiving vaccine). Dizzy & light-headed 24 hours after vaccine administration (almost passed out). Headache remains 12+ hours since it began despite the multiple doses of Tylenol described. |

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| 1078938 | 3/7/2021 | MD | 58 | F | 3/1/2021 | 3/2/2021 | Approximately 12 hours after injection, I woke up during the night and had a weird feeling like restless leg syndrome and felt nauseous. I got up to go to the bathroom and passed out. My husband helped me to the bed and got me some orange juice. I then experienced extreme uncontrollable shaking for about 10 minutes. The next day, I had a sore arm where the vaccine was administered. I have only had one flu vaccine in my whole life. I am not allergic to anything that I know about. I have had problems with passing out and have been diagnosed with vasovagal syncope. However, I have not passed out in over 10 years. |
| 1078781 | 3/7/2021 | CA | 27 | F | 3/6/2021 | 3/6/2021 | Site: Bruising at Injection Site-Mild, Systemic: Fainting / Unresponsive-Medium, Additional Details: Patient informed Rph that she always faint.Was called after 10minutes .Rph laid her on carpet .Patient woke up. Called 911. |
| 1078775 | 3/7/2021 | MA | 37 | F | 3/6/2021 | 3/6/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Additional Details: Patient fainted a few minutes after injection. Felt hot then tried to get up and fell to the ground. She was not injured. EMS was called and evaluated her. No signs of anaphylaxis. |
| 1078772 | 3/7/2021 | MA | 39 | F | 3/6/2021 | 3/6/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Medium, Systemic: Hyperventilation-Medium, Systemic: Nausea-Mild, Systemic: Shakiness-Medium, Additional Details: Patient felt faint immediately upon receiving the vaccination. received instruction to sit down. upon sitting down patient passed out/fainted/ muscle contractions in both hands were observed. 911 emergency services were contacted. patient then taken into ambulance for further evaluation. |
| 1078760 | 3/7/2021 | VA | 83 | F | 3/6/2021 | 3/6/2021 | Systemic: Fainting / Unresponsive-Severe |
| 1078689 | 3/7/2021 | TX | 54 | F | 3/4/2021 | 3/4/2021 | Fainting, shaking all body, difficulty breathing, hyperglycemia, convulsion, pain on shot area. Called 911 to translate at emergency room. |

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| 1078863 | 3/7/2021 | NY | 19 | F | 3/7/2021 | 3/7/2021 | Pt stated that she had become light headed and dizzy just after getting her shot. Pt stated that she also started to feel like her vision was starting to narrow. Staff stated that she had passed out for a couple of seconds and had become alert after laying her down. |
| 1079181 | 3/7/2021 | IL | 38 | M | 3/5/2021 | 3/6/2021 | I fainted the following evening after my vaccination. I felt fine all day and after dinner started to feel flush, vision became blurry and had trouble hearing. Within 3 minutes I fainted. Felt fine after coming to, and have felt fine so far the next day. |
| 1078765 | 3/7/2021 | NY | 53 | M | 3/6/2021 | 3/6/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Patient passed out and recovery after 40 seconds of chest compression-Mild, Additional Details: Patient was seen rocking back and forth in his chair according to 3 observers in the room, then fell back hit his head after observed his face turned pale. 3 Observers rushed over to him, patient was not breathing, unconscious and not responsive, eye ball stiff, sweating but cold. Eyelid peeled back and the eye is responsive to light. Started chest compression immediately and after 40 seconds of chest compression at third round, patient came back. no hx of preexisting condition or allergies note |
| 1079896 | 3/7/2021 | MI | 70 | F | 1/20/2021 | 1/21/2021 | After the first vaccine, patient stated she had chest and throat tightness for 7 days. After the second vaccine, 5 minutes later, patient stated she had severe dizziness, shortness of breath, fainted, shaking, elevated blood pressure to 161/70, passed out. A facility called 911 for the patient. Patient was taken to the emergency room and treated with Ativan and meclizine. 2 EKGs and CXR in ER were normal. Patient spend 1 night in the hospital. The next day, all symptoms returned. Patient was treated with benadryl, zofran, and meclizine. Patient is still taking meclizine for dizziness. Patient was treated as an outpatient with oral steroids. 2 weeks later, patient is still havng symptoms, but milder. |
| 1079230 | 3/7/2021 | IN | 70 | F | 2/21/2021 | 2/22/2021 | Chilled, nauseous, gastric distress, weak, no appetite, miserable, passed out 3 times |

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| 1078777 | 3/7/2021 | CA | 62 | M | 3/6/2021 | 3/6/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: Fainted but seems responsive-Medium, Systemic: Flushed / Sweating-Medium, Additional Details: Patient fainted from sitting after vaccination. No difficulty breathing/swallow, thus gave water and gatorade. He was responsive to my questions. He has history of anxiety to needles and he did not eat lunch before vaccine. He stayed seated for 1 hour to monitor. Then, walked an aisle before driving home. Asked him to eat first before driving home. Called him twice and he is home and feeling okay. Counseled to call pharmacy if any symptoms of allergic reaction to vaccine. |
| 1079921 | 3/7/2021 | CA | 19 | F | 3/7/2021 | 3/7/2021 | Syncope |
| 1079779 | 3/7/2021 | CA | 20 | F | 3/6/2021 | 3/6/2021 | Fainted x 10 seconds. Given juice, vitals stable. History of fainting during medical procedures. |
| 1079737 | 3/7/2021 | CA | 66 | M | 3/2/2021 | 3/3/2021 | Temperature 102-104 F 15 hours after vaccine. No temperature when going to sleep 3 hours earlier. Chills and severe shaking. Fainting when standing to go to bathroom (fell on bed no injuries). Chills and temperature continued for next 12 hours. Stayed in bed the entire next day (3 March). Temperature subsided and was able to work on 4 March. |
| 1079482 | 3/7/2021 | NY | 102 | F | 2/8/2021 | 2/8/2021 | 102 female who is a COVID survivor.. had a mild case of COVID in May 2020. Received first dose of Moderna at assisted living facility on approximately January 20th and suffered no ill effects. Had second Moderna vaccination late afternoon of February 8th. Later that evening or in the early morning of February 9th tried to go to the bathroom and either fainted or fell onto the bathroom floor on her face. Lay on the bathroom floor face down until assisted living facility staff found her in the morning when they were passing out medications. Taken to ER at hospital on 2/9/2021. Was not admitted to hospital- all CT scans and x-rays and blood work were normal. Taken back to assisted living facility where she exhibited dramatic change in behavior- uncooperative, refusing to eat or take meds, refusing to get OOB. Mentally a decline in cognition. Transferred to different facility with higher level of care on February 15th and is improving somewhat. |

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| 1079455 | 3/7/2021 | RI | 75 | F | 2/25/2021 | 3/2/2021 | Tachycardia. I fainted |
| 1079444 | 3/7/2021 | IL | 89 | M | 2/19/2021 | 2/20/2021 | woke up not feeling well, injection site red & swollen, as day progressed became sicker with flu like symptoms, tired, achy,. developed low fever of 101. about 2pm, took 2 tylenol, at about 5 pm went to use bathroom started feeling dizzy, then fainted. after about 5 min bp 107/53 pulse83. wen to bed, got up the next am felt much better, as day progressed felt fine |
| 1079415 | 3/7/2021 | | 53 | M | 3/7/2021 | 3/7/2021 | Diaphoretic, syncope for approximately 2 minutes, panic attack, rapid breathing. Transported to nearest ER by EMS. |
| 1079407 | 3/7/2021 | PA | 69 | F | 3/1/2021 | 3/2/2021 | Light headedness, dizziness, and weakness that occurred the morning after receiving the vaccine and lasted for 2 days. Patient fainted the morning after the second dose was administered. |
| 1079305 | 3/7/2021 | NY | 25 | F | 3/6/2021 | 3/6/2021 | Fever 102 degrees 12 hrs after injection lasting 8 or so hrs. 34 hrs later dizziness and fainting lasting a short while. |
| 1079346 | 3/7/2021 | OR | 45 | F | 3/5/2021 | 3/6/2021 | Passed out two times and was shaking upon waking. I didn't wake up fully for almost 1 hour. |
| 1079308 | 3/7/2021 | MA | 73 | M | 3/6/2021 | 3/6/2021 | Systemic: Allergic: Difficulty Breathing-Medium, Systemic: Chills-Medium, Systemic: Dizziness / Lightheadness-Severe, Systemic: Exhaustion / Lethargy-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Severe |
| 1080254 | 3/7/2021 | CA | 66 | F | 3/5/2021 | 3/5/2021 | Tingling, lightheaded, presyncope. BP readings: 97/62 (pulse 46), 98/60 (pulse 59). Given juice and water. |
| 1080046 | 3/7/2021 | VA | 34 | F | 3/4/2021 | 3/4/2021 | Headache, body ache, ache at injection site, chills, loss of balance, one episode of fainting, one episode of vomiting |

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| 1077360 | 3/6/2021 | OR | 39 | F | 2/15/2021 | 2/16/2021 | 24 hours after the 2nd dose my temperature rose 4 degrees, full body aches and sweating for 24 hours. Followed by dizziness and headache. Within two days my body began having seizures accompanied with ongoing flushing/cold sensations in the occipital region/top of spine, with a feeling of fainting and dizziness, nausea, without loss of consciousness. Sudden jerking movements of the arms, legs and the head/neck range from 2-5 minutes in duration and continue in clusters for 8-20 hours per day. This seizure activity has not subsided since February 17th, and is ongoing to date. MRI confirms no new structural abnormalities in the brain. CBC and metabolic panels are all within normal range. EKG normal. I am not epileptic. No history of drug use. No alcohol use. |
| 1078149 | 3/6/2021 | WA | 52 | F | 2/28/2021 | 2/28/2021 | On 02/28/2021 @ 21:00 pm I felt chilly , hot and dizzy . When I got home and 24:30 am I took a shower, then I got freezing, chilly and body shaking, also I went to bathroom may time. The whole morning I felt so tired, then I went down to kitchen to have breakfast, but I reacted with my food smell. Then I went back to my room because I couldn?t eat. During I went back to my room, I fainted at the stair. I hit my head against the wall. I did not realized I fainted after the fact. Sometime it is tough to breath and body aches. On day 2, I had headache and could not work. From then the vaccination until now (March 6th) my heads feel heavy. |
| 1077934 | 3/6/2021 | TX | 16 | F | 3/5/2021 | 3/5/2021 | Site: Pain at Injection Site-Mild, Systemic: Fainting / Unresponsive-Severe |
| 1077752 | 3/6/2021 | AZ | 49 | F | 3/4/2021 | 3/4/2021 | Shot at 11AM, arm soreness within two hours. Went to bed with fever, back pain, chills and chattering teeth. At 2 AM, awoke to drink water and urinate. Fainted while sitting, was passed out for about a minute, and appeared to stop breathing for about 10 seconds (per husband). Vomited. Returned to bed, still with fever, stomach aches. Awoke tired, lethargic, with fever. Acquired thermometer, fever peaked at 103 late afternoon. Took tylenol with little effect then with advil the fever started dropping. Went to bed day 2 with 102 fever and more spirit. Woke up day 3 with fever of 100, but much more energy. Submitted form at this point. |

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| 1077724 | 3/6/2021 | TX | 56 | M | 3/4/2021 | 3/4/2021 | Vasovagal syncope - lightheaded, did not faint |
| 1077595 | 3/6/2021 | NJ | 33 | M | 3/6/2021 | 3/6/2021 | History of syncope with injections in the past. 10 min after vaccine, felt dizzy, laid himself on the ground under. Bystander witnessed him lose consciousness for a few seconds. No seizure like activity seen. No confusion after the event and patient recalled when everything that happened. Also states he didn't eat today. Drank Gatorade, stayed recumbent for 30 min and felt better. Ekg sinus rhythm, vital signs stable. Declined to go to the ER. Went home with his fiancée who is a PA. |
| 1077556 | 3/6/2021 | WI | 45 | F | 3/3/2021 | 3/5/2021 | Felt feverish and achey starting 12 hours after injection, lasting a total of 54 hours. At 36 hours after injection I felt like I was going to faint. I sat down and put my head on the table. According to my husband, my eyes briefly rolled back into my head and I was convulsing for a brief period of time (5 seconds). I then sat straight up, sweating profusely, white a sheet and with a terrified look on my face started hyperventilating for a short period of time. My husband said I never actually fainted, but I don't have memory of this incident. After this episode passed I continued to feel feverish and achey. Temp about 100.7. Started to feel a little better 54 hours after injection. |
| 1077340 | 3/6/2021 | TX | 28 | F | 3/5/2021 | 3/5/2021 | Dizziness, fainting, difficulty breathing, pressure on chest, heart palpitations, high blood pressure, elevated heart rate, body temperature increasing. |
| 1078188 | 3/6/2021 | FL | 44 | M | 3/4/2021 | 3/4/2021 | I felt light headed, dizzy and I almost passed out approximately 20-25 minutes after the injection. I then took 1 tablet of Claritin in order to counter the reaction. I sat down outdoors, removed my mask and jacket so I could breathe better. I also ate a sandwich since I thought maybe I felt dizzy because I didn't eat a full breakfast. I stayed outdoors sitting down for 2 hours before getting up. I felt better after about 1 to 1.5 hours. However, as of March 6, 2021, sometimes I have a drowsy feeling like I'm on cold medication. However, I did not take any medication today. Also, for the 1st COVID vaccine I took on 11 Feb 2021, I took 1 tablet of Benadryl, which countered the allergic reaction which is why I did not have symptoms to report for the 1st dose. |

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| 1078118 | 3/6/2021 | CA | 49 | F | 3/1/2021 | 3/6/2021 | 50 yo F. Came with daughter. Pt with Hx of DM Type II diagnosed 6 yrs prev. Also hx of anxiety, not on anxiety meds. On Metformin 1200 mg daily. C/o syncope and tachycardia. VS x5 checked 11:06 am- 154/106 98%, 97.1 F. Had granola in the am, reported BS at 8:30am was 199 mg/dl. VS, heart rate elevated. VS 11:40 am- 137/97, 96%, 85 bpm, 98.7 F. Paramedics called 11:45 am and arrived 11:48 am. Checked VS 11:50 am, BS 124 mg/dl. Reported stable, able to go home, cleared by EMS. Pt insisted to drive home, and said she felt well and safe to drive self. Escorted to car by PHN. Instructed to call PCP with additional concerns, to seek UC if needed, and to call 911 for resp. distress; verbalized understanding. |
| 1077310 | 3/6/2021 | TX | 40 | F | 3/5/2021 | 3/5/2021 | Patient stated after she sat down she began to hear ringing in her ears and had tunnel vision; didn't remember after that; medic and this nurse ran to patient where she was laying face down. Patient began to come around and skin was pale and clammy to the touch. VS taken: HR: 82; BP: 140/70/ O2 Sat RA; 78%. Patient was speaking coherently after she woke up, was out for about 25 seconds. Patient stated she had a hx of fainting w/labs or shots. Placed cool, wet towels behind neck, forehead and lower back - patient stated it helped her feel better. VS retaken: BP: 134/66; HR: 77; O2 Sat RA: 98%. Patient sat up in a wheelchair and began to have color to face and feeling less clammy. EMT sat with patient until she was feeling better. Patient was joking and stated she felt embarrassed. Patient discharged to home. This nurse contacted her after clinic, she stated she was doing well and would be seeing us again for her 2nd Moderna dose. This nurse encouraged her to notify the next vaccinator of her hx of fainting - She stated she would. Patient appreciative for call. |

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| 1077559 | 3/6/2021 | TX | 59 | F | 3/5/2021 | 3/6/2021 | I received the moderna COVID vaccine. 13 hours later I woke up with a leg cramp. While walking downstairs I became very dizzy and sweaty chills. I sat in a chair. My husband came down a minute later and I was passed out in the chair. He was saying my name and rubbing my arms to wake me. It took him about one minute to get me to open my eyes and then another minute before I could coherently respond. He said my chin was tucked into my neck and I was pale and making noises for less than a minute. He said then I relaxed and responded coherently. My temperature was 94-95 for about an hour while I had chills but also was drenched in sweat. I was also throwing up clear fluid for about two hours. I felt nauseous for about 3 more hours. After that I just felt tired. |
| 1078416 | 3/6/2021 | CA | 70 | F | 3/6/2021 | 3/6/2021 | Patient was diaphoretic and fainted |
| 1077901 | 3/6/2021 | NY | 64 | M | 3/6/2021 | 3/6/2021 | PATIENT GOT THE VACCINE AND WAS TOLD TO SIT DOWN FOR 15 MINUTES . DURING THAT TIME PT FAINTED .CALLED 911 AND WAS TAKEN TO THE HOSPITAL |
| 1078559 | 3/6/2021 | CA | 70 | M | 3/6/2021 | 3/6/2021 | patient c/o of diaphoretic and fainted |
| 1078206 | 3/6/2021 | | 27 | F | 3/6/2021 | 3/6/2021 | Syncope, lightheaded, nausea. Pt is pregnant at time of vaccination. Transported to ER by EMS |
| 1078436 | 3/6/2021 | CA | 39 | F | 3/2/2021 | 3/2/2021 | I think I had a reaction to the shot I felt dizzy, hot, and not well. I don't remember much after that I was being observed and raised my hand then passed out. They called the hospital and EMT and I woke up lying down in a makeshift room. |

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| 1078624 | 3/6/2021 | AZ | 30 | M | 3/6/2021 | 3/6/2021 | Patient received his 1 dose of Pfizer vaccine and was waiting in our lobby for the recommended 15 minutes. He fainted after about 10 minutes. He fell from the bench to the floor where he landed on his stomach. When I ran over to him, his eyes were open but his body was limp. I tapped his back and asked if he was ok, and he was startled as if I woke him up from sleep. He was alert and was able to speak, he asked for water and I gave it to him. I asked if he wanted me to call emergency services but he declined. He then vomited in the waiting room trash can. His sister was with him and began to rub his back and fan him. I asked again if he needed to go to the hospital and again he declined. I told them to please wait in the lobby at least another 15 minutes before leaving and he did. I called to patient around 8pm to check on him and he said he was fine and had no more symptoms. |
| 1078386 | 3/6/2021 | PA | 23 | F | 3/6/2021 | 3/6/2021 | Patient reports a history of syncope with any sort of injection or vaccine. Five minutes after receiving her vaccine, she felt lightheaded and lost consciousness for a few seconds. Prior to losing consciousness she asked for assistance and somebody held her up when she lost consciousness. She did not hit the ground or otherwise injure herself. Upon awakening, she was fully alert and oriented and denied any chest pain or shortness of breath. Drank Gatorade. Felt better with no recurrence after observation period. |
| 1078369 | 3/6/2021 | KY | 26 | F | 3/6/2021 | 3/6/2021 | PATIENT EXPERIENCED SYNCOPE IN OBSERVATION AREA AFTER VACCINATION. WAS TREATED BY EMS ON SITE BUT NOT TRANSPORTED |
| 1078346 | 3/6/2021 | NY | 66 | F | 3/6/2021 | 3/6/2021 | Pt experienced anxiety immediately following the vaccine shot and fainted |
| 1078320 | 3/6/2021 | CA | 68 | F | 2/25/2021 | 2/26/2021 | I had chills, muscle aches, and I fainted when I got up to the bathroom, breaking my ankle. |

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| 1078300 | 3/6/2021 | IN | 80 | F | 2/1/2021 | 2/19/2021 | By afternoon I felt a little chilly and achy and took Tylenol. I woke at 2:00am the following morning to go to the restroom and my dog needed to go out. I felt light headed as soon as she was back in the house. I felt things going dark and I passed out in the hallway. I don't know how long I was out but when I came to, I felt like I couldn't move. I laid there for a while and finally crawled back to my bed. I was able to get back in bed. By then it was 3:00am. The next night I woke in the night and had an irregular heartbeat. I could not get back to sleep until it finally went away. For several days after the vaccination, I had very little energy. |
| 1078274 | 3/6/2021 | PA | 33 | M | 3/6/2021 | 3/6/2021 | Nausea, passed out, hands seizing/shaking |
| 1078510 | 3/6/2021 | | 29 | F | 2/27/2021 | 2/28/2021 | syncope episode with second vaccine dose. |
| 1075334 | 3/5/2021 | AZ | 37 | M | 3/5/2021 | 3/5/2021 | Felt dizzy immediately after vaccine and passed out. EMS stated low heart rate and blood pressure after waking up. |
| 1075360 | 3/5/2021 | WI | 71 | M | 1/30/2021 | 2/3/2021 | Vaccine on 1-30, developed dizziness and SOB 2-3, persisted intermittently until 2-5 when had syncopal episode with no LOC, symptoms gradually resolved over next few days with no further syncope |
| 1075372 | 3/5/2021 | TX | 49 | F | 3/4/2021 | 3/4/2021 | My arm became sore, and I was a little nauseated about 4 hours later which I expected. At 10pm I started feeling light headed and walked to the kitchen to get water. I began feeling weak and more dizzy and went back to my bedroom to lie down. I felt a rush to my head, passed out and woke up on the ground. I am unsure how long I lost consciousness: minutes/ seconds. I was able to get to my bed and called my husband for help. I broke into a hot, drenching sweat to the point I had to change my clothes. The dizziness eventually cleared. I have a headache and am still nauseated today but not dizzy. I have never had an experience like this before. |

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| 1075378 | 3/5/2021 | KY | 35 | M | 3/5/2021 | 3/5/2021 | PATIENT RECEIVED VACCINATION AND WAS THEN ASKED TO SIT IN LOBBY. AFTER BEING SEATED PATIENT PASSED OUT AND FELL OUT OF CHAIR, HITTING HIS HEAD AND BITING HIS LIP IN THE PROCESS. 911 WAS CALLED AND EPI PEN WAS RETRIEVED. PATIENT CAME TO AND WAS PALE, SWEATY, AND HAD CLAMMY HANDS. PATIENT REPORTED NO DIFFICULTY IN BREATHING OR FEELING OF THROAT SWELLING SO EPI PEN WAS NOT ADMINISTERED. BP WAS CHECK AND WAS EXTREMELY ELEVATED. AMBULANCE ARRIVED A FEW MOMENTS LATER AND EMTS ASSESSED PATIENT. PATIENTS BP HAD RETURNED TO NORMAL RANGE, COLOR WAS IMPROVED AND HE WAS NO LONGER SWEATING. EMTS ASKED PATIENT IF HE WANTED TO BE TAKEN TO THE ER FOR FURTHER EVALUATION AND PATIENT REFUSED. PATIENT SAT IN THE PHARMACY FOR A FEW MORE MINUTES AND WAS THEN DRIVEN BACK TO WORK. |
| 1075623 | 3/5/2021 | KY | 61 | M | 3/1/2021 | 3/4/2021 | Not sure if this was a reaction to vaccine or not? 3/4/2021 when I woke up to get out of bed, upon standing, I got a severe feeling of dizziness or vertigo that resulted in my legs giving out and me falling down. I didn't get hurt but it felt like I almost passed out. I fell backwards against a wall and slid down. I did not report this to my doctor previously listed. |

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| 1075744 | 3/5/2021 | IN | 52 | F | 3/5/2021 | 3/5/2021 | Patient rec'd vaccine at 1400. She went to wait her 15 minutes in the car and after about 10 minutes noticed eye sensitivity and headache. When symptoms did not pass after an additional 10 minutes she came back into the office. While waiting when her husband was checking her in, she "passed out." Episode lasted less than 1 minute. She was easily oriented to person, place and time. It was noted that she had some swelling to bilateral eyes. Patient was brought back to room, VS were checked and all were normal. She denied any chest pain, shortness of breath, wheezing, tongue swelling, itching, or tickling sensation to back of the throat. She was able to tolerate sips of water without difficulty. 50mg benadryl IM was given in the left deltoid. Approximately 5 minutes after IM injection patient again "passed out." She was seated at the time and slumped to her right, resting her head on her husband and did not fall from chair. She aroused after approx 2 minutes, and was a/ox4. VS were rechecked and were O2 99% on RA. HR 101, BP 124/88, RR20, temp 98.5/oral. Patient stayed at the clinic for an additional 45 minutes after which her eyesight was reported to be back to normal, her headache had improved and the lower eye edema had resolved. It should be noted that both the patient and the husband were not concerned with her "passing out." She states it happens because of pain and she was fearful of the injections. Patient also states that her neurologist told her that when "she is in too much pain, she will pass out.~~ |
| 1075800 | 3/5/2021 | KS | 35 | F | 3/4/2021 | 3/4/2021 | I got the shot at 6:30pm. Drove, went to the grocery store, came home, did chores. Around 9:45 started preparing for the next day (getting coffee pot ready, etc.) up until this moment I had no side effects except pain in my arm. Then at 9:45PM I began feeling light headed, ringing in my ears and fell unconscious. I woke up on my kitchen floor in a small pool of blood and disoriented. I do believe this reaction is related to the vaccine. I DO NOT have a history of fainting. I ate food and drank plenty of water throughout the day and after my vaccine injection. Everything about my day was typical except for the vaccination and losing consciousness. |
| 1075280 | 3/5/2021 | IN | 66 | F | 3/4/2021 | 3/5/2021 | Passed out. Low BP 83/42.Felt better after fluids. Also chills and achy flu symptoms lasting 12 hrs. This was 2nd dose; no reaction to first other than sore arm. |

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| 1075958 | 3/5/2021 | MD | 39 | F | 3/5/2021 | 3/5/2021 | Dizziness felt like fainting |
| 1074335 | 3/5/2021 | CA | 26 | M | 3/4/2021 | 3/4/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Additional Details: pt was walking out and collapsed on the floor, pt regained consciousness after couple seconds, pt is alert and responsive, and he thinks he just got up too fast, pharmacy gave pt water and he was okay after sitting and resting |
| 1075808 | 3/5/2021 | CA | 32 | F | 3/2/2021 | 3/3/2021 | Wednesday - 3/3/2021 2:00 AM - chills, fever and nausea 4:00 AM - passed out, duration unknown 6:00 AM- chills and fever until 6:00 PM |
| 1075246 | 3/5/2021 | ME | 67 | M | 3/4/2021 | 3/4/2021 | (3) syncopal episodes following vaccination, one of which resulted in a fall with direct injury to the base of neck, head, and right flank. Pt reported chest pain prior to syncope. |
| 1075237 | 3/5/2021 | TX | 24 | F | 3/5/2021 | 3/5/2021 | Patient reported dizziness at 30 min post injection but admitted symptom had started soon after injection. She was given po fluids and allowed to rest in recumbent position until improved. At time of discharge was ambulating without syncope but still had residual dizziness which family reported will typically persist for 1-2 days. |

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| 1075031 | 3/5/2021 | KS | 23 | M | 2/24/2021 | 2/24/2021 | <p>Progress Notes APRN (Nurse Practitioner) ? ? Family Medicine Pt called for follow up s/p covid-19 vaccination done on 02/24/21. He reports that he feels well. Sore at injection site but no other c/o. He voices appreciation for our call. APRN Progress Notes PA-C (Physician Assistant) ? ? Family Medicine Cosigned by: MD at 2/28/2021 7:35 AM Expand AllCollapse All COVID VACCINE CLINIC 2/24/2021 Date: 2/24/2021</p> <p>Subjective Patient is a 23 y.o. male who was seen at COVID Vaccine Clinic today for his first dose of the COVID 19 vaccination. He was given the Pfizer vaccination. During his 15 minute waiting period after the injection, the patient began to experience lightheadedness. He denied difficulty breathing, difficulty swallowing, throat tightness and nausea. He states he always gets lightheaded when he gets a shot. He denies any episodes of syncope in the past. This provider was notified of patient reaction and he was then assessed in the emergency bay area. Monitored patient for severe reaction symptoms, including but not limited to collapse, hypotension and rapid progression of symptoms. ALLERGY REVIEW OF SYSTEMS: Patient denies chills, facial swelling, chest tightness, shortness of breath, wheezing, vomiting and headaches +lightheaded: Previous Reactions: Always gets lightheaded after getting a shot. Denies other symptoms or syncope. Objective Vitals Vitals: 02/24/21 1406 BP: 119/67 Pulse: 58 SpO2: 100% Physical Exam Constitutional: Appearance: Normal appearance. HENT: Head: Normocephalic and atraumatic. Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Pulmonary: Effort: Pulmonary effort is normal. No respiratory distress. Breath sounds: Normal breath sounds. No wheezing or rales. Skin: General: Skin is warm and dry. Neurological: General: No focal deficit present. Mental Status: He is alert and oriented to person, place, and time. Assessment/Plan Treatment included: no therapy Follow up response to treatment: Good. Lightheadedness resolved prior to discharge. Patient discharge: Stable to go home and follow up with PCP. Differential Diagnosis: Vaccine-Related Anxiety (include misc mental health) PA-C Electronically Signed 2/24/2021 2:07 PM</p> |

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| 1074930 | 3/5/2021 | NY | 46 | F | 3/5/2021 | 3/5/2021 | Patient received vaccine at 10:39am and was in the observation area. At about 3 minutes (10:42 am) she began to feel " a tingly sensation in my tongue" and felt warm. She also had localized redness and swelling at the site of injection (Right deltoid). She denied any symptoms of chest pain, SOB, palpitations, difficulty swallowing, drooling, nausea/vomiting, dizziness or light-headed or near syncope. Patient was observed by provider for a course of one hour. We recommended to be taken by EMS to ER for further observation, she refused. Patient drove herself and was not able to take Benadryl. Initial vital signs taken 10:54am 177/114; HR 92; O2 98% RA; RR 18 -sitting position Second vitals 11:35am 134/96; HR 79; O2 100% RA ; RR 16- sitting position Patient was observed for an hour and decided to drive home. Recommend hydration and call 911 if needed. |
| 1074575 | 3/5/2021 | PA | 76 | M | 3/4/2021 | 3/5/2021 | 24 Hours after receiving my second dose of the Pfizer Covid-19 vaccine, I fainted. I was only unconscious for a few seconds, and seemed OK upon regaining consciousness. So far, it has not recurred. |

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| 1074471 | 3/5/2021 | FL | 39 | F | 3/2/2021 | 3/2/2021 | Evening of 2nd approximately 6pm diarrhea began with increasing frequency throughout the night. Lasted through the night several times an hour into the next morning. Around midnight dizziness,, faint and muscle weakness set in with feeling of extreme pressure on neck, especially right side where shot administered. Arms became tingly, tongue became tingly, hard to keep awake. After 12 hrs of extreme diarrhea, passed out for 12hrs straight. Awoke dehydrated, extreme muscle weakness unable to walk or stand, light headed, nauseous, dizzy, unable to grip or exert force. Felt like head was detached from body due to extreme pressure on neck. Rapid resting heart rate in 90s (usual testing HR in 50s). Constant rolling waves of abdominal cramps brought dizziness with each cramp, acid reflux, bloating and gas. These symptoms lasted through the evening of the 3rd into the 4th. Considered going to ER for help, as extreme dizziness and muscle weakness prevented walking. Fell asleep. 6am March 4th developed fever of 101. Continued extreme dizziness, pressure on neck, muscle weakness and feeling faint and extreme lethargy throughout day. Fever subsided to 99 by evening of 4th. Ate plain rice evening of 4th, 1st time eating in over 48hrs. Immediately passed out. March 5th still feeling weak, hard to stand, limited walking. Diarrhea has subsided, less pressure on neck and less dizziness. Feeling exhausted overall. Fall asleep easily and randomly. |

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| 1074327 | 3/5/2021 | SC | 64 | F | 3/4/2021 | 3/4/2021 | Systemic: Chills-Mild, Systemic: Diarrhea-Mild, Systemic: Dizziness / Lightheadness-Medium, Systemic: FAINTING- NO LOSS OF CONSCIOUSNESS-Medium, Systemic: Nausea-Medium, Systemic: Shakiness-Mild, Systemic: Tingling (specify: facial area, extremities)-Mild, Additional Details: IMMEDIATELY AFTER VACCINE, PATIENT STATED SHE WAS LIGHT HEADED. THEN PROGRESSED TO NAUSEA AND PLACED HEAD BETWEEN LEGS SAYING SHE FELT HOT. ICE PACKS WERE PLACED ON PATIENTS NECK. SHE SAID SHE NEEDED TO LAY DOWN AND TRIED TO TAKE HER TO MINUTE CLINIC BUT SHE WAS PLACED ON FLOOR BECAUSE SHE WAS UNSTABLE WALKING. SHE LOST CONTROL OF HER BOWELS AND HAD DIARRHEA ON HERSELF AND THE FLOOR. 911 WAS CALLED AND VITALS WERE TAKEN AND SHE WAS STABLE. SHE REFUSED TO GO TO ER BECAUSE SHE SAID SHE WAS BETTER. |
| 1074301 | 3/5/2021 | OH | 80 | F | 2/16/2021 | 2/17/2021 | Passed out; Felt tired; A spontaneous case report was received from a consumer concerning an 80 years-old female patient who experienced passed out (MedDRA PT: loss of consciousness) and felt tired (MedDRA PT: fatigue) The patient's medical history included cancer. Concomitant product use included chemotherapy and other medications (not specified). The patient received their first of two planned doses of mRNA-1273 (Lot # not provided) on an unknown date. On 16 Feb 2021, approximately one day prior to the onset of symptoms, the patient received their second of two planned doses of mRNA-1273 (Lot #011M20A) intramuscularly in an unspecified site for prophylaxis of COVID-19 infection. On 17 Feb 2021, one day after receiving the vaccination, the patient felt tired and passed out. The patient inquired if this was a normal side effect. Treatment information was not provided. The patient received both scheduled doses of mRNA-1273 prior to the events; therefore, action taken with the drug in response to the events is not applicable. The outcome of the events passed out and felt tired is unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested. |

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| 1074874 | 3/5/2021 | WA | 51 | F | 3/4/2021 | 3/5/2021 | Syncope, hypotension, Pt. Vitals returned to normal after the 30 minute observation. Pt. stated this was normal for her when she gets injections. |
| 1076012 | 3/5/2021 | NY | 21 | F | 3/3/2021 | 3/3/2021 | About 5 minutes after her vaccination, patient said she didn't feel well and then fainted. She woke up quickly and felt better after she rested and had some orange juice. |
| 1074553 | 3/5/2021 | NJ | 38 | M | 3/3/2021 | 3/3/2021 | FELT FLUSH, SYNCOPE EPISODE WHILE SITTING IN MONITORING CHAIR, REPORTS PREVIOUS FLUSH FEELINGS WHITH NEEDLES OR AFTER GETTING BLOOD DRAWN, VS WNL , AWAKE AND ALERT IN NO DISTRESS 120/73 BP 99% O2 76 PULSE. ASSESSED BY MD, MONITORED FOR ADDITIONAL 45 MIN, BUMP NOTED TO BACK OF HEAD, ICE PACK APPLIED, REASSESSED AND RELEASED HOME |
| 1077262 | 3/5/2021 | SC | 55 | F | 3/5/2021 | 3/5/2021 | Systemic: Fainting / Unresponsive-Medium, Systemic: Hypertension-Severe, Additional Details: patient received second dose of covid vaccine between 1-2 pm, waited in observation area for 15 minutes, returned to work about an hour later (on-site), entered into a room and immediately fainted hitting head. BP was checked and it was 189/100. EMS was called, patient went in to be checked out. When ending the on-site clinic at facility, we had not received any information from the patient. Healthcare person listed is the administrator of the facility. |
| 1076043 | 3/5/2021 | GA | 56 | F | 3/5/2021 | 3/5/2021 | At 1539 pt stated, " I just walked to the office and felt like fainting." Patient Care Technician led her to a chair and sat the patient down. Pt was seated and given water for approx. 10 minutes. Pt's vitals at 1539 T: 97.5, BP: 153/83, P: 100. Pt's vitals at 1545 BP: 146/93 P:94. ATt 1545 pt stated, "I feel better." Pt denied c/o dizziness. Patient walked to her office and monitored for additional 15 minutes before leaving the building. |
| 1074556 | 3/5/2021 | TX | 24 | F | 3/5/2021 | 3/5/2021 | Syncope upon injection. Protected patient from falling. EMS performed patient checks and vital signs. Vitals signs stable. Patient AMA |

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| 1077247 | 3/5/2021 | VA | 39 | M | 3/5/2021 | 3/5/2021 | Site: Redness at Injection Site-Severe, Systemic: Allergic: Anaphylaxis-Severe, Systemic: Allergic: Difficulty Breathing-Severe, Systemic: Fainting / Unresponsive-Severe |
| 1077239 | 3/5/2021 | AZ | 24 | M | 3/4/2021 | 3/4/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Nausea-Mild, Systemic: Shakiness-Medium, Systemic: Weakness-Medium, Additional Details: Patient recovered after supine positing for 15 minutes and water |
| 1077230 | 3/5/2021 | AZ | 75 | F | 3/5/2021 | 3/5/2021 | Weakness, syncope, headache |
| 1077218 | 3/5/2021 | AZ | 37 | M | 3/5/2021 | 3/5/2021 | PT RECEIVED COVID(MODERNA) VACCINE AND DURING 15 MINUTES WAIT AFTER VACCINATION THEY STOOD UP TO WALK TOWARDS PHARMACY AND EXPERIENCED A SYNCOPE EVENT. PT UNCONSCIOUS FOR 10-15 SECONDS. PHARMACIST ATTENDED TO PATIENT AND CONTACTED EMS. PT GIVEN WATER/PEDIALYTE. EMS CLEARED PT WITH SUSPECTED DEHYDRATION AND RELEASED TO SPOUSE. |
| 1077216 | 3/5/2021 | CA | 70 | M | 3/4/2021 | 3/4/2021 | Passed out (patient has a history of passing out after receiving vaccines). BP 153/81 (pulse 71), followed by 146/75 (pulse 72). |
| 1077288 | 3/5/2021 | TX | 25 | F | 3/5/2021 | 3/5/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Severe, Systemic: shaking (seizure?)-Mild |

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| 1077119 | 3/5/2021 | AK | 84 | F | 3/5/2021 | 3/5/2021 | This is an 84 year old patient who presented for her initial dose of the Pfizer/BionTech COVID-19 vaccine. About 10-15 minutes after receiving the dose, she experienced a burning sensation in her upper mid-chest, felt dizzy, felt nauseous. She also said that she initially had dyspnea, but denied cough or wheezing (she denies a prior history of chronic respiratory disease, such as asthma). She said that her throat began to feel tight, and she was administered epinephrine at the immunization point of distribution (at the gym). She was then transferred via EMS to the ER for further evaluation. She denied experiencing cutaneous symptoms. She denied vomiting, diarrhea, syncope. She states that she has an allergy to sulfa drugs (she develops hives) and has an allergy to penicillin (she states that she passed out after receiving a penicillin shot as a teenager, but did not have any other systemic symptoms). |
| 1077117 | 3/5/2021 | OH | 70 | F | 3/2/2021 | 3/3/2021 | Patient reported waking up the morning after her second dose of the Moderna COVID-19 shot fine, but within 5 minutes of waking she began sweating profusely, vomited, and passed out. She reported that the sweating and nausea persisted for about a day and a half and that she is feeling mostly better today (2 days later) |
| 1077073 | 3/5/2021 | CA | 65 | F | 3/5/2021 | 3/5/2021 | Syncope, roused after roughly 4 minutes. Patient seen by MD, had juice, observed for 30 minutes, experienced dizziness, see again by MD, eventually DC to home @1100 with significant other. |

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| 1076785 | 3/5/2021 | NH | 43 | F | 2/21/2021 | 2/22/2021 | 2am woke up with severe chills and a severe migraine. At 10am severe migraine progressed to skin on scalp feeling like it was pulled too tight. From there I began to feel an internal tremor in my head, almost like if you ran a jack hammer all day and then stopped, that shaky, off-kilter feeling. I used the bathroom that morning and had massive diarrhea, experience a vaso/syncope episode and passed out. All week I felt like this and experienced nausea, dizziness, heart palpitations, severe migraine, internal tremor, severe anxiety and severe thirst. By Friday, 2/26/21, it got so bad and my blood pressure dropped to 112/50, that I was taken via ambulance to the ER. They gave me IV fluids, ran labs, EKG, etc. Blood pressure went up to 137/91. Released to rehab at home. 2nd ER visit to Hospital on Sunday where they repeated labs, EKG, gave me fluids and treated symptoms. Both trips I was labeled Tachy. |
| 1076117 | 3/5/2021 | IL | 35 | F | 2/12/2021 | 2/13/2021 | intermittent episodes of subjective fever chills tachycardia nearly passing out headaches. Symptoms started approximately 9 days ago after having a second maternal vaccine. She states she is intermittently been feeling ill in terms of diffuse myalgias headaches today she had a racing heart rate and near syncope. Denies any chest pain shortness of breath abdominal pain nausea vomiting diarrhea. |
| 1076218 | 3/5/2021 | NY | 30 | M | 3/5/2021 | 3/5/2021 | Patient received dose of vaccine on right deltoid at 4:09PM at around 4:23PM developed symptoms. Symptoms described as: feeling "warmth, like if feels when you take NAICIN-flushing sensation but only minor". Other symptoms includes light rash in both arms, redness on face and arms. Excluding back, trunk and legs. Patient denies sore throat, swelling or tingling of tongue or mouth, lips. Denies drooling, no difficulty swallowing. Denies chest pain, SOB, palpitations, dizziness or light headed. No near syncope episodes. Patient refused Benadryl due to driving alone and also refused EMS to transport to ER. |
| 1076995 | 3/5/2021 | | 16 | M | 3/5/2021 | 3/5/2021 | Syncope post vaccine |

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| 1076232 | 3/5/2021 | TX | 19 | M | 3/5/2021 | 3/5/2021 | Patient ambulated to general observation, sat in chair and suddenly fell straight back and slammed back of head on floor. Patient was unconscious, pale. Immediately turned onto left side. within a few seconds began having generalized rigid jerking for approx 5 sec, then patient came too, sat straight up, disoriented looking around. Able to recall name. states he was here for covid vaccine. Assisted to w/c by 2 EMT's and taken to private observation area. Patient c/o nausea and head pain. Color pale. Has an almond size swollen area at posterior base of head. Initial VS - BP 90/p; HR 53; O2 91% on room air. Responding to questions, but states he feels disoriented. Bilateral pupils 3cm with right reacting sluggish. Patient states he is a student. EMT attempted to contact patient's father and LVM. Patient's step mother returned called. Informed her that patient is being transported to Hospital downtown FW for further eval. She asked him what did she need to do. Nurse informed that his vehicle will be left at the vaccine location and he will need assistance pending hospital eval. Patient then called his boss to notify him that he will not be at work tonight. Patient states that he had a reaction to his first HPV - states he fainted, but completed the series without further problems. Repeat VS at 1550 BP 90/p; HR 67, O2 98%. Color remains very pale. EMS activated. patient states he needs to lie down. Assisted to stretcher per EMT, elevated legs, cushion under head with ice packs on back of head. 1602 EMS arrived, BP 121/75; HR 69 O2 100% on room air. Transferred to stretcher 1605 Patient transported to Hospital |
| 1076189 | 3/5/2021 | NY | 30 | F | 3/5/2021 | 3/5/2021 | Pt has a history of fainting after receiving I.M. Injections. Pt states she is feeling faint and would like to lay down. Pt was moved to the exam room and monitored. Pts vitals are stable. Pt didn't require transport to hospital. |
| 1076873 | 3/5/2021 | | 28 | F | 3/5/2021 | 3/5/2021 | Hyperventilation w/ presyncope. Evaluated by EMS-Cleared. |
| 1076875 | 3/5/2021 | NY | 20 | F | 3/5/2021 | 3/5/2021 | Pt has a history of fainting after I.M. injections. Pt states she is feeling faint and may pass out. Pt was moved to the exam room and monitored. Pts vitals are stable. Pt states she is feeling better. Pt requested to leave. Pt didnt require transport to hospital. |

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| 1076881 | 3/5/2021 | NY | 45 | F | 2/20/2021 | 2/20/2021 | Fainted; Fainted/aggravated it; chills; fever; Headache; body aches; All night woke up with sweats and burning; All night woke up with sweats and burning; All night woke up with sweats and burning; This is a spontaneous report from a contactable consumer (patient). A 45-year-old female patient received the second dose of bnt162b2 (Lot/batch number and Expiration date were not provided), via an unspecified route of administration in left arm on 20Feb2021 08:30 at single dose for covid-19 immunization. Medical history included Vasovagal syncope, allergy to Sulfa drugs. Concomitant medication included venlafaxine hydrochloride (EFFEXOR), metoprolol. The patient previously allergy to cipro and levaquin. The patient previously received the first dose of bnt162b2 (Lot number unknown), at the age of 45-year-old, via an unspecified route of administration in left arm on 28Jan2021 15:30 at single dose for covid-19 immunization. About 11 hours after 2nd dose (20Feb2021 19: 30), the patient got extreme chills and fever, headache and body aches. All night woke up with sweats and burning. Fainted around 21Feb2021 06:00 (patient had vasovagal syncope so maybe aggravated it). No treatment received. The patient was no pregnant. The outcome of the events was recovering. Information on the lot/batch number has been requested. |
| 1076882 | 3/5/2021 | CA | 40 | F | 3/5/2021 | 3/5/2021 | At approximately 0924 client reported feeling light headed and nauseated. She was hyperventilating and very anxious. She quickly became pale and fainted. At 0925 she was awoken using a cold pack to her face and chest. Her vital signs were taken and stable. She continued to feel anxious, her nausea went away. She still felt dizzy and her fingers were tingling, at approximately 0934 she felt it difficult to swallow and like something was "swollen/tight" in her throat. Lungs were clear, she was swallowing normally. At 0940 she felt her neck still "swollen", upon assessment her submandibular nodes were enlarged to palpation. Benadryl 25 mg orally x1 was given at 0945, vital signs remained stable. She began to feel better at approximately 10:00 am, she recovered and was able to ambulate. A co-worker took her home at 10:51 am. |

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| 1076901 | 3/5/2021 | GA | 18 | F | 2/23/2021 | 2/23/2021 | Asthma; Syncope; Dizziness; Nausea; Vomiting; Severe headache; Fever; Muscle weakness; Muscle twitching; Fatigue; Chest tightness; This is a spontaneous report from a contactable consumer (patient). A 18-year-old female patient received second dose of BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Lot no: Em9810), on right arm via an unspecified route of administration on 23Feb2021 10:30 at single dose for covid-19 immunisation. The patient medical history was not reported. There was no known allergy. Concomitant medication included sertraline, amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL). Historical vaccine of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 02Feb2021 04:45PM on Arm Left for covid-19 immunisation. On 23Feb2021 10:30 patient experienced syncope (medically significant), dizziness, nausea, vomiting, severe headache, fever, muscle weakness, muscle twitching, fatigue, chest tightness, asthma. No treatment was received for the event. Patient not having COVID prior vaccination. Patient not tested COVID post vaccination. Outcome of the events was recovering.; Sender's Comments: Based on the strong temporal association, the association between the event syncope and the vaccine BNT162b2 administration cannot be completely ruled. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate. |
| 1076223 | 3/5/2021 | WI | 69 | F | 3/4/2021 | 3/4/2021 | Light headed. hot & cold flashes, muscle cramps, fainting spell and headache. |

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| 1073911 | 3/4/2021 | CA | 19 | F | 3/4/2021 | 3/4/2021 | 11A1 19 y old pt received 1 st dose Moderna vaccine, after 5 mins she had episode of syncope, fell from her chair and bump her head. She had seizure for about 10 seconds. After seizure she was A/O x4 , neurologically intact, good PERRLA. Her BP was 95/65, HR 59, O2 sat 98 RA. Pt able to speak and was aware of the situation. 911 was called to take the pt to the hospital for head injury to R/O any abnormality. |
| 1071844 | 3/4/2021 | WA | 20 | F | 3/3/2021 | 3/3/2021 | Fainted within five minutes of receiving and sitting after the vaccine. Experienced a complex migraine with aura for the entire day after, no relief until having slept through the night. |
| 1071978 | 3/4/2021 | MI | 53 | F | 3/4/2021 | 3/4/2021 | Patient fainted and became short of breath. Epinephrine and diphenhydramine administered and patient transferred to the emergency department. |
| 1072134 | 3/4/2021 | MN | 40 | F | 3/4/2021 | 3/4/2021 | Patient c/o being fearful of needles, complaints of feeling light-headed, dizzy, fainting. Feels cold and clammy, perspiration noted on forehead. Complains of nausea and pain in left lower quad. |
| 1072246 | 3/4/2021 | FL | 24 | F | 3/3/2021 | 3/3/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Headache-Mild, Systemic: Nausea-Mild, Additional Details: recieved vaccine after 10 min she became unresponsive. She was laid on the ground and given an epi dose by the nurse awhile the pharmacist called 911. She started to come back after 3 min she opened her eyes. The rescue came and asked anyone whoe was not family to leave. They gave her the ok to go. We contacted the pateint today. Her father says she is doing well and only complained of a mild HA and mild nausea last night. Will be seeing her doctor for further recommendations. |

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| 1072271 | 3/4/2021 | IL | 57 | M | 3/2/2021 | 3/2/2021 | At approximately 16:36 pt was noted writhing on the floor in the post-vaccine waiting area. Upon rapid assessment of pt, others advised to call 911. 911 was called. Pt appeared to be in pain and tense, eyes were tightly shut but pt was breathing and moving throughout the entire time, after about 10 seconds was able to speak and stated that he felt sudden onset of dizziness and fell onto the ground. Pt denied head injury or pain from fall, no signs of trauma noted to face, dentition, or head. He stated that he was able to hear the voices of people talking to him the entire time he was on the floor. Pt denied any LOC, recalled all events leading up to falling. Pt reports hx of syncope after an injection once before, years ago. Pt denied any past medical history. Pt denies taking any medications, and denies any allergies. Pt states he only take medication when he has headaches. Assessment: Pt appeared in mild acute distress. Pt moaning and grimacing initially, once verbal, speech was clear and he was able to speak in complete sentences. Pt face was symmetrical and had purposeful movement of all extremities. Moderate diaphoresis and facial pallor noted. VS @16:38 BP 162/100 HR 113 RR 24 O2 98% @1642 BP162/99 HR 94 RR 20 O2 97%. EMS arrival @1647 and pt was refusing to be transported to the hospital. Pt and pt's mother were advised of the importance of further evaluation in the ED despite pt insisting he felt better. Spoke with pt mother and family while pt was speaking with EMS and urged them to take pt to the hospital via private vehicle even if pt were to refuse ambulance transport. Understanding was verbalized. |

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| 1072529 | 3/4/2021 | NY | 57 | F | 1/20/2021 | 2/17/2021 | Fainted; dizziness; All night she was sick; Chills; Aches; A spontaneous report was received from a consumer concerning a 57 years old, female patient who experienced chills, aches, dizziness, fainted and was sick all night. The patient's medical history was not provided. Concomitant products included cetirizine and an unspecified nasal spray for allergies. On 20-JAN-2021 the patient received their first of two planned doses of mRNA-1273 (Batch number: 012120A) on 20-JAN-2021. On 17-FEB-2021, approximately one day prior to the onset of the symptoms, the patient received their second of two planned doses of mRNA-1273 (Batch number 016M20A) for prophylaxis of COVID-19 infection. On 17-FEB-2021, the patient was sick for all night, on the same day patient experienced chills and aches. On 18-FEB-2021, the patient had dizziness and fainted. Treatment information was not provided/unknown. The patient received both scheduled doses of mRNA-1273 prior to the events; therefore, action taken with the drug in response to the events is not applicable. The events, chills, aches, dizziness, was sick all night were considered unknown. The event, fainting, was recovered on 18-FEB-2021.; Reporter's Comments: This case concerns a male of unknown age who experienced a serious unexpected event of SYNCOPES along with NS unexpected events of dizziness, illness, pain, and a NS expected event of chills. The events occurred 45 minutes after the first dose of mRNA-1273. Syncopal event reported as resolved, but other event outcomes unknown. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. |
| 1072727 | 3/4/2021 | FL | 72 | F | 2/25/2021 | 2/25/2021 | Chills,fever,almost passed out,headache,sore arm |
| 1071727 | 3/4/2021 | MD | 78 | M | 2/4/2021 | 3/2/2021 | Patient presented to ED with constipation and near syncope. Patient sustained a left radial fracture after slipping on the ice a few weeks ago, and was prescribed oxycodone before and after surgery. Patient's constipation was treated with repeat enemas and stool softeners with resolution and patient is to be discharged today with daily miralax. |

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| 1072895 | 3/4/2021 | MA | 55 | F | 1/31/2021 | 2/1/2021 | I received my second Moderna COVID vaccine on 1/31 (lot: 028L20A, exp 7/29/21) . The next day 2/1 I had a severe reaction with temps to 103, chills, rigors, nausea and vomiting. I was in the bathroom vomiting and passed out, and fell and hit my head on the tub. On 2/8 for two weeks and had residual fatigue but no other symptoms. 2/24 around 7 pm I had sudden onset of paraesthesias (pins and needles) in both feet, over 30 min it progressed up to my knees and my legs and feet were numb. The next morning I went to the ER and was admitted. |
| 1071384 | 3/4/2021 | TX | 56 | F | 2/26/2021 | 2/26/2021 | 56 year old female presents with symptoms after getting 2nd dose of Moderna Covid Vaccine. Received first covid vaccine 1/26/21, and 2nd dose 2/26/21 at 11am. 30 minutes after getting vaccine, started feeling dizzy, like room is spinning, still has dizziness constant. It is not as strong now. Denies nausea with the dizziness. 2/27 Saturday 2 am, started with vomiting and pain to the left arm where she had injection. Only had vomiting Saturday, pain to left arm stopped 8-9pm that night. Started with fever, body aches, headaches, back pain, and feeling tired since yesterday, 2/28 around 6 am. Felt dizzy and fainted yesterday when she had fever. Temp max was 101.5F. Check today 99.5F 4 hours after taking Tylenol. Today started with cough. Has no appetite. Has increased water intake. Has been taking Tylenol/ Theraflu/ ginger with lemon tea. Denies any residual swelling or redness to left arm. Denies diarrhea, loss of taste or smell, or SOB. |

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| 1072900 | 3/4/2021 | CA | 77 | M | 2/10/2021 | 2/10/2021 | He received the vaccine and after 2 hours he went home and was paralyzed from the waist down. He tried to stand up and then he passed out on the floor for about 10-15 minutes. He went to sleep and woke up around 5 hours later. He then tried it again and urinated on himself and he fell down on the floor, passed out without getting up until the morning. He did call his doctor who was not available, spoke to the nurse and advised to go to the hospital. He is weak and cannot drive so he did not go to the hospital. He slept the rest of that day and the following day. Then when he saw his doctor about 2 days ago, he described his reaction and told to report the reaction and that he would report it himself. He was advised not to take the 2nd vaccination. He is no longer having the heavy reaction, his muscles are aching and his vision is blurred, especially on his back and the shoulder. His doctor did do blood work at the office visit. |
| 1072769 | 3/4/2021 | MO | 28 | F | 3/4/2021 | 3/4/2021 | patient experienced syncope while waiting in the post vaccination waiting area, she was sweating profusely and was unable to respond for a short amount of time, less than a minute. after about a minute she recovered and could respond normally. |
| 1071714 | 3/4/2021 | CA | 45 | F | 3/3/2021 | 3/4/2021 | Fainting in shower Weakness |
| 1071606 | 3/4/2021 | WI | 67 | U | 3/3/2021 | 3/3/2021 | Patient administered Moderna Covid-19 vaccine at 1:21 p.m. on 3/3/21. Patient at 1:36 p.m. experienced syncope while being monitored; EMS staff and RN responded to patient. EMS staff and RN spoke to patient and assisted patient to EMS cart. EMS staff took patient's vitals: pulse 70, respirations 22, blood pressure 159/85. ABC's clear at this time of response. Patient speaking after recovery from syncope. Patient, while strapped on EMS cart, began gagging and provided emesis bag. Patient transported to EMS ambulance (which was parked immediately outside the facilities doors). two to three minutes after syncope event where reportedly patient given Benadryl and IV fluids in ambulance and transported to ER. |

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| 1071578 | 3/4/2021 | IL | 73 | F | 2/24/2021 | 2/24/2021 | Patient states she was weak, and couldn't feel her arms or legs about an hour after getting her COVID 19 vaccine. States on the way home she ended up on the wrong side of the road and felt like she wasn't focused and this progressed to numbness. States that when she went to get out of her car she had a fall and is unsure if she passed out or just fell. States these symptoms lasted 3-4 hours but it gradually improved. States almost all symptoms had improved by the next day. |
| 1071529 | 3/4/2021 | AZ | 70 | M | 3/1/2021 | 3/2/2021 | Moderna COVID-19 Vaccine EUA In addition to the flu-like symptoms (headache, muscle and joint aches, fatigue, sore arm) I had an episode at 10pm on 3/2/21 where I had a sudden onset of profuse perspiring of the upper body and passed out for a short time. (falling while at the bathroom sink) I was so weak (could not stand) when I came to that I had to lie on the bathroom floor for 15 min. or so in order to get up. |
| 1071494 | 3/4/2021 | LA | 59 | F | 2/11/2021 | 2/12/2021 | Passed out in the bathroom. Hit face. Do not believe she was out very long. Sustained a swollen and bruised right eye that eventually moved to the left. |
| 1071235 | 3/4/2021 | PA | 37 | F | 1/14/2021 | 1/19/2021 | 34 week twin gestation at time of vaccination. Healthy pregnancy. No comorbidity. Developed headache and sore throat on Jan 19 . Headache continued and developed Pre-Eclampsia (diagnosed Jan 24th-25th). Emergent C-section for Pre-Eclampsia on Jan 26th. Infants spent 3 days in NICU for tachypnea/bradycardia/apnea spells and mother (the vaccinated patient) went to ICU at 12 hours postpartum for syncope episode. The twin infants birth weights were 5 lb 8 oz and 5 lb 13 oz and were discharged on DOL 3 to 5. Mother discharged home at day 3 to 4 post birth. |
| 1071399 | 3/4/2021 | | 51 | F | 3/3/2021 | 3/3/2021 | Pulse weak. Thready, Lips pale, Fainted. Refused transport. Evaluated by EMS-Cleared |
| 1071339 | 3/4/2021 | TX | 91 | F | 3/3/2021 | 3/3/2021 | Systemic: Allergic: Difficulty Breathing-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Shakiness-Severe, Additional Details: Pt experienced lower back pain, difficulty breathing, dizziness, light headed, shaking more than normal, cold, felt like she was fainting |

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| 1071317 | 3/4/2021 | CA | 41 | F | 3/3/2021 | 3/3/2021 | Severe nausea. Fainting, loss of consciousness for several minutes, unresponsive, required 911 call. Severe calf muscle cramp of right leg. |
| 1073100 | 3/4/2021 | ID | 38 | F | 3/3/2021 | 3/3/2021 | PATIENT STATED SHE FELT LIKE SHE WAS GOING TO PASSOUT, DIZZY. PT. STATED HISTORY OF FAINTING/SYCOPY. MEDICAL HISTORY INCLUDES ASTHMA, REACTIONS TO VACCINATIONS, AND VOMITS AFTER FLU SHOT. PT. BP 120/70 HR 79 O2SAT 97 CLAMMY SKIN, BREATH SOUNDS CLEAR BILATERALLYVAT 1555. OBSERVED TREATMENT: BP 130/76 HR 67 O2SAT 95 AT 1613 ELEVATED TO SITTING POSITION AT 1616 WITH NO NEGATIVE EFFECTS. |
| 1071331 | 3/4/2021 | CA | 22 | F | 3/3/2021 | 3/3/2021 | Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Shakiness-Medium, Systemic: Visual Changes/Disturbances-Severe, Systemic: Weakness-Severe, Additional Details: After 5 minutes patient stated that she is dizzy and her vision is blurry and going black. She then fainted and that was when the epi pen was given to the patient. She was unresponsive for a total of about 10 seconds. She was awake and responsive after the epi pen. She stated that she was still dizzy, but she did not have trouble breathing or swallowing. Patient states she had similar reaction when she had ears pierced and TB test. She was taken to hospital after by EMS. |

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| 1071141 | 3/4/2021 | PA | 92 | F | 1/15/2021 | 1/16/2021 | <p>she had not been eating properly; she was found lying on floor of her house - likely having been there for 3 hours. Next morning found lying on the floor of the bathroom; On helping up she was confused but otherwise ok; she was found lying on floor of her house - likely having been there for 3 hours. Next morning found lying on the floor of the bathroom; This is a spontaneous report from a contactable consumer. A 92-year-old female patient received first dose of bnt162b2 (Formulation: Solution for injection, Lot number: EK1768), via an unspecified route of administration, on 15Jan2021 at single dose for COVID-19 immunisation. Medical history included t2diabetes, hypertension, arthritis, previous episodes of falling. The patient's concomitant medications included rampril, glimepiride, gabapentin, sitagliptin, atorvastatin, tolterodine l-tartrate (PREBLACON) all at unspecified doses. It was reported that on 16Jan2021 at around 6pm she was found lying on floor of her house - likely having been there for 3 hours. On helping up she was confused but otherwise ok (as reported). She remained ok for several hours before going to bed. Next morning found lying on the floor of the bathroom. It was reported that ambulance was called but did not go to hospital due to COVID risk and overcrowding. It was reported that blood sample was taken on an unknown date in 2021 and analysed. The doctor called and reported no abnormal findings in blood sample. Suggested possibility that she had not been eating properly. The outcome of the event she had not been eating properly was unknown, while for other events was recovering. The events occurred in a country different from that of the reporter. This may be a duplicate report if another reporter from the country where the event occurred has submitted the same information to his/her local agency; Sender's Comments: Based on the information currently available, a possible contributory role of the suspect drug in the reported event Syncope cannot be completely excluded given the known suspect drug profile and/or implied temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and</p> |

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| 1071469 | 3/4/2021 | GA | 58 | M | 3/3/2021 | 3/3/2021 | Investigators, as appropriate. After developing soreness at the injection site about 6-8 hours post injection, I developed chills and thirst, at 4:30am I got up to go to urinate and afterward I was feeling light headed. I sat on the edge of the tub. After a couple of minutes I went to get up and fainted on the floor. My BP was 89/49 with a pulse of 86bpm. I was helped off the floor and back to bed where I lay with my feet elevated by a couple of pillows. No further issues at this time. |
| 1073852 | 3/4/2021 | MO | 66 | M | 3/4/2021 | 3/4/2021 | Customer had a vasovagal rx nearly immediately after receiving vaccine at approximately 1210. pulse of 50 when taken. Drooling, diaphoretic. unable to arouse when calling his name. did sternal rub, moved patient head to upright position and customer started to waken. asked for cold water and drank readily. started to ask coherent questions. sat with patient approximately 20-30 min before allowing him to leave.. He told us after the fact that he has passed out before when giving blood. Must lie down when giving blood or shots. He was not concerned because he has experience this same reaction . Pt left on his own accord at 1300. Did not tell staff of this problem before he got the vaccine. |
| 1073129 | 3/4/2021 | NY | 78 | M | 2/17/2021 | 2/27/2021 | Saturday 02/27 thru this morning: Low pains in upper left chest / Low pains in middle of left side of back Tuesday 03/02/2021: Headache and pain in left eye / Sitting watching tv on Tuesday 3/2/2021 and almost passed out Have never experienced anything like this before so think it may be vaccine related. Then saw the news report about women getting false positive mammogram results only on the same side they had their vaccine in and that seems to be the case with my events - all on left side. |

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| 1071263 | 3/4/2021 | | 21 | F | 3/1/2021 | 3/1/2021 | Patient witnessed slumped over in chair and unconscious. at approximately 12:52 PM. Patient aroused with physical stimulation. Patient immediately regains consciousness. Patient oriented to person, time, place and situation. Patient reveals history of syncope to a prior flu vaccine and Gardasil vaccine. Patient then loses consciousness. Patient aroused with verbal and physical stimulation. Patient regains consciousness immediately. 911 had already been activated at this point. Paramedics assumed care at approximately 1:00 PM. Patient refused transport to hospital. Patient advised to have someone drive her home. Patient monitored until transportation arrived. Prior to leaving facility, patient reassessed at approximately 1:30 PM. Blood pressure was 139/102 mmHg and pulse 90 bpm. Patient left facility at approximately 1:35 PM to roommate. Patient escorted to car by paramedic. Patient left facility alert and oriented to person, time, place, and situation with steady gait and unlabored breathing. |
| 1074028 | 3/4/2021 | CA | 30 | F | 3/2/2021 | 3/2/2021 | Started to feel sweaty and then felt faint and tingly. This started less than 10 min after injection. I have had this happen before with a previous injection a few years ago, except that time I actually passed out. This time I felt very faint and the nurses said I looked "grey and pale" but did not lose consciousness |
| 1073979 | 3/4/2021 | FL | 38 | F | 3/1/2021 | 3/4/2021 | patient passed out, woke up less than 1 minute later and was pale and nauseous |
| 1073978 | 3/4/2021 | NV | 28 | M | 3/4/2021 | 3/4/2021 | Patient fainted about 1 minute after vaccination; he lost strength in his legs and fainted for about 5 seconds. Patient became awake after and coherent of what was going on around him. He still felt weak afterwards and reported light headiness. The paramedics arrive and vitals were reported to be normal. Patient elected to go to the hospital. |
| 1073910 | 3/4/2021 | CO | 78 | F | 1/12/2021 | 1/13/2021 | When I got the vaccine it hurt so much that I jumped. It felt like it burned for like 3min. The next day I had shortness of breath & I fainted the next thing I seen when I woke up was the paramedics taking me in to the ambulance to do an EKG. Everything was good except my blood pressure dropped. I was not taken to the hospital. |

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| 1073898 | 3/4/2021 | AL | 25 | F | 3/4/2021 | 3/4/2021 | Patient has history of fainting after vaccines,blood work,or steroids shots. Patient started feeling nauseous after about 4 minutes then started to loose color in skin. Placed cool compresses to patient neck and forehead. Had patient lie down in supine position with feet elevated with cold compressed still applied. Patient stayed in this position until started feeling better, then had patient sit for a few minutes then gradually moved patient to chair. Observed patient in chair for around 30 minutes before patient facility. Patient never fainted just had the feeling. |
| 1074091 | 3/4/2021 | FL | 42 | F | 1/30/2021 | 1/31/2021 | Whole left arm hurt Severe headache 104.5 fever Passed out 2 different times Chills Delirious Lost control of bladder twice Seizure Breathing difficulties-responded to use of inhaler |
| 1073830 | 3/4/2021 | FL | 50 | F | 3/1/2021 | 3/1/2021 | funny taste in mouth, felt buzzed, headache, confused, tunnel vision, pale, fainted, rash on torso |
| 1073804 | 3/4/2021 | | 24 | F | 3/4/2021 | 3/4/2021 | Near syncope. |

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| 1073797 | 3/4/2021 | CA | 19 | F | 3/4/2021 | 3/4/2021 | <p>Approximately 1200 ,Pt answered no to all pre_vaccination questions. Pt. eyes closed and head dropped to right immediately after first dosed of Moderna #0032A21A was given in his in his L deltoid. Pt immediately came back to arousal after securing pt upright by his shoulder. STAT call for assistance. Onsite doctor called STAT site lead RN present Pt stated, Local Ambulance called STAT. ?Did I pass out?? ? Yes you did.? Pt is AAOx4, color slightly pale, skin normal. Initial VS BP 48/52,P 50, R 18 and regular,,Sat 97%, Legs elevated on chair. Pt remains alert and talking coherent. 2ND VS 55/50, P50,R16 and regular SAT 97%. Pt remains fully AAOx4. Stated ?I was very nervous? Onsite doctor now present. 3rd manual checked VS 97/43, HR 60, R18 reg and calm, Sat 97%. Pt says he did eat but had little to drink. 1 bottle of water given and tolerated well. Pt stated ?my visions was a little blurry and it was difficult hearing but now I am better?. Pt also denies any heart issues or syncope issues. EMT arrived approximately arrived at 1224. EMT report normal sinus rhythm, SAT 100%, all VS WNL. Pt coherent, calm and fully AAO x4. Pt was advised by onsite voluntary doctor just for caution and further eval to go with EMT to hospital but pt. stated ?I am ok. I do not want to go to hospital? Refusal letter was signed by pt. Pt also denied request to notify his Mom who pt said was waiting in car. Pt was able to stand without assistance and ambulated to post vaccination sitting area w/o any difficulties. Pt remained AAOx4 w/o any further issues and was D/C approximately 1pm. Initial incident was witnessed by nurse vaccinator and report documented by this document was written by Nurse .</p> |

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| 1073657 | 3/4/2021 | CA | | F | | | had a serious allergic reaction to her first COVID 19 shot; passed out while driving her car; On the way home she started to feel sick; She had a small accident, hitting a street sign; The next day she started having respiratory symptoms and spent the day in the ER because she was having difficulty breathing.; This is a spontaneous report from a contactable consumer via a Pfizer sales representative. A female patient of an unspecified age received her fist dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration from an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On an unspecified date, the patient had a serious allergic reaction to her first COVID 19 shot. She waited after receiving the shot for 15 mins and felt fine. On the way home, she started to feel sick and passed out while driving her car. She had a small accident, hitting a street sign. The next day she started having respiratory symptoms and spent the day in the ER because she was having difficulty breathing. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained. |
| 1073330 | 3/4/2021 | CA | 41 | F | 2/28/2021 | 2/28/2021 | After receiving the vaccine, patient experienced nausea with an episode of syncope. SBP 60 mmHg prior to syncope. Patient was given epinephrine 0.3 mg IM x1 dose. Patient was difficult to arouse and a second epinephrine 0.3 mg IM was administered! EMS was called on seen and patient was taken to the ER where patient received fluids and zofran and was discharged. Husband confirmed the patient has phobia for shot/needles. |
| 1073190 | 3/4/2021 | IN | 66 | F | 2/6/2021 | 2/10/2021 | She had syncope, nausea, vomiting on 2/10/21, 4 days after vaccine. She went to ED that day. She saw me today (3/4/21) and has had recurrent nausea, vomiting and dizziness but no further syncope. |
| 1073254 | 3/4/2021 | CA | 22 | F | 3/4/2021 | 3/4/2021 | PATIENT FELT LIGHTHEADED. WHILE TRANSPORTING HER TOTHE GURNEY PATIENT HAS A SYNCOPE AND HELPEDTO THE FLOOR BY THE OBSERVATION NURSE. BP CHECKED READ 80/ |

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| 1073901 | 3/4/2021 | GA | 63 | F | 3/4/2021 | 3/4/2021 | Patient with no history of fainting after receiving vaccines reported feeling faint 15 minutes after receiving first COVID vaccine. When patient was unable to clearly answer the pharmacist, 911 was called. Patient was assessed by EMS and it was determined patient experienced a vagal response. Patient remained in pharmacy until she felt better, approximately 1 hour after the side effect initially occurred. |
| 1073651 | 3/4/2021 | NY | 91 | M | 2/18/2021 | 2/20/2021 | syncope; nausea; vomiting; This is a spontaneous report from a contactable consumer (patient). A 91-year-old male patient received the first dose of bnt162b2 (Lot/batch number and Expiration date were not provided), via an unspecified route of administration in right arm on 18Feb2021 13:00 at single dose for covid-19 immunization. Medical history included dementia, diabetes, chronic kidney failure, known allergies: pencillin. Concomitant medication included insulin, metoprolol, memantine, omeprazole (PROTONIX), apixaban (ELIQUIS). On 20Feb2021 21:00, the patient experienced syncope followed by nausea and vomiting lasting about 4 hrs. No treatment received. Events resulted in Doctor or other healthcare professional office/clinic visit. The outcome of the events was recovered on 21Feb2021 01:00. Information on the lot/batch number has been requested. |
| 1073317 | 3/4/2021 | AL | 26 | F | 3/4/2021 | 3/4/2021 | PATIENT PASSED OUT AFTER RECEIVING MODERNA VACCINE, SAID SHE FELT HOT AND WEAK, PARAMEDICS CAME AND DETERMINED THAT HER BLOOD PRESSURE WAS LOW |
| 1073284 | 3/4/2021 | WI | 26 | F | 3/4/2021 | 3/4/2021 | Patient had syncope episode after vaccination. Last approximately 15 minutes and then with drinking water, distraction, and having a snack provided by clinic client was recovered. |

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| 1073422 | 3/4/2021 | MD | 56 | F | 2/26/2021 | 2/26/2021 | Extreme Body aches, extreme headaches, extreme chills, fever 105.2, pain in the arm, dizziness, nausea, fainted at 6 pm on 02/27/21,, no response or movement. Blood pressure dipped down to 60/42 ...Ambulance came. EMT measured the blood pressure... 60/42 Was taking Tylenol 2 tablets of 500 mg. (max out) Fever will go down for an hour but would be back with extreme chills. Symptoms Fever, chills, body aches persisted for 30+ hours. |
| 1073427 | 3/4/2021 | NM | 41 | F | 3/4/2021 | 3/4/2021 | Pt was given shot and told to sit for 30 minutes since she put on information form that she has fainted or felt dizzy after shots. All of a sudden she just fell over and both ran out to help patient. We held her head and talked to her to see if coherent, then we took blood pressure which was 110/90 which was normal for pt according to husband. We monitored patient for several more minutes and she said she felt fine. Her and husband walked out after about 20min or so. |

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| 1073431 | 3/4/2021 | NJ | 56 | M | 3/3/2021 | 3/4/2021 | <p>According to NJIIS registry, patient received Moderna dose 1 at "Rite Aid 00994" on 3/3/2021. Patient arrived in ED on 3/4/21 at approx 9AM via ambulance. ED physician note: "56-year-old male brought in by EMS intubated with CPR in progress. It was reported that he arrived to work and then passed out. CPR was initiated almost immediately. BLS determined that he was pulseless and AED was applied. He was defibrillated twice. He was then intubated by ALS and administered epinephrine twice with return of spontaneous circulation. He maintained a pulse for approximately 20 minutes when he again developed cardiac arrest. ACLS guidelines were again initiated and there was no return of pulse for approximately 20-25 minutes until he arrived in the emergency department. Emergency department CPR was continued and he was administered an additional epinephrine with return of a pulse. Is reported that he had no complaints prior to the event." Patient was intubated and ventilated, started on norepinephrine drip in ED. Twelve-lead EKG demonstrated right bundle branch block with left posterior fascicular block and diffuse QRS widening and diffuse repolarization abnormalities. Family consented to Cath Lab. Per Interventional Cardiologist note: "1. Angiography demonstrated proximal to mid LAD hazy 90-95% lesion likely culprit for cardiac arrest. 1 stent placed. 2. Diffuse distal right coronary disease that is likely nonculprit for cardiac arrest. 3. Left ventriculography demonstrated severe anterior wall hypokinesis with overall left ventricular ejection fraction of 40%. 4. Patient electrically and hemodynamically stable. Levophed has been stopped. Amiodarone bolus given in the Cath Lab for frequent ventricular ectopy. No drip was continued due to resolution of ectopy. 5. Dyslipidemia he will be on high-dose statin therapy. 6. Diabetic management as per primary team. 7. Quad-Lumen placed by me. Hypothermia protocol to be initiated in the ICU given GCS score less than 8 with no purposeful movements. Head CT scan completed before cardiac catheterization that demonstrated diffuse cerebral edema. 8. Prognosis guarded and likely poor. The next 24 to 40 hours will be critical. Family was updated in detail." Patient transferred to ICU post Cath Lab. Remains intubated, ventilated in ICU.</p> |

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| 1073434 | 3/4/2021 | TX | 21 | M | 3/4/2021 | 3/4/2021 | Pt fainted and looked to have seizing. pt revived and said he was fine, and asked for alcohol to smell. EMS was called and pt was examined. Pt later disclosed that he always faints when he gets shots and he has anxiety. Pt refused to go with EMS and pt mom said she would take him to doctor |
| 1073438 | 3/4/2021 | CA | 44 | F | 1/12/2021 | 1/13/2021 | I had Covid-19 in December 2020. On the following day of my first vaccine, in the middle of the night, I experienced chills, body aches. At 7am the next day I woke up feeling light headed and passed out. When I woke up I had thrown up on myself and started to hear a whooshing sound in my ears and I went back to bed. At 9am my symptoms started all over again. I live with my house maid and since I did not look well, she took me to urgent care. My BP had dropped and I was super dizzy. I got an IV drip for an hour, anti-nausea medication. My blood was also drawn and found to have underlying anemia. My urine test was negative. The pulse oximetry was fine and by the next day I slowly started to feel better. |

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| 1073516 | 3/4/2021 | SC | 73 | F | 1/26/2021 | 1/26/2021 | <p>food poisoning; First got really sick; nausea/She got sick to her stomach; head colds/feels like coming down with a cold; Feeling unwell/she wasn't feeling well; Dry heaved for 40 minutes. Saliva in her stomach was coming up, not food. Felt like it lasted forever.; sinus problems.; vomiting; Pain injection site; Slight headache; Chills, feels like coming down with a cold; Tired; This is a spontaneous report from a contactable consumer (patient) via Medical Information Team. A 73-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number: RL3249), via an unspecified route of administration at left arm on 26Jan2021 14:00 (also reported as 17Jan2021 - pending clarification) at SINGLE DOSE for COVID-19 immunisation. The patient had no prior vaccinations within 4 weeks. Medical history included diabetes, cancer (prior to receiving COVID-19 shot. Stated she was 14 years cancer free), allergy, shingles shot which hurt at the injection site, shrinks every year (Doesn't know exact number, but a little under 5 feet). The patient had no family medical history. Concomitant medication included mometasone furoate (FLONASE [MOMETASONE FUROATE]). On an unspecified date, the patient experienced she got sick to her stomach, food poisoning, "nausea/She got sick to her stomach," "head colds/feels like coming down with a cold," "feeling unwell/she wasn't feeling well," "dry heaved for 40 minutes. Saliva in her stomach was coming up, not food. Felt like it lasted forever," sinus problems, vomiting, and first got really sick. On 26Jan2021, the patient experienced tired, slight headache, chills feels like coming down with a cold, and pain injection site. The patient reported that she received the first dose of the Pfizer vaccine and experienced side effects including nausea, head colds, and sinus problems. She was concerned that this may be covid and if it will be safe for her to get the second dose of the vaccine as scheduled. The patient further reported that she first got really sick. Never had the flu and always gets head colds or food poisoning on an unspecified date. After reading material passed out, perhaps she was treating COVID and not a cold or allergy. The patient took first COVID-19 shot on 26Jan2021. Thought everything was fine. The patient was close to bedtime then noticed she wasn't feeling well. Looked at side effects and has</p> |

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like six of them at the same time. Right as she was going to rest, she got sick to her stomach. Never was sick to her stomach except when she was food poisoned. The patient had dry heaved for 40 minutes. Saliva in her stomach was coming up, not food. Felt like it lasted forever on an unspecified date. The patient asked that if she does have COVID, should she take the second shot? Wanted to get tested because Pfizer materials says exactly what her headache and sinus stuff was about. Now she was scared. The patient also reported that she wanted to take the second COVID-19 shot. If she does have COVID, thinks it's not the thing to do right now. It was confirmed she has not had a positive COVID test after receiving the first COVID-19 shot. Should have read material prior to and maybe wouldn't have taken the first COVID-19 shot. Confirmed symptoms she mentioned occurred after the COVID-19 shot. The patient came home from COVID-19 shot feeling fine. Didn't get sick until close to bedtime. Appointment for COVID-19 shot was 2:30PM. Clarified six symptoms previously mentioned: The patient had pain at injection site just two days and was gone. Began shortly after she got home from the COVID-19 shot. Went to lift arm up and it didn't feel good. Began an hour or two after COVID-19 shot. The patient was tired unusually early in the day. Felt like she didn't want to do anything. Couldn't use her left arm. Clarified left arm was injection arm. Tiredness has subsided and only lasted a couple of days. It was further reported that patient never gets headaches. It started after vomiting which didn't last long. It bothered her and then was gone by the time she went to sleep. The patient had chills, feels like coming down with a cold on an unspecified date which subsided right before dinner around 3PM-4PM. The patient had to put on a fluffy robe to keep warm. It was also reported that the patient did not have a fever. It was also reported that shingles shot hurt at injection site where pain lasted a week and a half. Temperature went from 98.6 degrees to 99 degrees. The patient was taking stuff now and monitoring to see if she can see any signs. The patient was feeling unwell on an unspecified date which has subsided except for allergies and she was concerned. The patient also experienced dry heaving: didn't have anything in her stomach on an unspecified date which subsided. Even after she ate yesterday, hasn't had any dry heaving except for night of

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| 1073295 | 3/4/2021 | FL | 52 | F | 2/26/2021 | 2/26/2021 | <p>the COVID-19 shot. The patient underwent lab tests and procedure which included body height: little under 5 feet (doesn't know exact number), temperature: went from 98.6 degrees to 99 degrees, and COVID test: negative (she has not had a positive COVID test after receiving the first COVID-19 shot). Therapeutic measures were taken as a result of sinus disorder which included sinus medication and was squirting Flonase in her nose. On an unspecified date, the patient recovered from slight headache. The patient had not yet recovered from the event nausea and vomiting. The outcome of the events chills, tired, food poisoning, first got really sick, head colds/feels like coming down with a cold, feeling unwell/she wasn't feeling well, dry heaves, sinus problems, and pain injection site were unknown.</p> <p>Day 1, 26 Feb 2021; headache began at noon; severe fatigue at 6:00 pm; 103 degree fever at midnight Day 2, 27 Feb 2021: 103 fever for 3 hours, reduced and maintained at 100 with alternating extra strength Tylenol with 800 mg Motrin every 4 hours; continued severe fatigue; continue headache, nausea started at 5:00 pm Day 3, 28 Feb 2021: Nausea, diarrhea, muscle pain, vomiting, headache, 100 degree fever for 24 hours, 6:00 pm passed out for less than 1 minute when standing to go to bathroom to vomit (aware, controlled fall); 2nd episode of passing out sometime after midnight, tried to stand, completely blacked out, woke up disoriented, called 911, transported to ER; bruised upper left arm, left side jaw/neck hitting furniture in fall, hit head on floor</p> |

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| 1069010 | 3/3/2021 | CA | 40 | F | 3/2/2021 | 3/2/2021 | At roughly 9:00pm I was scrolling through my phone when it became very difficult to focus and I felt nauseous. I got up to go to the bathroom and became extremely dizzy and my heart felt like it was going to beat out of my chest. I was having difficulty breathing and felt disorientated. I crawled up the stairs and when I reached the top I stood up to walk and promptly fainted/passed out. According to my husband I was out for roughly 30 seconds. He described my body as completely tense (formed fists, shaking). I don't have any recollection of passing out. When I came to I was overwhelmed with nausea and immediately vomited. I was sweating profusely and struggling to breath. After I vomited, within minutes (less than three) I felt fine. My heart rate returned to normal and I wasn't dizzy or nauseous. |
| 1069243 | 3/3/2021 | | 22 | F | 3/1/2021 | 3/1/2021 | Patient fainted and was sweating while in post vaccination observation area. Patient recovered and mother took patient to ED for follow up. Patient discharged from ED with no issues. |

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| 1069050 | 3/3/2021 | OH | | F | 1/28/2021 | 1/1/2021 | <p>passed out; almost delirious; couldn't lift leg; pain went all the way down left side of body; sweating; chills; felt heavy weight on chest; left leg hurting so bad like a charley horse; weak all over; allergic reaction; pain in left arm at injection site; felt extremely tired; A spontaneous report was received from a consumer, via notification from another manufacturer, concerning a 79 year-old female patient who experienced an allergic reaction (hypersensitivity); passed out (loss of consciousness); almost delirious (delirium); couldn't lift leg (femoral nerve injury); pain radiating down leg (pain); sweating (hyperhidrosis); chills; heavy weight on chest (chest discomfort); leg hurting like Charlie horse (muscle spasms); weak all over (asthenia); pain in left arm where she got the shot (injection site pain); felt extremely tired (fatigue). The patient's medical history included sinus issues and drug allergies to glycopyrrolate, sulfa, meloxicam, erythromycin and azithromycin. The patient stated that she had a long list of names and ingredients of things she is allergic to. Products known to have been used by the patient, within two weeks prior to the event, included Amiodipine. On 28 Jan 2021, approximately 12 hours prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 (Batch number: 028120A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. The patient reported that she received the vaccine dose around 12:00 or 12:30 pm. The patient reported that she woke up with extreme pain in the left side and in the left arm where she got the shot. The pain went all the way down her body and she reported it as severe pain. She reported that the pain would not go away. The patient reported that she started sweating, had chills, and she felt heavy like a weight on her chest, but she was breathing okay. Her leg on the left side started hurting so bad that it was like a big Charley horse that would not go away. She got out of the bed and tried to see if she could stand on it, but she could not. She tried to rub it, but it did not help. She tried to walk on it, but by that time she was almost delirious. She was sweating so bad and she was weak all over. She had become extremely tired and she ended up laying on the floor because she could not get her leg to lift in order to get back in the bed so she just laid on the floor. By that point, she did not know if she had passed out or fallen asleep, but she does not</p> |

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| 1069062 | 3/3/2021 | MS | 34 | F | 3/1/2021 | 3/1/2021 | <p>think she fell asleep because it was too much pain to sleep. When she woke up and came to, the pain in her leg was gone. However, she was still sweating. She could not get back in the bed. The following morning, she was extremely weak and tired. She still felt heavy on her chest like something had been pushed on her. She was hurting, weak, and tired, but the pain was not extreme like it had been that night. She clarified the time of onset for this event was around midnight, but she could not look at the clock to confirm the exact time. She reported the event either started the night of 28 Jan 2021 or early in the morning hours of 29 Jan 2021. She called her doctor, Moderna, and the pharmacist to ask about the ingredients of the vaccine. Treatment information was unknown. Action taken with mRNA-1273 in response to the events was withdrawn. The events, passed out and pain in left leg, was considered resolved the following day. The events of sweating, weakness, tiredness, and heavy chest was improved the following day. The outcome of the events, allergic reaction, delirious, pain in left arm, pain in left side of body, chills, couldn't lift leg, was unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.</p> <p>Patient fainted after receiving the vaccine and regained consciousness after 30 seconds. She was sitting and was laid down in the counseling room with her feet elevated for approximately 10 minutes. She was given food and water and moved to the sitting area where a ride came to pick her up.</p> |
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| 1069166 | 3/3/2021 | WI | 59 | F | 3/2/2021 | 3/2/2021 | Client received the vaccine and was sitting for her 15 minute observation period. About 10 minutes into her observation period, client stated she felt dizzy and her neck hurt. RN got an icepack to her neck and was about to get client's jacket off and client fainted. Client was guided to the ground, RN did a sternal rub and after about 15 seconds after initial loss of consciousness, client regained consciousness. Client stated she felt like she was going to vomit and client was turned on her side. Client then stated her lips were numb but denied any SOB. She remained alert and orientated and continued to deny SOB. EMS arrived, client was given fluids, Benadryl, Pepcid, and solumedrol. Client was stable and transported to ER via ambulance |
| 1069288 | 3/3/2021 | CA | 76 | M | 3/2/2021 | 3/3/2021 | Initially night of the vaccine 3/2/2021 body felt hot, felt sweaty but temp was 98.0, unable to sleep through the night. just felt uncomfortable. Morning of 3/3/2021 woke up with extreme pain in injection sight, sweaty, but cold, dizzy and weak, no fever., Could not stand up. Was sat down on sofa for maybe 2 mins. all of a sudden shoulders drooped, head fell forward, I asked "dad are you ok" there was not a response, I walked closer to him and his head flew back, his eyes were slit open, and he started gasping for air 3 times then slumped forward and passed out. 911 was called paramedics checked all vitals including blood sugar, oxygen, heart rate etc everything registered as normal. |
| 1069289 | 3/3/2021 | MD | 58 | F | 3/3/2021 | 3/3/2021 | Systemic: Exhaustion / Lethargy-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Hypotension-Severe, Systemic: Weakness-Severe |

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| 1069304 | 3/3/2021 | CA | 65 | M | 3/3/2021 | 3/3/2021 | <p>Patient received his first Pfizer COVID vaccine on 3/3/21. Patient was conscious with no apparent issues after administration. Patient was asked to sit down for 15-minute observation afterwards. A few minutes later patient was swaying back and forth in his chair and saying he was feeling faint. I repeatedly addressed patient by his first name and asked if he could hear me and repeatedly asked if he was okay. Patient began slumping down in his chair but was still conscious. Patient was not responsive but made eye contact with me. Patient requested water. After giving patient water and observing him drink he began looking nauseous and threw up. Patient then passed out in his chair. I supported the patient upright in his chair and made sure he did not fall down or injure his head. I then immediately tapped him on both shoulders and repeatedly called his name. Patient then became responsive and 911 was called. While waiting patient said he was starting to feel better and was able to support himself in his chair. I did not observe any injuries due to fainting. When the ambulance came patient agreed to be taken to the hospital.</p> |

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| 1069465 | 3/3/2021 | LA | 78 | M | 2/5/2021 | 2/24/2021 | <p>March 3, 2021 SUBJECT: Moderna COVID-19 Vaccine, Side Effects This letter/email is addressed to a number of individuals with a request that you seriously evaluate the below discussion, take action to alert medical staff of your respective agencies of these side effects, and work with the manufacturer, Moderna, to address them. As the recipient of them it has thus far been debilitating and interfered with my daily activities. It is my hope that the medical community can find ways to prevent or treat them such that daily activity can be unimpeded. I will first provide a chronology of my medical history and my Moderna vaccine experience. Then I will discuss my observations. My medical history: Age: 78 Gender: Male Pre-existing Conditions: Medications Hypertension: Blood pressure medication, 50 mg of Metoprolol Succinate ER daily Cholesterol: Atorvastatin, 40 mg daily Medical History 2018: Triple By-Pass Surgery 2019: Passed out, Hit head on falling, Brain bleed: Subdural Hematoma, Hospitalized: No surgery required and released. Subsequently, pacemaker installed. 2021: Moderna COVID-19 Vaccine administered. First Dose: Lot Number: 011J20A, Date: 01/08/2021, Clinic Site: Pharmacy Second Dose: Lot Number: 032L20A, Date: 02/05/2021, Clinic Site: Pharmacy Side Effects to Moderna Vaccine administration First Dose: Administration Site: Swelling, Site Redness and Fever. All dissipated within week after administration Second Dose: Fever and Chills day following administration. Lethargic for several days following administration. These symptoms disappeared. Observations February 24, 2021: Began to experience dizziness, symptoms progressed to mild vertigo. Based on history of presentation of these symptoms, assumed I had an inter-ear problem and began taking Zyrtec D, half a tablet. Experience with Zyrtec D has been that ear dries out and symptoms of dizziness and disorientation disappear. In this case the symptoms of vertigo progressed to the point of difficulty in walking and loss of balance. Stopped taking Zyrtec D on Friday, February 26th. February 26, 2021: Had more severe vomiting, walking difficulty and lose of balance. Used walker to stabilize walking. At approximately 7 to 7:30 PM, following consultation with wife and daughter, decided to go the emergency room of the Medical Center (MC). Was quickly seen by emergency room staff. Following questions on medical</p> |

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history, the ER doctor, based on head bleed history, I believe, had a CT conducted. I do not recall any questions about COVID-19, but do think we told them that both myself and my wife had been vaccinated for COVID-19. I specifically recall that prior to my transport, a nurse came in to do a nasal swab for COVID-19. I informed her that I had been vaccinated, but she said this was a requirement for admission to the location where I was being transported. Following the CT scan, the ER physician determined he believed there was a possibility of a small new brain bleed. At approximately 2 to 2:30 AM I was transported by ambulance to Health Center at approximately 5:00 AM. I am not certain about the exact times here. February 27, 2021: Health Center administered a number of tests including CT scan, EKG, and an echocardiogram. While there, physical therapists came to see me twice and exercised me to improve my balance and walking ability. The last one recommended exercises to help reset my vestibular system. Based on the administered CT scan there, the physicians saw no evidence of a new brain bleed and were prepared to release me. At the time of that discussion in my room, the attending nurse pointed out to the physician there that my blood pressure was elevated. He ordered a new EKG and deferred on releasing me until a cardiologist reviewed the results. Their concern was that I was experiencing episodes of atrial fibrillation (AFib). Subsequently, the cardiologist reviewed the new EKG and concluded the episodes were within the normal range, my understanding, but did note that my heart rate was elevated. At no time did the medical staff raise or question the possibility of COVID-19 side effects as being a possible explanation for my disorientation or heart rate problem. I was released later that day. February 28, 2021: While speaking to her sister, my wife shared with her my experience of dizziness and disorientation. Her sister related that her husband had and was experiencing a similar event. Further, her husband's sister had experienced a similar event. Additionally, the husband's sister had experienced vertigo. On further discussion it was determined all three of us had received the Moderna Vaccine, and approximately three to four weeks post second dose administration, developed these symptoms of vertigo. This prompted me to go to the internet for information on

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vaccine side effects. The Food and Drug Administration Fact Sheet, revised 12/2020 in the Section Titled: What are the risks of the Moderna COVID-19 vaccine? speaks of severe allergic reactions including: a fast heartbeat and dizziness and weakness. I believe that I have suffered these two reactions. March 1, 2021: Called both hospitals to alert them to inform their respective staffs of the need to question the possibility of these side effects should other patients present in their emergency rooms. In my case, it may have helped to alleviate my concerns had I been informed of these possible side effects. At MC I left a voice mail for the Chief Medical Officer and at Health Center I spoke to the Nursing Supervisor. The nursing supervisor advised me to report my side effects and directed me to call the entity who had administered the vaccine doses. I called the Pharmacist and spoke to her. She said she would report my concerns through her reporting system. Further she informed me that there was a medication my primary care provider could prescribe. I called my primary care provider, and he has prescribed Meclizine, 25 mg tablets. I am currently taking ½ tablet, three times per day. A whole tablet made me drowsy. As of today, March 3, 2021, I am still experiencing disorientation. Hopefully this will subside and disappear. The above discussion is provided to assist medical professionals to further assess the side effects of the Moderna COVID-19 Vaccine. I am glad that I received it. I have no complaint about the care I received at the two medical facilities referenced. In fact, I think it was excellent. However, it would have helped me to have raised by either or both of them that my symptoms may have been COVID-19 Vaccine related. Further, it may have changed how they proceeded in assessing my situation. As an industrial hygienist with statistical training, it seems to me somewhat unusual to have three members of my extended family experiencing similar dizziness and weakness side effects, and for us all to have similar time periods following the administration of the second dose. Perhaps, if related to the vaccine, this cluster would suggest that this side effect may be more common than a ?remote chance.? Should any of you have further questions or wish to speak to me, please do not hesitate to call. Since I get a lot of calls from numbers I do not recognize, I do not always answer, but a voice mail left

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| | | | | | | | with a return call number normally results in a return call. Today, I received a return call from the Chief Medical Director of MC and told her she would receive a copy of this document. Thank you for your attention to this matter. |
| 1069004 | 3/3/2021 | NY | 64 | M | 2/19/2021 | 2/19/2021 | The patient reports fatigue beginning the day of the vaccine, and persisting to the time of this report. He had residual episodes of fatigue (1 per week) after his stroke 11/20, however after the vaccine he has been fatigued all day. His neurologist changed his Plavix to Brilinta on 2/11/2022 due to fatigue, without effect. During these episodes he sleeps excessively He does not report insomnia, dysarthria, focal weakness/numbness, dizziness or fainting, or new memory issues. |
| 1069317 | 3/3/2021 | GA | 70 | F | 3/3/2021 | 3/3/2021 | PATIENT STATED TINGLING SENSATION ABOUT 15 MINUTES AFTER IMZ GIVEN, THEN SYNCOPE, THEN LOSS BODY FUNCTION 10 MINUTES LATER. CONSCIOUS ENTIRE TIME, ABLE TO BREATH ON OWN |
| 1068937 | 3/3/2021 | NY | 47 | M | 3/2/2021 | 3/2/2021 | Patient received 1st dose of his Covid vaccine; after~10 min, during observation period, he was noticed to become pale ,diaphoretic and with decreased level of responsiveness; was put on the stretcher. Physician who was monitoring the vaccination area reported: "BP 110/64 HR 76 Sat 95% Patient was feeling better upon being placed supine and was verbalizing as well. Denied chest pain and shortness of breath. Just felt dizzy and weak." Patient was taken to ER; CBC,CMP,ECG- all normal and he was discharged after 2 hrs of observation with diagnosis of Vasovagal Syncope. Today, patient is well and went to work as per his spouse. Patient has history of similar syncope or near syncope events in the past during stressful situations, like seen blood . |
| 1068899 | 3/3/2021 | MI | 23 | M | 3/1/2021 | 3/1/2021 | Patient felt synope/fainting. Onsite EMS was called vitals BP 108/66 BG 108 99% O2 room air HR 58. Patient was treated and released agianst medical advice. |

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| 1068796 | 3/3/2021 | | 26 | F | 1/27/2021 | 1/27/2021 | Patient received Moderna 0.5 ml at approximately 1115 on 2/27/21. During her 15 minute observation period she became lighted headed and then fainted was lying on floor. Patient was transported to provider area via wheelchair. Where vital signs were monitored. Patient was administered 25 mg Benadryl at 1125 and Tylenol 650 mg at 1213. during recovery period her vital signs stabilized and she was discharged by the provider at 1225 tom the care of her mother. |
| 1068782 | 3/3/2021 | NJ | 31 | M | 3/2/2021 | 3/2/2021 | Felt dizzy then Felt nauseous then passed out |
| 1068604 | 3/3/2021 | NJ | 55 | F | 2/23/2021 | 2/24/2021 | severe naseau and dizziness fainted 2xs out 2 minutes injured chin and jaw from falling face first on bathroom tile floor |
| 1068521 | 3/3/2021 | CA | 34 | F | 3/2/2021 | 3/2/2021 | Systemic: Dizziness / Light headiness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Hypotension-Severe, Additional Details: Patient was given the 1st dose of the Pfizer COVID vaccine around 4:50pm PST without incident and she was directed to wait for 15 minutes in the store. the pharmacy technician monitoring patients noticed around 4:57pm that patient was pale and slumped over in her chair & alerted me. Immediately, patient fainted while seated, into arms. 911 was alerted & they came 10 mins afterwards. EMS found her BP to be low and recommended she go to the ER, but she refused. |
| 1068483 | 3/3/2021 | NY | 26 | M | 3/2/2021 | 3/2/2021 | Patient stated to RN at observation that " he wants to lay down". RN stated that "she held his head" as he experienced a syncope event. RN notified Nurse Practitioners . EMS activated. Patients assessed and found to be alert and oriented to place and person. Patient stated that he felt dizzy. Vital signs monitored and patient found to be hypotensive, diaphoretic, and flushed. Epinephrine administered X3 with vital signs monitored in between. Vital signs stabilized and patient transferred to hospital with EMS. |

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| 1068364 | 3/3/2021 | WV | 63 | F | 2/12/2021 | 1/13/2021 | All hair has fallen out; Heartburn; Nausea feeling; Passed out; Wasn't feeling right after dose; Face was tingling; Burning feeling in head; A spontaneous report was received from a Consumer regarding a – 63Years-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced events like passed out, Wasn't feeling right after dose, face was tingling,bBurning feeling in head, devastated about hair loss after 1st dose, Heartburn and Nausea. The patient's medical history was not reported. Relevant concomitant medications were reported like amitriptyline, duloxetine, gabapentin, metformin, Nexium, hydrocodone, potassium, Proair, ropinrole, simvastatin, spironolactone, Topamax, vitamin d, vitamin b12. On 12-Feb-2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot/batch:030m20a) intramuscularly for prophylaxis of COVID-19 infection. On 12- Feb-2021, the patient experienced the event like Passed out. On an unknown, date the patient experienced events like Wasn't feeling right after dose, Face was tingling, Burning feeling in head, Devastated about hair loss after 1st dose, Heartburn nausea feeling and Nausea. Laboratory details not provided. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events Passed out, Face was tingling is resolved. The outcome of the events Devastated about hair loss after 1st dose is Recovering/Resolving. The outcome of the events like Wasn't feeling right after dose, Burning feeling in head, Heartburn nausea feeling and Nausea are unknwn; Reporter's Comments: Based on the information provided which includes a strong temporal association, a causal association between the reported events and the administration of the mRNA-1273 cannot be excluded. Nausea is consistent with the known safety profile of the vaccine. |

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| 1068262 | 3/3/2021 | PA | 42 | M | 2/14/2021 | 2/14/2021 | random heart-racing; random dizziness; occasional headaches; Temperature between 100-102 for 30hrs; flu-like symptoms; extreme burning resulting in fainting; extreme burning; This 42-year-old male patient contactable consumer (reported for himself) received the second dose BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) (lot EN5318,; expiration not provided), via an unspecified route of administration, on 14Feb2021, 12:00 PM (at the age of 42-year-old) as a single dose for COVID-19 immunization, in Left arm. The facility where COVID-19 vaccine was administered was at a hospital. Prior to the vaccination, the patient was not diagnosed with COVID-19. Historical Vaccine included first dose of BNT162B2 (Lot number: e18982) intramuscularly on 24Jan2021 at 09:00 am for COVID-19 immunization on left arm. The patient did not have any other vaccine within four weeks prior to the vaccination. No relevant medical history reported. Concomitant medication included: Levothyroxine 125 "mg", once a day. On 14Feb2021 at 12:15pm, the patient experienced extreme burning resulting in fainting. Ekg normal in ER. Day-2 flu-like symptoms, temp between 100-102 for 30hrs. Day-2 and now day-3, random dizziness, feeling of heart beat, random heart-racing, occasional headaches, no current fever. Events resulted in doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care. The clinical outcome of the events extreme burning resulting in fainting, flu-like symptoms, temp between 100-102 for 30hrs, random dizziness, random heart-racing, occasional headaches, was unknown. It was reported that since the vaccination, the patient had not been tested for COVID-19. No follow-up attempts are possible. No further information is expected. |

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| 1068250 | 3/3/2021 | | 30 | M | 2/8/2021 | 2/13/2021 | Fainting episode; Loss of hearing; Left collar-bone lymph node enlarged noticeable swelling to area and left lower neck near carotid artery/lymph nodes; Soreness in area; Cold sweats; Light-headedness; This is a spontaneous report from a contactable consumer, the patient. A 30-year-old male patient received the first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: UNKNOWN), via an unspecified route of administration in the left arm on 08Feb2021 at 07:00 (at the age of 30-years-old) as a single dose for COVID-19 immunization. The patient did not have any relevant medical history. The patient did not have any allergies to medications, food, or other products. Prior to the vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient's concomitant medications were not reported. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient had no symptoms until 5 days post vaccination. On 13Feb2021 at 12:15, the patient experienced fainting episode, loss of hearing, left collar-bone lymph node enlarged (noticeable swelling to area and left lower neck near carotid artery/lymph nodes), soreness in area, cold sweats, and light-headedness. The events required a visit to the physician's office and emergency room (as reported). The clinical outcomes of the fainting episode, loss of hearing, left collar-bone lymph node enlarged, soreness in area, cold sweats, and light-headedness were unknown. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up. |
| 1069470 | 3/3/2021 | NC | 20 | F | 3/3/2021 | 3/3/2021 | Patient passed out, but came to a minute later. Has a history of passing out with vaccines. Called EMS to check her okay and their cleared her. She waited 30 minutes post vaccine and left with mother. |

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| 1067940 | 3/3/2021 | MI | 68 | F | 2/12/2021 | 2/13/2021 | Passed out and fell on the bathroom floor; didn't feel well; Passed out and fell on the bathroom floor; Nauseated; Arm was sore; A spontaneous report was received from a consumer concerning a 68-years-old, female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) experienced arm was sore, nauseated, didn't feel well, passed out and fell on the bathroom floor. The patient's medical history was not provided. Concomitant product use was not provided by the reporter. On 12 Feb 2021, approximately one day prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 (Batch number not provided) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 13 Feb 2021, the patient experienced sore arm, not feeling well, nausea, passed out and fell on the bathroom floor. Treatment information was not provided. Action taken with mRNA-1273 in response to the events was not provided. The outcome of the events arm was sore, nauseated, didn't feel well, passed out and fell on the bathroom floor were unknown.; Reporter's Comments: This case concerns a 68-year-old female who experienced serious unexpected events of Loss of consciousness, along with nonserious unexpected malaise and fall and NS expected vaccination site pain and nausea. The events occurred 2 days after the first dose of mRNA-1273. Treatment not reported. Event outcome unknown. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. |
| 1069914 | 3/3/2021 | IN | 65 | F | 3/2/2021 | 3/2/2021 | Moderna COVID-19 Vaccine EUA fatigue, aches, weakness, dizziness, fainting, headache mostly the morning after receiving the shot symptoms gradually subsided during the day |

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| 1068233 | 3/3/2021 | | | F | | | increased blood pressure; spiked heart rate; nausea; dizziness almost to the point of fainting; dizziness almost to the point of fainting; This is a spontaneous report from a contactable consumer (patient). A female patient of an unspecified age received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date unknown) via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On an unspecified date, the reporter wants to know if it is recommended for her to get the second dose of the bnt162b2 after she has experienced side effects from the first dose. The patient stated that she had increased blood pressure, spiked heart rate, nausea, dizziness almost to the point of fainting that the patient ended up in the emergency room. The patient also wanted to know if she has to wait some time before she gets the second dose and how long she can wait. The patient queried does she have to start over if she waits longer than the recommended period? The outcome of the events was unknown. Information about lot/batch number has been requested. |
| 1070960 | 3/3/2021 | TN | 44 | F | 1/25/2021 | 1/26/2021 | Pale, clammy, diaphoretic associated with vomiting and near syncope 12 hours status post vaccine. Then within 24 hours post vaccine developed burning in chest. 36 hours post vaccine severe chest pain. Described as elephant on chest radiating down left arm to left jaw associated with paleness and diaphoretic. Hurt to take in deep breath and pain worsened upon lying down. Relieved with motrin 800 mg. I continued motrin every 6 hours until I could follow up with cardiologist on Friday 01/29/21. EKG showed ST elevation in all leads. Stat echo was performed at facility. Diagnosed per doctor with acute Pericarditis. Started on Colchicine 0.6mg twice daily X 10 days. Other doctor followed up and continued Colchicine 0.6 mg x 90 days. |
| 1071025 | 3/3/2021 | MT | 57 | F | 2/19/2021 | 2/21/2021 | Patient call the pharmacy on 3/3/21 and reported that a couple days after being vaccinated on 2/19/21 she experienced nausea, vomiting, diarrhea, and fainted. The paramedics were called by the patients husband when she fainted. The took her to the hospital for observation. The GI events lasted for a few days and resolved. |

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| 1069844 | 3/3/2021 | | 30 | M | 2/8/2021 | 2/8/2021 | Patient had tightness in throat, then syncope shortly after, which led to him falling to the floor from a chair and hitting his head. After patient was released from vaccine site, he developed shortness of breath, and went to the ER, where he was given diphenhydramine, which patient says helped. Patient then had 10 days of symptoms neurological and cardiovascular symptoms (slowed cognition, mood changes, somnolence/hypersomnia, palpitations) and went to ER four times and was diagnosed with a concussion/post concussive syndrome. He was referred to neurology and had an EEG conducted. He was given prednisone during this time. |
| 1070975 | 3/3/2021 | AZ | 24 | F | 3/3/2021 | 3/3/2021 | Patient was given the vaccination and then waited seated for 15 minutes. At 15 minutes patient started to stand and then fainted. Patient was breathing and had a pulse. Patient was placed on back and feet elevated and 991 was called. Patient was coming too as paramedics arrived. paramedics checked vitals. Eventually patient was able to walk out on her own and did not want to go to hospital. |

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| 1069632 | 3/3/2021 | MN | 55 | M | 3/2/2021 | 3/2/2021 | Presented to ED for evaluation of generalized lower extremity weakness, falls. The patient states that he carries a diagnosis of MS and typically is fully functioning without assistance of a cane or walker. The patient states that yesterday morning around 0900 he received the second dose of his Moderna COVID-19 vaccine and was otherwise feeling fine but by last night (12 hours after the vaccine) the patient states he tried to get out of bed and was transferring when he felt his bilateral legs give out, causing him to slide to the ground. His wife then came to help and states that the patient was completely weak in the legs, and was unable to even lift his legs up to get back into bed. They then tried to walk him again a short time later and he again stumbled with weakness in his legs. Since that time, the patient states he has been minimally ambulatory and has been using a cane, but still needs large assistance to get around his home. The patient states he has baseline foot drop but feels this is worse in his legs today. He went to clinic this morning for his symptoms where he was noted to have an elevated temperature and was diffusely weak in his lower extremities. Given this, the patient was referred to the ED for further evaluation. The patient denies any weakness in his upper extremities or facial asymmetry. He denies sensation change in his extremities nor any recent illness such as cough, shortness of breath, chest pain, sore throat, nausea, vomiting, urinary symptoms, or leg pain. He has no history of stroke. He denies any injuries or head injury, syncope from his falls. He was admitted to the hospital where he will receive further symptomatic treatment as necessary. No treatment provided in emergency department for weakness. |
| 1070910 | 3/3/2021 | IN | 19 | M | 3/2/2021 | 3/2/2021 | Vaccine was administered to patient. Within 10 minutes of administration, the patient had an episode of syncope and fell out of his chair. I immediately went out to help the patient and a technician called for EMS. The patient woke up within 2 minutes and reported feeling dizzy, tired, and numb. While waiting for EMS to arrive, the patient was situated in a sitting position and I continued talking to him to keep him awake. EMS assessed him and took him out to the ambulance to wait for a relative to come. It is unknown if the patient went to the emergency room or not. |

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| 1070906 | 3/3/2021 | | 37 | M | 2/22/2021 | 2/22/2021 | suffered a syncopal episode after being administered COVID-19 Pfizer vaccine #1 dose at the conference room downstairs at our clinic. Prescriber came and upon arrival, patient was alert and oriented x 3 laying on the ground. Blood pressure was initially elevated but decreased towards the end of visit. The rest of his vital signs were normal. His lungs were clear to auscultation bilaterally and his heart was regular rate and rhythm. EKG was normal. Patient reports he has had previous syncopal episode when having blood drawn. Patient likely suffered an episode of vasovagal response syncope. Patient was sat upright and sat on a chair for 15 minutes prior to discharge. He has no more syncopal episodes after that and felt back to baseline prior to discharge |
| 1070903 | 3/3/2021 | IL | 40 | F | 2/23/2021 | 2/24/2021 | Syncope times 5 at home starting at 630 am. Called 911. Syncope 2 times at hospital. Hospitalized 2 days until it subsided. Blood pressure kept dropping and heart rate kept spiking. Had chills and aches off and on for 48 hours. orthostatic hypotension. It?s now been 5 days since being released and I?m still dizzy. Feels like I?m off balance/vertigo. Syncope has subsided but dizziness is still present. |
| 1070863 | 3/3/2021 | CA | 48 | F | 3/3/2021 | 3/3/2021 | after injection pt complained of dizziness and not feeling well. initial vital BP 66/52 HR 68 RR 15 spO2 97% RA. pt was in sitting position. became clammy, diaphoretic, blurred vision, and feeling worse and passed out. pt assisted to floor. MD called to bedside, 0.3 epi pen given to left thigh. no respirstory distress noted. fire and EMS on scene to transfer to ED. pt now a&ox4. VSS now. |
| 1070795 | 3/3/2021 | | 34 | F | 2/27/2021 | 2/28/2021 | At 1 am - 11 hours after vaccine; Felt dizzy and lightheadedness. She passed out for a few seconds, laid down, very dizzy, tinnitus. 3am to 10 am Pulse rate is high 120-150 Tired and weak on Sunday, but heart rate returned to normal again. |

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| 1070752 | 3/3/2021 | MI | | F | 2/12/2021 | 2/15/2021 | passed out several times; vertigo/dizzy; This is a spontaneous report from a contactable consumer (patient) from Pfizer-sponsored program. A 43-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; batch/lot number and expiration date unknown), via an unspecified route of administration on 12Feb2021 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient previously took the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on an unspecified date for COVID-19 immunization. The patient received the second dose on 12Feb2021 and woke up yesterday (15Feb2021) dizzy and passed out several times. The Dr diagnosed her with vertigo and gave medication for that (medication not named). The patient wanted to know if Pfizer COVID vaccine is linked with vertigo or not. This is her third time being transferred, she was clearly not feeling greatest and she has been on the phone for almost 30 minutes. The outcome of the events was unknown. Information on the batch/lot number has been requested. |

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| 1070736 | 3/3/2021 | FL | 79 | F | 2/15/2021 | 2/15/2021 | nearly fainting; Head ache; fatigue; upset stomach; vomiting; chills; new mouth sores; painful arm; This is a spontaneous report from a contactable consumer (patient) reported for herself that a 79-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL9365) via an unspecified route of administration in the right arm on 15Feb2021 12:00 AM at single dose for covid-19 immunisation. Medical history included allergy to bees and wasps. The patient was not pregnant at the time of vaccination. Concomitant medications included rosuvastatin and olmesartan medoxomil. The patient previously received first dose of BNT162B2 (lot number: EL1283) via an unspecified route of administration in the right arm on 21Jan2021 12:00 AM at single dose for covid-19 immunisation. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. After receiving the second dose, the patient experienced headache, fatigue, upset stomach and nearly vomiting, chills, nearly fainting and new mouth sores, painful arm on 15Feb2021 13:15. No treatment was received for the adverse events. The patient has not been diagnosed with COVID-19 prior to vaccination. The patient has not been tested for COVID-19 since the vaccination. Outcome of the events was recovered in Feb2021. |
| 1069723 | 3/3/2021 | ME | 16 | M | 3/3/2021 | 3/3/2021 | Given history of anxiety around needles, visual aura, paleness after episode, and quick recovery to baseline presentation most consistent with syncope with myoclonus. Seizure less likely given that this is different than his typical semiology and he has been well controlled on his current AED regimen. Discussed with the Neurology attending of the week who was in agreement. Point of care blood glucose was found to be 111. Per neurology recommendations, Trileptal level was drawn. Patient was observed for 1hr and remained at baseline with no additional events concerning for seizure. Patient and mother were informed about vasovagal syncope and instructed on precautionary measures to take with future shots. Given return precautions. |

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| 1070980 | 3/3/2021 | AZ | 57 | M | 3/3/2021 | 3/3/2021 | Patient became hypotensive and bradycardic in the 40s. Patient passed out 4 times. EMS called over. Patient refused IV or further medical treatment. 30 min with EMS. Then observed for an additional 30 mins in the observation area of the POD. |
| 1070735 | 3/3/2021 | MI | 66 | F | 2/17/2021 | 2/18/2021 | I passed out going down stairs; woke up disoriented; weak; dizzy; bloody nose; This is a spontaneous report from a contactable consumer (patient). A 66-year-old female patient received her second single dose of bnt162b2 (Pfizer-BioNTech Covid-19 vaccine, lot number EM9810) at her left arm, at 11:00AM 17Feb2021, for Covid-19 immunization. The patient received her first injection (Lot number EL9765) on 27Jan2021 10:15AM at her left arm. The patient's medical history was not reported. The patient had no other vaccine in four weeks and had no other medications in two weeks. The patient was fine for 10 hours afterwards, went to bed, woke up disoriented weak and dizzy. She passed out going down stairs, came to on the floor at the bottom of the stairs, bloody nose, about an hour later passed out again in the kitchen and woke up on the floor. No warning either time, like light switch being turned off. The patient never had a reaction to anything before, never passed out before. She felt better at time of reporting. The adverse events happened at 07:00 AM 18Feb2021. The patient had not received any treatment for the events and not covered from the events. The patient had no Covid prior vaccination and Covid was not tested post vaccination. |
| 1069656 | 3/3/2021 | CA | 81 | M | 2/23/2021 | 2/23/2021 | Extreme loss of strength and energy at 2pm followed by and hour long bout of chills and uncontrolled shaking starting at about 9:15pm. On the following day (2/24) I felt extremely weak and fainted at about 7:00am. So weak it took about 15 minutes before I could raise myself up from the floor. Felt weak and unsteady all day and had muscle aches all over. Slept on and off for most of the day. |

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| 1069741 | 3/3/2021 | KY | 46 | F | 2/26/2021 | 2/26/2021 | Patient described feeling strange and remained at facility for observation for 30 minutes. 2 Benadryl administered. She went back to work at a high school. When still feeling unwell, went to see school nurse. Felt faint, syncope, numbness of right cheek, tachycardia. Ambulance called and patient was taken to ED. Later that night had flu like symptoms at home. |
| 1069904 | 3/3/2021 | TX | 20 | F | 3/3/2021 | 3/3/2021 | post vaccination, pt fainted. bp 132/84, HR 66. pt. aao x 3 almost immediately after fainting episode. Nurses kept patient on the floor, w/ legs elevated above pt.'s chest, and head on pillow. Mom stated, "this is just like when you had the Gardasil." 2n d bp 130/82, HR 62. Mother repeated the statement regarding the Gardasil, and also stated that "it was like she was having a seizure, but it was in the doctor's office so they just took care of everything." Note: Before vaccination, employee reviewed pre-vaccination checklist questions w/ Pt. Pt denied any previous reactions to vaccines. |
| 1069978 | 3/3/2021 | MD | 71 | M | 2/25/2021 | 2/25/2021 | Patient has a debilitating headache on the Friday, Saturday, and Sunday after the second dose. He still had the headache but not as bad on Monday, Tuesday, and Wednesday after the second dose. On Wednesday morning, he passed out three times while in the shower and bathroom. He has been admitted to the hospital. They have ruled out a heart attack and most likely ruled out a stroke. He is still undergoing tests. |
| 1070022 | 3/3/2021 | MD | 63 | M | 3/3/2021 | 3/3/2021 | patient passed out while waiting in the observation area after the vaccine administration. He passed out briefly about 1 minute then regained consciousness. He then responded to pharmacist questions. 911 arrived and took him to the hospital |
| 1070548 | 3/3/2021 | PA | 33 | M | 3/3/2021 | 3/3/2021 | within 15 minutes of immunization, patient experienced a feeling of fainting, lightheadedness, and ringing of the ears. Patient laid on the floor for an additional 30 minutes and was then released after feeling better. |

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| 1070556 | 3/3/2021 | AL | 84 | F | 2/19/2021 | 2/20/2021 | 02/20/2021 at 6:30am when getting up, dizziness, nausea, vomiting, fainted, fell and hurt back. 9:00am when getting up a second time, again - dizziness, nausea, fainting , falling and hitting head in bathroom. During day , hematoma over left eye, swelling, no Headache, no blurred vision, back pain increased. Treated with heat. |
| 1070592 | 3/3/2021 | OR | 23 | M | 3/3/2021 | 3/3/2021 | Vaccine administered at 0939. At 0945 patient passed out in the observation area. Nursing staff responded to the situation. Patient woke up within one minute. VS upon regaining consciousness were as follows: BP- 98/74, HR-74, O2 -98. Pt and his parents verify that he has had fainting spells in the past when getting a vaccine or seeing blood. Pt confirms this has happened at least 5 times in the past. Pt moved to a more private observation area. Pt given water and sat under observation for several minutes when he reported feeling unwell again and asked to lay down. Vital signs taken again at this time (0955) and were as follows BP - 94/55, HR - 50, O2-98. |
| 1070596 | 3/3/2021 | FL | 54 | F | 1/29/2021 | | Suffered syncope dec 10 th .. assumed post viral work up was done essentially negative. Was slowly improving except for a little brain fog . covid test was neg then . First vaccine dose was on Jan 4 th .. min arm soreness for 24 hrs and no reaction after that Second dose was on Jan 29 th .. started with tachycardia to 110 that night and developed POTS .. with severe flares the next 2 weeks,,, now im 4 weeks out suffering from hyperadrenergic POTS / severe flares with in appropriate tachycardia(proven by holter) and inc blood pressure with it . |
| 1070614 | 3/3/2021 | CA | 24 | F | 2/8/2021 | 2/9/2021 | At 12:45 am, I had chills and got up to obtain more acetaminophen. When I was at the counter to grab the medication (about 5 min after getting out of bed), I felt suddenly nauseous and saw stars. I woke up on the floor (syncope), ran to the bathroom and started vomiting. I do not know how long I was unconscious for. |

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| 1065138 | 3/2/2021 | | | F | 2/11/2021 | 2/12/2021 | hard of hearing; rash; faint; being hot; short of breath; headache; was achy; extremely tired/extremely exhausted; This is a spontaneous report from a contactable nurse (reporting for mother). An 89-years-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Solution for injection, lot number and expiry date not reported), via an unspecified route of administration on 11Feb2021 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The first dose of BNT162B2 as COVID-19 immunization was received on an unknown date. Reporter was calling regarding side effects of the Pfizer COVID vaccine. Reporter stated that her mother (patient) is 89 years old and her mother was hard of hearing since an unknown date. Her mother got the second dose of the product 11Feb2021 and she was fine that Thursday, and by Friday (12Feb2021) her mother had a headache, was achy, and extremely tired. On Saturday, her mother felt a little bit better. On Sunday (14Feb2021), her mother had an episode of being hot and faint, and short of breath and extremely exhausted. This morning (15Feb2021), her mother was experiencing shortness of breath, and a rash and was exhausted. Reporter wa wondering if shortness of breath could be a side effect of the product. The outcome of the events headache, achy, and "extremely tired/extremely exhausted" was recovering, while for events hard of hearing, being hot, faint, short of breath and rash was unknown. Information about lot/batch number has been requested.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported event syncope cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate. |

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| 1066137 | 3/2/2021 | MD | 40 | F | 3/2/2021 | 3/2/2021 | The patient became light headed and fainted two minutes after the administration of the Covid vaccine. She then slipped off the chair. Upon her assessment, no injuries were noted. After a few seconds the patient was alert and oriented. She reported having similar previous experiences with vaccine administrations. She also stated she had the White coat syndrome. |
| 1066475 | 3/2/2021 | MO | 35 | F | 2/22/2021 | 2/22/2021 | About 5 minutes after first dose, patient complained of feeling weak, tired, and lightheaded. Staff noticed she looked pale. She was transferred to a wheelchair, became unresponsive and slumped, and had decorticate posturing for about 15 seconds. Patient awoke and was immediately oriented. Patient was taken from clinic to ED via wheelchair. Of note, patient stated she has a history of syncope, which is worse when needles are involved, and has had similar episodes with phlebotomy in the past. Discharged home in stable condition. |
| 1066442 | 3/2/2021 | TX | 73 | F | 2/26/2021 | 2/27/2021 | Weakness, headache, dizziness, fainting |

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| 1066333 | 3/2/2021 | DC | 83 | F | 2/25/2021 | 2/26/2021 | Got the vaccine and was feeling tired, and her arm hurt, an all she wanted to do was lay in bed with her heating pad. The following day she woke up with a headache, some nausea but nothing came up. She also had diarrhea and her arm was sore. She felt weak, and since she had COVID she has had shortness of breath. She stayed in the bed all day unless she had to as her arm felt like it was made of metal and was extremely tired. She was moving around upstairs and somewhere around 8:00 PM she went to the bathroom, was sweating profusely and wiping herself with tissue, and apparently turned out the light and apparently passed out as she woke up on the floor in the hallway and could not get up right away. She could not use the left arm, was able to get herself up with the help of the door to stand on her feet. She walked into her room and sat on the bed, and did not lay back down and grateful that she did not fall down the steps. She went back to bed, but in the morning she was terrified and her family heard her talking to the doctor on call who told her to go to the ER. In the ER they told her that she had syncope, seen by Dr. at Health Care. She was admitted at 11:11 AM on 2/27/21. She was given IV, had a CAT scan of her head, told her that it did not reveal any blood. After several hours they discharged her. She called her doctor and she has an appointment tomorrow morning. She is feeling tired, not sleeping well. |
| 1066295 | 3/2/2021 | FL | 58 | F | 3/1/2021 | 3/1/2021 | 58 F with complicated medical history including urostomy, frequent UTI, fibromyalgia, seizures, presenting to the ED for presyncope/seizure following a COVID vaccination today. She reports that after getting the vaccine she felt dizzy. she is able to recount the events, no tongue biting. She was given diazepam via EMS en route. Has not missed any doses of medications. No other complaints. Symptoms started following the COVID vaccination and no other symptoms today. |

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| 1066278 | 3/2/2021 | MO | 55 | F | 2/19/2021 | 2/19/2021 | Per patient's report: She received her first dose of Pfizer COVID-19 vaccine and developed soreness at localized injection site and felt sleepy, otherwise no adverse reaction signs or symptoms patient reported. On 2-19-21 at 2:30 PM she received her second dose of the Pfizer COVID-19 vaccine at a mall. She reports the lot number of the vaccine was EL9269. She was monitored for 15 minutes after receiving the second dose. She and her husband left and took the car to a car wash where she fell asleep on her way home and her husband woke her up when they got home. At about 320 or 3:25 PM, she noticed that her face felt puffy and she had a sensation that her face was sliding down, she developed tongue swelling, blurry vision, dizziness, and she reports that she was talking funny/slurring her words. Her husband got a flashlight and looked in her throat and said that her throat was swelling. She felt like falling asleep. Her husband used her EpiPen on her. The EpiPen worked right away to improve the symptoms. She took no other treatments at home. Her husband drove her to the hospital where she slept the entire way. She never developed rash, flushing, skin itching, wheezing, coughing, chest tightness, shortness of breath, nausea, vomiting, diarrhea, fevers, chills, or joint pains. She does not know if she passed out, she states it was hard to stay awake. She reports having some abdominal cramping and churning for the following 2 to 3 days afterwards. She was discharged from the hospital ED where she was never admitted. They gave her an albuterol inhaler to use every 4 hours for 6 days after she left the ED. She went home at about 10:00 PM and went to bed about 10:30 PM. She woke up at 3:00 AM crying and then fell back asleep and woke up again around 7:30 AM. She did not develop any local injection site reactions on her arm this time. |
| 1066208 | 3/2/2021 | ID | 65 | F | 2/27/2021 | 2/27/2021 | Fever 100 - 101.5 24+ hours Chills 3.5 hours at noon 2-28, dizziness, nausea 2-3 hours one episode syncope with fall, no injury extreme lassitude 24 hours |

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| 1066482 | 3/2/2021 | OH | 46 | F | 2/26/2021 | 2/26/2021 | The nurse that administered the vaccine at 4:00 pm and states patient went limp and had vasovagal syncope immediately upon withdrawing needle from muscle and occurred immediately after vaccine administration. The nurse lowered the patient slowly to the ground and put the pt's feet up. The pt has had prior episodes of vasovagal syncope in the past. Her pulse was noted to be in the 70s. Small eyelid and lip twitching noted. Pt had no injury as a result of the syncopal episode. Patient transported to the Emergency Room for evaluation at 4:09 pm. Blood pressure upon arrival in the EC was 143/74, pulse 57, Resp 14, pulse ox 99%. Patient able to open eyes to command and nod yes or no. Blood Glucose was 74 and ECG was unremarkable. Discharged to home at 1822. |
| 1066109 | 3/2/2021 | NC | 41 | M | 2/25/2021 | 2/25/2021 | Patient received first dose of Moderna covid-19 vaccine and went to the 15 minute monitoring area. Per the ED notes patient felt dizzy and developed tunnel vision prior to the patient passing out 15 minutes after getting the vaccine. Similar episodes in the past due to fear of needles. Patient was on floor and rapid response called, patient taken to the ED for evaluation and was discharged in stable condition with vasovagal syncope. |
| 1066048 | 3/2/2021 | MA | 61 | F | 3/2/2021 | 3/2/2021 | Patient had a syncope episode aprox. 30 minutes after administration. She passed out while in observation. Paramedics on scene responded and gathered information. She passed out again and at that point she was put on the stretcher and brought to a nearby hospital. |

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| 1065918 | 3/2/2021 | TX | | F | 1/4/2021 | 1/1/2021 | Was found by her family after collapsing on 06Jan2021 /syncope; extreme fatigue; sleepiness; headache; vomiting; weakness /notes 3/5 strength; difficulty speaking /speech disorder /vocal weakness; difficulty walking /gait disturbance; lower extremity weakness /progressive lower extremity /Muscular Weakness; hyporeflexia; Vitamin B12 Decreased; difficulty speaking /speech disorder /vocal weakness; This is a spontaneous report from a non-contactable consumer (patient). A (age: 39; unit: unknown) female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Lot: EJ1686), intramuscularly at left arm on 04Jan2021 at single dose for covid-19 immunisation. Medical history included hypothyroidism, attention deficit hyperactivity disorder, shellfish allergy. Current illness was none. Concomitant medication included levothyroxine, lisdexamfetamine mesilate (VYVANSE). The patient previously took ceclor and experienced drug hypersensitivity, took first dose of bnt162b2 at single dose for covid-19 immunisation and experienced mild symptoms after the first vaccination, but no neurologic or vascular symptoms at that time. Patient experienced extreme fatigue and sleepiness the day following her second vaccination for Covid 19 and was found by her family after collapsing on 06Jan2021 at 05:30. Upon arousal, she experienced headache, vomiting, weakness, difficulty speaking and difficulty walking with lower extremity weakness. She was taken to urgent care and subsequently admitted for evaluation at hospital and found to have a normal chemistry, blood count, normal lumbar puncture and normal imaging of her neck and brain. Discharge summary notes 3/5 strength and hyporeflexia throughout. Patient had tele visit consult with Psychiatry and Neurology. She was subsequently to be discharged to a Facility without explanation for her sudden onset of progressive lower extremity and vocal weakness. Symptom: Asthenia, Blood Thyroid Stimulating Hormone Normal, Computerized Tomogram head, Computerized tomogram head normal, CSF cell count normal, CSF culture, CSF protein normal, fatigue, full blood count normal, gait disturbance, headache, Hyporeflexia, Lumbar Puncture Normal, Metabolic Function Test Normal, Muscular Weakness, somnolence, speech disorder, Spinal X-Ray Normal, syncope, Vitamin B12 Decreased, vomiting. |

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| 1065676 | 3/2/2021 | ME | 83 | M | 2/8/2021 | 2/11/2021 | <p>Serious criteria was permanent disability and the patient was hospitalized for 4 days and had emergency room visit. Existing hospitalization was not prolonged. Lab Data on 06Jan2021 included: Normal BMP, CBC, normal TSH (thyroid stimulating hormone), low B12, Lumbar Puncture: normal, cell count and protein, culture pending, Cervical Spine X-ray: Normal, CT brain (non contrast): normal. The outcome of events was not recovered. No follow-up attempts are possible. No further information is expected.</p> <p>Patient was admitted at Hospital from 2/11/2021 to 2/17/2021 after a fall with presyncope. Patient sustained head trauma with scalp laceration and staple were placed. Patient has longstanding history of atrial fibrillation and has been taking Eliquis. He was initially seen in the office complaining of fatigue blaming it on the Eliquis that was started. Patient had a Covid vaccination on 2/8/2021. Patient denies any respiratory symptoms. No cough no chills no fever. Complain of exertional shortness of breath. He was seen in the emergency room at and tested positive for COVID-19.</p> |
| 1065456 | 3/2/2021 | WI | 70 | F | 2/14/2021 | 2/26/2021 | <p>Friday 2-26 had rapid heart rate despite taking ivabradine, fainted 3 times Sunday 2-28. All dysautonomia symptoms increased - sweating, extremities turning purple, syncope, indigestion, etc.</p> |

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| 1065142 | 3/2/2021 | MA | 29 | M | 2/10/2021 | 2/12/2021 | syncope; pleurisy; difficulty breathing; Flu-like symptoms; fever; chills; muscle and joint aches; muscle and joint aches; persistent headache; This is a spontaneous report from a contactable health care professional (patient). A 29-year-old male patient received the second dose of BNT162B2 (Pfizer-BioNTech COVID-19 vaccine, lot number: EK4176) in the hospital, via intramuscular route on 10Feb2021 at 10:30 at a single dose on the right arm for COVID-19 immunization. Medical history included Non-Hodgkin's lymphoma from 2010 to 2011 and allergies to penicillin on an unknown date and unknown if ongoing. Prior to vaccination, was the patient not diagnosed with COVID-19. The patient's concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient did not receive any other medications within 2 weeks of vaccination. The patient received the first dose of BNT162B2 (lot number: H9899) in the hospital, via intramuscular route at 01:15 PM on the left arm for COVID-19 immunization. Since the vaccination the patient has not been tested for COVID-19. It was reported that on 12Feb2021 at 08:00 PM (also reported as '3 days after injection') the patient experienced flu-like symptoms that included fever, chills, muscle and joint aches, and a persistent headache. On 13Feb2021 (also reported as 'on the 4th day', the patient developed pleurisy and difficulty breathing and had 2 syncope events the morning of 14Feb2021 (also reported as 'on the 5th day'). The patient was taken by ambulance and admitted to ER for further testing. It was determined that all symptoms likely related to the second dose of the COVID-19 vaccine recently received. Pleurisy persists one week following vaccine dose. The patient went to the emergency room/department or urgent care due to the events. As treatment for the event, the patient was monitored and given IV fluids over 12 hour stay in CDU. The outcome of the events was recovered with sequelae (reported as recovered with lasting effects). The events were reported as non-serious.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events due to temporal relationship and current known drug safety profile. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures |

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| | | | | | | for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate. | |
| 1065985 | 3/2/2021 | NY | 73 | U | 3/2/2021 | 3/2/2021 | Syncope and incontinence |
| 1066492 | 3/2/2021 | CA | 36 | F | 3/1/2021 | 3/1/2021 | Systemic: Fainting / Unresponsive-Medium, Additional Details: wjile monitoring pt after giving the vaccine , she fainted but after few minutes she said she is feeling berrer, refused us to call 911 she said she panics quick and had history of panic attack |

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| 1065380 | 3/2/2021 | NY | 82 | M | 2/13/2021 | 2/14/2021 | <p>Passed Out; Felt really bad and weak; Achy in his shoulders and neck; Chills; Temperature started at 99.6 then 100-101F; Burn really bad when he urinated; Traces of blood in urine; Threw up really bad; Fatigue; Joint Pain; Nausea; A spontaneous report received from a Consumer concerning, 82-year-old male patient who received first dose of the Moderna COVID-19 vaccine and experienced a lot of incidences. /MedDRA PT: [Incidences] The patient's medical history included Type 2 Diabetic. Patient's concomitant included Metformin 500mg daily. On 13FEB2021, the patient received their 1st dose of the two planned doses of mRNA-1273 in right arm (Batch #: 011M20A) intramuscularly for prophylaxis of COVID-19 infection. Patient friend stated he got the Moderna vaccine on 13FEB2021 at 2:30pm in the right arm. He urinated fine at church the next day on 14FEB2021. At 2:30pm, Patient friend stated he started feeling bad and weak and could barely unlace his shoes. Patient friend stated that he had achy in his shoulders and neck, and chills. Patient friend stated he is a type 2 diabetic and he thought his blood sugar was very high and took a 500mg metformin (usually takes it once a day). Patient checked blood sugar which was 99 (low for him). Patient friend stated that she gave him apple juice to bring it back to normal. Patient friend stated his temperature started at 99.6F and an hour later it was 100-101F. Patient was told by HCP to take Tylenol. Patient friend stated that he had burning and traces of blood in his urine. Patient friend stated that the second time he urinated; it was less burning. Patient friend stated that he had severe vomiting and passed out. Patient went to bed at 7PM and then at 8:45PM, without the Tylenol, temperature went back to 99.6F. Patient friend stated that he feels completely fine now. Patient friend stated that she only gave him only two 500mg Tylenols for the whole 24 hours of the reactions. Patient friend stated that he had other symptoms including fatigue, muscle pain, joint pain, chills, nausea, vomiting, and fever but no headache. Patient friend would like to know if the Moderna COVID-19 do something to his kidney or bladder? Patient friend would like to know if he should get the second Moderna COVID-19 vaccine. However, the patient still would like to get the second vaccine to be protected from COVID-19. Patient was treated with 1 500mg Metformin and 2 500mg Tylenols. Action taken</p> |

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| 1067250 | 3/2/2021 | | 28 | M | 1/8/2021 | 1/8/2021 | <p>with mRNA-1273 in response to the event was not provided/unknown. The outcome of the event was unknown/not reported.; Reporter's Comments: This case concerns an 82-year-old male who experienced a serious unexpected event of Loss of consciousness along with NS unexpected feeling abnormal, dysuria, blood in urine, and NS expected fever, chills, myalgia, arthralgia, nausea, vomiting, fatigue. Event onset 1 day after the first dose of mRNA-1273. Treated with Tylenol. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.</p> <p>This is a 28 Years old Male presenting for initial allergy evaluation. Patient reports he received his first COVID vaccine (Moderna) on base on 8 Jan 2021. Was in his usual state of health. Waited 15 minutes without adverse reaction. About 35-40 minutes after vaccination while driving home, felt like his tongue was bigger inside his mouth. Patient's wife is a nurse, looked in his mouth, also felt the tongue and uvula were swollen. He did think his airway was compromised. Also had fever about 7 hours after the shot (~100F) resolved with Tylenol. Admits to soreness at injection site and generalized arthralgias for 2 days after injection. Denies associated lightheadedness, syncope, shortness of breath, wheezing, cough, urticaria, conjunctivitis, rhinitis, vomiting, abdominal pain or diarrhea. Swelling persisted 1.5-2 hours and spontaneously resolved. Did not seek medical attention. Presented to POD for second COVID vaccine dose (due 5 Feb 2021) and was turned away after mentioning his symptoms and was recommended to follow-up with the clinic. He has never experienced swelling before. Vaccines are otherwise up to date; has tolerated all other vaccines. Denies a history of anaphylaxis. Denies adverse reaction to any prior medications. Denies a history of adverse reaction to venom and latex. States gluten sensitive (bloating, diarrhea after ingestion). Denies a history of food allergies. Reports he is allergic to cats and has seasonal allergy symptoms controlled with Benadryl PRN. Denies a history of adverse reaction to polyethylene glycol (PEG), a polysorbate, or polyoxyl 35 castor oil containing injectable or vaccine. Takes an OTC stool softener PRN containing docusate and sennosides.</p> |

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| 1065749 | 3/2/2021 | MO | 84 | M | 2/22/2021 | 2/22/2021 | blurred vision, dizziness, passed out went to hospital by ambulance heart rate was 40 |
| 1067440 | 3/2/2021 | CA | 34 | F | 3/2/2021 | 3/2/2021 | Patient received vaccine without incident & was instructed to sit in the waiting area for observation. 7 mins after her vaccine, pharmacy technician alerted me, Provider that Patient was pale and slumped over in her chair. Patient fainted and fell into rn arms and I called 911. EMS arrived about 15 mins after the call and assessed patient vitals. They found her BP to be low and recommended that she be taken to the hospital for observation. patient refused to be taken and signed a waiver. |
| 1067336 | 3/2/2021 | CA | 39 | F | 3/2/2021 | 3/2/2021 | Syncope episode 15 mins after receiving vaccine. Pt reported feeling anxious and has history of syncope with blood draws. |
| 1067153 | 3/2/2021 | WI | 20 | M | 3/2/2021 | 3/2/2021 | after 15 min. observation period become light upon standing. walked to exit and fainted. patient revived, 911 called., they assessed and delivered treatment: OBSERVATION AND FLUIDS. patient arranged own transport. |
| 1066513 | 3/2/2021 | CA | 38 | M | 3/1/2021 | 3/1/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild |
| 1067130 | 3/2/2021 | CA | 70 | F | 2/24/2021 | 2/25/2021 | Vomiting, vertigo, fainting, migraine, nausea, body aches, fatigue |
| 1067445 | 3/2/2021 | CA | 20 | M | 3/2/2021 | 3/2/2021 | patient c/o feeling nausea and hot. patient then asked for water. patient then became unresponsive for approximately 30 seconds. seizure like active noted, patient began to have involuntary movement of upper and lower extremities that lasted approximately 10 seconds. Patient accessed for gag reflex and then offered water upon becoming responsive. Patient tolerated water well. Patient offered wet paper towels. Skin noted to be cool and clammy. Vital signs assessed noted to be BP 105/74 and HR 69. Patient alert and oriented x 3, placed in wheelchair for continued observation. Mother stated that syncope activity is normal for patient upon receiving injections or blood draws, seizure like activity is not normal per mother. Patient taken to observation area by paramedic. |

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| 1067058 | 3/2/2021 | AZ | 19 | F | 2/27/2021 | 2/28/2021 | Headache, joint pain, light fever, light-headedness. I almost passed out trying to walk to the dining hall for dinner. |
| 1066668 | 3/2/2021 | NY | 76 | M | 2/21/2021 | 2/23/2021 | fainting (vagal reaction) |
| 1067394 | 3/2/2021 | NY | 45 | F | 2/28/2021 | 3/1/2021 | got up to go to the bathroom in the middle of the night - felt slightly nauseated but did not vomit, also felt off balance. Fainted while leaving the room, fell backward and hit my head, elbow, and shoulder on the door frame. My husband heard the fall, and when he came to see what happened I was unresponsive. Took several minutes for me to regain consciousness. Have a large bump/bruise on the right side of my skull, above the right ear, a bruise on my right shoulder, and a bruise, abrasion and bump on my right elbow. |
| 1067050 | 3/2/2021 | VA | 82 | F | 2/27/2021 | 2/27/2021 | patient came in for covid vaccine clinic. got her vaccine and at the 15 min mark, got up to leave and got dizzy for 15 seconds then it resolved. no syncope, cp, SOB, HA, or slurred speech. we kept her another 20 minutes to monitor. her son was with her and took her home afterwards without complication. she had not eaten yet today which she postulates as the reason. she has had some water. she is not in any beta blockers. she has no hx of diabetes. bp 130/64, O2 sats 99%, HR 67, RR 16, appears well, pleasant, conversive. |
| 1066626 | 3/2/2021 | NY | 34 | F | 2/27/2021 | 2/28/2021 | Woke in the middle of the night after receiving the Covid shot to use the bathroom. Checked temperature and it was 99.8 got back into bed and as I got into bed experienced sudden severe dizziness/spins. I covered my face and told my husband that I was dizzy, began to lay down - and woke to him yelling my name. I fainted in bed. He said I was mumbling and making strange noises but was unresponsive for a few seconds. When I woke, I felt extremely hot and was drenched in sweat. I was also extremely confused and had a very hard time speaking/explaining to my husband where the Tylenol was, where the thermometer was, etc. it was very scary. |
| 1066649 | 3/2/2021 | CA | 51 | M | 2/25/2021 | 2/28/2021 | fever to 104, thrombocytopenia. Started 2/28/21. had leukocytosis, near syncope and high recurrent fever with all cultures negative. Is improving as of 3/2/21. |

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| 1066708 | 3/2/2021 | PA | 64 | F | 3/2/2021 | 3/2/2021 | Pt received first dose of COVID19 moderna vaccine today. After 15min observation period, patient felt well and was discharged. Was in lobby of the center when, per a witness, the patient fainted. The patient recovered consciousness without issue. An MA came to report incident to provider. Was going to bring the patient back to vaccine clinic for further observation. When the MA returned to the lobby, the patient had left. |
| 1066733 | 3/2/2021 | | 73 | M | 3/2/2021 | 3/2/2021 | syncope, hypotension and urinary incontinence |
| 1066927 | 3/2/2021 | CA | 79 | F | 3/1/2021 | 3/2/2021 | After awakening at 11p.m., 1a.m. , and 3:00a.m. , I was off balance and found myself on the bathroom floor. I must have passed out but don't remember how. I had no injuries that I could see. I lay there for a while. I carefully got up and crawled back into my bed. I lay there until about 6:00 a.m. I again carefully arose, and I felt OK. |
| 1066952 | 3/2/2021 | MI | 39 | F | 3/2/2021 | 3/2/2021 | Patient got the vaccine and within minutes she became gray in color, limp, and her head went down. she then started to take deep breathes and her body stiffened right up and she stopped breathing for a second. we called 911 as soon as we noticed something was off with her. When she came to a few minutes later she knew she passed out but that was it. she did not go with the EMS, another staff member took her to the ER. |
| 1066997 | 3/2/2021 | IL | 33 | F | 2/11/2021 | 2/12/2021 | I received the vaccine at approximately 1245 on February 12, 2021. Approximately 12 hours later I got up in the night. I experienced ringing in the ears, sharp intense headache, blurred vision. Experienced confusion. Fainted. Asked my husband to get me Benadryl. Took 50 mg of Benadryl and slept for another 5 to 6 hours. I experienced body aches, chills, headache, heart palpitations, intermittent blurred vision for 4 to 5 days afterwards. |
| 1062713 | 3/1/2021 | IL | 44 | F | 2/26/2021 | 2/27/2021 | About 12 hours after the shot, I started running a fever and was very achy. It got progressively worse. Around 4:15 am I got up to use the restroom and I passed out. My husband was able to get me to regain consciousness. I then passed out again after about 10 minutes. We then went to the ER because I had a laceration on my eye, and head pain from hitting my night stand, wall, and floor. |

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| 1063179 | 3/1/2021 | MD | 25 | M | 3/1/2021 | 3/1/2021 | Syncope reaction, BP 94/72, P 58, RR 22, 93% O2 Sat water intake encouraged, BP at 12:45 110/92, P 65 RR 18 |
| 1062920 | 3/1/2021 | MD | 26 | F | 2/25/2021 | 2/26/2021 | Vasovagal Syncope- fainting about 15 hours after the 2nd dose vaccine was administered. Contacted PCP for consult. Brain fog, headache, nausea, body aches. |
| 1062835 | 3/1/2021 | NY | 35 | M | 3/1/2021 | 3/1/2021 | Pt states he has a history of fainting after shots. Pt states he is feeling like he is going to faint. Pt was seated in a wheelchair and moved to the exam area. Pts vitals are stable. Pt states he is feeling better after laying down for 30 minutes. Pt does not require transport to hospital. Pt states he is feeling better and would like to leave. Pt was walked out to his car and driven home by his wife. |
| 1062870 | 3/1/2021 | NY | 35 | F | 3/1/2021 | 3/1/2021 | Pt fainted in her chair, fell to her knees and slid her head along the floor causing two abrasions to the right side of her face. Pt states she has a history of fainting after getting blood drawn. Pt denies any head or neck pain. Pt denies any dizziness or blurry vision. Pts pupils are equal and reactive. Pt is moved to the exam room and seated on a cot. Pts vitals are stable. Pt states she is feeling better after laying down for 20 minutes. EMS advised that she should go to the hospital for an evaluation. Pt refused transport to hospital. Pt was walked out to her car/ Pts husband drove her home. |
| 1062906 | 3/1/2021 | NY | 38 | U | 12/30/2020 | 12/30/2020 | Patient experienced a near-syncope event 20mins post vaccine. Presented to ED. No anaphylactic symptoms expressed. Assessed and released |
| 1062725 | 3/1/2021 | NJ | 44 | M | 2/28/2021 | 2/28/2021 | Pfizer-BioNTech COVID-19 Vaccine EUA: During observation, vaccine recipient had a near syncope event. They were diaphoretic. They were monitored by the EMS. No further intervention. |
| 1063020 | 3/1/2021 | MI | 69 | F | 2/21/2021 | 2/27/2021 | Day1- headache in nasal sinus area and between eyes, Day 2- muscle aches, joint pain, dizziness, nausea, lack of appetite. That evening, awoke out of sleep at 3 am with extreme abdominal pain, walked to bathroom and almost passed out, had to lay on the floor for 15 minutes.. After a half our it happened again. No diarrhea but had 2 soft formed stools (very unusual for me). A lot of nausea, weakness and abdominal pain. Chills for 2 days. |

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| 1063040 | 3/1/2021 | MN | 43 | F | 2/26/2021 | 2/27/2021 | Chills, disorientation, black out/white out, fainting |
| 1063093 | 3/1/2021 | LA | 68 | F | 2/7/2021 | 2/8/2021 | severe chills nausea low grade fever stomach cramps PASSED OUT/Fainted |
| 1063138 | 3/1/2021 | WI | 75 | M | 2/15/2021 | 2/15/2021 | Pt felt lightheaded and faint immediately after receiving Moderna vaccine (given around 1305). Pt laid down on bed and observed with blood pressures taken several times over next 15 minutes (was 66/43, then 74/44, 86/45, then 99/64). Pt reported feeling better. Pt reported only eating a bowl of cereal and some cookies prior to his appointment. Pt was offered water and snacks. After about an hour, pt felt well enough to take a cab home. Pt reported a history of fainting after vaccines in the past. Pt instructed for his second dose to tell the nurse about this and have his second dose lying down, and to eat a good breakfast and drink water prior to coming in for the vaccine. |

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| 1062678 | 3/1/2021 | CT | 60 | F | 2/9/2021 | 2/9/2021 | <p>About an hour after receiving the vaccine my arm was very sore, it felt like someone punched me in my arm. That night I couldn't lift my arm. I took Tylenol and put on ice on it. The next morning, I was going to the bathroom and I almost passed out. I was able to catch myself before I passed out. I felt nauseous and dizzy, I felt like I was going to throw up but I couldn't. I had chills. I went downstairs to try and drink some orange juice, I sat here and was gasping to catch my breathe. I kept thinking it was just my anxiety and kept trying to catch my breathe. I kept drinking the orange juice and the dizziness seemed to go away. I went to work, I was tired, chills and this lasted for 2 days. on Friday the 12th the rash (the rash which I developed from the 1st dose) seemed to get worse, when I took a shower, the heat from the water seemed to make the rash redder. I continued Hydrocortisone cream and then switched to Lubiderm. Neither seemed to help much so I kept switching between the two, eventually the rash did get lighter, it went away under my breast area but it is still there on my stomach. I filed a VAERS report for the first dose as well. About 8 days after receiving the vaccine, I have a tattoo on my right thigh and a red bump appeared on my tattoo, it was hurt. It was a bump and the next day the bump burst, it was hard and crusty. Then a rash developed around the tattoo. I have also had on and off fluttering of my eyelid since receiving the vaccine. I had made a dermatology appointment but I canceled it because it seems like the rash is going away and my deductible is too high. 2/26/2021 My right arm from the shoulder from down to fingers, is numb and hurting. Yesterday 02/28/2021, I got up in the morning and felt like I was going to pass out, I came downstairs and I got some orange juice. I got dizzy and couldn't catch my breathe, I told my husband to call 911, because I thought I was having a stroke. My husband said I passed out, my eye and my mouth were open, he shook my shoulders and called my name no response this lasted for about 3-5 seconds, then I take a deep gasp and came back. I was sweating profusely and pale. EMS arrived, transported me to hospital. My blood pressure was high while I was sitting and it was low when I tried to stand. I went to hospital 02/28/2021. The ER diagnosed with my syncope and wanted me to follow with a cardiologist. They believe since it was 2 weeks out since the vaccine,</p> |

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| 1061921 | 3/1/2021 | MN | 66 | F | 2/14/2021 | 2/14/2021 | they do not believe it was the vaccine. Passed out; Felt lightheaded; Upset stomach; A spontaneous report was received from a consumer concerning a 66 year old female patients who received Moderna's Covid 19 vaccine(mRNA1273) experienced loss of consciousness, dizziness and abdominal discomfort. The patient's medical history was not provided. Concomitant product use was not provided/unknown by the reporter. The patient received first of two planned dose of mRNA-1273 for prophylaxis of Covid 19 infection on 14-FEB-2021 intramuscularly in left arm. Patients felt lightheaded and fell unconscious at evening of vaccine administration. EMS was called ,but patient regained consciousness by the time EMS arrived. Patient also experienced abdominal discomfort on the day she got vaccinated. Treatment information was not provided. Action taken with mRNA-1273 in response to the event(s) was not provided/unknown. The outcome of the event were considered as recovered/resolved. |
| 1063099 | 3/1/2021 | MS | 23 | M | 3/1/2021 | 3/1/2021 | Patient fainted post injection. He stated that he had anxiety and felt like his blood sugar might have dropped. EMTs checked him over and patient declined treatment. |

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| 1062606 | 3/1/2021 | CT | 49 | F | 2/20/2021 | 2/20/2021 | Patient is a 49 y.o. female hx of asthma, GERD p/w L sided lower and upper facial droop in the context of receiving Moderna vaccine 2 days ago. Reports she noticed the facial droop a few hours after receiving the vaccine. Also has had generalized myalgias, denies f/c. Denies camping trips/going in the woods, never been diagnosed with lyme disease. Denies rash, hearing changes, vision changes, CP, SOB, abd pain, n/v/d/c, f/c, dysuria pain/weakness/numbness of the extremities, Pt received first dose of Covid vaccine on 2/20/2021. A few hours later noted mild facial droop, started to note numbness getting worse over 2 day period and presented to ED. Had labs, lyme negative. Diagnosed with bells palsy and discharged on prednisone, has 2 days left. The following day symptoms started to improve and she feels they fully resolved at this point. BP was elevated in ED, she reports she doesn't have a BP cuff at home but will get one. Feeling well overall but does occasionally experiencing symptoms of heart racing and chest tightness. Attributes this to anxiety and stress, mother just passed away. Denies CP, syncope. |
| 1062494 | 3/1/2021 | TX | 57 | M | 3/1/2021 | 3/1/2021 | 7 PM developed muscle pain and could barley pick up the right arm, chills and fever, blood pressure was elevated, passed out |
| 1062381 | 3/1/2021 | CA | 30 | M | 2/28/2021 | 2/28/2021 | Systemic: Allergic: Anaphylaxis-Mild, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Mild, Systemic: Hypotension-Mild |
| 1062373 | 3/1/2021 | TX | 45 | M | 2/27/2021 | 2/27/2021 | Systemic: Fainting / Unresponsive-Mild, Additional Details: Patient fainted for a brief moment after he received the COVID vaccine. Called 911 to have him checked out. |

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| 1062264 | 3/1/2021 | CO | 21 | F | 2/13/2021 | 2/13/2021 | <p>Patient fainted and hyporesponsive.; Patient fainted and hyporesponsive.; This is a spontaneous report from a non-contactable other healthcare professional. A 21-year-old non-pregnant female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), Lot number: En9265, intramuscular on 13Feb2021 at 14:00 (at the age of 21 years old) as a single dose in the right arm for COVID-19 vaccination. The patient's medical history and concomitant medications were not reported. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient fainted and was hyporesponsive on 13Feb2021. The patient did not receive treatment for the events. The outcome of the events was recovered in Feb2021. It was also reported that since the vaccination, the patient had not been tested for COVID-19. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Based on vaccine-event chronological association, a causal relationship between events fainted and was hyporesponsive and BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p> |

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| 1062249 | 3/1/2021 | NC | | M | | | <p>Passed out; This is a spontaneous report from a contactable consumer (patient's mother) from a Pfizer-sponsored program. A male patient of an unspecified age received the first dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on an unspecified date at a single dose for covid-19 immunization. The patient medical history was not reported. Concomitant medications were not reported. On an unspecified date, the patient experienced: passed out (hospitalization, medically significant). The patient's mother called-in on-behalf of her son who passed out in a restaurant and was taken into the hospital due to this emergency. The patient's mother was worried saying that her son was due for the second dose of the COVID-19 vaccine. The patient's mother was unable to identify when her son received the first shot of the vaccine. The patient's mother was also unable to identify why her son passed out. The mother's concern was that her son already missed the second dose. The clinical outcome of the event, passed out, was unknown. The batch/lot numbers for the vaccine, bnt162b2, were not provided and will be requested during follow up.</p> |

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| 1062239 | 3/1/2021 | SC | 72 | F | 2/8/2021 | 2/1/2021 | Passed out; Constant running nose; Cough; bad cough; Sore throat; Diarrhea; This is a spontaneous report from a contactable consumer. A 72-years-old female patient received the second of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), lot number: EL9267, Expiration Date May2021, via an unspecified route of administration on 08Feb2021 (at the age of 72 years old) as SINGLE DOSE in the left arm for COVID-19 vaccination. The patient's medical history and concomitant medications were not reported. Historical information included BNT162B2 dose 1 for COVID-19 vaccination. The patient developed the sore throat on 09Feb2021, Cough; bad cough on 10Feb2021, constant running nose on 11Feb2021. On 11Feb2021, the patient passed out in the bathroom floor, had an ambulance here. Patient still coughing a little, not as badly. The patient experienced diarrhea in Feb2021. Treatment for all events included cetirizine (ZYRTEC), Triamcinolone (NASACORT), pseudoephedrine (SUDAFED), dextromethorphan hydrobromide, guaifenesin, paracetamol, pseudoephedrine hydrochloride (DAYQUIL). Outcome of the events Passed out, Sore throat, Constant running nose, Diarrhea was unknown. Outcome of the events Cough; bad cough was not recovered |

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| 1062205 | 3/1/2021 | NC | 43 | F | 2/4/2021 | 2/4/2021 | she may have been panicked; she already has a pre-existing cardiac arrhythmia, but it seemed to have gotten worse after receiving the 1st dose/More arrhythmia problems; she already has a pre-existing cardiac arrhythmia, but it seemed to have gotten worse after receiving the 1st dose/More arrhythmia problems; left arm soreness; she felt ugh, like she was getting sick; sensation like she was going to pass out; Headache; This is a spontaneous report from a contactable nurse (patient). This 43-year-old female patient female received dose 1 of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Lot number EM9810, intramuscular on left deltoid on 04Feb2021 as single dose (at the age of 43 years) for Covid-19 Immunization. No medical history reported, and no concomitant medication reported. Historical vaccine included BNT162B2 for Covid-19 Immunization. Medical history included Pacemaker in Jun2019 and ongoing, sick sinus syndrome, and pre-existing cardiac arrhythmia ongoing. Historical vaccine included Tetanus, Tetanus made her arm sore, the soreness from tetanus was worse than the soreness from COVID vaccine since it lasted a week with tetanus, no lot number reported. No concomitant medication was reported. The patient experienced she already has a pre-existing cardiac arrhythmia, but it seemed to have gotten worse after receiving the 1st dose/More arrhythmia problems on 05Feb2021 considered medically significant with outcome of not recovered, Within 15 minutes after receiving the vaccine she felt like she was going to pass out three times on 04Feb2021 considered medically significant and recovered on 04Feb2021, she may have been panicked on unspecified date with outcome of unknown, left arm soreness on 05Feb2021 with outcome of recovered on Feb2021, and she felt ugh, like she was getting sick on 05Feb2021 with outcome of unknown. The patient did not receive treatment for events. She stayed an extra 30 minutes to be monitored after the initial waiting of 15 minutes since she had to drive home, then she felt better. She has not called her cardiologist since she has the history of arrhythmias. She had the more arrhythmias start on the evening of the 05Feb2021, states it was weird because it seems to happen more in the evening between 6 and 9pm, sometimes as late as 10pm. However, 'yesterday' it started happening during the day, and it is more frequent, not constant, it just |

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| 1063219 | 3/1/2021 | FL | 83 | M | 2/27/2021 | 2/27/2021 | <p>happens. States it is hard not think about it when her heart is having hiccups since that is what it feels like. She knows what it feels like because when her pacemaker goes off ventricularly she can feel it. She had arrhythmias before the vaccine but has not had issues with arrhythmias continuously. She was diagnosed with sick sinus syndrome and they do not know if it is cardiology or neurology, states it has been an issue for her for the last two years (2019). Lab data included weight of 284-286. She is asking if there is any data that supports her getting the second dose on 25Feb2021. She has read that some people tend to have more side effects with the second dose. The patient had no prior vaccinations (within 4 weeks).; Sender's Comments: Based on vaccine-event chronological association, a causal relationship between events worsening arrhythmia and pre-syncope and BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p> <p>swollen, tender left shoulder, nausea, vomiting, syncope referred to primary provider if symptoms worsen</p> |

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| 1061978 | 3/1/2021 | TX | 61 | M | 1/22/2021 | 1/1/2021 | <p>he was not comfortable; allergic reaction; dizziness; feeling a lot of pressure in his head like his "brain wanted to pop out of his head"/ his brain wanted to swell up; felt like he was going to lose his mind / go crazy; fever; headache is recurring- worse at bedtime; almost passed out; This is a spontaneous report from a contactable consumer reporting for himself. A 61-years-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number: EL9621), intramuscular on the left arm on 22Jan2021 (reported as 07:45 to 08:00) at a SINGLE DOSE for prevent COVID, at 61 years old. Medical history included triple bypass surgery from an unknown date. There were no concomitant medications. The patient previously took morphine and experienced the same thing with his brain, almost identical to what he was experiencing after the COVID vaccine. He reported that the first time he received morphine it was fine and then he got a shot of morphine and he experienced the pressure on his brain after receiving morphine, about 5 or 6 years before reporting time. He stated it was almost the same reaction. He was given a shot of Demerol (he was not sure if it was Demerol) to counteract it. History of all previous immunization reported as none. No additional vaccines administered on the same date. No prior vaccinations within 4 weeks. The patient reported he experienced an "allergic reaction"/ bad reaction to his first dose of BNT162B2 on 22Jan2021. His symptoms included dizziness as soon as he got the vaccine, got dizzy right off the bat, still dizzy, very little; feeling a lot of pressure in his head like his "brain wanted to pop out of his head"/ his brain wanted to swell up; felt like he was going to lose his mind / go crazy; fever; headache is recurring- worse at bedtime. Symptoms (unspecified which) reported as recurring and are notably worse at bedtime. Patient is hesitant to receive the second dose. The patient stated he just went to sleep and prayed and then when he woke the next day, at night it did it again. At night it comes and goes, and he still has it happen but not like the first time. He tried to describe that he was washing his hands and he almost passed out like on an unspecified date in Jan2021, he was going to lose his mind. Last night he went to bed no problem, he felt a little pressure on his brain, stated it is hard to describe, it was not a good feeling. He was running a fever. Last night he</p> |

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| 1062382 | 3/1/2021 CA | 30 M | 2/28/2021 | 2/28/2021 | <p>had a slight fever, like it was going away. He was not able to drive when this was happening and today was the first day he could drive and he was not comfortable (27Jan2021). The patient declined any treatment. He already talked to his doctor and was told to call Pfizer. He asked if he was to get the second shot, is there something he could take to make that feeling go away or counteract it. No relevant tests were reported. Events did not require a visit to the emergency room nor physician office. The outcome of the events, allergic reaction, headache is recurring- worse at bedtime, almost passed out and he was not comfortable was unknown. Outcome of the events dizziness, "feeling a lot of pressure in his head like his brain wanted to pop out of his head/ his brain wanted to swell up", felt like he was going to lose his mind / go crazy, and fever was reported as recovering.</p> <p>Systemic: Allergic: Anaphylaxis-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Hypotension-Mild</p> |
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| 1061908 | 3/1/2021 | TX | 52 | M | 2/13/2021 | 2/13/2021 | Fainting twice; Low blood pressure; Sweating like hell; Dizziness; Significant chill; Body was feeling hot; A spontaneous report was received from a consumer, a 52 years-old male patient, unknown race and ethnicity, who was administered Moderna's COVID-19 vaccine, who experienced fainting twice (syncope), low blood pressure (hypotension), sweating like hell (hyperhidrosis), dizziness, significant chills (chill), and body was feeling hot (pyrexia). The patient's current conditions included epilepsy and slight cholesterol. Historical condition was not reported. Products known to have been used by the patient, within two weeks prior to the event, included eslicarbazepine acetate, simvastatin, atorvastatin, sertraline hydrochloride, acetylsalicylic acid, ubidecarenone, vitamins nos, fish oil and cyanocobalamin. On 13 Feb 2021, prior to the onset of symptoms, the patient received their second planned dose of mRNA-1273, (lot number: 030M20A), intramuscularly into right upper arm for prophylaxis of COVID-19 infection. On 13 Feb 2021, after administering the vaccine, patient stated that everything was normal. The patient stated that he went to bed at 9 pm and at 11 pm, he started feeling significant chill and body was feeling hot. On 14 Feb 2021, at 2 am, the patient woke up to go restroom because he was sweating like hell and felt dizziness. The patient's wife noticed that the patient had fainted, and she stood him up and fainted again. His wife made him sat down on the bed and called 911. Once the paramedics arrived, the patient underwent electrocardiogram (EKG) that was normal and checked his blood pressure (BP) that was at 95/82 (unknow units). The patient stated that his BP was usually normal at 120/80 or 85. The paramedics took him to hospital. In the ambulance, they performed another EKG and BG which came out to be normal. The patient was taken to the hospital and they performed multiple blood test that came out to be normal. The patient stated that the nurse gave him unspecified intravenous (IV) liquid as treatment medication for the events which he does not remember. The patient also informed that the doctors concluded that this may happen due to Moderna COVID-19 vaccine. The patient was discharge from the hospital at 4:14 am of 14 Feb 2021. The patient does have light dizziness but not heavy and no other symptoms. The outcome for the event(s), fainting twice, low blood pressure, sweating like |

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| 1061905 | 3/1/2021 | UT | | M | 1/13/2021 | | hell, significant chills, and body was feeling hot were considered as resolved/recovered on 14 Feb 2021 and that of event, dizziness, was reported as not recovered.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Further information has been requested. |
| 1061658 | 3/1/2021 | UT | | 60 | F | 2/26/2021 | 2/28/2021 Fainting Extreme muscle aches |

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| 1062199 | 3/1/2021 | NJ | 56 | F | 1/31/2021 | 1/31/2021 | almost passed out; dizzy; clammy; hot; kept taking my Blood Pressure and pulse ox. Both very, very low; kept taking my Blood Pressure and pulse ox. Both very, very low; This is a spontaneous report from a contactable other healthcare professional. A 56-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot: reported as 96.8), via an unspecified route of administration in the left arm on 31Jan2021 14:15 at a single dose for covid-19 immunization. The patient's medical history included Lupus, Fibro, Hyperthyroidism, Hashimoto's, IBS all from an unknown date. Patient has no known allergies. Concomitant medication included pantoprazole, xylometazoline hydrochloride (SUDAFED [XYLOMETAZOLINE HYDROCHLORIDE]), vitamin c [ascorbic acid], vitamin d3 and calcium (CALCIUM). 15 minutes after the shot while waiting, 8 minutes into it the patient felt dizzy, clammy, hot, and almost passed out. Nurse gave patient oj, oxygen, EpiPen, checked sugar, and kept taking her blood pressure and pulse ox. Both very, very low until it came back up within 20 minutes. The patient declined hospital due to feeling better. Called the doctor next day to discuss what happened. She recommended no 2nd shot. The outcome of the events was recovered. The patient has not had Covid prior to vaccination and patient has not tested post vaccination. |
| 1064281 | 3/1/2021 | CA | 77 | F | 2/26/2021 | 2/26/2021 | Feeling cold despite warm room and clothing starting about 10 hours after injection. Uncontrollable shivering starting about 12 hours after injection and lasting an hour, nausea, headache, weakness, passed out when I got out of bed the next morning, exhaustion and diarrhea lasting two days. |

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| 1285022 | 3/1/2021 | PA | 67 | M | 2/5/2021 | 2/5/2021 | I received the Eli Lilly monoclonal antibody infusion on Feb. 12 after testing positive for COVID-19 on Feb. 10. I received the Pfizer vaccine on Feb. 5, and had muscle aches, chills and a cough. I passed out at home on the 10th, cut my forehead, and had to receive stitches. That is when I tested positive for COVID-19. I continued to be symptomatic and opted for the monoclonal infusion. About 5 hours after I received the infusion, I became completely disoriented. I was unable to stand and did not know where I was. My wife summoned an ambulance, and I was taken by ambulance to a local hospital. I received fluids intravenously. I was released from the emergency room about 6 hours later. |
| 1063949 | 3/1/2021 | LA | 61 | F | 2/18/2021 | 2/24/2021 | Intense dizziness to the point of almost fainting. It started the day before and culminated in almost fainting in the grocery store. I was quiet that night and it seemed to pass by the next morning, so altogether about 36 hours or so, with one substantial episode. |
| 1064018 | 3/1/2021 | | 40 | M | 3/1/2021 | 3/1/2021 | fainted with preceding anxiety after getting the vaccine |
| 1064070 | 3/1/2021 | MI | 20 | M | 3/1/2021 | 3/1/2021 | PATIENT PASSED OUT WITHIN 5 MINUTES OF RECEIVING THE VACCINE AND WAS OUT FOR APPROXIMATELY 1 MINUTE BEFORE COMING TO. PATIENT CLAIMS TO HAVE THE SAME THING HAPPEN TO HIM AFTER HAVING BLOOD DRAWN. PATIENT REMAINED LIEING DOWN FOR APPROXIMATELY 5 MINUTES BEFORE MOVING TO A SITTING POSITION WHERE HE STAYED FOR ABOUT 30 MORE MINUTES. HE THEN GOT UP AND WALKED AROUND BEFORE CALLING FOR A RIDE HOME. |

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| 1064090 | 3/1/2021 | CA | 26 | F | 2/24/2021 | 2/24/2021 | 26 Y female who presents with a chief complaint of syncope. Pt says that pta, she passed out shortly after she got her covid vaccine. Says she received the vaccine, and stood up to go to the observation area. Was walking through the doorway when she started to get lightheaded. Says she grabbed ahold of the door frame, and slid down to the ground. Denies injury. Denies any prodromal symptoms, no SOB, chest pain, rash, abd pain, back pain. No leg swelling or calf muscle pain. No other complaints. History/exam more consistent with vasovagal syncope as opposed to reaction from the vaccine. Canadian syncope rule puts her at very low risk (-3 points, 0.4% risk of 30-day serious adverse event). Pt without ectopy on ED monitoring during observation period. F/u with pmd in 3 days for recheck, pt agrees to return for any further concerning symptoms |
| 1063889 | 3/1/2021 | OK | 82 | F | 2/25/2021 | 2/25/2021 | Immediately after receiving the vaccine, client started c/o severe pain in her arm and lightheadedness and shallow breathing. vital signs monitored. no meds administered. Son at her side. This information was obtained from her son. He says she has bad arthritis and the shot hurt her and she almost passed out. She has had no other problems since and didn't have any with the first dose. |
| 1064235 | 3/1/2021 | AL | 40 | F | 2/28/2021 | 2/28/2021 | patient experienced swelling of the arm and fainted. patient was provided 2 cold packs from local emt. 1 cold pack for arm. 1 cold pack for head/neck. patient was also monitored for cardiac abnormalities. no heart abnormalities were found. patient was able to return to vehicle. |
| 1063896 | 3/1/2021 | AZ | 83 | F | 2/3/2021 | 2/3/2021 | Evening of day of vaccination, had fever, chills high blood pressure and pulse. Lasted all night and next day started to get less until Friday morning. Feeling good that day and went to friends house for dinner. At end of dinner felt like going to throw up but instead I passed out for 1-2 minutes (have never passed out in my life!). Medics came and ran several tests but all was okay and I have had no trouble since. |
| 1064297 | 3/1/2021 | AL | 49 | F | 2/28/2021 | 2/28/2021 | patient had swelling of arm and fainted. patient was provided a cold pack for their arm and head/neck. symptoms resolved |

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| 1064309 | 3/1/2021 | IN | 70 | F | 2/26/2021 | 2/26/2021 | 13 min. after injection I had dizziness, feeling faint and sweating. Clinic gave me water and cold rags. Pharmacist let me stay until I felt I could drive. I came home and took Tylenol for headache. 5 hrs later I felt extremely ill with joint pain , fever , dizziness. Vomiting occurred during the night along with fainting. Next morning drank tea, no food. Slept all day until 5pm. Slept through night. Sun. still had extreme joint pain and headache. Was able to eat a light meal. Today I ate normally, went to physical therapy with a reduced routine. I still have a headache as of Mon. night. I know these seem like Normal side effects, but these were like having the worst Flu ever. |

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| 1064312 | 3/1/2021 | MI | 77 | M | 2/26/2021 | 2/27/2021 | Reported via Nurse Triage / PCP: Fainted earlier, eyes rolled back, mouth was drooping. Nausea, weakness, and chills. BP was 107/75, HR in the 70s. Currently alert and resting. States that patient had his 2nd covid vaccine yesterday AM and then develop chills and clammy skin last night. Symptoms worsened today and patient became weak and fainted. Was unconscious for about 5 minutes and while unconscious, mouth was open and drooling and became incontinent and eyes rolled back in head. Is awake and alert now, but still weak and only able to take 1 or 2 steps. No chest pain or breathing difficulty and no fever. Feeling very nauseous. Caller requesting prescription for zofran. Yesterday AM 2nd vaccine. Last night chills. This AM feeling weak. Today at 11am he felt weak with ambulation. He fainted. Was unconscious for 5 min. Had drooping of the face. He was unresponsive during this time. Had incontinence of urine. Then became awake but very weak still. Only able to walk a few steps. He is communicating. No chest pain. No current fever. No shortness of breath. BP 107/75 with HR 70. He has been very nauseated. He is drinking only small sips of water. Does not seem like a usually COVID-19 vaccine reaction. Given the LOC with urinary incontinence and sustained weakness, I advised ER evaluation to rule out neurological issues. Pt's daughter in agreement. They will go to ER. From Emergency Department: Patient presenting with chief complaint of syncopal episode which was witnessed by his wife. He reported the got dizzy and lightheaded and then passed out while seated. The reported duration of his loss of consciousness was somewhat inconsistent, unclear how long he passed out for, there was however no postictal state. He was not noted have any shaking or seizure activity, he did have an episode of urinary incontinence. He has not been feeling well ever since receiving his 2nd COVID-19 vaccine. By the time of my exam patient states that he is completely asymptomatic, he states he is feeling much better after receiving IV fluids. His lab work is remarkable for a slightly low sodium, compared to his previous levels which were many months ago. Unclear of the acuity of this, although upon further discussion with the patient he has been drinking large amounts of water since his vaccine trying to stay hydrated. I advised him to substitute to some electrolyte balanced fluids and to have his sodium rechecked by his |

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| 1064407 | 3/1/2021 | PA | 66 | F | 2/27/2021 | 2/27/2021 | PCP to ensure that this is transient. With negative testing and resolution of his symptoms he is stable for discharge home. Close return precautions were given. |
| 1062376 | 3/1/2021 | KS | 23 | F | 2/28/2021 | 2/28/2021 | very tired, migraine, low-grade fever, nausea, diarrhea, redness and swelling around the injection site. I passed out twice due to weakness and lightheaded feeling. |
| 1062376 | 3/1/2021 | KS | 23 | F | 2/28/2021 | 2/28/2021 | Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Hypotension-Mild, Additional Details: @~1415 HR 63 BP 118/58; @~1430 BP128/92; @~1445 HR 71 BP: 127/87; Pt had gotten up to walk around store (stated she hadn't had an allergic reaction or fainted with a vaccine before), came back within 5 min and stated she was feeling hot, temp was 96.8. I asked pt to sit down and on her way over she fainted; denied hitting her head, only her arm. Responded almost immediately, proceeded to take vitals and monitored. |
| 1063275 | 3/1/2021 | CO | 73 | F | 2/27/2021 | 2/28/2021 | Awakened at about 5 am , approximately 18 hours after the injection. Got out of bed to go to the bathroom and passed out. I am not sure how long I was unconscious,, but when I came to I was on the floor and unable to move. I called out to my husband and he got me up, but I could not walk. He got me back into bed. Several hours later he assisted me in walking and I am walking ok now. |
| 1064129 | 3/1/2021 | WV | 78 | M | 2/26/2021 | 2/27/2021 | Approx. 16 hours after injection I started shivering and cold sweats. was weak. and just out of it. Went to bed and by mid afternoon shivers were gone as well as sweating. Slept all day and into the evening, by 10pm or so all seemed back to normal. Mid afternoon I sat up on the edge of the bed to go to the bathroom and passed out falling on my left knee (bad one) and hit my forehead on the bathroom door scraping and bruising same above left eye brow. Walking with pain in left knee but getting better daily. |

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| 1063479 | 3/1/2021 | MI | 59 | M | 2/28/2021 | 2/28/2021 | Patient received covid shot, was sitting in chair after shot, felt sudden urge to have BM, stood up and passed out. Bradycardia (Per ems reading of 58 and then 41, current in hospital 62), and Hypotension (Per ems 88/64 and then 68/42) He was required to stay for 15 mins afterward for symptom monitoring. He then proceeded to feel ill after the vaccine, became sweaty, lightheaded, and felt gassy. He then stood up to use the restroom, and stated he felt he was going to pass out and fell to the ground, hitting his head against the ground. He denies any full LOC. Did sustain a laceration to L forehead. He denies any preceding vertigo, chest pain, or DIB. |
| 1063307 | 3/1/2021 | MI | 85 | F | 2/24/2021 | 2/24/2021 | THE PATIENT PASSED OUT ONCE SHE WAS HOME. SHE PASSED OUT IN THE BATHROOM AND THEN AGAIN WHEN CRAWLING TO HER BED. AFTER THAT SHE DID NOT PASS OUT. SHE WAS VACCINATED AT ABOUT 10AM AND THEN WENT HOME AND PASSED OUT AROUND 12NOON AND PASSED OUT AGAIN SHORTLY AFTER NOON. SHE HAS NOT PASSED OUT SINCE THEN. SHE DID NOT CONSULT HER PCP. SHE DID NOT CALL AN AMBULANCE. SHE SAID SHE PASSED OUT YEARS BEFORE AFTER TAKING ADVIL. THE PATIENT DID NOT KNOW IF SHE HAD EATEN BEFORE GETTING HER SHOT THAT DAY. SHE WAS NOT ABLE TO TELL ME WHAT TIME SHE NORMALLY EATS BREAKFAST. I ADVISED HER TO CONSULT WITH HER PCP REGARDING WHETHER OR NOT SHE SHOULD GET THE |
| 1063322 | 3/1/2021 | FL | 75 | M | 2/27/2021 | 2/27/2021 | Convulsive Syncope |

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| 1063386 | 3/1/2021 | AR | 59 | F | 2/25/2021 | 2/27/2021 | Moderna COVID-19 vaccine EUA difficult time gathering all information due to poor cell reception. Called about 42 hours 1/28/21 after first dose, reported she fainted in her driveway, was instructed by nurse to call ambulance or go to her PCP. She had an appointment the next day so she waited until the next day and saw APRN. 1/29/21 called to follow up on initial report and get infor for health checker website, she had sore arm and chills AM 1/26/21 at aprox. 24 hours after first dose, right ear was itchy, hot and swollen. 36 hours later B/P dropped and stated she fainted in driveway. 1/29/21 feeling okay. Dose 2- she had a box of benadryl chewable with her in case she needed, administered 2/25/21 and waited in clinic for 30 minutes no issues. 3/1/21 she called clinic and reported 2/27/21 AM she had welts on upper body and face. In the PM her ear gor itchy and her throat swelled some, but was able to swallow. Stated she did not take benadryl as she wanted to see what was happening to her. Sunday AM noticed her upper lip swollen some and stayed that way most of the day. 3/1/21 she called today to report reactions, |
| 1063449 | 3/1/2021 | NY | 31 | F | 2/26/2021 | 2/26/2021 | Reported trouble breathing , then fainted , was assisted to the floor. epi pen givenx2 Large Tonic Clonic like movements with no loss of consciousness (pseudo seizure) was taken to ED |
| 1063471 | 3/1/2021 | | 75 | F | 3/1/2021 | 3/1/2021 | Near syncope-dizzy, lightheaded, diaphoretic, blurred vision, decreased responsiveness. Evaluated by EMS- BP 100 palp, BS 110, decreased responsiveness. 2:36 pm-transported by rescue squad. |
| 1063887 | 3/1/2021 | VA | 51 | F | 3/1/2021 | 3/1/2021 | Patient was administered the first dose in the Pfizer COVID vaccine series. During the observation portion, the patient passed out in the observation area approximately 10 minutes after receiving the dose and became non-responsive with ragged breathing. The pharmacy team responded and administered a dose of epinephrine 0.3mg to the patient immediately and called for EMS who arrived on the scene |
| 1063531 | 3/1/2021 | | 47 | M | 3/1/2021 | 3/1/2021 | Pt developed syncope and LOC for ~ 3 min. VS WNL when monitored.No other adverse reaction noted. |

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| 1063544 | 3/1/2021 | MN | 49 | F | 2/20/2021 | 2/21/2021 | Fever 103.0 F, Chills, Muscle Pain, Headache, Night Sweats, Dizziness/near-syncope, tachycardia (120's bpm), nausea, severe fatigue, severe soreness at injection site (but mild swelling, mild itching). Starting from 3:30 am on 02/21/21 until about 3 pm on 02/22/21. Milder headache and fatigue throughout rest of that week. Back to normal now. |
| 1063591 | 3/1/2021 | | 45 | F | 2/26/2021 | 2/1/2021 | Vasovagal Near Syncope Lightheadedness, Hypotension, Nausea Patient is a 45-year-old female with history of hypertension, anxiety. Patient received vaccination at 14: 05, approximately 5 minutes later at 14:10, Vasovagal response |
| 1063637 | 3/1/2021 | IL | 69 | F | 3/1/2021 | 3/1/2021 | Patient presents with vaccine reaction Had first dose Pfizer COVID vaccine and walked into waiting room for observation and started to feel like drank sometimes warm and then became dizzy shortly after that. Waited a couple minutes in waiting room and then told observer up front what she was feeling. Was asked if wanted a wheelchair to come back to examination room and patient declined and able to walk back down the hall accompanied by her husband. Denies nausea, abdominal pain, no SOB, no syncope, no recent illness, denies fevers cough, ill contacts Working wood burning project and was up till 3am and then unable to go sleep yet today. Also has stress with only child with being treated for stage 4 breast cancer Did eat breakfast around 9am- granola and cup of tea this am. Nothing since then. Current B/P 164/110 and then 10 minutes later was 150/86. Patient verbalized has history hypertension even with medication. Denies visual changes, denies headaches Vaccine reaction Symptoms resolved. Told patient if start to feel bad again let someone know (husband, COVID hotline, PCP). Increase fluids, discussed sleep hygiene.Patient and/or guardian verbalized understanding |

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| 1063679 | 3/1/2021 | KS | 65 | F | 2/25/2021 | 2/26/2021 | The morning after receiving Covid-19 vaccination I fainted. I was sitting, working on an i-pad and got up to go to another room. I walked through the house to another room. I noticed my arms and legs felt kind of rubbery and that I didn't seem to have control of them. I fell to the bed and lost consciousness for 5-10 seconds. This was all observed by my spouse. I recovered quickly. The remainder of the day I had a slight headache and felt slightly nauseous. I took acetaminophen before going to bed and woke up the following morning with no complaints . |
| 1063750 | 3/1/2021 | TX | 69 | F | 2/27/2021 | 2/28/2021 | Moderate to severe pain and feeling of blacking out/fainting with nausea morning after. Fever the night of. Stayed in bed and rested.Fell good today just a little sore so do not have full use of arm without. |
| 1063817 | 3/1/2021 | MI | 52 | F | 2/15/2021 | 2/16/2021 | Fainted Fast heart rate Headaches Dizziness |
| 1063466 | 3/1/2021 | PA | 45 | F | 2/4/2021 | 2/5/2021 | after having the fever of 102, fainting and throwing up I had horrible vertigo and nausea. had to go on anti vert and anti nausea meds, now 1 month later, I am still dizzy in the morning, my muscles ache terrible , especially my lower leg muscles , joint pain, and I am so exhausted |
| 1060497 | 2/28/2021 | WV | 26 | F | 2/26/2021 | 2/26/2021 | Extreme fatigue, body aches, chills, sweating, passed out while showering the next day |
| 1060978 | 2/28/2021 | | 49 | M | 2/24/2021 | 2/26/2021 | 2/24/2021 2/26/2021: High Fever and body ache till 2/26 early morning. 2/26/2021: Became very dizzy and FAINTED/PASSED OUT in Restaurant after eating dinner and had 1 beer/1 smoke. Went and sat in a chair when dizzy and passed out in the chair. Created panic in the restaurant. Was Fever free since morning. PASSED OUT FOR about 5 minutes. Woke up and profuse sweating for about 3 minutes after which felt normal. |
| 1060498 | 2/28/2021 | CA | 73 | M | 2/21/2021 | 2/21/2021 | 10 hours after second dose I started feeling fever, chills, shivering, having to get up to pee every 45 minutes. Symptoms got worse all night, additionally with nausea and vomiting. Twice while sitting on the toilet holding barf bowl, I fainted, waking up finding myself lying on the floor. Symptoms subsided 14 hours after they started. |

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| 1060596 | 2/28/2021 | IN | 70 | F | 2/24/2021 | 2/25/2021 | Woke up at my usual time the day after vaccine. Felt a little warm but not feverish and did not take my temperature. After walking to kitchen to let cat in from garage I stopped at the nearby kitchen sink and began to shake (I believe just my upper body). I had to grab onto sink to steady myself. Shaking was only seconds long. Then I must have fainted as I awoke (quickly) on the floor alongside the cupboards and sliding glass door. I laid there conscious about 15 minutes till I felt confident I could get up on my own. As result of fall I bit upper and lower lip on right (no blood just skin injured), must have clenched my teeth because my left posterior teeth were sensitive to cold and I injured my right ankle. After I got up and realized my ankle hurt with pressure I put on a support knee high to control swelling. Injury seemed to be focused on the ankle bone. I applied ice for recommended 20 on 20 off protocol for most of both 2/25 and 2/26, elevated and took OTC Aleve as directed on package. Bruising observed from heel, behind ankle bone and front of ankle. Called PCP, she recommended continue as I have and she will contact me tomorrow, March 1 |
| 1060784 | 2/28/2021 | | 79 | F | 2/28/2021 | 2/28/2021 | fever, syncope after vaccine |
| 1060813 | 2/28/2021 | KY | 27 | F | 2/28/2021 | 2/28/2021 | Patient fainted approximately 5-10 minutes after receiving the vaccine while in the waiting area. Pharmacist and staff rushed to patient to provide care and she had quickly regained consciousness. EMS arrived soon after and cleared the patient. No treatment was given and the patient was feeling normal before leaving. |

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| 1060871 | 2/28/2021 | ID | 68 | M | 2/25/2021 | 2/25/2021 | After about 3 hours (around noon) I began to feel like I was coming down with a cold and fever. By 4PM I had chills and body aches. By 8 pm I took my temperature and it was a low grade 99.8. Through the remainder of the night the chills worsened to the point where I was shaking uncontrollably and I could not get warm. I was also very dizzy. The next day (2/26/21) was more of the same along with a very painful headache and muscle aches especially in my shoulders and neck. That night all of those symptoms continued along with very sharp stabbing pains in my left leg above the knee cap. The dizziness also continued and I nearly passed out trying to get out of bed early in the morning. My fever had increased to 100.5 at the highest. I was also very weak by the end of the day on 2/26/21. On 2/27/21 I was beginning to feel a bit better but still had that low grade fever (now about 99.8) a headache and I remained very weak. The weakness was especially evident in my legs - it was very hard to stand up. It is now 2/28/21 and I am feeling nearly 100% myself again. From all I had read and understood I was expecting to have a reaction to the 2nd vaccine. I did not consider any of this life threatening nor necessary to call my PCP. Still, I wanted to report these reactions as it is my understanding the adverse reactions to the 2nd vaccination are common in people much younger than me. |
| 1060862 | 2/28/2021 | WA | 67 | M | 2/26/2021 | 2/27/2021 | Low grade fever and general body aches starting at 1:00 AM (12 hours after injection). At 9 AM, passed out in shower. When I awakened (about a minute later) I was unable to stand so I crawled to from the shower to bedside, but passed out again when I tried to pull myself up from the floor into bed. My wife called 911 and the local fire department responded. The EMT took my blood pressure while I was lying on the floor with my feet elevated and it was 78/34. The EMT called an aid car and I was transported to a local ER. At the ER, I received 2 liters of fluids over the next 4 hours. I had an EKG, chest X-ray, blood work, and urine analysis which all were clear. After 4 hrs, I was released and returned home. |
| 1061210 | 2/28/2021 | AL | 35 | F | 2/26/2021 | 2/27/2021 | Vasovagal syncope (4 times) between 4:00 and 4:30 a.m. |

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| 1061048 | 2/28/2021 | RI | 77 | F | 2/28/2021 | 2/28/2021 | Pt c/o nearsyncope shortly after vaccination. no loc. no vertigo. hx afib that is rate controlled w/o meds. sx pr to assessment. BP and blood glucose wnl. HR=75-80 irreg irreg. 12-LEAD: AFIB RATE:78 NO ST/T CHANGES. PT REMAINS ASYMPTOMATIC AFTER 30MIN monitoring. pt and daughter declined transport to hospital for further eval. ems refusal signed |
| 1061080 | 2/28/2021 | WV | 76 | F | 2/26/2021 | 2/27/2021 | Almost exactly 24 hours after 2nd shot, my mom was getting her hair done and she started breathing hard. Hairstylist removed her mask and she then passed out. Called 911. They observed my mom sweating, her lips and hands were swollen, she was slack jawed, pale and clammy. After several minutes she came out of it. Was given a piece of candy thinking it was a sugar low, but her sugar was high 285 @9:00am. Her color was still pale and she was still incoherent. While still on with 911, she became more lucid and said she was feeling better, so ambulance was canceled. I drove her home and checked her sugar @11:00 - 295 and BP 125/55 pulse 75. She stayed with me for the rest of Saturday. Her sugar was still high Saturday evening and Sunday morning. Upon checking her blood sugar log, her sugar had gone up for a week following the first shot. |
| 1061095 | 2/28/2021 | KS | 20 | F | 2/24/2021 | 2/24/2021 | Dizziness, nausea, syncope, tachycardia (heart rate was 177) |
| 1061102 | 2/28/2021 | MA | 57 | F | 2/27/2021 | 2/27/2021 | Pt presented for 1st dose of COVID-19 vaccine at . Pt completed COVID Vaccine Consent Form which was reviewed by immunizer prior to administration. Pt reported hx of syncope >10 yrs ago after blood work. ~2 mins after vaccine administration pt reported not feeling well and became unconscious. Seen by immunizer who called for help and caught pt prior to falling from seated position. O2 Sat ~99% and HR 60 bpm and BG 140 mg/dL. Pt was addressed while she regained consciousness (able to state name and location). 911 was called and onsite within 5 mins. Pt's husband alerted and she was taken to Hospital for further testing. |

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| 1061127 | 2/28/2021 | MO | 76 | F | 2/26/2021 | 2/26/2021 | Patient began feeling tired 1 hour post dose. At 3 hours post dose, patient began feeling woozy, dizzy and disoriented. Patient got dizzy and passed out while walking to bathroom. She fell and sustained a significant laceration to her arm. She continued to feel dizzy and "just not right" several times over the hour until she finally called 911. When paramedics arrived, she continued to lose consciousness and required full assistance to be placed onto the stretcher. Her BP was all over the place for the better part of 6 hours, with highs as high as 145/95 and lows as low as 81/42. This reaction lasted for a total of 8 hours. |
| 1061173 | 2/28/2021 | KY | 84 | F | 2/13/2021 | 2/28/2021 | RECEIVED PFIZER COVID VACCINE 1ST DOSE ON 02/13/21. WENT TO ER ON 02/28/21 WITH COMPLAINT OF BRADYCARDIA AND FELT FAINT. DIAGNOSED WITH SYNCOPE AND COLLAPSE AND ABCESS OF LOWER LEFT LUNG WITH PNEUMONIA. ADMITTED TO HOSPITAL. |
| 1061195 | 2/28/2021 | NY | 21 | F | 2/28/2021 | 2/28/2021 | The vaccinating nurse reported that within 15 seconds of being vaccinated the patient states she needed to lie down and then slumped with apparent loss of consciousness. She was pulled to the floor by her companion, possibly hitting her head. She awoke, according to the nurse in about 45-60 seconds and shortly after was A&Ox4, moving all extremities. BP 127/84 P68 O2- 98% She was placed on a board and transported to ED for possible head injury The patient arrived fully alert and did not report previous episode of vasovagal syncope. After she had the incident her mother stated she had had such an episode at age 10 with a vaccine. |
| 1060832 | 2/28/2021 | AL | 71 | F | 2/26/2021 | 2/26/2021 | 2/26 9 pm Headache, dizziness, fatigue, slight fever 2/27 8 am Fainted, hit head |
| 1061044 | 2/28/2021 | RI | 88 | F | 2/28/2021 | 2/28/2021 | C/O near syncope following vaccination. No HX of similar. No CP/SOB. No HA. No focal deficits. No HX diabetes. FSBS: 86; BP: 130/80; HR: 52 (regular); no B-blockers or other rate controlling medications. EKG: sinus bradycardia. No blocks No ST/T changes. Intervals normal. Symptoms resolved at rest. HR remains in 50s. Care transferred to ambulance paramedics & patient transported to acute care ED. |

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| 1059525 | 2/27/2021 | CA | 41 | F | 2/26/2021 | 2/26/2021 | patient that fainted today. She reported on her screening questionnaire of passing out after receiving a injection. She was placed for 30 minute observation. The patient fainted several minutes after being seated. It was observed that she fell over from the chair and hit her head. Patient denied any symptoms other than her right toe being sore.. A + O x 4 medically stable. VS stable. EMS was dispatched due to patient hitting her head and c/o feeling dizzy still...however, patient declined services. She was with her husband and he agreed to drive her home. |
| 1059438 | 2/27/2021 | KY | 59 | F | 2/22/2021 | 2/23/2021 | Modern COVID-19 Vaccine EUA I received my COVID vaccine at 7:00pm on 2/22/2021. At 1:00 am 2/23/2021 I woke up to use the restroom. I fainted and cut my forehead in the fall. I was shaking uncontrollably following this. My husband bandaged my forehead and checked me for a concussion. Sometime after 2am I realized I was in atrial fibrillation. I have a Kardia app that confirmed this. I tried at home methods to go back in rhythm. At 8am I called my cardiologist. He advised me to go to the emergency room. At this time the Kardia app indicated I was no longer in Afib but still had a fast heartbeat. At the emergency room I had a normal EKG, CAT scan, blood work and chest X-ray and went home about 11am. |
| 1059366 | 2/27/2021 | NH | 66 | F | 2/22/2021 | 2/23/2021 | Woke up at midnight with fever, chills, thirst. Tossed and turned all night, cold and thirsty. Drank about 20 oz of Crystal Light Peach Tea over night. Got up at 5am to get more to drink and find another place to rest. went into my kitchen to fill container and passed out. Woke a few seconds later. Left side of my forehead was bruised and swollen above left eye. Over the last 4 days both eyes an cheeks are bruised. All day felt like I had the flu without the fever. I did not go to the hospital. |

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| 1059264 | 2/27/2021 | MA | 67 | M | 2/26/2021 | 2/26/2021 | Systemic: Fainting / Unresponsive-Severe, Systemic: shortness of breath-Severe, Systemic: Seizure-Severe, Systemic: Shakiness-Severe, Additional Details: Patient was sitting in observation when he suddenly had his head and eyes rolled back. Patient's daughter alerted the pharmacist on duty that he felt like he couldn't breathe. Patient went into a possible seizure. His eyes rolled back and his body went stiff. After a few minutes, patient was alert and oriented enough to answer questions coherently before the ambulance arrived. Patient went on the ambulance. |
| 1059555 | 2/27/2021 | MI | 26 | F | 2/26/2021 | 2/27/2021 | 2 fainting episodes the next day after receiving the vaccine. The first time I realized I was losing consciousness but the second time I fainted I didn't know what happened. |
| 1059241 | 2/27/2021 | TX | 65 | F | 1/29/2021 | 1/29/2021 | Face red Coughing Trouble breathing Nauseous Heart racing Fainted Inability to speak due to throat swelling up |
| 1059280 | 2/27/2021 | TX | 45 | F | 2/23/2021 | 2/26/2021 | Blood pressure 65/33. Severe Diarrhea, moderate abdominal cramps, severe dizziness, close to fainting. Minor chest pressure |
| 1059253 | 2/27/2021 | RI | 16 | M | 2/26/2021 | 2/26/2021 | Systemic: Fainting/Unresponsive-Medium. Additional Details: Patient fainted about 5 minutes after receiving 2nd dose of vaccine. Pt hit his head on a table on way down. EMS called. PT was alert and oriented, but was taken to the hospital for evaluation by ambulance. |
| 1059857 | 2/27/2021 | NJ | 74 | M | 2/26/2021 | 2/27/2021 | Headache and syncope with head injury. |
| 1059900 | 2/27/2021 | PA | 29 | F | 2/27/2021 | 2/27/2021 | Patient felt hot, had nausea, and passed out transiently. She woke after approximately 2-3 seconds and felt well after lying down for 1-2 minutes. |
| 1059921 | 2/27/2021 | MI | 25 | F | 2/26/2021 | 2/26/2021 | 9:00 am - vaccine 10:00 am - 5:00 pm - sore arm 5:00 pm - 8:30 pm - body aches chills fever 8:30 pm - passed out 8:45 pm - passed out again (ambulance came and took me to the ER) 9:00 pm - passed out for the third time in the ambulance 9:00 pm - 1:00 am - in the ER. tests were given. everything came back normal. discharged. |

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| 1059974 | 2/27/2021 | WI | 38 | F | 2/27/2021 | 2/27/2021 | After vaccination was complete, patient went to sit down because she said she "felt a rush". Pharmacist was called over and patient had her head between her knees while sitting in the waiting area. She said she felt very dizzy but sitting forward wasn't helping. Then about 30 seconds later patient stated she was going to pass out and wanted to lay on the floor. While getting up she fell down and passed out, hitting her head on the cement floor. 911 called. Patient came to about a minute later and stated she was going to throw up. She spit a bit but didn't vomit. She turned very pale and then turned bright yellow. She was in and out a consciousness for a few minutes until paramedics arrived. They examined her and took her to the er to verify if she had a concussion and make sure she was okay. |
| 1060024 | 2/27/2021 | MO | 65 | M | 2/27/2021 | 2/27/2021 | Patient passed out in the immunization chair - Passed out 2 minutes after the vaccine, came-to a few seconds after, was fine after that |
| 1060191 | 2/27/2021 | NC | 70 | F | 2/22/2021 | 2/22/2021 | headache, chills, fever, red swollen right arm, nausea, and fainted four times on day two. all symptoms lasted 5 full days and nights. |
| 1060277 | 2/27/2021 | CA | 18 | F | 2/27/2021 | 2/27/2021 | Staff at facility informed staff that a staff member had passed out. RN from drug store found client sitting in a chair, awake and alert, no signs of injury. Had client lay down and elevated legs. BP at 1:50 PM is 122/86, HR is 100, regular and strong, color is good, mentation is good, no signs of injury, client state she feels "weird and tingling". Patient monitored for over 30 minutes with multiple BP and HR checks and mentation checks. One dose of Bendaryl 25 mg given at 1:57 PM. Orthostatics completed at 2:00 PM. Both HR and BP remain WNL and client continues to be awake and alert,. Ambulated to bathroom with RN at side. Patient declines need for EMT and went home with her boyfriend at 2:20 PM, BP at 132/88, HR at 80. |

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| 1059263 | 2/27/2021 | MA | 67 | M | 2/26/2021 | 2/26/2021 | Systemic: Fainting / Unresponsive-Severe, Systemic: Seizure-Severe, Systemic: Shakiness-Severe, Additional Details: Patient was sitting in observation and his head and eyes rolled back. He was observed to go into a shock state, possibly seizure for a few minutes. After a few minutes, patient regain orientation and was alert and was able to answer questions before the ambulance arrived. Patient left with the ambulance to the emergency room. |
| 1059732 | 2/27/2021 | NJ | 52 | F | 2/25/2021 | 2/26/2021 | Pain in arm, very tired and slight chills and achy at night. Mostly fine. Just wanted to report that I woke at 4:30am and was very nauseous and dizzy. I went to the bathroom and thought I would be sick, but I remember being so dizzy that I went to lay on the floor by the toilet but my husband said he heard a thud, and came to find me passed out. Then I was shaking (a vaso vagel response I guess) til I came to. The ems came, but everything was fine, so I elected to stay home. I threw up a 1/2 hour later and then felt better, and slept for a few hours. The rest of the day I was just exhausted. Today I woke up feeling fine! Just wanted to report the episode in case you track vomiting and dizziness and fainting. |

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| 1057806 | 2/26/2021 | MN | 40 | M | 2/25/2021 | 2/25/2021 | <p>Within one minute of receiving vaccine, the patient became pale, stated that he felt dizzy and fainted. Patient regained consciousness within one minute. Upon regaining consciousness, patient reported feeling lightheaded and dizzy but was oriented to person, place and time. Skin was warm and dry but pale in color. After regaining consciousness, patient also stated that he has a history of fainting 5-6 years ago after receiving an influenza vaccination. (During screening questions, patient denied having any reactions to vaccines in the past) Patient independently moved from a chair to a laying down position on a cot and expressed an improvement in how he was feeling. Vital signs taken after event as recorded below. When asked patient stated that he does recall times when he thinks he may have been hypoglycemic in the past. Patient also states that he has been very nervous about receiving injections throughout his life. EMS called and assessed patient at the vaccination clinic site. Patient drank a 10 oz bottle of orange juice prior to EMS arriving and when EMS staff obtained his blood sugar the result was 97. EMS stated that patient was stable and all vital signs were stable. Patients skin color improved to pink. Patients wife was called by patient and she provided transportation home for patient. Prior to leaving the vaccination clinic, patient was walking around for several minutes and denied any feelings of being lightheaded or dizzy. VITALS SIGNS: 5:06pm: Heart rate: 50, Oxygen Saturation: 99% on room air 5:15 pm: Blood pressure: 100/78 ; Heart rate: 50; oxygen saturation 99% on room air. 5:20pm: Blood pressure 98/76 Heart rate:52; oxygen saturation 96% on room air. 5:34 pm: Blood pressure 92/68 Heart rate: 53 oxygen saturation 97% on room air. Vital signs taken by EMS staff were not recorded by public health nursing staff.</p> |

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| 1057752 | 2/26/2021 | OH | 22 | F | 2/24/2021 | 2/24/2021 | Patient states she returned to worksite after vaccine received and felt fine. States around 12:00 pm she was having a conversation with a coworker about her history of fainting spells when she speaks about medical procedures. While she was talking to coworker she fainted and hit the back of her head on the floor. States she recovered within 5 minutes. School nurse was notified and reported a faint pulse and blood pressure was low (around 80/40). Was transported home by parents. States she felt groggy after fainting and a slight headache, tunnel vision, and muffled hearing that resolved the next day, 2/25/2021 around 7:00 pm. States she has a bump on the back right side of her head but denies other injuries. States she did return to work the next day. |
| 1057741 | 2/26/2021 | MI | 48 | M | 2/25/2021 | 2/25/2021 | client was administered vaccine by IM inj. LD in a semi fowlers in private room at 06:20pm. Client remained alert and moved to chair in sitting position. client then had an episode of syncope in chair and was held upright. client had reduced consciousness but was able to respond verbally to voice. client was assist of two to a wheel chair and moved back to private room and administered O2 via NRB @ 4pm. Client responded well and quickly, was more alert and oriented x3. client given orange juice at 06:30 and was fully alert and orientated, talkative and calm. O2 off at 06:35. Continued to monitor symptoms q 5 mins for 30 mins. Client is an athletic runner. His BP remained in the 92/48 range and his HR at 54. Client was released 06:55. |

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| 1056193 | 2/26/2021 | NC | 70 | F | 2/11/2021 | 2/12/2021 | fainted twice while visiting the bathroom; BP was 145/85; arm was sore; This is a spontaneous report from a contactable consumer reporting for herself. A 70-years-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot_number m000007217771.CSN20 447277212), via an unspecified route of administration in left arm on 11Feb2021 16:45 at single dose for covid-19 immunisation at Public Health Clinic/Veterans Administration facility. Medical history included hypertension, blood cholesterol increased, anxiety, allergies, allergies to penicillin, Sulfa drugs and Crustacea. The patient previously took tetracycline and experienced drug hypersensitivity. The patient was not pregnant at the time of vaccination. Concomitant medication included olmesartan medoxomil (unknown manufacturer), diltiazem hydrochloride (unknown manufacturer) and sertraline hydrochloride (SERT). On 12Feb2021 her arm was sore but she was not really feeling anything more. On 13Feb2021 morning at 04:45 the patient fainted twice while visiting the bathroom. Upon checking of the BP it was 121/75. Later in the day the BP was 145/85. The patient was completely normal before the shot. It seems that the vaccine affected my BP. The outcome of the events was recovered in Feb2021. No treatment was performed. The patient did not have COVID-19 prior to vaccination and was not covid tested post vaccination. |
| 1057775 | 2/26/2021 | PA | 27 | F | 2/24/2021 | 2/25/2021 | At around 11PM on 2/24/21, I had a severe headache, fatigue, chills, nausea, muscle and joint pain, and felt feverish. At around 2AM, I had vasovagal syncope (I lost consciousness and then woke up covered in sweat). Directly after I regained consciousness, I vomited several times over the next couple of minutes. I drank water and took Tylenol to try and alleviate symptoms. After that, I no longer vomited or lost consciousness but I continued to feel feverish, had a severe headache, fatigue, chills off and on, nausea, and muscle and joint pain until around 4PM on 2/24/21. |

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| 1057556 | 2/26/2021 | CA | 70 | F | 2/10/2021 | 2/10/2021 | slight soreness on head; Knees extremely sore; passed out; fuzzy feeling; This is a spontaneous report from a contactable consumer(patient). A 70-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EM9809) on 10Feb2021 at 16:30 at single dose via an unspecified route of administration on right arm for COVID-19 immunization. Relevant medical history included type 2 diabetes mellitus, hypertension and allergy to Victoza. Concomitant medications included metformin, dulaglutide (TRULICITY), atorvastatin and fluoxetine. On 10Feb2021 at 21:00 about the patient five hours after vaccine in kitchen washing dishes, passed out. No symptoms or light headedness leading up to this event. Patient woke up on floor hit head minor and knees. On 11Feb2021 the patient complained slight soreness on head, fuzzy feeling. Knees extremely sore, small cut on ankle. Her doctor advised to report this due to the time event happened in relation to vaccine (as reported). No treatment reported for events. At the time of the reporting the patient was recovering from the events. . |
| 1057781 | 2/26/2021 | OR | 90 | F | 2/22/2021 | 2/23/2021 | syncope followed by ER visit w/ many negative tests. persistent weakness, apathy and loss of appetite |

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| 1056646 | 2/26/2021 | FL | 71 | F | 1/21/2021 | 1/1/2021 | My arm hurt; I started to get little tired; I couldn't watch TV; My stomach suddenly did not feel well; Nauseous; I got cold; Sick; was very hot and so hot; was round up/she was feeling she would faint; waves of feeling like i would pass out; it was just being very hot, then being cold; Blood drained from my head, I just knew I was going to pass out; I took 0.2 rather than the 0.3ml of the first dose; very fast heart rate intermediately for many day; squeezing of chest; muscle hurting/Pain in my body in every muscles, my fingers, my hands, my calves, my feet, my back, neck, everything; digestive disorders; feeling gassy, uneasy; stomach abdomen was just tight; abdominal issue; feeling gassy, uneasy; stomach abdomen was just tight; This is a spontaneous report from a contactable consumer (patient). A 71-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; lot number: E18982), on 21Jan2021 (at the age of 71-year-old) at single dose for COVID-19 immunisation. The patient reported that based on her history of reactions to medications, the nurses giving injections "decided 0.2ml instead of 0.3ml", which is what they gave, so she got 0.2 that is two-third of the shot. The 2nd shot was for 8'oclock on 11Feb2021. She is very sensitive to shots, vaccines, and to all medications and injections and things like that. She has sensitives thanks to two concussions she had in her life. She never was before that she had two concussions. Second one had a crazy man hit her after that just noticed that just have reactions not adverse or dying but definitely take rest of everything. So she take less of a shot, like a dental shot or cortisone shot, which she had taken in the past. If she has dental shot she cannot take Novocain, had to take Carbocaine or Marcaine and they give her half. Also she had been taking cortisone shot for shoulder for rotator cuff injury. They also have to give her less. Or flu shot: she takes half one week and come back for the other half the next week. Just have reactions. She told to when arrive for medication and did have one anaphylactic reaction but that was to cat skin dye, was told to this two nurses who was administering the vaccine and said to them she was really afraid to take. It is just too much for her. She knows her body. She is sure have reaction but is really afraid and don't know what is the first one will do to her. They just did two nurses and she decided that she will be |

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taking 0.2 instead of 0.3ml which is what they gave. She got 0.2 so that two third of the shot and waited the half an hour, a nurse watched her card and 7 other cards. She did not have the anaphylactic reaction. She went home. Her arm hurt and started to get little tired. The events started the day that she got the shot. Like about 3 or 4 hours later. It is just few hours later she couldn't watch TV so went to laid down and an hour later she woke-up. She walked to her kitchen and blood drained from her head, she just knew she was going to pass out. Her stomach suddenly did not feel well. She tried to get back her bed but she was round up and as far as the bathroom. She got very nauseous, she laid down on bathroom floor. She thought she was sick but didn't round up having to use toilet of few times. Although while she was feeling she would faint. She was very hot and so hot. While lie down, she couldn't even pulling off her pajamas. So when she got cold so she was pulling a towel down and stop and she laid to for two hours, she finally got to her bed. It was a terrible experience. Next day she drank water and had potatoes prepared and went up eating back to later baked potatoes. Next day luckily she did not have repeat of the nausea. She didn't have that anymore of. She did have abdominal issue just not diarrhea or anything but just not feeling well, feeling gassy, so uneasy. This all lasted, that part lasted for 7 days. What concerned her was especially beside first day it was few days she got off again. She was just feel blood drain but not this first time she laid on floor. She couldn't sit on chair to watch TV for about 3 days. She mostly laid on bed but she would get very hot and then very cold during the day. She would get very fast heart beat not continue but really fast like heart was pounding her chest. She felt like someone has their hand inside her body squeezing her chest. She got afraid but didn't want to go hospital. She didn't think she was sick enough. She was concerned. So that was happened and this last was for about 7 days. Then the squeezing of chest part went away. She doesn't want to wind-up on the floor feeling that sick again, she felt so sick it felt like food poisoning. After that, it was just being very hot, then being cold, the fast heart rate, every muscle hurting. Those were the main things that continued for a week. And digestive disorders. It all lasted for about 13 days. She was concerned she had a very fast heart rate intermediately

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for many days, for about a week. And that's considered an adverse reaction and also she was getting waves of feeling like she would pass out, everything would drain from her head. She experienced stomach ache, feeling hot then cold. She wants to do precautions before taking the second dose on 11Feb2021. She did take may be 3 days later two Tylenol but didn't take anything (clarification requested). She didn't even take vitamins during that time. She was afraid to take anything so she did not. At the same time also there was pain in her body in every muscles, fingers, hands, calves, feet, back, neck, everything. Her stomach abdomen was just tight. She was concerned that last for few days. In last few days she started feel herself and now she is going again tomorrow. So that how she reacted. She doesn't know how much of this shot she told them she could tolerate because everybody is saying second shot will give you more reactions. All she can take this more than that because that was lot. She wants to be herself, don't want laying on floor, don't want to have 105 temperature or anything. The patient was asking if she should take another 0.2ml another two-third of the shot. She just asked them for half that is 0.15 would that be a big difference. She needed to know by 8 o'clock tomorrow. I might be in a queue to get it. She stated: 'So, that's my concern. I'm all alone, I'm a senior, I have no family. I lost my mother to covid. I know I need this vaccine, but I just, I cant get that sick and I'm so afraid I'll wind up with a 105 something, fainting away and no one knowing'. She was asking if reactions after the 2nd dose are worse than the 1st dose, if she didn't have anaphylaxis after 1st one, she shouldn't have it a 2nd time, right. She said, "1st half of flu shot, I get sick, then the 2nd half nothing". She also asked if she can take medications after the vaccine, like Tylenol, or irritable bowel syndrome (IBS) medication she takes as needed. The events resolved, but the patient reported it took her like 13 days before she felt better.

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| 1057778 | 2/26/2021 | CA | 54 | F | 1/13/2021 | 2/3/2021 | After 2nd dose on 2/3/21, I waited 10 minutes and felt tingling and cold, heaviness and blood pressure dropped significantly. They put me onto a gurney and monitored my BP and waited, gave me some juice and crackers, but I continued to have the sensation of fainting (syncope). They transferred me to the ER for further monitoring. After a while, it stabilized more, but still continued to happen throughout the day. |
| 1057238 | 2/26/2021 | CA | 56 | M | 2/24/2021 | 2/25/2021 | Episode of syncope approximately 14 hours after receiving the vaccination. Recovered within several minutes without adverse consequences. |
| 1056971 | 2/26/2021 | NE | 72 | F | 2/25/2021 | 2/26/2021 | Patient reports running a fever through the night of the 25th. She woke up on the 26th no feeling well, took her blood sugar which was 142 mg/dL. Shortly after she checked her blood sugar she passed out. Her daughter is a nurse and when she arrived, she checked the patient's blood pressure which was noted to be in the 90s systolic. Shortly after that a re-check of her blood pressure improved to 117/60. Patient was scheduled to be seen with her primary care provider on the 26th to verify that patient was stable. |
| 1056956 | 2/26/2021 | IL | 63 | M | 2/23/2021 | 2/24/2021 | Morning after shot was at church and all of a sudden got nauseous and very hot for a number of minutes, then passed out before leaving church. Had a cut lip, nose and have a stiff(sore) neck last day or so. |
| 1056857 | 2/26/2021 | UT | 40 | F | 2/2/2021 | 2/3/2021 | Headache, fatigue, vomiting, fainting, muscle soreness, digestive issues. |

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| 1056638 | 2/26/2021 | IL | 47 | F | 1/11/2021 | 1/12/2021 | Rigors and severe back pain; Rigors and severe back pain; syncope; prolonged PT; Loss of work as a physician for 2.5 weeks; This is a spontaneous report from a contactable physician (patient) A 47-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in left arm on 11Jan2021 12:30 at single dose for COVID-19 immunisation. Medical history included gastrooesophageal reflux disease and allergies. The patient was not pregnant. Concomitant medication included lansoprazole (PREVACID). The patient experienced rigors and severe back pain, syncope, prolonged pt and loss of work as a physician for 2.5 weeks on 12Jan2021 with outcome of recovered with sequelae in Feb2021. The events resulted in Emergency room/department or urgent care, Hospitalization, Disability or permanent damage. The patient was hospitalized due to the events for 2 days. The patient received steroids, pain meds, muscle relaxers as treatment for the events. The patient did not have COVID-19 prior to vaccination and was not covid tested post vaccination. Information on the Lot/Batch number has been requested.; Sender's Comments: Based on a compatible temporal relationship and known product safety profile causality between event chills and syncope and BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), cannot be excluded. The events prolonged PT and loss of work as a physician for 2.5 weeks are attributed to intercurrent conditions that were unlikely related to BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE). The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate. |

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| 1056513 | 2/26/2021 | | | F | | 1/1/2021 | <p>Passed out; Shakes so bad; So sick; Headache; Muscle pain; Temperature for five days (102.7F); A spontaneous report was received from a consumer, female patient of unknown age, with unknown race and ethnicity, who was administered Moderna's COVID-19 Vaccine (mRNA-1273) and experienced passed out (loss of consciousness), shakes so bad (tremor), so sick (malaise), headache, muscle pain (myalgia), and temperature for five days (102.7F) (pyrexia). The patient's medical history was not provided. No concomitant medications were reported. On an unknown date in JAN 2021, the patient received their first of planned doses of mRNA-1273 (batch number: unknown), intramuscularly for prophylaxis of COVID-19 infection. The patient reported that the difficulties which she experienced after the first Moderna vaccine were terrible and so bad. The patient had all the side effects, which includes headache, muscle pain, passed out, fever, and was so sick. The patient wanted to report the side effects and unsure if she should take the second vaccine or not. The patient doesn't think that she can handle the second vaccine. She had a temperature of 102.7 F and was shaking so bad. The patient second vaccine was due in 28 days in February. Upon callback, the patient had a hard of hearing and stated that the vaccine hit her hard and had a temperature for five days. She was concerned about getting the second dose. No treatment medication information was reported. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events, passed out, shakes so bad, so sick, headache, muscle pain, and temperature for five days (102.7F), were not reported.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Further information has been requested.</p> |

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| 1056497 | 2/26/2021 | | 22 | F | | | Severe anaphylaxis allergic reaction; Passed out on the ground; A spontaneous report was received from a consumer concerning a 22-year-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and passed out on the ground and had a severe anaphylaxis allergic reaction. The patient's medical history was not provided. Concomitant product use was not provided by the reporter. On an unknown date, prior to the onset of the events, the patient received their second of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. About 10 minutes after receiving the second dose of the Moderna vaccine, the patient passed out on the ground having a severe anaphylaxis allergic reaction. Treatment for the event included two doses of epinephrine IM in addition to diphenhydramine, ondansetron, and steroids to prevent a rebound reaction. 911 was called and after epinephrine and diphenhydramine were administered, the patient was immediately transported to the hospital where she stayed for 6 more hours for observation, fluids, and further medications. Action taken with mRNA-1273 in response to the events was not applicable. The events, passed out on the ground and severe anaphylaxis allergic reaction, were considered resolved; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Anaphylactic reaction is a listed event in CCDS. |

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| 1056463 | 2/26/2021 | NE | 77 | M | 2/10/2021 | 2/10/2021 | felt like crap; became hot; left hand suddenly started jerking and left hand was having spasms; Vasovagal Syncope, Post Immunization Reaction; became cold; sweaty; sore arm; achy; A spontaneous report was received from a consumer concerning a 77-year-old, male patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced vasovagal syncope, post immunization reaction (syncope vasovagal). The patient's medical history, as provided by the reporter, included chronic cough, acid reflux, minor allergies, hypercholesterolemia and a penicillin allergy. Concomitant product use included esomeprazole, atorvastatin, famotidine, cetirizine, Montelukast, Vitamin D, zinc, fiber pills and antacids. On 10 Feb 2021, several hours prior to the onset of symptoms, the patient received their second of two planned doses of mRNA-1273 (Lot #:030M20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. After the injection in the evening on 10 Feb 2021, the patient reported experiencing a sore arm. During the night, he became cold, sweaty and achy. On 11 Feb 2021, the patient stated he "felt like crud" and was still achy and his left arm hurt more. The patient sat down at the table and again became "hot" and "sweaty." His left hand suddenly started jerking and having spasms, and the patient's head went back and then forward and he became unresponsive for approximately 2 to 3 minutes. After the episode, he went to a sofa chair and fell asleep for 1 to 1.5 hours. The patient's wife called a nurse at the Hospital to report the events, and the nurse suggested to take him to the emergency room (ER) immediately. At the ER, a series of tests/labs were performed including complete blood count (CBC) differential with platelets, COVID-19 test, cardiac panel-acute, comprehensive metabolic panel, electrocardiogram (EKG), and chest x-ray. All test results were normal. The patient's COVID-19 test was negative. Treatment for the event included IV fluids (sodium chloride IV). The patient was discharged from the ER 2 to 3 hours after treatment with a discharge diagnosis of "vasovagal syncope, post immunization reaction." The patient received both scheduled doses of mRNA-1273 prior to the event; therefore, action taken with the drug in response to the event is not applicable. The event, vasovagal syncope, post immunization reaction, was considered |

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| 1057989 | 2/26/2021 | AL | 55 | F | 2/20/2021 | 2/21/2021 | recovered/resolved.; Reporter's Comments: Based on the current available information which indicates a strong temporal association between the use of the product and the onset of the reported events, a causal relationship cannot be excluded. |
| 1056869 | 2/26/2021 | TX | 66 | F | 2/25/2021 | 2/26/2021 | I received injection at approx. 1:30 on 02/20/21. No issues. At around 5-6PM started to feel tired. Went to bed around 9 PM. Woke at around 4 AM to go to bathroom felt fine upon awakening, Once in bathroom felt nauseated, and dizzy. Washing hands felt REALLY nauseated, next thing I know, my husband is hovered over me, as I had passed out unconscious onto bathroom floor. I landed on my left side. No blood. Started immediately with visible chills, and fever accompanied by headache and dizziness. Fever lasted until Wednesday mid morning. Dizzy lightheadedness, and Headache is still on going. Primary care Dr. had X-rays, and MRI to rule out broken bones and/or concussion. Tests confirmed I had not broken anything, and I had not a concussion. Dr. suspects the issues I am experiencing are from vaccine reaction. |
| 1059142 | 2/26/2021 | CA | 67 | F | 2/24/2021 | 2/24/2021 | fainted at 5 am following her second Moderna Covid vaccine taken the day prior. This is the second time this occurred in that she fainted the next day when she took the first Covid shot 30 days ago. Paramedics were called, her vitals were normal and it was recommended that we do not transport her to the hospital. When this occurred the first time, she was taken to her neurologist who diagnose a syncope for the incident. |
| 1058035 | 2/26/2021 | IL | 45 | F | 2/12/2021 | 2/13/2021 | ALOC, passed out 30 minutes after vaccine - syncope. BP 146/77 (pulse 59), O2 sat 98%. |
| | | | | | | | Saturday morning after waking up I felt extreme dizziness, fever, cold sweats, aches throughout shoulders, spine, and hips, and after getting up passed out twice. |

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| 1057563 | 2/26/2021 | NJ | 22 | F | 2/6/2021 | 2/7/2021 | fainted; Nausea; Headache; Slight fever; This is a spontaneous report from a contactable consumer (patient). A 22-year-old female patient receive first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on the left arm on 06Feb2021 17:00 at a single dose for COVID-19 immunization. Medical history included asthma. The patient's concomitant medications were not reported. The patient is not pregnant. On 07Feb2021 09:15, the patient fainted 16 hours after getting the shot. The patient also experienced nausea, headache and slight fever. The events were assessed as serious (medically significant). No treatment was received for the events. The outcome of the events was recovered on an unspecified date. Information about batch/lot number has been requested. |
| 1059086 | 2/26/2021 | CA | 24 | M | 2/26/2021 | 2/26/2021 | On Friday morning 2/26/21, we had a 24 yo male patient who had an anaphylactic reaction after his first dose of Pfizer COVID vaccine. He was instructed to wait on the chair, but had stood up at some point but was still in the pharmacy waiting area. A team member noticed he had fainted and called for help. The pharmacist on duty and immunizing tech came immediately to help him to a chair. At that point, he was conscious and talking. Then within a few seconds he started convulsing on the chair and lost consciousness. His eyes were open and head tilted back. A team member immediately called 911 and pharmacist administered 0.3mg Epipen to the thigh. We removed his face mask to check his breathing and also to allow him to breathe more easily. We also adjusted his head more forward and he started coughing. After about 15 seconds, he regained consciousness and could answer questions. EMT arrived soon after and took over. Patient does not have allergies or any history of anaphylaxis/ severe reaction from vaccinations. He did express some fear of needles and did not eat breakfast yet. |
| 1058977 | 2/26/2021 | WI | 68 | F | 2/19/2021 | 2/19/2021 | Dose 2 received 9:50 a.m. on 2/19/2021. By 4:00 p.m. chills. By 7:00 a.m. 2/20/2021 chills, headache, nausea, vomiting, muscle aches, and dizziness. The dizziness resulted in fainting and falling at approximately 9:00 a.m. Headache similar in intensity to migraine. |

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| 1058943 | 2/26/2021 | NC | 74 | F | 2/23/2021 | 2/24/2021 | Pre-syncope |
| 1058909 | 2/26/2021 | CA | 70 | F | 2/26/2021 | 2/26/2021 | Approximately 4 minutes post vaccine pt fainted in chair during obs. Pt transferred to gurney, RRT called at 0840, they arrived 0846. Denies high BP. Vitals taken (0843)198/95, HR 96 o2 97% T-98.6. Pt comes to and reports hx of fainting with needles and nausea. No medical hx. Currently feels better and refuse to go to ER x3. V/s(0846) 195/95 HR 81 o2 97%. Husband by bedside fans pt. Continues to refuse ED service. (0855) 124/60 HR 81 o2 97% RRT left at 0852. Pt became anxious 0942 BP 173/81 HR 83 o2 97% pt wants to be released home AAO. D/C @ 0945 with husband. |
| 1058900 | 2/26/2021 | NH | 51 | M | 2/20/2021 | 2/20/2021 | 24 hours of flu like symptoms and headache Then fainted and suffered a skull fracture and subdual hematoma and frontal lobe edema |
| 1058879 | 2/26/2021 | AZ | 18 | F | 2/26/2021 | 2/26/2021 | vasovagal fainted, fell. Resolved |
| 1058834 | 2/26/2021 | PA | 66 | F | 2/25/2021 | 2/25/2021 | Patient said she wasn't feeling well about 10 minutes after receiving her vaccine. She felt dizzy, thought she was going to faint. We gave her ice for the back of her neck. We checked her blood pressure, it was 230/130, pulse was within normal limits. Pulse ox was low. An ambulance was called. She removed her mask and stepped back so that she could breath better and her oxygen and coloring improved. She said that her lips felt numb, so we gave her some benadryl just in case. We did not give an epi pen due to her increased blood pressure. Her blood pressure did start improving but was still high when the ambulance came. They took her to the ER for evaluation and she will be following up with her pcp also. The hospital felt that it was just a fainting episode. |

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| 1058145 | 2/26/2021 | TX | 52 | F | 12/24/2020 | 12/25/2020 | fever; fainting spell; fatigue; cough; headache; myalgias; Case reference number MOD-2021-013971 is a spontaneous case report sent by a Physician on 25-JAN-2021 00:00:00 , which refers to a Female aged 52 Years . On 24-Dec-2020 the patient took Moderna COVID-19 vaccination. Some 2 days later, the patient developed fainting. The next day of vaccination the patient also developed cough,headache,myalgia,fever,fatigue. The patient experienced the following serious criteria: Medically Significant. The eventual diagnosis made on was Syncope . The Physician did not declare any relatedness between fainting and Moderna COVID-19 Vaccine. The medical reviewer may provide a case evaluation statement, including other possible etiological and confounding factors, e.g. (only limited information has been obtained so far, it is difficult to assess the cause and effect relationship; the co-medications y and x should also be considered causative as the reported event is labeled for both drugs; the company's view is the event is not due to the drug for the following reasons – (probably due to pre existing disease); there is no plausible mechanism to implicate the drug. . Terse Narrative (for narratives and signal review) Brief 3 line summary of above for Regulatory Authority listing: Report Source- Physician, Age- 52 Years, Sex- Female, Suspect Drug- Moderna COVID-19 Vaccine, Treatment- Diagnosis\Outcome- fatigue - Recovered/Resolved,fainting - Recovered/Resolved,fever - Recovered/Resolved,myalgias - Recovered/Resolved,headache - Recovered/Resolved,cough - Recovered/Resolved.; Reporter's Comments: Patient ID: Investigator Site: Case reference number MOD-2021-013971 is a clinical trial case report which refers to a 52 Years old Female patient. The patient experienced fainting which resulted in medically significant . . The patients started Moderna COVID-19 Vaccine on . Some 2 days later, the patient developed fainting.' Relevant laboratory results included and relevant physical signs were <LIST PHYSICAL SYMPTOMS>. The patient experienced the following serious criteria: -Medically Significant The eventual diagnosis made was Syncope .The event(s) were: fatigue - Recovered/Resolved,fainting - Recovered/Resolved,fever - |

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| | | | | | | | Recovered/Resolved,myalgias - Recovered/Resolved,headache - Recovered/Resolved,cough - Recovered/Resolved. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. |
| 1058802 | 2/26/2021 | CA | 31 | F | 2/23/2021 | 2/23/2021 | Near syncope on escalator - vision started to go black. BP 114/74, pulse 78, 99% O2. |
| 1058262 | 2/26/2021 | GA | 68 | M | 2/26/2021 | 2/26/2021 | Patient passed out at the milk department but the patient says it is not due to the vaccine he just did not eat. |
| 1058526 | 2/26/2021 | MD | 44 | F | 2/26/2021 | 2/26/2021 | Pt given 0.5cc COVID #2 injection (Moderna), was waiting in patient area for 30 minutes due to h/o other reactions previously. 20 minutes after injection, pt remarked that she felt hot. Brought back to resp clinic, wasn't having any SOB or CP, didn't appear very flushed. Was shaking. Pulse ox applied, O2 stayed between 98 & 99% RA. HR was initially in high 80's (pt on 50mg metoprolol QD), climbed up to 109. BP (lg cuff, rt arm) was 144/91. Pt became nauseated, vomited phlegm. Did not feel presyncope. Ice applied to back of neck. No redness at injection site. Heart exam: no murmurs or irregular heartbeat; lungs CTA throughout, no stridor or wheezing. Pt remarked that the heart racing, shakiness & heat felt like previous times when she was given racemic epi for reactions. Was monitored for 30 minutes, HR stabilized in low 80's, sensation of heat dissipated. Was allowed to leave 50 minutes after vaccination given, and advised to call for EMT if symptoms came back. She expressed understanding, and was told to NOT drive herself home (family member was with her). |

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| 1058602 | 2/26/2021 | KS | 35 | F | 2/24/2021 | 2/24/2021 | <p>Progress Notes PRN (Nurse Practitioner) Family Medicine Pt called for follow up s/p covid-19 vaccine done on 02/24/21. She reports doing well just feeling a little tired. She had a few periods of dizziness/lightheadedness yesterday but nothing that lasted long or caused syncope. She feels better today other than the slight tiredness. She is appreciative of the phone call. Denies any other questions or concerns.</p> <p>PRN Progress Notes APRN (Nurse Practitioner) Family Medicine Cosign Needed Expand AllCollapse All COVID VACCINE CLINIC 2/24/2021 Patient</p> <p>DOB: 3/3/1985 Date: 2/24/2021</p> <p>Subjective Pt is a 35 y.o. female who was seen at SVH COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. She was given the Pfizer vaccination in the left deltoid muscle. During her 30 minute waiting period after the injection, the patient began to experience lightheadedness and dizziness. She denied rash, hives, welts, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, facial swelling, lip swelling and tongue swelling. This provider was notified of patient reaction and she was then assessed in the emergency bay area. Monitored patient for severe reaction symptoms, including but not limited to blood pressure abnormality , hypotension, rapid progression of symptoms and respiratory distress. PMH of vagal symptoms. Not on any medications. ALLERGY REVIEW OF SYSTEMS: Patient complains of dizziness Patient denies chills, fever, malaise/fatigue, facial swelling, itching in ears, sore throat, frequent throat clearing, eyes watering, eyes itching, puffy eyes, eye redness, cough, chest tightness, shortness of breath, wheezing, rash, hives, eczema, itching of skin, vomiting, abdominal pain, muscle aches and headaches</p> <p>Previous Reactions: vagal. Allergies to morphine and paxil--breaks out in rash Pt ate this am around 6 am. She usually eats around 11 am. Objective Vitals Vitals: 02/24/21 1058 02/24/21 1114 BP: (!) 134/96 119/74 Pulse: 78 74 SpO2: 100% 100% Physical Exam Constitutional: General: She is not in acute distress. Appearance: Normal appearance. She is well-developed. She is not ill-appearing, toxic-appearing or</p> |

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diaphoretic. HENT: Mouth/Throat: Mouth: Mucous membranes are moist. Pharynx: Oropharynx is clear. Eyes: Conjunctiva/sclera: Conjunctivae normal. Pupils: Pupils are equal, round, and reactive to light. Neck: Thyroid: No thyromegaly. Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Heart sounds: Normal heart sounds. Pulmonary: Effort: Pulmonary effort is normal. No respiratory distress. Breath sounds: Normal breath sounds. No wheezing. Musculoskeletal: Cervical back: Neck supple. Skin: General: Skin is warm and dry. Neurological: General: No focal deficit present. Mental Status: She is alert and oriented to person, place, and time. Psychiatric: Mood and Affect: Mood normal. Behavior: Behavior normal. Thought Content: Thought content normal. Judgment: Judgment normal. Assessment/Plan Treatment included: water and snacks Follow up response to treatment: excellent. Patient discharge: Stable to go home and follow up with PCP. Differential Diagnosis: Vaccine-Related Anxiety (include misc mental health) and Systemic reaction (hypoglycemia, hypotension, generalized rash) RN Electronically Signed 2/24/2021 1:06 PM

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| 1058613 | 2/26/2021 | AZ | 51 | F | 2/24/2021 | 2/25/2021 | I had the usual flu-like symptoms starting around 9 pm the day of the vaccination 24th) - headache, chills, lethargy, loss of appetite, injection site pain. I didn't notice anything else overnight, exception injection site pain increased. The next morning I got up around 6:45 am to feed my pets. I felt woozy walking about 25 m from the bedroom to the pet food location, and also very flushed and hot. I started sweating copiously while I was getting the food out, and then I fainted. I don't know how long I was unconscious but I suspect not more than a minute or two. I didn't seem to injure myself when I fell, other than a bruised elbow and hip I was able to finish feeding the pets, crawl to the bathroom (I had a strong accompanying urge to evacuate my bowels), and then get into bed. I went back to sleep at around 7:15 am and by 10:00 am I felt more normal, still with some chills and headache, general lethargy, and not much appetite. Those symptoms lasted through the evening until I went to bed at 9:00 pm, gradually decreasing. Today I feel mostly fine, although dehydrated. I did not record my temperature during the fever spike, nor receive medical attention. |
| 1058641 | 2/26/2021 | TX | 38 | F | 1/22/2021 | 1/24/2021 | Heart palpitations over 120 resting rate tired and dizzy fainting tired |
| 1058694 | 2/26/2021 | WA | 25 | F | 2/26/2021 | 2/26/2021 | patient had vasovagal reaction and felt light headed. She got on the ground herself and put her feet up, prevented fainting. She recovered within minutes and was given apple juice. This has happened before with other needles and procedures. She fully recovered after about 10 minutes. |
| 1058700 | 2/26/2021 | FL | 69 | F | 2/4/2021 | 2/9/2021 | Felt normal side effects for 24 hours . 3 days later started with weakness, diarrhea , slight fever. 5 days later having bouts of weakness, not able to think clearly an BP was elevated to 160/90. Now for 2&1/2 weeks symptoms continue up till today when almost passed out, BP190/99. Feel terrible. Have apt next week with my Dr. Getting scary. |

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| 1058703 | 2/26/2021 | CT | 96 | F | 1/27/2021 | 1/28/2021 | Excerpt taken from patient's medical record notes. Recreational Therapist was in room with patient who was at baseline mentation at that time, and was getting patient a cup of tea. Rec Therapist observed patient to "all of a sudden slouch down toward left side" and became unresponsive. Therapist called for help, and Registered Nurse (RN) and Certified Nurse Aide (CNA) came into room. Patient was initially non-responsive and profusely sweating and hot to touch. Vitals were taken (see below). The patient then slowly became responsive after approximately 4 minutes and was visibly nauseous and appeared like she was going to vomit, but ultimately did not. Patient was assisted into bed, APRN was called, order for vital signs to be taken every 4 hours for 72 hours, and Electrocardiogram (EKG) to be performed. EKG results were abnormal, indicative of infarct; APRN ordered transport to Emergency Department. Patient returned from Hospital ED at approximately 10:45 PM same day (1/28/21), with transfer paperwork documenting a Hospital diagnosis of "Syncope" without any additional lab results or any new medication or treatment orders in the documentation. Follow up the next day (1/29/21) by RN at the Nursing Facility--RN logged into the Hospital medical Charting system, only to find that there was no record whatsoever of the patient being in the Emergency Department on 1/28/21--no notes, no labs, no summary from a practitioner. Patient recovered and has resumed close-to-baseline activity and functioning. |

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| 1053668 | 2/25/2021 | WA | | F | 1/4/2021 | 1/5/2021 | swelling to head; swelling to left back knee; swelling to left hip; swelling to left foot; hit head; bump on back of the head; fainted; sleepiness; left arm pain; acute body aches; fatigue; flu like symptoms; A spontaneous report was received from a healthcare professional concerning a 65-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced flu like symptoms, acute body aches, sleepiness, fatigue, left arm pain, fainted, on blood thinner and worried about a cerebral bleed because she hit her head, bump on the back of the head, swelling to head, swelling to left back knee, swelling to left foot, and swelling to left hip. The patient's medical history was not provided. Concomitant medications included warfarin (5mg, 7.5mg). On 04 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (Lot number: 041L20A) in the right arm for prophylaxis of COVID-19 infection. On 05 Jan 2021, the patient experienced flu like symptoms which lasted 8 hours. On 02 Feb 2021, the patient received their second of two planned doses of mRNA-1273 (Lot number: 013M20A) in the left arm for prophylaxis of COVID-19 infection. On 02 Feb 2021, the patient reported experiencing acute body aches, sleepiness, fatigue, and left arm pain. On 03 Feb 2021, approximately at 3am, the patient fainted and was out for 10-15 mins. She is on blood thinner and is concerned about a cerebral bleed because she hit her head. On an unspecified date, the patient was experiencing swelling of left back knee, swelling of left foot, swelling of left hip and swelling of head. Treatment included paracetamol and ondansetron. Action taken with mRNA-1273 was not applicable as the subject had already received both scheduled doses. The events flu like symptom was resolved on 05 Feb 2021. The outcome for the events, acute body aches, sleepiness, fatigue, left arm pain, fainted, on blood thinner and worried about a cerebral bleed because she hit her head, bump on the back of the head, swelling to head, swelling to left back knee, swelling to left foot, and swelling to left hip were unknown.; Reporter's Comments: Based on the information provided, a causal association between the reported event of swelling of the head and mRNA-1273 use ids assessed as not related as swelling was due to subject hitting her head. Based on temporal association between the other reported events and mRNA-1273 use, |

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| | | | | | | | a causal relationship cannot be excluded. |
| 1054067 | 2/25/2021 | WI | 21 | F | 2/23/2021 | 2/24/2021 | Patient passed out just after getting to work. She hit her head - cheek & chin - causing abrasion/contusion. This was NOT witnessed; she does NOT recall passing out or hitting her head. A co-worker noticed something wasn't right & had her sit down. They called my wife who picked her up & brought home & rested. Approximately 5.5 hours later, after feeling "better," she got up to get something to eat. While returning to bed (to rest & eat the small container of applesause) she felt as though she were going to pass out again & quickly sat down on the steps. However, she did not call for me (I was in the room nextdoor) for a few minutes... seemingly having "zoned out" but she does not think she lost consciousness. |
| 1054321 | 2/25/2021 | MD | 75 | F | 2/15/2021 | 2/16/2021 | Passed out the morning after the vaccine which resulted in a broken ankle. I have never passed out before |
| 1054268 | 2/25/2021 | MN | 26 | F | 2/18/2021 | 2/18/2021 | Patient presented for second dose of covid vaccine. She was administered Pfizer vaccine. Patient fainted approximately 1 minute after administration of vaccine. Started as syncopal episode then patient started seizing - tonic/clonic. Patient was still seated in chair and seizing lasted about 1 minutes. 911 called. BP 138/78. P 115. Patient moved to cot after she was alert and oriented. By the time paramedics arrived patient was awake and oriented. She refused transport by EMS. She left with fiancé who was driving patient. |
| 1054253 | 2/25/2021 | WI | 70 | F | 2/8/2021 | 2/8/2021 | PT WAS GIVEN VACCINEE. WITHIN 3 TO 5 MINUTES, SHE APPEARED TO BE HAVING A SEIZURE. AID WAS ADMINISTERED. RPH HELD HER UPRIGHT (PT WAS FALLING OUT OF HER SCOOTER). 911 WAS CALLED AND ICE PACK APPLIED TO CHEST TO HELP WITH FIGHT OR FLIGHT FEELING. SHE WAS NAUSEOUS, LIGHT-HEADED, AND FAINTED. PT WAS HELD UNTIL EMT'S ARRIVE, AT WHICH POINT SHE WAS COHERENT. STAFF AT FACILITY BROUGHT THE PATIENT ORANGE JUICE. SHE WAS OK WITH SITTING AND STANDING BP O F96/62. SHE FELT BETTER AND REFUSED TO GO TO THE HOSPITAL. |

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| 1054242 | 2/25/2021 | AZ | 41 | F | 2/9/2021 | 2/16/2021 | Patient reported Shortness of breath and that she almost passed out after walking up the stairs. She reported fluctuation of heart rate for about an hour, heart rate went up to 119 then drastically dropped to 36 then up to 147 then back to 119. |
| 1054194 | 2/25/2021 | CA | 37 | F | 1/20/2021 | 1/21/2021 | Fainted on 1/21/2021 as she was feeling ill and going to her bathroom. Awoke, no issues since this time. |
| 1054116 | 2/25/2021 | AL | 49 | F | 2/17/2021 | 2/18/2021 | My left arm was very sore , red and hurting pretty bad. I went to bed around 10:00pm thinking everything was ok and it was a normal reaction. Woke up around 1:30am arm hurting so I got up to get some more tylenol. I immediately felt sick to my stomach (both ways) and I passed out and broke my nose. I was coherent at times and other times I could not seem to answer any questions. My husband got me to the ER and they took my blood pressure 4 or 5 times and the nurse said "I can't get a blood pressure". Another nurse came in and said we will take this one ! My blood pressure had bottomed out and caused all sorts of things going on. I left ER after 4 1/2 hrs. with a BP of 107/57 but I am not sure how low it got! At one point my husband looked at monitor and my bottom number was 39 but it is all a blur to me. As of today I still feel week (heavy arms) and I am concerned about taking my second dose! |
| 1054509 | 2/25/2021 | NH | 61 | F | 2/1/2021 | 2/2/2021 | Woke during the night (approx 11hrs post-vaccine) with 10/10 joint pain in shoulders and hips, unable to get comfortable; continued with pain, extreme weakness, exhaustion, nausea, and mild headache until approx 5pm the day after vaccine (Day 2). Slept most of the day and through the following night. Fainted x1 first thing in the morning; Vomited x1 after small snack and tea; unable to eat all day. Symptoms resolved by day 3 and able to go to work |
| 1054005 | 2/25/2021 | MA | 27 | M | 2/24/2021 | 2/24/2021 | Vaso-vagal syncope after shot. Continued to feel unwell after 10 min monitoring time. Transported to hospital for further evaluation. Discharged after approximate 2 hours observation. |

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| 1053976 | 2/25/2021 | IL | 21 | F | 2/4/2021 | 2/4/2021 | Moderna COVID-19 Vaccine EUA. Approximately 3 minutes after her vaccine pt became unconscious and unresponsive for a short time. Pt was quickly awoken by RN. Pt states that she has a history of syncope following venipuncture that she forgot to disclose. Approximately 15 post episode pt stated that her vision had been restored but her hearing still felt "off". Pt was given 12 oz water, crackers and juice. Pt called roommate to pick her up to bring her home. Approximately 25 minutes later, pt reports some left arm pain but was feeling better. At 1345 pt was discharged by her own choice and left with her roommate. Pt still felt "off" but reported that this was likely just due to anxiety. Pt and roommate given instructions to go to nearest ER if symptoms returned. |
| 1053847 | 2/25/2021 | NY | 29 | M | 2/25/2021 | 2/25/2021 | Patient verbalized he was dizzy and fainted for about 5 seconds while sitting on chair. Physician and NPs on site attended to him. He is assessed, vital signs monitored. EMS was called. Patient stabilized. He was talking and alert and oriented to person, place, and time. EMS arrived and patient was transported to local hospital. Patient's wife was present and was made aware of where her husband would be transported. |

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| 1053571 | 2/25/2021 | FL | 28 | F | 1/28/2021 | 1/28/2021 | <p>Jaw pain; Syncopal episode/Syncope; Fell; Dizziness; Nausea; Felt flu-like; Injection site pain; Fatigue; Headache; Muscle pain; Chills; Fever; Felt unwell; A spontaneous report was received from a nurse concerning a female 28 year old, patient who experienced same day injection site pain, fatigue, headache, muscle pain, chills, fever, felt unwell and flu-like. On 29/Jan/2021, she developed dizziness, nausea, a syncopal episode and fell and hit her jaw, which developed into pain. . The patient's medical history was not provided. Concomitant product use was unknown by the reporter. The patient received their second dose of mRNA-1273 lot 028L20A on 28-JAN-2021. On 28-JAN-2021 approximately 1 day prior to the onset of the symptoms, the patient received their second of two planned doses of mRNA-1273 Lot number 028L20A intramuscularly for prophylaxis of COVID-19 infection. A patient received her second dose of Moderna vaccine on 28/Jan/2021 at 8 AM, lot 028L20A. Same day at 17:00, she experienced injection site pain, fatigue, headache, muscle pain, chills, fever, felt unwell and flu-like. On 29/Jan/2021, she developed dizziness, nausea, a syncopal episode and fell and hit her jaw, which developed pain. She was seen in the emergency room (ER) and released with a diagnosis of syncope and jaw pain. Resolution dates not reported. Treatment information was not provided/unknown. The patient received both scheduled doses of mRNA-1273 prior to the event(s); therefore, action taken with the drug in response to the event(s) is not applicable.; Reporter's Comments: This report concerns a 28--year-old female who received Moderna's COVID-19 Vaccine (mRNA-1273), Lot # not provided, and within 2 days, experienced injection site pain, fatigue, headache, muscle pain, chills, fever, felt unwell and flu-like, dizziness, nausea, a syncopal episode and fell and hit her jaw, which developed into pain. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: MOD21-024340:Crosslinked: Same Reporter MOD21-024360:Crosslinked: Same Reporter MOD21-024368:Crosslinked: Same Reporter MOD21-024387:Crosslinked: Same Reporter MOD21-024396:Crosslinked: Same Reporter MOD21-</p> |

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| | | | | | | | 024411:Crosslinked: Same Reporter |
| 1053765 | 2/25/2021 | PA | 49 | F | 2/24/2021 | 2/24/2021 | Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Mild, Systemic: Hypertension-Medium |
| 1053667 | 2/25/2021 | MS | 77 | F | 2/9/2021 | 2/10/2021 | Passed out; A spontaneous report was received from a consumer concerning a 77-year old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and patient passed out. The patient's medical history was not provided. Concomitant product use was not provided by the reporter. The patient received their first of two planned doses of mRNA-1273. Batch number not provided on an unknown date. On 09 Feb 2021, prior to the onset of the symptoms, the patient received their second of two planned doses of mRNA-1273: LOT 041L20A. intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 10 Feb 2021, She got up this morning and passed out while standing at the kitchen island for 2-3 minutes. She wants to know if she should be checked out. Treatment information was unknown. Action taken with mRNA-1273 in response to the events was not applicable. The outcome of the event was unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. |

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| 1053662 | 2/25/2021 | TX | 74 | F | 1/18/2021 | 1/18/2021 | <p>Passed out because her sugar went down 1.30 and blood pressure went down; Shaking; Started having twinkle tongue, tongue started getting heavy; A spontaneous report was received from a consumer, a 74-year-old female patient, who was administered Moderna's COVID-19 vaccine (mRNA-1273) and experienced started having twinkle tongue, tongue started getting heavy/ paresthesia oral, passed out because her sugar went down 1.30 and blood pressure went down/ loss of consciousness and shaking/tremor. The patient's medical history included was asthma from an unknown date. Products known to have been used by the patient, within two weeks prior to the event, included "advitrol inhaler" as an indication for asthma from an unknown date, levocetirizine dihydrochloride, "blood pressure pills" and "asthma medication" from an unknown date. On 18 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (Lot number: 041L20A) and expiration date 03 Jul 2021 intramuscularly in her left arm for prophylaxis of COVID-19 infection. On 18 Jan 2021, approximately fifteen minutes after the vaccine, the patient started having twinkle tongue, tongue started getting heavy when she was on her way home. The patient had asthma so she took her medication and was okay. One week later on an unknown date, the patient passed out because her sugar went down 1.30 and blood pressure went down and was shaking which lasted for ten seconds. The patient mentioned something like that never happened before. The patient also mentioned she was having asthma issues so was waiting to see her allergies Doctor and was tested for covid-19 on an unknown date but had no result yet. Treatment information was not provided. The Action taken with the second dose of mRNA-1273 in response to the event was not reported. The outcome of the event, started having twinkle tongue, tongue started getting heavy was considered as recovered on 18 Jan 2021. The outcome of events, passed out because her sugar went down 1.30 and blood pressure went down and shaking were unknown.; Reporter's Comments: Very limited information regarding this event has been provided at this time. The patient reports that she passed out because her sugar went down and blood pressure went down. Further information has been requested.</p> |

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| 1054513 | 2/25/2021 | FL | 21 | F | 1/6/2021 | 1/6/2021 | States about 3 hours after administration she felt nauseous, dizzy, cold, clammy, blurry vision, ringing ears, near syncope, visited ED. |
| 1054624 | 2/25/2021 | NM | 24 | M | | 2/17/2021 | fainted, low heart rate |
| 1053779 | 2/25/2021 | NC | | F | 2/4/2021 | 2/4/2021 | Fatigue; Fever; Headache; Passed out; Tachycardia; Shaking; High blood pressure; Breathing issue; A spontaneous report was received from a female patient, unknown age, who received Moderna's COVID-19 Vaccine (mRNA-1273) and passed out, tachycardia, shaking, experienced high blood pressure, breathing issues, fatigue, fever, and headache. The patient's medical history was not provided. No relevant concomitant medications were reported. On 04 Feb 2021, the patient received their first of two planned doses of mRNA-1273 (Batch number not provided) for prophylaxis of COVID-19 infection. The patient reported that a few minutes after receiving the Moderna vaccine shot, she passed out, was shaking, had high blood pressure, and breathing issue. Emergency services (911) was called and the patient was transported to the hospital. The patient recovered after an hour, but since has been feeling fatigue, fever, and headache time to time. No treatment information was provided. Action taken with second dose of mRNA-1273 in response to the event was not reported. The events passed out, tachycardia, shaking, high blood pressure, and breathing issues were considered recovered/resolved on 04 Feb 2021. The outcome of the events fatigue, fever, and headache were not reported.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the onset date of the events, a causal relationship cannot be excluded. |
| 1055758 | 2/25/2021 | NY | 51 | F | 2/2/2021 | 2/3/2021 | syncope, patient was monitored and given IV fluids, low blood pressure |

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| 1054564 | 2/25/2021 | CA | 34 | M | 2/18/2021 | 2/19/2021 | Blacked out: I was attempting to put on a sweater to go to the bathroom. I had my arms up and felt a lot of pain in my arm, and blacked out and fainted. I don't recall the events for the next 60 seconds. My wife said that I fell on the bed, was unresponsive, saw foaming at the mouth, had seizure, and urinated in my pants. She adjusted the bed so that my head is up, and threw cold water at my face, mouth and teeth, which made me responsive, and then walked me to the bathroom. During the night, I had fever, Chill, pain at injection site, vomit, nausea, headache, light-headed. I didn't have appetite in the morning and had nausea and headache. I felt better ~3pm when I could finally eat rice, yogurt and chicken. I am feeling well now, but worry that the seizure had caused any long term damage. |
| 1055811 | 2/25/2021 | CA | 67 | F | 2/22/2021 | 2/23/2021 | I received this vaccine at a walk-in-clinic, called STAT Med. About 12 hours after receiving the vaccine I felt nauseated but finally managed to sleep. The next afternoon on February 23 I became very ill with vomiting and diarrhea all at the same time. I nearly passed out several times. First responders arrived and found my blood pressure to be about 70/30. Got in ambulance and given fluids. Arrived at hospital around 5:15 pm. Got more fluids and numerous blood tests, none of which were very remarkable. My WBC was 17 but nothing else was wrong. Left hospital at 9:00. Physician assumes Covid vaccine cause these side effects. |
| 1054557 | 2/25/2021 | HI | 38 | M | 2/23/2021 | 2/23/2021 | Flu like symptoms followed by two episodes of fainting and convulsions requiring ambulance 15 hours after vaccine. |
| 1055322 | 2/25/2021 | TX | 60 | F | 1/20/2021 | 1/21/2021 | Got out of bed day after - 30 min later got super nauseated - passed out face down on ceramic tile in bathroom- broke nose - bruised both knees - busted forehead open- chills started about 1 hour later and lasted for several hours- temp of 100.4- |

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| 1055302 | 2/25/2021 | FL | 43 | M | 2/25/2021 | 2/25/2021 | Pt reported before shot that has had history in past of fainting after vaccinations. After receiving the shot, had him sit in a chair next to the table for a few minutes to see if would occur again. After about 2 minutes, pt began reporting that he felt that he was about to faint again. He began to dry heave and passed out momentarily for 2 seconds before coming back to. Pharmacist caught him before he fell. Gave pt water and took blood pressure. Patient began to feel better. Sat for 30 minutes and then he felt fine to leave. |
| 1055160 | 2/25/2021 | AR | 79 | F | 2/25/2021 | 2/25/2021 | Pt felt "off" some minutes after receiving vaccine. reported to staff and fainted upon standing. eased her to floor and elevated legs. regained consciousness immediately. called 911. heart rate low blood pressure normal. clammy before faint quickly regained color. EMS took over and transported pt to hospital |
| 1055138 | 2/25/2021 | FL | 52 | F | 2/24/2021 | 2/25/2021 | Following morning after vaccine: Adverse events started at 6:00 AM -Fainting? 3 times. Hit my head on the tile. Fainting occurred until 12 Noon. -Excessive Sweating-6-noon. Clothing was drenched -Diarrhea-Morning -7:00 AM -Vomiting-7:00 AM -Headache-All Day -Pain at injection site-All Day |
| 1055133 | 2/25/2021 | OH | 67 | F | 2/25/2021 | 2/25/2021 | S/P Covid Vaccine 1st dose, pt alert/oriented, calm, answering Covid questions appropriately. Prior to vaccine. pt reports she doesn't really like vaccines. Vaccine administered at approx 2:34 pm. Pt reports she doesn't feel well, reports she did not eat or drink today. This nurse gave her water to drink. Pt unable to drink, briefly passed out in chair approx 2:36pm. Myself and RN lowered pt from chair to floor. Site Director called EMS. RN assisted by raising pt's legs above heart level. RN checked b/p 70 palp, pts airway maintained, rechecked b/p 80 palp. As pt returned to consciousness reports she is about to vomit, assisted pt to (R) side >vomited small amount clear liquid x2 into bag provided, pt reports she feels better. EMS arrived, transported pt to ED via stretcher @ 2/40 pm, pt's coat, eye glasses, and purse placed on stretcher with pt. Pharmacist contacted pt's husband at 2:40 pm. Site Director notified. |

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| 1054571 | 2/25/2021 | NY | 63 | F | 2/24/2021 | 2/25/2021 | Dizziness, Fainting, Loss of Consciousness, Low blood pressure -- duration several minutes followed by fatigue resting in bed. |
| 1055086 | 2/25/2021 | | 85 | F | 2/23/2021 | 2/23/2021 | ~~Patient with a PMH of HTN, Afib RVR (on Eliquis), nonischemic CMO, HFrEF (EF 25%), HLD, HLD, Fe deficiency anemia, Pulmonary HTN, rectus sheath hematoma presented to ED with LUE edema and pain that started a couple of hours after second dose of COVID vaccine administration. Patient had received COVID vaccine shortly after noon day prior to admit on RUE. She reports that she had been experiencing some nausea as well. She was admitted to the hospital for overnight observation secondary to transient alteration of awareness after she presented to the ED for arm swelling where experienced a syncopal episode lasting approximately 1 minute. She was monitored on cardiac tele which showed Afib with appropriate rate control overnight. For her left upper extremity swelling an U/S was done which was negative for thrombus, only a hematoma. Her arm pain was controlled and supportive with a compress. Patient had no further syncope, Afib rate controlled, and hemodynamically stable. Discharged home 2/24/21. |
| 1055062 | 2/25/2021 | CA | 27 | F | 2/24/2021 | 2/24/2021 | 10 minutes post 2nd vaccination patient passed out and had shortness of breath. Patient was administered Epi via EpiPen and transported to the hospital. |
| 1055021 | 2/25/2021 | IL | 77 | F | 2/24/2021 | 2/25/2021 | Fever, syncope. Pt has small rash to administration site. |
| 1054894 | 2/25/2021 | PA | 74 | F | 2/23/2021 | 2/23/2021 | About 6 hours after getting vaccine, I experienced extreme fatigue and passed out briefly on the bathroom floor. When I came to, I had no recollection of passing out. It was only for a minute or two. I felt better and not as tired. I felt okay the next couple of days. |
| 1054865 | 2/25/2021 | MD | 60 | M | 2/25/2021 | 2/25/2021 | RPh administered the vaccine, and the patient passed out 10 minutes afterwards and hit his head. Patient felt very faint even after sat up with feet up. Patient was given orange juice and he drank it all. Paramedics arrived and checked him out. 45 minutes after him passing out, patient felt fine and went back to work. He had gashed his head open on the fall. |

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| 1054648 | 2/25/2021 | CA | 81 | M | 2/22/2021 | 2/23/2021 | Severe hives accompanied by shivering, significant itching, three fainting episodes close together about 8 hours after the onset of the hives and very low blood pressure following the fainting episode. At home treatment taken on phone advise from Doctorr with Benadryl and Fomantadine with no effect. Prednisone now prescribed. Doctor had suggested a visit to ER but this was taken as the patient was more stable at this time. Potential life threatening event due to the fainting and low blood pressure/heart rate. These symptoms have ocured on previous occassions as a result of virus and other infections. |
| 1336338 | 2/25/2021 | OH | 54 | M | 2/22/2021 | 2/23/2021 | Generalized not feeling well the day after vaccine administered then progressed to dizziness, nausea. Approx 20 hours after receiving his second dose of Moderna from Health Department he had a syncope episode with LOC of a few seconds. He sustained head injury that was treated and sutured. No further side effects after day 2 of vaccine. |
| 1055128 | 2/25/2021 | | 81 | M | 2/19/2021 | 2/20/2021 | Patient presented to ED due to AMS, syncope. Wife reported that he became confused with generalized weakness and dropped his food on the floor and became unresponsive with his eyes and mouth open. Patient was febrile to 103 on admission w/o leukocytosis. He was admitted to hospital medicine for acute encephalopathy with associated loss of consciousness. Neurosurgery consulted but no neurosurgical intervention needed. Patient improved & discharged home 2/24/21. |
| 1052124 | 2/24/2021 | OH | 22 | M | 2/23/2021 | 2/23/2021 | Conducting Covid Vaccine Clinic. Patient had already received his vaccination. At 2:74PM Staff yelled to nursing staff for help. Patient was passed out, hyper extended in chair. He jerked once and staff got him on the floor. He took 15 seconds to speak at which time he refused Epinephrine. Staff got him up into chair once he was alert and oriented. He was able to speak clearly, stating he felt tingling in his right arm and then throughout the rest of his body before passing out. Blood pressure was 118/82. At 3:05PM, he was up, walking around, alert and oriented x3. Staff drove him home and instructed him to contact his physician. Follow up today, 2/24/21 patient states injection site is sore but he is ok and has an appointment to speak with his physician. |

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| 1052263 | 2/24/2021 | MA | 26 | F | 2/23/2021 | 2/23/2021 | I was given Moderna vaccine first dose in right arm. Sat down in observing area, within a few minutes I had a weird feeling, felt queezy. As soon as I felt queezy I passed out. I woke up they said within about 30 seconds and had full body sweats. Stomach ache, dizzy and head was tingly like I would pass out again. My calfs hurt like they had previously had muscle cramps. I went to ER, blood and urine tests were fine, heart and blood pressure was fine. Dr said he did not believe it was an allergic reaction, and that it was a stress response. I am not sure if it is because I had COVID in December. |
| 1052480 | 2/24/2021 | NM | 37 | F | 2/23/2021 | 2/23/2021 | Light headed immediately following vaccine (may not be related to vaccine, because I have long standing pre-syncope). Felt sluggish and tired the rest of the day. Overnight, I got a severe headache and throbbing in my arm where I received vaccine that kept me awake. Went to bed cold and then woke up several times very hot and sweaty, but don't know if this was related to vaccine, since this happens on occasion without the vaccine. |
| 1052098 | 2/24/2021 | PA | 70 | M | 2/19/2021 | 2/20/2021 | Syncope, rash itching |
| 1052514 | 2/24/2021 | OH | 43 | F | 2/24/2021 | 2/24/2021 | Became lightheaded/faint and had facial flushing. Unable to stand up for fear of syncope. |
| 1051681 | 2/24/2021 | | 67 | F | 2/23/2021 | 2/24/2021 | woke up this morning and fainted |

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| 1051341 | 2/24/2021 | NC | 69 | F | 1/24/2021 | 1/24/2021 | <p>The itching was located just below the injection site at a spot where the skin was a little red; The itching was located just below the injection site at a spot where the skin was a little red; terrible itching in her left arm; out of balance, her balance was messed up; nervous; Sweaty; Feeling hot; felt like her heart was racing fast; felt dizzy/terrible lightheadedness; Feeling anxious; trouble sleeping; sharp pain in her muscle; This is a spontaneous report from a Pfizer-sponsored program. A contactable other health care professional reported that a 69-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; lot EL9263) via an unspecified route of administration at arm left on 24Jan2021 13:00 at single dose for covid-19 immunisation. Medical history included drug allergies, IV contrast reaction. The concomitant medication was not reported. It was reported patient got the Pfizer COVID 19 vaccine Sunday 24Jan2021 at 13: 00PM in the left arm. She was scheduled for the second dose of the vaccine 16Feb2021. she got the vaccine and was perfectly fine; she started the wait time of 45 minutes and about 10 minutes into it she got really hot and felt like her heart was racing fast; felt dizzy on 24Jan2021. A nurse practitioner and a doctor came over and sat with her; she got some water and she was okay. They thought it was anxiety related to coming into a crowd, but for the next 36 hours she continued to feel anxious and on edge; she felt like she had too much caffeine. That night she had trouble sleeping; she had sharp pain in her muscles on 24Jan2021, it would be in one of her thighs then the other one. This was about 12 hours after the vaccine. States she took some tylenol and it did help. Adds she just continued to feel anxious and she was sweaty. States she has never has anything like this before. Today she felt perfectly fine; all of her symptoms had resolved. Then today, when she was driving to a routine GYN exam and she experienced a terrible itching on her left arm on 24Jan2021. It was sudden and startled her. The itching was located just below the injection site at a spot where the skin was a little red, feathery red, just below the injection site. Now the itching has stopped but it is still red. she couldn't hardly feel it being injected, she doesn't usually have reactions to vaccines, she never had anything, but she has a few drug allergies, and she was separated out, she was flagged to wait 45 minutes</p> |

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after, instead of the 15. She does have an IV contrast reaction, and some other things, nothing she knew was in the vaccine, she was fine and wasn't worried that she was aware of. She thinks she got too hot, she had on a coat, she was sitting and panning through stuff, reading on her phone, and all of a sudden she had terrible lightheadedness, she never fainted in her life, she is pretty sturdy, she didn't know what to think, she was lightheaded, and it was not vertigo, not like the room was flying, but she was like out of balance, her balance was messed up, and she sat there a minute, she was too hot, she got out of her coat, and it got worse, she could feel her heart racing, and she was talking to herself, she thinks she nervous, she could feel her heart pounding, and was instructed to raise her hand if she had issues, so she raised her hand, a nurse practitioner came over, she raised her hand, and the doctor making rounds came over and he said take off your mask off, she did, that helped somewhat, it was that blasted mask, she couldn't get enough air, he gave her water, she thinks she got too hot and perhaps got nervous and didn't think she was she said she's not been around people, and was suddenly in a huge crowd, everyone was appropriately distanced, it was an extreme presentation, after 5-6 minutes, she was good, it went away, but for 36 hours she didn't feel right, she could feel sometimes her balance wasn't right, she was just not herself, she could do her usual, she lives on a farm, she did usual farm stuff, but was not herself, and in the night, she woke several times, her heart was beating too fast, too much, but she went back to sleep, and she told her son, she said it felt like she had had 4-5 cups of really strong coffee. So the next day she was ok. Absolutely her normal, and then she didn't think anything about it, and was driving to a routine GYN exam, which was canceled last moment due to an emergency, she was driving and suddenly her arm started itching, this was Tuesday, so 48 hours after, not the site, it was distal, underneath it, maybe 2-3 inches under injection site. The site did nothing, she looked that night, no redness, lump, no raised area, no warmth, nothing, but then she had itching, intense itching like poison ivy, and she scratched and thought wait a minute, at her appointment she looked at her arm, this area was 3-4inches under the site, that was red, feathery looking and flat, macular, not

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| 1051921 | 2/24/2021 | AZ | 61 | F | 2/18/2021 | 2/18/2021 | <p>raised, no induration, no warmth, no lump, no pain, it was feathery dusty red and the next day it was gone, she did nothing to it, she thought to put hydrocortisone, and looked at it, but it was so faint and wasn't itching. The seriousness was reported as non-serious. The outcome of the events was Feeling hot was recovered on 24Jan2021; Heart rate increased; felt dizzy; Muscle pain; Sweaty was recovered on 25Jan2021; Feeling anxious was recovered on 26Jan2021; Vaccination site rash; Vaccination site erythema recovered in 2021. Vaccination site pruritus was recovering; Difficulty sleeping; Loss of balance, Nervous was unknown.</p> |
| 1051871 | 2/24/2021 | | 63 | F | 2/4/2021 | 2/4/2021 | <p>Covid 19 Vaccine screening questionnaire reviewed , administered Covid vaccine; patient developed coughing spells, non productive after 2-3 minutes after the vaccine administration, she states she felt like fainting. Lung sound checked - no wheezing. Pulse Oximetry checked 96%. Observed for 30 mins in the field. Intermittent coughing still noted. Pulse oximetry remained 96%, no shortness of breath or difficulty breathing. After 30 mins, patient continue to cough , states she feels tickles in her throat that makes her cough and she has a headache. Patient given Benadryl 25 mg p.o. and monitored for 30 mins. Patient felt better after 25 mins of observation and minimal coughing , pulse oximetry @ 96-98% denies SOB or difficulty breathing . Patient sent home with husband and advised to rest at home and call 911 if she develops SOB or difficulty breathing. Followed up call over the phone at 5: 00 PM , patient states she fell asleep when she went home and no cough , no SOB or difficulty breathing.</p> <p>I want to report an unusual reaction that I had to the 2nd Covid vaccination. I rec'd my 2nd vaccination on 02/04/2021 @ approx. 5:15, within a few hours I started to have normal and expected reaction. Approximately 9am the next morning I passed out without any type of warning (dizziness etc) I passed out another 2 times during Friday morning. I stayed in bed the remainder of Friday, felt sluggish on Saturday and back to normal on Sunday.</p> |

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| 1051720 | 2/24/2021 | FL | 61 | M | 1/4/2021 | 1/6/2021 | 1/04/2021, 1/25/2021 Pfizer ej1685, en5318 Reports that he "passed out" on 1/6 at work, taken to ER and was diagnosed with kidney failure & hyperkalemia, also positive for covid. Hospitalized till 1/13, underwent dialysis. Received 2nd vaccination 1/25, once again "passed out" in breakroom while at work. Pt was awoken after approx 1 hour, unable to move arm at that time, went home and did not seek medical care at that time. Pt was re-hospitalized on 2/2/2021 due to difficulty breathing & AMS. Dx with pneumonia & hyperkalemia at that time, discharged home 2/11/2021. Continues on hemodialysis 3x/week. |
| 1051717 | 2/24/2021 | NJ | 28 | F | 2/20/2021 | 2/21/2021 | Dizziness episode with almost fainting that lasted about 10 minutes. Happened day after vaccine and then again 3 days after vaccine. nausea was present but not enough to vomit. Slight vertigo still present days after |
| 1051603 | 2/24/2021 | AZ | 94 | F | 2/22/2021 | 2/22/2021 | Systemic: Dizziness / Lightheadness-Mild, Systemic: Exhaustion / Lethargy-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: pt was not responding well, urinated on self and felt nauseas. Pt is on hospice and felt dizzy even before the vaccine.-Mild, Systemic: Nausea-Mild, Additional Details: Pt was dizzy and fell 02/21/21 at the site; paramedics called; refused to be hospitalized. Pt vaccinated 02/22/21, was dizzy and urinated on self, paramedics called, refused to be hospitalized. Staff told vaccinators then that pt was hospice and own guardian, so nothing could be done. |

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| 1051446 | 2/24/2021 | MA | 79 | F | 2/8/2021 | 2/8/2021 | grade 2 allergic reaction; short of breathe; flushed; she was an oncology patient with large granular lymphocytic leukemia and received BNT162B2; she was an oncology patient with large granular lymphocytic leukemia and received BNT162B2; This is a spontaneous report from a contactable other healthcare professional. A 79-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EL9262, NDC number of COVID Vaccine: 59267-1000-1; Expiry Date of COVID Vaccine: 31May2021), intramuscularly at Left Deltoid on 08Feb2021 10:30 (either 10:30AM or within that hour or prior) at single dose for COVID-19 immunization. Medical history included anxiety, panic disorder, asthma, obstructive sleep apnea, additional Information for Other Conditions: She was oxygen Dependent, coeliac disease, allergy, Additional Information for Other Conditions: She had Medication, Environmental, and Food Allergies, central neuro hearing loss, vertigo, Allergic rhinitis, gastroesophageal reflux disease (GERD), Additional Information for Other Conditions: Esophageal Reflux, osteopenia, impaired glucose tolerance, hypothyroidism, claustrophobia, rheumatoid arthritis (she had arthritis for which she took Orencia for), history of coronary heart disease, diabetes, she would be a targeting patient, as she was an oncology patient with large granular lymphocytic leukemia she met criteria for the pandemic, as well as they put down that she was due for immunization. She had anaphylaxis to bees. With adhesive tapes she got dermatitis. With shellfish she got hives. She had a gluten sensitivity and with mango her mouth gets fuzzy. Family Medical History Relevant to AE(s): her sisters had a few cancer. There were no concomitant medications. The patient previously received levofloxacin she had hives, with quinolones drug class she had hives, with thiopental she had hives and needed IV Decadron for it, with sertraline she has syncope, with Revatio she had an adverse event of joint and muscle pain, with ciprofloxacin she had tachycardia, with Enbrel it caused a drug induced pulmonary fibrosis granulomatosis, with Montelukast she had a headache and muscle pain, nitrofurantoin she had headache, with Symbicort it gave her hoarseness, she took Orencia for arthritis, she got the flu Vaccine in Sep2020. That was most recent. The patient had a grade 2 allergic reaction |

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1052516 2/24/2021 SC

68 M

2/20/2021

2/20/2021

on 08Feb2021. The patient was watched after administering the vaccine on 08Feb2021 as she had background of multiple allergies and asthma. She was watched for 30 minutes in the oncology unit infusion suite. The reaction happened within 5 minutes of administration. Seriousness Criteria: Caller explained that this reaction was mild to moderate, there was a grade to intervene but at no point was she unstable, she did have a significant anxiety disorder, and so she was nervous about getting the vaccine. She was short of breathe, odd and flushed. She was physically stable, her vitals were stable and there was no angioedema. Reporter seriousness for grade 2 allergic reaction: Medically significant. The patient recovered, as a treatment they gave her IV Benadryl 50mg and IV fluids, she also had her own albuterol inhaler. In the pandemic, they are not doing nebulizers. The outcome of events allergic reaction, shortness of breath and flushed was recovered on 08Feb2021. Relatedness of drug to reaction(s)/event(s). Reaction assessed: Grade 2 allergic reaction; Source of assessment: Primary Source Reporter. Method of assessment: Global Introspection. Drug result: Related. Causality: reporter stated that she did think the patient's base line anxiety played into the reaction she experienced, the reaction was aggravated by it.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of grade 2 allergic reaction, short of breathe and flushed due to temporal relationship and current known drug safety profile. The patient's underlying allergic physique also predisposed the patient to developing the event. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

In under two minutes fainted. Believed to be Vasovagal syncope although patient has never fainted in the past and even with getting other vaccines.

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| 1051718 | 2/24/2021 | MI | 80 | F | 2/11/2021 | 2/18/2021 | Vaccine administered on 2/11/21. Presented to emergency department on 2/18/21 following an episode of syncope and collapse at home. Patient reports becoming dizzy and diaphoretic at home and passed out in bathroom. Presented with left-side rib pain and headache attributed to hitting door and ground during fall. Was checked for COVID19 prior to transferring to observation unit and was found to be positive. Patient was discharged home in stable condition from observation on 2/19/21. |
| 1053311 | 2/24/2021 | LA | 69 | M | 2/18/2021 | 2/20/2021 | The patient was admitted for recurrent syncope that began on Friday evening 2/19. He fell twice and struck his head, knocking 2 teeth loose. He continued to feel lightheaded the next day and came to the ED and was admitted for syncope workup. His workup was negative. On discharge, patient recalled that he received his 1st Covid vaccine. His symptoms resolved after admission. This event was likely related to his vaccination. |
| 1052607 | 2/24/2021 | NY | 38 | M | 2/23/2021 | 2/23/2021 | Patient reports approx. 5-10 min after receiving first dose of COVID vaccine, he became hypotensive (98/60), dizzy, diaphoretic and near syncope. States he was monitored by EMT for a short time after this happened, did not need to use his EpiPen, but did take Benadryl. Reports that after 5-10 min his symptoms improved/resolved, and he has felt fine since. States he is feeling great today. He was advised by PCP NOT to get the second dose of the vaccine, and if he would like a second opinion, will need to be referred to an allergist. Patient declined referral, leaning towards not getting the second dose. |
| 1052492 | 2/24/2021 | MD | 73 | F | 2/24/2021 | 2/24/2021 | Syncope, BP 88/67, P 59, R 20, Was assisted to chair, given apple juice, crackers, water VS after 15 minutes: BP 124/74, P 111, R 18, VS after 30 minutes 121/93, P 101, R 18 |
| 1279586 | 2/24/2021 | | 73 | M | 2/6/2021 | 2/6/2021 | Narrative: symptoms were present prior to vaccination, but syncope occurred after vaccination. Low likelihood that vaccine was causative in our estimation. |

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| 1053201 | 2/24/2021 | MD | 55 | F | 2/19/2021 | 2/20/2021 | Two episodes of syncope close together, 2nd episode resulted in fall with head hitting a wall, diarrhea/loose stools after 2nd episode. Treated at ER with fluids, CT scan of head, chest x-ray, ECG all normal |
| 1053174 | 2/24/2021 | CA | 34 | F | 2/23/2021 | 2/24/2021 | I received a vaccine at 4 PM on 2/23/21. In the middle of the night I started having the chills. I woke up around 6 AM the following day and felt extremely fatigued. Around 6:30 AM I became nauseous and very lightheaded. I had to brace myself against a counter so I would not fall down and faint. I rested all day then around 1 PM I got up and fainted. I woke up a moment later and had an intense ringing in my ears for several minutes. I felt fatigued the rest of the day. |
| 1053149 | 2/24/2021 | NC | 31 | F | 2/23/2021 | 2/24/2021 | Dizziness, nausea, blurred vision, blacking out, fainting |
| 1052880 | 2/24/2021 | PA | 84 | F | 2/17/2021 | 2/24/2021 | 11PM CHILLS, TEETH CHATTERING, BODY SHAKING, NAUSEA. APPROX 2-3 AM 2/18/21 ON WAY TO THE BATHROOM LOSS OF CONSCIOUSNESS-FELL HIT HEAD, PASSED OUT 2 X MORE. PARAMEDICS CALLED ADMITTED TO HOSPITAL EEG, CAT SCAN, NO FEVER, CHILLS 4-5AM SWEATING PROFUSLY, LOW BP, POSTURAL HYPOTENSION, DISCHARGE FRIDAY 2/19/2021 . SATURDAY 2/20/2021 HIGH BP > 170. BP CURRENTLY UNSTABLE HIGH AND LOW |
| 1053119 | 2/24/2021 | TX | 67 | F | 2/24/2021 | 2/24/2021 | Short of Breath, Dizzy, Pale, Low BP and Heart Rate, Syncope, Nausea. |

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| 1053072 | 2/24/2021 | TN | 33 | F | 2/24/2021 | 2/24/2021 | At about 1458 patient received first dose of Moderna COVID-19 vaccine Lot number 031L20A expire 07/22/2021 in Left Deltoid by RN at vaccine site. Pt was instructed to wait 15 minutes in personal vehicle in designated parking area for monitoring. At 1508 patient whom was sitting the passenger seat of personal vehicle c/o SOB, and chest tightness to LPN who was monitoring the parking lot. Nursing Supervisor was dispatched over to the patients vehicle. On assessment patient stated she had a "loss of senses, SOB, chest tightness and cold chills". Pt confirmed she has no allergies and never had any reactions to medications or vaccinations. When asked pt to elaborate on s/s pt explained tunnel vision and sweating and "throat itchiness". Pt was breathing slightly labored 12 respirations a minute pulse rapid and bounding pt pale and diaphoretic and cool to touch. 1510 called made to 911. 1510 bp 60/30 Diphenhydramine and Epinephrine drew up into syringe for precaution. While RN rechecked bp to confirm. Recheck was confirmed 60/30. At 1513 pt states "I think I am feeling better, my senses are starting to come back and breathing feels better" Pt reports she passed out once giving blood. EMS arrived at 1515. At 1515 recheck b/p was 80/40. It was determined that pt did not require Diphenhydramine and Epinephrine due to pt quickly feeling better and s/s improving pt was determined to have a vasovagal response. At 1520 b/p 106/62 normal respirations at 14 a minute. EMS left at 1522 gave pt a cold paper cloth and water to drink. Dr. was called at 1525 where he was made known of the situation. His instructions where to advise pt to get second dose of Moderna in a hospital setting for close monitoring and advise that pt do not drive home. Pt made aware of instructions from MD. Pt was not driving. At 1552 patient feeling better and requests to leave. Pt reported she has no feeling of SOB or tightness. Pt not as pale as she was at begging of the event. |

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| 1053008 | 2/24/2021 | OR | 27 | F | 2/12/2021 | 2/12/2021 | Patient had a syncopal episode within 10 minutes of having her vaccine. She was standing at the check out desk having her information entered into our state system and she passed out. She had no warning it was coming. She fell backwards and hit her head. She was aroused to sternal rub. She was emotional when she aroused. She new where she was and that she had a vaccine. Her vital signs were normal. Her significant other was contacted. Do to hitting her head we advised she be evaluated through an emergency department. She was called the next day. She had a brain CT which was normal and she was released. On follow-up she was feeling well. |
| 1052890 | 2/24/2021 | VA | 58 | F | 2/24/2021 | 2/24/2021 | Fainted twice on the sidewalk within an hour and a half of shot. Ambulance was called. |
| 1053144 | 2/24/2021 | | 65 | M | 1/31/2021 | 1/31/2021 | syncope, hypotension, chest pain |
| 1285008 | 2/24/2021 | | | F | 2/16/2021 | | My 20 year old daughter had the mederna vaccine The following morning she fainted and blacked out for 4minutes She now has tiredness ,pain in her neck and swelling in her neck Heart rate increased also |
| 1052816 | 2/24/2021 | MS | 88 | M | 2/15/2021 | 2/16/2021 | Patient became dizzy, passed out and hit head on wall, Ambulance called, taken to nearest Hospital. |
| 1049041 | 2/23/2021 | PA | 69 | M | 2/5/2021 | 2/5/2021 | patient states that immediately following administration of covid vaccine on 2/5 he began to experience profuse sweating, dizziness and nausea. He went home and then went to the ED for syncope on 2/6. Prior to ED, patient states that he became so dizzy that he lost control of his head and it slammed on the table he was sitting at leading him to go to the ED. The ED note is without mention of the vaccine. However, when pt saw me on 2/9, he states that all of his symptoms were r/t the vaccine. He left ama from the ED who wanted to admit him for a cardiac eval. I did not witness administration nor did I know patient prior to visit. I just saw him following his ED visit. It is not my intent to mislead the Department of Human and Health Services, I am simply reporting what the patient told me. |

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| 1049175 | 2/23/2021 | KS | 38 | F | 2/19/2021 | 2/20/2021 | Passed out once over the weekend (2/20/2021-2/21/2021). Feels like she has a racing heart - started over the weekend and has persisted. I gave the pt instructions to see her PCP for evaluation. Pt stated she did have N/V, headache, low grade fever, body aches, and chills over the weekend as well but those symptoms have gone away. |
| 1049215 | 2/23/2021 | | 36 | F | 2/12/2021 | 2/13/2021 | Passed out twice. Nausea and Headache. |
| 1049231 | 2/23/2021 | NY | 22 | F | 2/20/2021 | 2/20/2021 | Patient assessed via virtual visit on 2/21 Got 2nd dose of Moderna vaccine on 2/20. On way home was having tongue swelling. Sharp CP radiating to diaphragm and throat swelling since last night. +wheezing. Walking from bed to bathroom gets SOB SOB gradually worsened as time passed Dizziness since difficulty breathing paresthesia in hands diaphoresis - pt attributes to fever/chills she has been getting since having the vaccine Denies n/v, abdominal pain, syncope Dyspnea, oral swelling, CP began s/p Moderna vaccine 2 of 2 and gradually worsening Advised ER via ambulance. Pt prefers to wait for her dad to take her to the ER Counseled pt on risk of death due to airway cut off due to worsening sx: bronchial inflammation/throat swelling or decreased oxygen to heart/brain with dizziness (MI/stroke). Advised tools EMS would be able to administer life saving medications to support her in these emergent situations and quickly get pt to ER vs having her die in car with dad bearing guilt of losing daughter. Pt expresses understanding, will wait for her dad. Suggested pt have a code word to say so if things getting worse her dad pulls over to call 911. Pt agreeable. |
| 1049534 | 2/23/2021 | GA | 79 | F | 2/18/2021 | 2/19/2021 | Grandson reported that she passed out while getting dressed for the day and that her arm was extremely sore and painfully. At the time of event it was reported that her BP was WML and she had not eaten since the night before. She is not a diabetic. |
| 1049695 | 2/23/2021 | NM | 30 | F | 1/29/2021 | 1/29/2021 | 1414: Patient had c/o "heart flutters" fell faint(fainted) and assisted safely to the ground. Patient was monitored and released. No further intervention |

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| 1048896 | 2/23/2021 | VA | 86 | F | 2/12/2021 | 2/23/2021 | HAD SHOT IN LEFT ARM - AT 6:00PM LEFT HAND WENT NUMB. AT 8:00 HAD SEVERE CHILLS & HIGH TEMPERATURE WHICH LASTED FOR 24 HOURS. HUGE BODY PAIN & COULD NOT MOVE ANYTHING. NECK & HEAD HURT SO BAD I COULDN'T STAND TO MOVE. I COULDN'T LIFT ARMS TO DRINK WATER. SON TOOK CARE OF ME ALL DAY THE DAY AFTER THE SHOT. HAD BRAIN FOG. COULDN'T THINK WHAT I WANTED TO DO OR WHAT I WAS DOING. LASTED FOR A WEEK. AFTER A WEEK I TRIED TO DO MY USUAL WORKING OUT ROUTINE, BUT WHEN I TRIED TO RIDE THE ELLIPTICAL I BROKE OUT IN A HUGE SWEAT AN ALMOST PASSED OUT. THAT LASTED UNTIL 2/22/21, WHICH WAS YESTERDAY, WHEN I WAS FINALLY ABLE TO RIDE ELLIPTICAL WITHOUT ANY ADVERSE REACTIONS. (I'M 86, BUT A VERY ACTIVE 86. I PLAY TENNIS 2 TIMES A WEEK & WHEN WEATHER IS NICE I RIDE MY BIKE FOR 15 MILES A COUPLE TIMES A WEEK.) LIFT WEIGHTS 3 TIMES A WEEK AFTER RIDING ELLIPTICAL FOR 45 MINUTES. NOT A TYPICAL 86 YEAR OLD PERSON. |

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| 1048202 | 2/23/2021 | NC | 76 | F | 2/4/2021 | 2/4/2021 | passed out / fell; passed out / fell; developed a nose bleed that would not stop; This is a spontaneous report from a contactable consumer. A 76-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiration date were not reported), via an unspecified route of administration on 04Feb2021 at single dose for COVID-19 immunization. Medical history included high blood pressure, diabetic, stage 3 kidney disease, known allergies to penicillin. The patient's concomitant medications were not reported. It was reported that patient got the shot on Thursday morning (04Feb2021) and later that evening reported as at 10:00pm, the patient developed a nose bleed that would not stop. By 10:30pm she passed out/fell, site car management was called and she was sent to the ER where she stayed for evaluations for 2 days. The reporter does not think the Covid shot was connected to the event. No treatment was given to the patient. The patient had no covid prior to vaccination and was not tested for covid post vaccination. The patient was recovering from the events at the time of the report. Information about lot/batch number has been requested. |
| 1049590 | 2/23/2021 | OK | 30 | F | 2/22/2021 | 2/22/2021 | PATIENT BEGAN TO HAVE SHORTNESS OF BREATH AND PASSED OUT AFTER ADMINISTRATION |
| 1048887 | 2/23/2021 | | 31 | F | 1/22/2021 | 1/22/2021 | Near syncope, dizziness, unresponsive to sternal rub. RRT called and transported to ER where she regained adequate mentation without intervention. |

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| 1048866 | 2/23/2021 | AL | 35 | F | 2/19/2021 | 2/19/2021 | I started having minor body aches about six hours post vaccine. I woke up that night nauseous and dizzy. I passed out on the way to the kitchen to get water. My husband somehow heard me and helped me back to the bedroom where I passed out again. I was eventually able to get back in bed without passing out, though I couldn't get warm and had severe body aches for most of the night. It was like having a very high fever, only there was no fever. I was clammy, but no fever. Around 4:30 a.m. the 'non-fever' broke and the chills and body aches stopped. I was extremely fatigued for the next two days and felt myself again by the third. The arm in which I received the shot hurt pretty bad Friday too but that was the least of my concerns. I did not seek medical treatment for these symptoms. |
| 1048744 | 2/23/2021 | CA | 21 | M | 2/21/2021 | 2/21/2021 | Systemic: Syncope -Severe, Systemic: Hypotension-Severe, Additional Details: Reported blood pressure after 911 paramedics arrived was 56/59. Patient was transported to facility. Called facility 3 times to follow up, but no response yet from facility director. Will follow up again on 2/23/21 in the AM. |

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| 1048683 | 2/23/2021 | VA | 82 | M | 1/25/2021 | 2/2/2021 | <p>passed out; light headed; This is a spontaneous report from a contactable consumer (patient's daughter). An 82-year-old male patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EK4176), via an unspecified route of administration on 25Jan2021 09:50 at single dose for covid-19 immunization. Medical history included visual problem. The patient's concomitant medications were not reported. The patient experienced passed out on 02Feb2021 and light headed in 2021. Clinical course: Consumer was calling regarding her dad who got the Pfizer COVID-19 vaccine. She said her dad had an event and she took him to his cardiologist who checked him out and suggest they call about it. She said that her dad passed out a week and a day after getting the vaccine and had been light headed. She said she was concerned that the second dose of the vaccine was supposed to be worse for effects, and she knew he was supposed to get it, but she wasn't sure that he should. She said her dad would say to call his daughter, because he had a visual problem, which he had since before the first dose of the COVID-19 vaccine. Caller said that NDC/EXP were not provided on the handwritten card. She said it said he got his first dose 25Jan2021. She said that the report she filed online asked what time he got the vaccine dose, and she put 09:45AM since it would not let her put 09:50AM, it was really at 09:50AM. Outcome of events were unknown.</p> |

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| 1048664 | 2/23/2021 | FL | 68 | F | 1/15/2021 | 1/15/2021 | <p>Passed out; Felt like two sticks in her stomach; Feeling of a warm flush; Fell on head; Sore arm; A spontaneous report was received from a consumer concerning a 68-years-old, female patient who experienced feeling of a warm flush, sore arm, felt like two sticks in her stomach, passed out and fell on head. The patient's medical history was not provided. Concomitant product use was not provided by the reporter. On 15 Jan 2021, approximately prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 [Lot number 01ZC207] intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 15 Jan 2021, the patient felt like two sticks were in her stomach and then a feeling of a warm flush going through her body. She also had a sore arm. Patient felt like she was going to pass out and did pass out and fell on her head. Treatment information was not provided. Action taken with mRNA-1273 in response to the events was not provided. The events feeling of a warm flush, sore arm, felt like two sticks in her stomach, passed out and fell on head were considered not recovered/not resolved.;</p> <p>Reporter's Comments: Based on the current available information and temporal association between the use of the product and the onset date of the events, a causal relationship cannot be excluded.</p> |

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| 1048663 | 2/23/2021 | FL | | F | 2/5/2021 | 2/5/2021 | <p>Passed out; Blood pressure dropped; Neck ache; Body ache; Dizziness; Nausea; Vomiting; Severe chills; Injection site swelling; A spontaneous report was received from a consumer, concerning a 86-year-old, female patient, who received Moderna's COVID-19 vaccine and experienced passed out, blood pressure dropped, neck, body ache, dizziness, nausea, vomiting, severe chills and injection site swelling. The patient's medical history was not provided. Concomitant product use was not provided. On 05 Feb 2021 at 10:00 am, prior to the onset of the events, patient received their first of two planned doses of mRNA-1273 (Lot number: unknown) intramuscularly for prophylaxis of COVID-19 infection. On 05 Feb 2021, initially patient had injection site swelling. Then 22 hours later on 06 Feb 2021, she passed out, her blood pressure dropped, had nausea, vomiting, severe chills, neck and body ache, and dizziness. No treatment information was provided. Action taken with mRNA-1273 in response to the events were not reported. The outcome of the events, passed out, blood pressure dropped, neck, body ache, dizziness, nausea, vomiting, severe chills and injection site swelling were unknown at the time of this report.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.</p> |

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| 1048203 | 2/23/2021 | PA | 73 | F | 2/6/2021 | 2/7/2021 | I had passed out hitting a table bumped head and back.; very dry mouth; felt very light headed; Thought maybe I may have been dehydrated; This is a spontaneous report from a contactable consumer (Patient). A 73-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL3249), via an unspecified route of administration at Left arm on 06Feb2021 07:45 at single dose for covid-19 immunization. The COVID-19 vaccine was administered at Hospital. Medical history included High blood pressure. Concomitant medications included losartan, atorvastatin calcium (LIPITOR) and vitamins. Patient was not pregnant. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient woke up 1:30 am 07Feb2021very dry mouth, used restroom, felt very lightheaded, went back to room, next thing she heard was glass breaking. She had passed out hitting a table bumped head and back. Her boyfriend was with she helped she up. Said her legs went out from under her. Thought maybe she may have been dehydrated though she had drunk water throughout the day and before bedtime. No treatment received for the events. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient was not been tested for COVID-19. The outcome of the events was recovered on an unknown date in Feb2021. |
| 1049717 | 2/23/2021 | CA | 90 | F | 1/26/2021 | 1/27/2021 | The next day, patient was found down by children (lives alone.) Was confused, had had fecal incontinence many hours earlier (dried) . Neither syncope nor fecal incontinence had occurred before. Previously managed to walk w walker or holding on, do her own basic ADLs (toilet, use microwave, eat.) Now bed bound and requires 24 hour care, unable to stand even with assistance/PT. Mental state has returned to baseline. Spent a week in rehab but could barely comply w PT instructions due to pain/dizziness. |

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| 1048196 | 2/23/2021 | FL | 48 | F | 12/24/2020 | 12/24/2020 | <p>Passed out/ Status post syncopal episode; Double vision; Diagnosis of static vision; Hypothyroid; Diarrhea; Injection site pain; Headache; A spontaneous report was received from a healthcare professional concerning a 48-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced hypothyroidism, passed out/status post syncopal episode, diarrhea, injection site pain, headache, static vision/double vision. The patient's medical history was not provided. Concomitant medication history was not provided. The patient received their first of two planned doses of mRNA-1273 (batch number: unknown) on 24 DEC 2020. On 21 JAN 2021, the patient received their second of two planned doses of mRNA-1273 (batch number: 028L20A) intramuscularly for prophylaxis of COVID-19 infection. The patient developed injection site pain and diarrhea after the second dose. She continued to have the headache from the first dose that was administered. On 03 FEB 2021, the patient experienced double vision and dizziness while driving to work. The patient passed out at work and was admitted to the hospital. A CT of the brain showed no acute findings and her CT angiography was normal. The patient was discharged in less than 24 hours with the diagnosis of static vision, hypothyroid and status post syncopal episode. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the event passed out/status post syncopal episode and static vision/double vision were resolved. The outcome of the events hypothyroidism, diarrhea, injection site pain, and headache were unknown.; Reporter's Comments: Very limited information regarding this events has been provided at this time. Further information has been requested.; Sender's Comments: MOD21-024368:Crosslinked: Same reporter MOD21-024340:Crosslinked: Same reporter MOD21-024343:Crosslinked: Same reporter MOD21-24360:Crosslinked: Same reporter MOD21-024387:Crosslinked: Same reporter MOD21-024396:Crosslinked: Same reporter MOD21-024411:Crosslinked: Same reporter</p> |

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| 1047831 | 2/23/2021 | WA | 65 | F | 2/4/2021 | 2/5/2021 | acute flu lasting 3 days followed by 1 day with lighter symptoms. The 3 days included acute pain,fatigues,sleepiness,chills, body aches . On day 2 about 28 hours after taking the vaccine I walked to the bathroom and fainted. I am 65 and have never fainted. |
| 1048208 | 2/23/2021 | VA | 82 | M | 1/25/2021 | 1/25/2021 | passed out; felt lightheaded; This is a spontaneous report from a contactable consumer (patient). An 82-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration at the right arm on 25Jan2021 09:45 at single dose for COVID-19 immunization. Medical history included hypertension, hypothyroidism, high cholesterol. The patient has no known allergies. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient received unspecified medications within 2 weeks of vaccination. On 25Jan2021, the patient felt lightheaded since vaccine. On 02Feb2021, the patient passed out. The patient has never passed out before. He went to the cardiologist on 04Feb2021 and had EKG and review of BP readings and HR readings etc., all checked out ok. Today was 08Feb2021 and still lightheaded. The cardiologist suggested we call you but cannot get through. We were extremely concerned about getting the 2nd vaccine because of reports of worse symptoms with that one. We cannot get through to you and do not know what to do. The 2nd vaccine was scheduled for 15Feb2021.The events resulted in doctor or other healthcare professional office/clinic visit. The patient has not recovered from the events. Treatment was received for the event passed out and ordered Exam-EKG-Holter Monitor. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient has not been tested for COVID-19. Information on the lot/batch number has been requested. |
| 1050404 | 2/23/2021 | TX | 19 | F | 2/22/2021 | 2/22/2021 | Pt had a panic attack due to fear of needles. Hyperventilated and appeared to be near fainting, but did not lose consciousness. EMS reported to care for patient, and she was removed by stretcher. |

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| 1049678 | 2/23/2021 | OR | 63 | F | 2/21/2021 | 2/22/2021 | I was fine til about 2am when I was faint and light headed with flu-like symptoms, stuffy nose, body aches + terrible migraine headache. Was so sick that I was unable to find my migraine meds (prescribed by doctor). Have history of migraines but haven't had one in several month...I was dizzy and worried about thowing up and fainting. Note: usually never recieve the flu shot but not during 2020. |
| 1050464 | 2/23/2021 | | 23 | F | 2/23/2021 | 2/23/2021 | 10 minutes post vaccination during observation, patient fainted and did not rouse immediately. I administered ammonia inhalant was used within 1-2 minutes of her LOC, and patient gained consciousness but was diaphoretic and pale. Within 2 minutes of the ammonia inhalant, she began convulsing (full body convulsions, eyes rolled) For 30-45 seconds. She had continued LOC for 1-2 minutes, 15L O2 mask was administered, and patient slowly came in and out of consciousness for the next 5-10 minutes, bradycardic 35-45 bpm, BP 72/50, HR irregular, RR 16 BS clear. At the time of observed convulsions, 911 was called and arrived within 10-12 minutes. When EMS arrived, she remained pale but with some improved pallor, HR 45 bpm, and more alert. Transported by EMS to hospital for eval. |
| 1049722 | 2/23/2021 | MI | 22 | M | 2/22/2021 | 2/22/2021 | One minute following vaccination, patient hunched over and fainted. Nursing staff lowered patient off chair and onto floor, raised patient feet above heart level. Patient woke 15 sec later and sat up slowly. Patient given juice and granola bar. Patient observed for total of 50 minutes. Patient vitals remained within normal limits throughout observation period. Patient released after reporting feeling better and all symptoms diminished. No other severe symptoms or concerns noted during observation period noted. |

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| 1050316 | 2/23/2021 | CA | 23 | F | 2/19/2021 | 2/19/2021 | From patient note: 2/19/21 Day of Vaccination - Morning of the vaccination had burning in arm at and around the injection site with severe soreness of arm developing over the day. After 5 hours faintness, sore neck/shoulders, trembling hands, "super shaky", also headache with stabbing pain in head and neck which continued for several days. Tight chest developing within 3 hours gradually turning into extreme difficulty breathing by 9pm. Around 9pm both arms from shoulders to fingertips went numb and tingly "like nerves were TV static". Throughout night drank about 1 bottle of water per hour, each time getting up and taking a few steps vision would start blacking out, would feel clammy, and would barely make it back to bed before fainting. Extreme muscle and joint pain made walking difficult for 3 days.. Fever of 99-101 for 3 days. Day 2 - extreme back pain accompanied by heartburn On 2/22/21 reports doing better but continuing to have soreness, night sweats, chills |
| 1050309 | 2/23/2021 | CA | 64 | F | 1/15/2021 | 1/16/2021 | I had my 2nd dose of covid vaccine on 1/15, around 5 pm. Next day when I got up about 7:20 I felt dizzy nausea and wanted to vomit. Then I passed out, I fell down and hit my face on the floor. My family called 911 paramedica. They ,measured d my blood pressure and it was too low. The area around my right eyebrow was swollen and my neck hurt as precaution I went to the hospital. I suspect the incident and its symptom are side effects of the vaccine given the timing. Later on I had headache off and on and brain fog. |
| 1050246 | 2/23/2021 | NY | 41 | F | 2/22/2021 | 2/23/2021 | Vomiting fainting fever |

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| 1050244 | 2/23/2021 | FL | 41 | F | 2/19/2021 | 2/22/2021 | Anaphylactic shock? Shortly after receiving the vaccine my arm was sore and I had a severe headache. Approximately 24-48 hours after I received the vaccine I started developing a red, hot, itchy raised rash on my ears and buttocks which became more prevalent and peaked around 80-90 hours later. Approximately 82 hours after I received the vaccine, I began to feel nauseous, dizzy, and fatigued so I stood up to get ready for bed early. While brushing my teeth, I went pale white and felt like I was going to vomit. I put the toothbrush down and got on floor. My pulse felt like it had stopped. I tried to check my pulse and I could only detect one beat every other second. I called for my spouse and by the time he got to bathroom I was passed out. I came back to after about 30 seconds and was convulsing from chills. He put a blanket on me and grabbed my Apple Watch to try to get my pulse which read in the 50s (so I assume it was much lower when I passed out). My hands and feet were tingly and I stayed on the floor until my pulse got back up. I then had diarrhea. At this point in time the rash was most prevalent and was present mostly on my buttocks but also on my ears, scalp, pointer finger on right hand, thighs, and hips. I went to doctor the following morning an my vitals, blood sugar, EKG, urine screen were stable and indicated no issues. 106 hours later I still have the rash on all areas mentioned and am dizzy, nauseous, and fatigued. |
| 1050226 | 2/23/2021 | NJ | 58 | F | 2/12/2021 | 2/20/2021 | Suddenly became dizzy, My family who consists of 3 nurses were with me at the time. Had a witnessed vasovagal syncope episode . Turned white, lost consciousness for about 90 seconds. No pulse was felt by my daughter who is APN. 3 chest compressions were done, then color in my skin began to return (per my family). I was then transported to the emergency room. Cardiac work up for heart attack was negative, vital signs were stable after initial episode. Was admitted to hospital for 18 hours for observation. I have no medical history and had no changes in my daily routine |

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| 1050217 | 2/23/2021 | CA | 51 | F | 2/18/2021 | 2/18/2021 | 2/18 6 pm nasauaes, dizzy, chills, headache 10 pm 103 fever , nasueas, dizzy, aches,pains, headache 2/19. 10am fainted, vomiting, chills, fever 2/20 fever , felt I was fainting again, extreme body shakes , vomiting , headache, night sweats 2/21 nasueas, dizzy , nightsweats 2/22 nasueas, dizzy, headache |
| 1050205 | 2/23/2021 | NJ | 48 | M | 2/8/2021 | 2/8/2021 | Started with tiredness, then arm got sore and was painful to lift. Later in the day, body and joint aches started. 12 hours after dose, started to get very cold and this turned into violent and uncontrollable shaking from chills. Then headache started 13 hours after dose (the headache lasted for 2 days and was the last symptom to go). Fever fluctuated between 101.5 and 102.1. Later felt very nauseous, felt like I had to vomit but didn?t. Went to the bathroom and there I got dizzy and almost passed out but didn?t. Fever up and down all day the next day. Could only eat a little Campbell?s chicken noodle soup and a small can of coke. By the next evening (day 2) I started to feel better just exhausted and a headache. Went to sleep early, next day (day 3) still had the headache and was exhausted. By Day 4 I was about 80 % back to normal and feeling much better. I didn?t take any fever reducers or other medications during this time. It was all worth it to be vaccinated, |
| 1050017 | 2/23/2021 | IN | 81 | F | 2/17/2021 | 2/18/2021 | 12:01 am 2-18-21 pt. felt sick went to bathroom, passed out and lost control of bowel. Said she felt like she had the "flu". |
| 1050198 | 2/23/2021 | GA | 78 | M | 2/16/2021 | 2/17/2021 | Got up to go to the bathroom in the middle of the night, was dizzy. Wife walked with him because of the dizziness. On way back to bed he passed out and I tried to help ease him down. Came back almost immediately. Got on hands and knees and crawled to bed. Ran a fever of 100.3 all Wednesday and stayed in bed because of dizziness. By Thursday he was fine again and started doing his normal activities. |

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| 1049925 | 2/23/2021 | CO | 34 | M | 2/18/2021 | 2/18/2021 | headache, fever (presumed), extreme chills, extreme dizziness, extreme body aches. Worst of this was over by mid-day the following day. Chills, dizziness, and body aches continued mildly through Sunday. I also passed out/blacked out the night of getting the vaccine while using the bathroom. Unclear if this was simply due to standing too quickly while experiencing the above mentioned symptoms and blood rushing to my head or a true side effect of the vaccine. |
| 1050048 | 2/23/2021 | OK | 42 | F | 2/22/2021 | 2/23/2021 | I woke up at 4:30am to shower. Once in the shower I got lightheaded, yelled for my husband, and as he was getting there I fainted in the shower. I came to, rested a second but when he helped me up I fainted a second time. Laid in bed for several hours. Took blood pressure/heart rate around noon and heart rate was 115. |
| 1050072 | 2/23/2021 | CA | 37 | F | 2/19/2021 | 2/19/2021 | Patient reported at 6:40 pm that she had thrown up and was having nausea. EMS attendant was on standby and took vitals: 129/89 BP, Resp 16, lungs clear on auscultation, pulse 104, blood sugar 69. Patient reported she had not eaten since 12:00 pm. Patient reported at 6:50 pm that her nausea was improving. At 7:00 pm, patient had a near-syncope event and was diaphoretic. She was placed in a wheelchair and taken to a private area. She appeared struggling to focus, but was responsive to questions. She developed a rash on her chest and an ambulance was called related to dermal, CNS, and GI symptoms. On ambulance arrival, Diphenhydramine 15 mg IV was given and patient was transported to ER. |
| 1050074 | 2/23/2021 | MD | 79 | M | 2/23/2021 | 2/23/2021 | Passed out, I.V. and fluids, transported to the hospital |
| 1050124 | 2/23/2021 | CA | 30 | F | 2/19/2021 | 2/19/2021 | 1st Covid vaccine on 2/19/2021, patient had syncope in the parking lot, unable to speak, confused taken to the hospital by ambulance. |
| 1050135 | 2/23/2021 | MA | 67 | M | 2/23/2021 | 2/23/2021 | Patient fainted when walking to bathroom after observation. |

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| 1050147 | 2/23/2021 | IN | 48 | F | 2/6/2021 | 2/16/2021 | The day of the injection, approx. 3-4 minutes after getting the injection, I almost passed out. I became hot, sweaty, dizzy and my head starting to buzz. The nurse on-site provided me a couple cold packs and after about 30 minutes, I felt better. The nurse described my response as a "vascular" reaction. Later that night, I got a headache and night sweats and bouts of nausea. They only lasted a day. Approx. 10 days after the injection, the injection site became red, swollen, itchy and uncomfortable to the touch. Then it traveled down my arm and created a large red, swollen, itchy area on my entire upper arm. I advised my doctor and she provided me a Rx for a topical steroid and oral steroid. After 5 days of treatment, it is 90% better. The injection site still hurts. |
| 1050166 | 2/23/2021 | IN | 30 | M | 2/23/2021 | 2/23/2021 | Patient experienced light headedness and symptoms consistent with syncope, as well as nausea. the syncope event occurred in the chair without a fall. per patient reporting patient had not eaten 8 hours prior to administration time and also experienced anxiety with vaccines. patient was given supportive care including assisting to the floor carefully with a pillow provided and feet elevated. patient was also provided with juice to support any potential low blood sugar. |

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| 1045537 | 2/22/2021 | TN | | M | 1/11/2021 | 1/14/2021 | <p>Covid-19; Strep throat; Slid down the wall and passed out; Hacky cough; Slight headache; Tired; Fever; A spontaneous report was received from a consumer concerning a 73-year-old, male patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced hacky cough, slight headache, tired, slight fever of 100.4, covid-19, strep throat and passed out. The patient's medical history included artificial hips. Concomitant medications reported included salbutamol, fluticasone propionate, salmeterol xinafoate, salbutamol sulfate, apixaban, mirabegron, metoprolol, cetirizine hydrochloride, colecalciferol, zinc, ascorbic acid and rutoside for unspecified indication. On 11 Jan 2021, the patient received their first of two planned doses of mRNA-1273 intramuscularly in the right arm for prophylaxis of COVID-19 infection. Reporter stated that the patient was not aware of being exposed to COVID on 10 Jan 2021. They found out the following week after receiving the vaccine. The patient had COVID test on 19 Jan 2021 and tested positive. On 14 Jan 2021, the patient developed hacky cough, slight headache, tired, slight fever of 100.4 degree fahrenheit. The treatment information included fluticasone propionate, salbutamol, steroids, montelukast and azithromycin. On 17 Jan 2021, the patient got up to go to the bathroom and slid down the wall and passed out. The treatment information included fluticasone propionate, salbutamol, steroids, montelukast and azithromycin. Action taken with RNA-1273 in response to the event was not provided. The outcome of the events hacky cough, slight headache, tired, slight fever of 100.4, covid-19, strep throat and passed out was unknown.; Reporter's Comments: This case concerns a 73-year-old male with a serious expected event of loss of consciousness along with a NS unexpected COVID-19, streptococcal pharyngitis, cough and NS expected fever, headache, fatigue. Event onset 9 days after the first dose of mRNA-1273. Treatment included fluticasone, salbutamol, steroids, azithromycin. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.</p> |

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| 1045735 | 2/22/2021 | MA | 29 | F | 2/20/2021 | 2/20/2021 | Around 5:30 PM I began experiencing normal symptoms like headache and muscle ache. At 8:15 PM I began to feel light headed, nauseous, and short of breath. Around 8:20 I needed to lay on the floor to prevent myself from fainting. My eyes were rolling back because I was borderline unconscious. I felt like I had no control of my body and had to go to the bathroom. For around 15 minutes I was on the floor convulsing, shaking as if I had chills and my muscles were involuntarily tensing. My pulse was extremely low. After the convulsions stopped I remained on the floor an additional 15 minutes. Around 8:45 PM I was able to return into my bed with assistance. My nauseous remained and I began experiencing chills. I slept on an off the entire night. At about 1 AM what I suspect was a fever began to break and I was extremely sweaty. For the following day I experienced exhaustion and muscle soreness. I am still experiencing exhaustion. I recognize a bulk of my symptoms were normal but the convulsions, losing consciousness, and inability to control my body seemed worth reporting. |
| 1046278 | 2/22/2021 | MA | 80 | F | 2/11/2021 | 2/11/2021 | Chills, pain throughout body, fainting (30 hours after injection, general weakness for 40 hours |
| 1046129 | 2/22/2021 | OH | 70 | F | 2/12/2021 | 2/12/2021 | Approx. 1 hr. & 20 min. post injection, severe reaction: Severe upper abdominal pains, multiple, uncontrollable formed to diarrheal bm's triggered vagal response, passed out, severe diaphoresis, violent chilling loss of control of bowel movements. Lasted approx. 30-35 minutes. crawled with head hanging to floor to keep from passing out, to locate a phone for help. after several of agonizing attempts to try and climb up to couch to elevate legs high above head and laying there for approx. 20 or more min. blood pressure came up some. (Did not call emergency services) afraid of hospitalization due to all chronic health problems, (forgot to report earlier that I am Hypothyroid as well) previously hospitalized for a Thyroid Storm. This is day 10 from injection and still have nausea, dizziness & fatigue, (also have couple episodes of abdominal pain). (I want to add that I felt completely fine prior to receiving 2nd Pfizer Covid dose). I am contacting my doctor today to receive some IV fluids. |

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| 1045917 | 2/22/2021 | IL | 37 | F | 2/20/2021 | 2/20/2021 | 10 minutes after vaccine patient said she was feeling lightheaded and wanted to lay down. Laid her down and put feet up and she was also very cold. Laid for 15 minutes, when trying to sit up with 2 assists. She was up for 30 seconds and was lightheaded again. Laid her down and she passed out. Smelling salts had to be used to wake her up. Vital signs were not un-normal. Continued to lay for 30 minutes. She was alert and orientated. |

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| 1045871 | 2/22/2021 | MA | 42 | F | 2/5/2021 | 2/5/2021 | <p>Patient reports that she received dose one of the Pfizer COVID-19 mRNA vaccine last Friday, February 5, 2021 at 2:03 PM. She received this here at facility campus vaccine clinic. She felt a strange tingling sensation immediately upon receiving the injection that extended from the injection site across her upper back but otherwise tolerated the injection well. Because of her history of food allergy she was advised to remain at the vaccination clinic for 30 minutes. During that 30-minute wait period she felt generally well however began to develop pruritus at her back in the legs. She did not mention this to the staff at the vaccine clinic and did not look at her skin. The pruritus was not too bothersome and she left the vaccine area after 30 minutes and walked down to our clinic to return to work. Her pruritus intensified very quickly upon returning to her desk and within a few minutes of after her return she went into the bathroom to look at her back and had patches of red, raised, urticarial lesions across her back. She began to feel itchy all over her body. She remained at work and did not take any medication or seek any medical help. She did not look at her legs. The pruritus intensified and when she looked at her skin of her legs approximately 1 or 2 hours later she had developed urticaria essentially head to toe. She had large confluent patches of urticaria at bilateral thighs, urticaria at her face, trunk, arms, legs. At this point she felt otherwise well. She went home and took 10 mg of Claritin and applied a topical Benadryl cream to her skin. This was not helpful. She had severe pruritus of her eyes and eyelids. She took 50 mg of oral Benadryl which also was not particularly helpful. Sometime in the middle of the night that night she developed chills, felt feverish, and developed intense muscle and joint aches. She took an unknown dose of ibuprofen with minimal improvement in muscle and joint pain. She did have improvement in fever. Following day was Saturday, she spent the whole day in bed in extreme pain. She describes the pain at her wrists as feeling as though "somebody was breaking my bones" with any movement of her wrists. She had pain even laying flat in her bed and had severe pain at all of her joints with movement. She tried taking a flexeril with no improvement. She recalls a T-max of 102 sometime on Saturday or Sunday. At that time she had been taking ibuprofen around-the-clock. She also took 10 mg of</p> |

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Claritin approximately every 4 hours. Each night she also took 50 mg of Benadryl. She continued to experience urticarial skin rash and intense pruritus of the skin. The urticaria waxed and waned during this time. She also developed a fever blister at her lower lip. She spent most of Sunday in bed also. She was feeling a bit better by Monday however still had intense pruritus. Skin rash was much improved at most of her body however she still had mild urticaria at her face. She did not have a fever on Monday but was continuing to take ibuprofen around-the-clock. She discontinued ibuprofen yesterday and has not had fevers or chills since Sunday. At this point her urticaria has essentially resolved. She continues taking claritin 10mg BID to 3 times a day and also 50mg bendaryl at bedtime. She did not experience any bruising related to this rash however did have excoriation from scratching particularly at her face. Throughout the course of these days she did not have any episodes of angioedema of the lips, tongue. She denies difficulty breathing, cough, wheezing, shortness of breath, throat tightening, nausea, vomiting, diarrhea, dizziness, lightheadedness, syncope. She has a history of oral allergy syndrome with peanut. Promethazine has caused diplopia, weakness. Simvastatin caused muscle weakness. She has never had any issues with vaccines. She has been getting a flu shot yearly with no difficulty. Her most recent vaccine was October 8, 2020, quadrivalent influenza vaccine. No known history of allergy to polyethylene glycol. No history of chronic urticaria. She takes NSAIDs frequently without any difficulty. She has not taken any NSAIDs prior to receiving this injection or developing this urticaria. She had however taken 10 mg of Claritin prior to receiving this injection. She has no history of anaphylaxis. She has undergone surgery under general anesthesia on more than one occasion without issue. No history of reaction to stinging insect venom. She receives immunotherapy for inhaled environmental allergens here in our office and has done well with this. She denies any recent medication changes or new over-the-counter medications. She has not previously been diagnosed with COVID-19.

1045807 2/22/2021 NJ 25 F 2/21/2021 2/22/2021 Syncope

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| 1046321 | 2/22/2021 | | 19 | F | 1/15/2021 | 1/15/2021 | Dizziness, near syncope that resolved immediately when put in supine position |
| 1045653 | 2/22/2021 | | 42 | F | 2/16/2021 | 2/17/2021 | dizziness, HA, loss of consciousness, convulsive syncope |
| 1045637 | 2/22/2021 | MI | | F | | | I passed out, I was unconscious on the floor, my eyes were open and looked very strange he said, I was making gurgling sound.; I was unconscious on the floor/Tried to wake me up but it didn't work; Lethargic; This is a spontaneous report from a contactable consumer (patient). A 82-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) , via an unspecified route of administration at left arm on an unspecified date at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient reported that: " I passed out the next morning for about 8 minutes my husband said, I was unconscious on the floor, my eyes were open and looked very strange he said, I was making gurgling sound. He threw water on me and he tried to wake me up but it didn't work. I came out of it I was very lethargic the whole day but the next day I was feeling a little bit better". No therapeutic measures were taken as a result of events. The patient outcome of lethargic was recovering; the outcome of the other events was recovered. The information on the batch number has been requested. |

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| 1045635 | 2/22/2021 | MO | 74 | M | 2/4/2021 | 2/9/2021 | Death; Passed out; Stomach was bothering; Constipated; Difficulty breathing; Weakness/Event: Weakness was reported as worsened; a temperature of 99.4 degrees; Sweaty; Cold; Muscle ache; Body Aches; Diarrhea; Nausea; Vomiting; Fatigue/Tiredness; His raspy throat felt like he had mucus stuck in his throat; Cough; Raspy throat/worsened; This is a spontaneous report from a contactable consumer reporting her husband. A 75-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EM9810, Expiry Date: Jun2021) at the age of 74- year-old via an unspecified route of administration on 04Feb2021 09:15 at single dose in Arm, Right for COVID-19 immunisation. Medical history included type 2 diabetes mellitus for about 20-25 years, ongoing kidney disease from 2005, ongoing chronic kidney disease, cardiac pacemaker insertion. The patient was diagnosed with kidney disease in 2005, but it was about 1 to 1-1/2 years ago that his kidney disease progressed to Stage 4 Kidney Disease. She said the Veterans Administration diagnosed her husband with his kidney disease, but her husband saw a private doctor, as well as, a VA doctor for his care. There were no concomitant medications. The patient previously received the first dose of BNT162B2 (Lot Number: EL3248; Expiration Date: Apr2021) at the age of 74- year-old Intramuscularly at approximately 08:45AM on 15Jan2021 in right arm for COVID-19 immunisation and had no reaction. There were no additional vaccines administered on same date of the Pfizer suspect. There were no Prior Vaccinations within 4 weeks. The patient had symptoms start earlier in the day of Tuesday, 09Feb2021, after his second COVID-19 Vaccine shot (04Feb2021). The reporter said she and her husband didn't think anything of his symptoms at first. The patient had a temperature of 99.4 degrees on 09Feb2021. She didn't check her husband's temperature again after that time because the nurse at her husband's doctor's office said her husband's temperature was not at an area of concern. The patient was sweaty, off and on, starting 09Feb2021. She clarified he would be sweaty and the cold, but nothing extreme. The patient developed muscle aches, body aches, diarrhea, nausea, and vomiting on 09Feb2021. She clarified her husband had fatigue, tiredness, and had trouble with a raspy throat. His raspy throat started Tuesday evening (09Feb2021). |

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His raspy throat felt like he had mucus stuck in his throat, and he was unable to clear the mucus from his throat. The reporter called her husband's primary care doctor on the morning of 10Feb2021 because her husband was having trouble with a raspy throat, and difficulty breathing. She said on Tuesday night (09Feb2021) her husband had to sleep sitting up because he couldn't lay down with his breathing. He was able to eat breakfast (clarified as oatmeal and an orange), lunch (clarified as soup and a salad), and dinner (clarified as soup and half a sandwich. She said her husband ate all the meat and half of the bread on the sandwich) on 10Feb2021. Her husband's primary care doctor wasn't available to speak to on Wednesday morning (10Feb2021), but the doctor's nurse said it sounded like her husband was having a reaction to his second COVID-19 Vaccine shot. The reporter said her husband's doctor instructed her later in the day to take her husband to the Emergency Room or Urgent Care if he didn't feel any better. Her husband's throat raspiness got worse in the evening of 10Feb2021. His breathing also became worse after dinner in the evening of 10Feb2021. The patient leaned forward over a couple pillows while sitting on their couch as it was easier for him to breath by doing that. They decided at 11:00PM that her husband should go to the Emergency Room. She said her husband was getting very weak, so she and her husband debated if she should call # for an ambulance, or if she should drive him to the Emergency Room. She said her husband was able to dress himself, but with some difficulty, and she assisted walking him from their house to their car. She said she had turned to walk away from her husband while he was at the side of their car, and then she heard her husband make a noise. He had appeared to have passed out. She clarified in the past, her husband had passed out prior to his pacemaker. She said she dialed #, and the # operator told her how to tell if her husband was still breathing. She said she couldn't tell if her husband was still breathing. She said when the ambulance arrived at her house, the ambulance staff worked on her husband for a long time. The reporter thought her husband had died at the time he had collapsed at the side of their car. The patient took a sugar free cough syrup Tuesday night (09Feb2021), and then again a couple times on Wednesday (10Feb2021) as treatment. The patient had thrown up a couple times,

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but found that the sugar free cough syrup soothed his cough the night before (09Feb2021). She said her husband had taken 2 TUMS early on Wednesday morning at approximately 2:00AM (10Feb2021). He had said his stomach was bothering him on 10Feb2021. He said he thought he may be constipated, so he took 1 Senokot (Clarified as GeriCare Senna-Plus Natural Vegetable Laxative with Stool Softener) on 10Feb2021. She clarified her husband had diarrhea on 09Feb2021, but felt on 10Feb2021 he may have been constipated. There were no adverse events required a visit to Emergency Room since Patient's wife stated she was getting her husband to their car, so she could drive him to the Emergency Room, when her husband collapsed and died or to Physician Office as they spoke with the nurse at her husband's primary care doctor's office. Weakness was reported as worsened. The outcome of events Sweaty, Cold, Muscle ache, Body Aches, Fatigue/Tiredness, Raspy throat/worsened, Difficulty breathing, Weakness was not recovered; and of the remaining events was unknown. The patient died on 11Feb2021. The patient's official time of death was Thursday, 11Feb2021, at 12:08AM. Cause of death was unknown. An autopsy was not performed and it would take 3 weeks for a death certificate to be issued. The reporter stated she thought it was important to notify Pfizer of her husband's passing because his side effects fell within the expected time period after receiving his second COVID-19 Vaccine.; Reported Cause(s) of Death: Death

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| 1045629 | 2/22/2021 | MA | 53 | F | 2/2/2021 | 2/1/2021 | <p> Syncope; headache; body aches; intermittent fevers with flushing/chills; intermittent fevers with flushing/chills; intermittent fevers with flushing/chills; nausea night of 2nd inj and next day; Severe fatigue; joint pain; I felt very ill; akin to the flu; This is a spontaneous report from a contactable nurse(patient). A 53-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date were not reported), via an unspecified route of administration on the left arm on 02Feb2021 11:45 AM at a single dose for COVID-19 immunization. Medical history included Crohns disease which is in remission (No immunosuppressants in 5 years) and shellfish sensitivity. The patient received the first dose of BNT162B2 on 15Jan2021 for covid-19 immunization and experienced syncope. The patient is not pregnant at the time of vaccination. Facility where the most recent COVID-19 vaccine was administered was hospital. The patient was not diagnosed with COVID-19 prior to vaccination. Since the vaccination, the patient was not tested for COVID-19. Concomitant medication included duloxetine hydrochloride (CYMBALTA), trazodone, buspirone hydrochloride (BUSPAR), lisdexamfetamine mesilate (VYVANSE) methylfolate and Ma. The patient experienced syncope after injection in Feb2021. A few episodes in 18 hrs, the patient experienced headache, body aches, intermittent fevers with flushing/chills, nausea night of 2nd injection and next day in Feb2021. The patient experienced severe fatigue, joint pain, felt very ill, akin to the flu in Feb2021.No treatment received for the adverse events. The patient underwent lab test included body temperature: intermittent fevers in Feb2021.The outcome of the events was recovering. Information on the lot/batch number has been requested.; Sender's Comments: A contribution from BNT162B2 to the event syncope is possible based on available information. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate </p> |

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| 1046359 | 2/22/2021 | CO | 75 | F | 2/18/2021 | 2/19/2021 | I have had every effect listed on the paper of side affect including, difficulty of breathing, fainted, dizzy, nauseous, I have spent days in bed |
| 1045547 | 2/22/2021 | NJ | | F | 2/8/2021 | 2/8/2021 | Fell; Blurred vision; Very weak; Passed out; A lot of pain; Chills; A spontaneous report was received from a 66-year- old female patient who experienced a lot of pain, chills, fell, blurred vision, very weak and passed out. The patient's medical history was not provided. Concomitant product use was not provided by the reporter. The patient received their first of two planned doses of mRNA-1273 (Batch number: 039K20A) on 08 Feb 2021, intramuscularly in left arm for the prophylaxis of COVID-19 infection. On 08 Feb 2021, the patient experienced pain at injection site, chills. On 09 Feb 2021, the patient fell, had blurred vision, very weak and passed out. She spoke to her doctor who recommended rest. Treatment information was not provided. Action taken with mRNA-1273 in response to the event was not reported. The outcome of the event passed out was resolved; outcome of the events, pain at injection site, chills, fell, blurred vision, and very weak, was unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the onset date of the events, a causal relationship cannot be excluded. |

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| 1045521 | 2/22/2021 | IL | | F | 2/4/2021 | 2/4/2021 | Fainted; Diarrhea; Nausea; Warm body temperature; A spontaneous report was received from a consumer, regarding herself, a 82-year-old, female consumer who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced fainted, diarrhea, nausea and warm body temperature. The patient's medical history reported included ulcerative colitis. Concomitant product use was not provided. On 04 Feb 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot Number: 038K20A) intramuscularly for prophylaxis of COVID-19 infection. On 04 Feb 2021, in the evening, after receiving the vaccine, the patient was fainted and started to experience diarrhea, nausea and warm body temperature. The event fainted was considered to be medically significant. Treatment for the events not provided. Action taken with the second dose of mRNA-1273 in response to the events were not reported. The outcome for the events, fainted, diarrhea, nausea and warm body temperature were resolved on 05 Feb 2021.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the onset date of the events, a causal relationship cannot be excluded. |

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| 1047225 | 2/22/2021 | CA | 65 | F | 2/17/2021 | 2/17/2021 | <p>Feeling mostly normal but tired fell asleep at 11PM day of second vaccine. Woke up 1 hour later and got up to go to the bathroom but felt fine. Went out to the hall bathroom so as not to wake husband in Master bath. Urinated and got up slowly as I always do and walked out to the hallway to go back to bed. I lost consciousness and came to when my husband who heard a thud came and found me out having fallen down the stairs.. head on the landing and feet above the landing. I have no recollection of it once leaving the bathroom and i would have headed away from the stairs which was just to the left of the bathroom doorway. I didn't feel any pain. Later found a bump on my forehead of the right side of my face and a bruised lip. He said my back was wet with sweat and I took a couple minutes to come to. After returning to the bed.. i immediately had to empty bowels. Diarrhea.. then the rest of the night in Chills. No fever. Slept most of the next day and night. Headache and joint aches and swelled lymph nodes in neck.. Fatigue through 20th. Mostly better by the 21st. Still today on 22 I am being careful when going from prone to standing. I feel more head pressure getting up and maybe I notice a little nausea when rising. I may just be worried about fainting again. It has never happened to me before. I do have very good blood pressure on the lower side so I was always careful to get up slowly but never fainted. Neck is sore.. Not sure if lymph nodes or something to do with fall.</p> |

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| 1045625 | 2/22/2021 | VA | 22 | F | 1/22/2021 | 1/22/2021 | <p>Syncopal episodes X 4; Fever; chills; pain/aches; Condition Aggravated; This is a spontaneous report from a non-contactable consumer. A 22-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number: EL1284) intramuscularly in left arm on 22Jan2021 at single dose for COVID-19 immunization. Medical history included traumatic brain injury from 2019 and ongoing, syncope from 2019 and ongoing (both reported as current illness: traumatic brain injury? 2019 syncope? 2019). Concomitant medication included midodrine. The patient experienced fever, chills, pain/aches, on 22Jan2021 pm, condition aggravated on 22Jan2021, syncopal episodes X 4 on 23Jan2021 - transferred to ed - admitted. Events categories per reporter was permanent disability, hospitalized (3 days in hospital), emergency room visited. No office visited. The outcome of the events was not recovered. No follow-up attempts are possible. No further information is expected.</p> |
| 1047489 | 2/22/2021 | TX | 91 | F | 2/4/2021 | 2/6/2021 | <p>She had the vaccine on Thursday and no visible side effects. On Saturday she was very weak and had to be lowered to the ground. She was drooling and staring vacantly and was not responding to questions. This lasted for a bit. I called the ambulance which took her to the hospital. They hydrated her and sent her home with no idea what caused it. The next day she was sitting on the toilet and passed out with her eyes closed. She started drooling. I again called the EMTs and they came. She had come to and they said she fainted and it was probably because she was having a bowel movement. This has not happened before or since these two episodes. I do not know if she should get the next shot.</p> |
| 1046417 | 2/22/2021 | MI | 29 | F | 2/8/2021 | 2/8/2021 | <p>Patient felt syncope / fainting unknown cause . Onsite EMS was called vitals BP 100/54 100% O2 room air HR 88 BG 130 Patient refused evaluation/care went home against medical advice.</p> |
| 1047732 | 2/22/2021 | DC | 29 | F | 2/12/2021 | 2/13/2021 | <p>The morning after the vaccine, pt noted low grade fever and general weakness, syncope with loss of consciousness for undetermined time period, facial trauma resulting in fractures of maxilla and teeth</p> |

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| 1047669 | 2/22/2021 | IL | 62 | F | 1/1/2021 | 1/23/2021 | 01/23 Hives began on thigh and progress to arms, torso, underarms and then both thighs. 01/25 Called dr and had a Telemed call with NP on Tues. 01/26. Predisone and Benadryl was prescribed. Thurs. 01/28 Call to let them know that it wasn't working. I went into the office for one shot of Solumedrol. This help and they were gone. They gave me second dose of Predisone to take in case it came back and to continue the Benadryl. 02/8 Second vaccine. Hives began that night: arms, torso, thighs, hair. Call the Dr. on 02/10 and suggested I go to an allergist. Went to allergist on 02/11 she said to only take one Predisone, Allegra one am and one at noon, then take zertek at nighttime. The Predisone created a major brain fog, I had to stop. Saw the allergist on 2/18, she agreed to get off the Predisone. 02/11 I passed out in the am and when I woke up with vomit running down my face. Still suffering with hives this entire time. 02/17 my face, lips, tongue started to swell and I had chest pain for 90 minutes. My feel swelled and I have hives so bad on my feet I could not walk or put on shoes. 02/20 Woke up with sweat on my chest. My hands were so swollen I had to have my wedding ring was cut off . 02/21 I went to the Urgent Care and received a shot of Solumedrol. They said this should last me for a few days. 02/21 woke up 3 time throughout the night soaked in sweat. |
| 1047614 | 2/22/2021 | MI | 59 | F | 2/10/2021 | 2/11/2021 | Fainted on 2/11/2021, bowel incontinence, and vomiting |
| 1047433 | 2/22/2021 | OH | 68 | F | 2/10/2021 | 2/11/2021 | headache and stomachache for 3 days, passed out at 1:30 AM Feb. 11. Life squad called BP 90/60. Swelling of left upper arm, swollen lymph node under left arm that lasted 4 days |
| 1047349 | 2/22/2021 | OH | 40 | F | 2/22/2021 | 2/22/2021 | Patient felt light headed 5 minutes after receiving the vaccine. Patient had an episode of syncope, which was attended by EMS. Patient regained consciousness within 30 seconds of episode. Patient has had previous episodes of syncope, but not with vaccinations. All vitals were normal when checked by EMS. Her BG was 121 mg/dl. Patient recommended to go to the hospital to get checked out but patient refused. Waited for husband to come pick her up - 5:45pm. |

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| 1047043 | 2/22/2021 | FL | 66 | F | 2/20/2021 | 2/21/2021 | At 3 a.m. on the 21st, approximately 18 hours after vaccine, got up to go to the bathroom. Felt weak and passed out on bathroom floor. |
| 1046592 | 2/22/2021 | | 94 | F | 2/18/2021 | 2/19/2021 | Per patient's daughter, the patient told her that she "passed out" while she was on the toilet the day following vaccination. States she felt weak. Per daughter the patient is doing fine now. |
| 1047618 | 2/22/2021 | MI | 44 | F | 2/20/2021 | 2/20/2021 | Mild dizziness started within 5 minutes. Within 20 minutes my tongue started to swell, but only the front to middle part, not the back part. I was still able to breathe. After 25 minutes, I was unable to stand and nearly passed out twice trying to get to some place safe. I could not verbally communicate and was lacked strength to move. I started drinking as many fluids as possible with the assistance of family. Symptoms began to subside after 3 hrs. After 4 hrs, I regained strength and was not dizzy if I stayed in place. I continued to push fluids and rested. I needed to be careful not to drink anything too cold as i would develop the chills. The next day, there was no dizziness but I was very groggy. I continued to push fluids. I would develop a headache if I did not drink at 16 oz every hour. The following day, I was still groggy, but was functional and felt okay to drive. |
| 1046514 | 2/22/2021 | SC | 73 | F | 2/3/2021 | 2/8/2021 | Admitted with syncope and began to have pancytopenia |
| 1047107 | 2/22/2021 | NY | 76 | F | 2/1/2021 | 2/16/2021 | I received my 2nd vaccine at 12:15 at the facility on Tuesday, Feb. 16. At about 10:30 that night I began to feel a bit light headed. I went to bed around 11:30 and didn't sleep very well. On Wed. am after going to the bathroom, I felt woozy while washing my hands. When I thought I felt better, I made my way back to the bedroom and passed out. I fell on my right side, bruising the right side of my face, my right hip and my right thigh. I apparently had my left hand under me when I fell because I broke the knuckle under the pinkie of my left hand. |

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| 1046637 | 2/22/2021 | OH | 68 | M | 2/16/2021 | 2/16/2021 | Felt dizzy, blurry vision, passed out, pale. Short of breath and vomited. RPh gave epinephrine which worked right away. Squad came and took to ED where he was observed for 4 hours. They did a chest xray, troponin, EKG, Lab work. Everything normal. Name of physician or treating hospital: ED- MD. Pharmacist advised not to get the 2nd dose. ED MD advised to get a 2nd dose. His MD told him to get the 2nd dose in a medical setting where he can be monitored. |
| 1046642 | 2/22/2021 | CA | 32 | F | 1/5/2021 | 1/8/2021 | Syncope, went to urgent care . |
| 1046832 | 2/22/2021 | | 27 | F | 2/22/2021 | 2/22/2021 | Near syncope, evaluated by EMS -dizzy, lightheaded. BP 128/72. Monitored for 30 minutes, symptoms resolved. Discharged home at 1:30 pm. |
| 1046970 | 2/22/2021 | WY | 81 | F | 2/19/2021 | 2/20/2021 | Nausea, vomiting, diarrhea, dizziness, fainting |
| 1047747 | 2/22/2021 | IL | 31 | F | 2/1/2021 | 2/1/2021 | Nausea Dizziness Lightheadedness Dehydration Systolic hypotension Afebrile Syncope without collapse Tachycardia Anxiety Anxiety attack Panic attack Tachypnea Pain upon palpation at site Erythema at site Swelling at site Muscle pain at site that lasted for 3 weeks Weakness that lasted for 7 hours |
| 1044319 | 2/21/2021 | MT | 65 | M | 2/19/2021 | 2/20/2021 | Fatigue, weakness; fainting; dizziness. |
| 1044114 | 2/21/2021 | NY | 22 | F | 2/19/2021 | 2/20/2021 | Fever of 102 and dehydration contributed to a syncope collapse early the morning after vaccination (7:15 AM 02/20/21). Just before collapsing, I experienced nausea, dizziness, confusion, weakness, and seeing all black in my field of vision. Emergency Room doctors say it was very likely related to an adverse reaction to the second Pfizer Covid vaccination. Treatment included Tylenol and Ibuprofen, rest, and fluids. |
| 1043956 | 2/21/2021 | PA | 80 | M | 2/11/2021 | 2/11/2021 | Systemic: Fainting / Unresponsive-Medium |

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| 1044051 | 2/21/2021 | TX | 28 | F | 2/20/2021 | 2/21/2021 | Felt tired and arm was heavy for a few hours right after then I went to bed around 11 pm and woke up at 1 am with my arm extremely itchy and swollen feeling like it does when I'm having an allergic reaction to my allergy shots (which I haven't had in two weeks) so I got up to go check it out in the bathroom and then it looked fine so I sat down to go to the bathroom then felt faint so I moved to the floor and passed out for approx 20 seconds according to my partner then came to with a giant gasp for air and then drank a sip of water and threw up and felt dizzy for a bit after that |
| 1044084 | 2/21/2021 | PA | 55 | M | 2/9/2021 | 2/10/2021 | injection site soreness, shoulder tightness increased to a shock along nerve to back of thumb within 24hrs. Arm began to pull up with pain through forearm and biceps increasing through 72 hrs. Began meloxicam again at 60 hrs. Woke up at 84hrs with severe arm pain, unable to move arm without pain. Cold sweat and nearly fainted. Pressure/pain in shoulder, biceps, elbow/forearm wrist. Called sibling who is physician and began treating shoulder with ice, tylenol and benedryl. Pain controlled to moderate through day 10 but lifting arm at shoulder or extending results in shock at back of thumb and pain through biceps and forearm. Back base of thumb completely numb. Went to urgent care facility 10 days after injection and |
| 1044238 | 2/21/2021 | GA | 68 | F | 2/14/2021 | 2/15/2021 | Patient received vaccine around 3:00 pm on 2/14/21. Around 7:00 am on 2/15/21 she went outside to walk her dogs and began to have "tunnel vision". She says she almost passed out. She proceeded to sit down on a chair nearby. Patient was feeling clammy and sweating. Husband came out to help her back into the house. He took her blood pressure reading and it was 79/50. He claims it came back up pretty quickly. Patient says she put wash cloth on face and relaxed for that half of the day. By 1:00 pm that afternoon she felt fine. |

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| 1044256 | 2/21/2021 | KY | 83 | M | 2/12/2021 | 2/20/2021 | RECEIVED 1ST DOSE OF PFIZER COVID-19 VACCINE ON 02/12/21 ON 02/20/21 REPORTED TO ED AFTER BECOMING LIGHT HEADED AND HAVING A SYNCOPAL EPISODE. REPORTED SOME SOA ON EXERTION THAT DEVELOPED EARLIER THAT DAY. ON 02/20/21 PT ADMITTED INPATIENT TO HSOPITAL WITH DIAGNOSIS OF SYNCOPE AND COLLAPSE, AOMMUNITY AQUIRED PNEUMONIA, ACUTE COLITIS, AND LEUKOCYTOSIS. |
| 1044260 | 2/21/2021 | WY | 80 | F | 2/18/2021 | 2/18/2021 | 10:30 pm same day/night -- extreme cold; dizziness; 4 fainting spells; head rush-inflamation extreme the next day and Saturday. I found myself looking up at the ceiling 4 times during the night after fainting dead away. Frightening as that has never happened to me before. It was the weekend; I was unable to reach any doctor for advice. Plus with a major snow storm we were snowed in and I couldn't get out. This was the sickest I've ever been in my life! |
| 1043906 | 2/21/2021 | CO | 52 | F | 2/15/2021 | 2/16/2021 | Woke at 1:00am with severe aches, weakness and dizzy. Fainted and vomited. Could not stand up independently to get to bathroom. *This is in addition to becoming flushed right after shot and also getting sinus headache, congestion and cough within hour of vaccine. Severe chills and aches started at 6:00pm 2/15/21 but the event at 1:00 am 2/16/21 was extreme. Felt somewhat better in morning so did not call doctor. Aches gone later on 2/16. Mild-moderate Cough and sinus congestion and some weakness/fatigue remained through today 2/20/21 - (much better this evening). |
| 1044772 | 2/21/2021 | WA | 48 | F | 2/19/2021 | 2/20/2021 | Fainting, nausea, chest pain |
| 1044078 | 2/21/2021 | ME | 35 | F | 1/13/2021 | 1/14/2021 | Syncope I was treated for a split lip, severe neck pain, pinched nerve resulting in L arm paralysis Muscle relaxers and pain killers were prescribed Arm movement returned after about 3 weeks |
| 1044434 | 2/21/2021 | AZ | 76 | F | 1/23/2021 | 1/25/2021 | Syncope 18 hours post injection, Feb 13 left eye irritation with tearing, Feb 14 mild case of Bell's Palsey right side of face, along with headache, herpes on left corner of mouth, fatigue and ?Epstein-Barr. I was exposed to the virus by my hairdresser on 2-11-21 and she developed symptoms and tested positive 4 days later |

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| 1044796 | 2/21/2021 | NY | 25 | F | 2/21/2021 | 2/21/2021 | Patient kneeled downed to the floor with no injuries, no fall. Patient then noted to become unconscious for 2 minutes (6:40pm-6:42pm) with palpable pulse and labored breathing. Patient was assisted to the floor, placed on her left side with aspiration precautions maintained. Initial vital signs at 6:44pm: BP 100/60, HR 90, O2 Sat 74%. Patient regained consciousness at 6:42pm and was verbally responsive. At 6:50pm vital signs as follows: AO x3, BP 100/70 , HR 104, O2 85%. Patient's main complaint was syncope. Continued with vital signs and monitored vital signs until EMS arrival. |
| 1044729 | 2/21/2021 | CA | 66 | F | 2/21/2021 | 2/21/2021 | Patient vaccine was part of mass vaccination event. received vaccine, initially right after injection noted palps but hr when checked by rn hr was normal. patient noted she then went to have coffeecake and coffee. 2 hours after vaccine developed throat fullness and tongue swelling. no wheeze no syncope no respiratory arrest |
| 1044848 | 2/21/2021 | TX | 72 | F | 2/20/2021 | 2/20/2021 | About 30 minutes after getting vaccine, when I was told I could go...I experienced extreme faintness. I made it to my and home, but could not get out of car after arriving. Eventually I did, but could barely move and dropped everything at my door. Could not undress because I let so faint. Then I started feeling cold. Made it to a chair and slept there about 5 hours before everything went away. I had rad all possible side-effects, but did not see feeling lightheaded and almost fainting or fainting on the list. |
| 1044720 | 2/21/2021 | ID | 64 | F | 2/18/2021 | 2/18/2021 | 2/18/21 time around 9pm, sore arm along with red rash, still remains today but better. Had this reaction 1st vaccine 1/18/21 Moderna Lot #011620A. 2/19/21 body soreness, hands hurt, general not feeling well. 2/20/21 Awake at 2:00 am fever, dizziness, unable to walk straight and passed out. Slight temp w/tingling and numbness in both arms from mid shoulder to fingertips. Vision blurred and wavy. Rested all day. Today, 2/21/21 felt better at 8:00, vision better and tingling & numbness gone in arms. Foggy head, unable to focus on numbers. Resting but having to do chores for work week tomorrow. Vision still not 100%. |

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| 1044622 | 2/21/2021 | CA | 72 | F | 1/29/2021 | 1/29/2021 | Approx 2 1/2 hours after my first vaccination I was sitting watching TV and got a very sudden and very intense metal taste in my mouth. I waited about 2 minutes to see if it would go away abd then got up to go get a drink of water to try to make the taste go away. As soon as I stood I nearly fell abd felt I was about to pass out. I told my husband I was not OK abd went a few feet out my front door to an outside chair for more air. I felt extremely lightheaded. After maybe 5 minutes the metal taste went away abd I felt a little less light headed. I went back inside abd sat again but almost instantly the metal taste came back. I sat outside until the metal taste went away again. My husband brought me water to drink. The light headed ness eased up but didn?t go away until 4 PM that afternoon. It was a terrifying feeling. I emailed my doctor mg d also called ER to see if I should go to the hospital. I had an online appointment with an ER doctor who had not heard about those side effects before abd was only interested in whether I was having trouble breathing. I was not having trouble breathing. My Dr. emailed back stating I should go for my second shot, which I have not had yet, and take Benedryl. I?m scared about having these side effects again. I nearly passed out and if the second one is worse as I?ve heard I just don?t know if I should have it. |
| 1044551 | 2/21/2021 | OR | 74 | F | 2/21/2021 | 2/21/2021 | Felt lightheaded and dizzy after injection, then fainted |
| 1044511 | 2/21/2021 | TN | 60 | F | 1/22/2021 | 1/23/2021 | Patient states the day after vaccine received she has a headache and fever of 101.9 and hot flashes, She states she was attempting to go to bed and she felt hot, dizzy and passed out and fell and hit head. She states she was checked by her PCP the following Monday with no further symptoms. |
| 1044841 | 2/21/2021 | TX | 30 | F | 2/15/2021 | 2/16/2021 | 3AM: Severe dizziness, fainted while sitting down. All day 02/16: Low energy, very tired, feeling weak. Nausea at times, low appetite. Dizzy at times. |

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| 1042757 | 2/20/2021 | IL | 59 | F | 1/13/2021 | 1/16/2021 | On January 16th I started feeling very dizzy in my eyes got blurry very dry mouth and palpitations, and I almost passed out at home, my husband had to take me to Er. They wanted to keep me in the hospital but I told him I will follow up with my doctor on Monday, I did not want to stay on the floor with covid patients the test that they had ordered at the hospital were normal they did not order a CMP they only did a basic metabolic panel and that was normal, so I followed up with my doctor on Monday which was January 18th, and she ordered CMP and all the labs, when they threw my blood my liver enzymes were very elevated over the thousands LT ASG and the and others, then the doctor ordered a second set of blood works of CMP just to make sure it wasn't a fluke, they were even more elevated they were over 1,400. |
| 1043369 | 2/20/2021 | OH | 40 | F | 2/20/2021 | 2/20/2021 | Patient felt lightheaded and had already left observation area 10 minutes earlier than her 15 minute recommended timeframe. She sat herself down due to feeling of syncope and stayed with EMS to lay down for 20-25 minutes. |
| 1042868 | 2/20/2021 | CO | 52 | M | 2/15/2021 | 2/15/2021 | Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Hypotension-Severe, Systemic: Seizure-Medium, Systemic: Shakiness-Severe, Additional Details: About 5 minutes after receiving vaccine, patient was seated in observation area and notified facility staff member who was in charge of observing patients that he felt faint. Staff member reported patient quickly turned extremely red and was showing seizure-like activity, unconscious. She alerted the pharmacists to come over I came over and patient appeared bright red, pupils extremely dilated and was not conscious, grabbed pt arm he woke up and then showed typical vasovagal symptoms thereafter. |

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| 1042873 | 2/20/2021 | IN | 19 | F | 2/19/2021 | 2/19/2021 | At 6pm on Feb 19, I was very cold no matter how many layers of clothing I put on. Around 8pm I started getting chills and a headache. Around 10pm I almost fainted going up the stairs (I turned white and felt the blood drain from my face, I got very dizzy and had to sit down with supervision). I woke up at 12:30am and had a fever of 101 F and took some acetometaphine to hopefully lower my fever. I checked my temperature again at 8:30am this morning (feb 20) and was at 99.5 F and a slight headache. |
| 1043002 | 2/20/2021 | MI | 27 | F | 2/17/2021 | 2/17/2021 | Patient passed out after given the vaccine. Onsite EMS was called they woke the up vitals BP 113/63 99% O2 room air HR 84. She responed that usually happens every medical procudure or so. She was monitored. Patient treated, Left aginst medical advice. |
| 1043134 | 2/20/2021 | MI | 53 | M | 2/4/2021 | 2/4/2021 | Patient felt Syncope / Fainting . Onsite EMS was called vitals BP 92/66 BG 80 98% O2 room air HR 68. Patient Refused Evaluation/Care, Left aginst medical advice. |
| 1043197 | 2/20/2021 | FL | 80 | F | | | Rapid heart, increases BP, fainting, heady feeling, nausea, |

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| 1043255 | 2/20/2021 | NC | 61 | F | 2/20/2021 | 2/20/2021 | <p>Patient presented for COVID vaccination today, first dose. Prior to receiving dose, she mentioned to RN that she has a history of vasovagal syncope following her shingles vaccine. She routinely has flu vaccines without any adverse reaction. RN requested I standby and observe while patient receives vaccine. Within minutes of receiving vaccine, patient endorses prodromal symptoms lightheadedness, hot flashes, then lost consciousness while seated in the chair. After approximately 1 minute, the patient did regain consciousness. She was given orange juice and crackers and felt well enough to ambulate to a chair in the observation area. Vital signs were WNL and she was monitored closely in the observing area. She continued to complain of "queasiness" often stating that she just feels that she would like to go lay down and nap in her car. Rechecked her blood pressure which dropped to 94/64, patient states she usually runs low but systolic within the low 100's. She was taken to a private hallway where she laid down on a stretcher. Blood sugar checked reading 121. She was given more water but she was uninterested in any more food, as she questions if the orange juice and the crackers were the cause of the queasiness. Blood pressure was rechecked and she was again WNL. Given her persistent fatigue and "queasiness", team lead contacted ED charge nurse to discuss case. The recommendation was to have the patient further evaluated. Discussed with team lead, and it was agreed upon that this was best course of action given her persistent symptoms. EMS was called. Per EMS report, patient's blood pressure did rise which patient attributed to excitement/anxiety surrounding the situation. Patient ultimately declined EMS transfer to ED. Her husband arrived to drive her home. Discussed the importance of monitoring symptoms for the next 48 hours. If she has any worsening "queasiness", weakness, fatigue, nausea/vomiting, throat swelling, wheezing, dyspnea then she is to call 911 immediately. Patient verbalizes understanding and is agreeable to emergency services should any of these problems occur.</p> |

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| 1043427 | 2/20/2021 | | 62 | F | 2/20/2021 | 2/20/2021 | Pt assessed after receiving COVID-19 vaccination drive thru site. She reported onset of mild lightheadedness and a non-specific "funny feeling" in her head. No vertigo or presyncope. No other new neurologic changes such as vision changes or extremity weakness. No chest pain, palpitations, dyspnea. No other signs of allergie/anaphylaxis (ie rash, throat swelling, GI side-effects). She reports hx of high blood pressure and is on one BP medication but cannot recall the name. States she took it today. Reports eating breakfast this morning. Exam notable for BP 140/85, HR 60. Pt well-appearing, no acute distress, no obvious CNS or peripheral deficits. RRR, normal s1/s2, no m/r/g. Lungs CTAB. No obvious rash or facial swelling. During course of evaluation pt reported symptoms improved but did not quite resolve. Advised pt to continue monitoring at vaccination site for additional 15 minutes. Offered juice, crackers, fluids which she declined though did drink some of her own water. Upon reassessment pt reported continued improvement though symptoms had not completely resolved. Offered to have EMS come assess pt though she declined. Warning signs/symptoms discussed with pt for when to seek out care at ED. She is in agreement. |
| 1043457 | 2/20/2021 | SC | 68 | M | 2/20/2021 | 2/20/2021 | The patient became lightheaded and pale and said he felt like he was going to pass out. He then had a syncope episode where he was unresponsive for 15 to 20 seconds and then became responsive. It took him 15 to 20 minutes to recover and regain balance to stand up and walk. He rested with his head down as he was nauseas and tired from the event. He stood up once he was able and alert. |

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| 1043515 | 2/20/2021 | OH | 68 | F | 1/15/2021 | 1/15/2021 | 14 HOURS AFTER #2 VACCINE INJECTION, STARTED WITH SUDDEN ONSET OF GENERALIZED ACHING, CHILLING, VERY TIRED JUST WANTED TO LAY DOWN AND CLOSE MY EYES. ORAL TEMPERATURE WAS 99.8F. AT 3 AM, WAS UP FOR SECOND TIME TO URINATE, ON WAY BACK TO BED FELT WEAK AND DIZZY AND PASSED OUT, UNKNOWN FOR HOW LONG. WOKE UP ON FLOOR SOAKED IN PERSPIRATION, FELT WEAK. THEN FELT LIKE I WAS GOING TO VOMIT AND HAVE A STOOL., CRAWLED TO BATHROOM. IT WAS ALL I COULD DO TO PULL MYSELF UP TO COMMODE(I LIVE ALONE). HAD ONE LOOSE STOOL, NO VOMITTING BUT DRY HEAVES X5. THEN JUST LAID ON FLOOR AT BATHROOM, WAS COLD BUT TOO TIRED TO CRAWL OVER TO BED TO PULL DOWN BLANKET. SLEPT ON FLOOR, WOKE UP 4 TIMES AND JUST ROLLED OVER FELT VERY SLEEPY AND COLD. WOKE UP 7AM, FELT MORE NORMAL AND BY NOON SEEMED NORMAL. |
| 1043621 | 2/20/2021 | WA | 24 | F | 2/19/2021 | 2/20/2021 | felt fine minus some soreness at injection site until 2:30am the following day. woke up to take my dog out to potty and after getting outside became light headed. made my way back into the house and then fainted and was too weak to get back up. had to have boyfriend come help walk me back to bed. slight weakness, minor headache, and fever since then. |
| 1043714 | 2/20/2021 | OH | 19 | F | 2/19/2021 | 2/20/2021 | Pt fainted at work twice |
| 1043756 | 2/20/2021 | CO | 43 | F | 2/19/2021 | 2/19/2021 | Syncope lasting 45 seconds with accompanying nausea and dizziness that occurred 1 and 1/2 hours post vaccine. Required ambulance from restaurant to hospital. Discharged after 2 hours. Mild nausea and dizziness remain 24 hours post vaccination. |
| 1043782 | 2/20/2021 | CA | 71 | F | 2/1/2021 | 2/20/2021 | Morning after I had 2nd shot I felt woosy and passed out on kitchen floor. Called 911 and went to ER. They said I was 4th person they'd seen who passed out |

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| 1043339 | 2/20/2021 | TN | 30 | F | 2/18/2021 | 2/18/2021 | Fever of 102. Extreme fatigue. Headache. Feeling faint (nearly passed out multiple times). Chills. Body aches. Headache /overall bad feeling began about 30 min after shot. Continued to get worse. Following day, could not work or care for myself. Currently on the 3rd day and still have headache. |
| 1043273 | 2/20/2021 | CA | 72 | F | 2/15/2021 | 2/16/2021 | Tuesday am: I woke up the next morning after the shot, feeling fine. I went to have my hair done around 10am and then by 11am it hit me hard. It began with vomiting and then I passed out. The next thing I recall I was on my home couch around 8pm feeling very weak. I'm told my husband came to get me.- It wasn't until today, Saturday, that I am starting to feel somewhat better. Still a little weak, but able to take of myself. |
| 1041285 | 2/19/2021 | TN | 34 | F | 1/4/2021 | 1/11/2021 | I was shadowing another interpreter on Jan. 11, 2021 and started to feel warm, nausea. I sat down and the PA asked if I was ok and then I don't remember anything. I then fainted and my Heart rate was 30 and they called a code blue. They took me to the ER and ran test and gave me IV and everything came back normal. After that incident, there was at least two other times I had to sit down because I was getting all the same symptoms again and thought it would happen again. I did donate blood on January 8. I was feeling fine when prior and the following two days. |

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| 1041235 | 2/19/2021 | MI | 77 | M | 2/11/2021 | 2/12/2021 | <p>Patient reports at least two falls following COVID vaccine. Requiring assistance to stand up. Legs reported as "giving out" resulting in falls. Reports being shaking within 24 hours following vaccination. Reports extreme weakness and needing to be lowered to the floor at least twice. This is new for him. Did not report feeling dizzy; blood sugar was reported as normal during the time. No confusion or feeling out of it reported at the time. Ended up with abrasions. Patient has been having bilateral leg weakness since Friday evening, patient had Covid-19 vaccine on Thursday. Wife called Sunday at 0130 after 2nd episode of leg weakness and fall (see previous note). His first fall was Friday evening around 2030. Saturday his wife reports that he was walking on his own without his walker but did have complaints of fatigue and decreased appetite, which she attributed to his Covid-19 vaccine. Sunday morning at 0130 was his second fall, an ambulance was called and patient refused ED after being assisted by EMS. Patient did not have any dizziness or syncope, just states that his legs were too weak and gave out. Wife states that patient has improved today, is using his walker and walking without difficulty. Yesterday she states that she pushed food and fluids due to decreased urine output. Urine output has returned to normal last night and today, appetite and fatigue have also improved. Assessment 1. Fall from standing, initial encounter 2. Multiple abrasions 3. Adverse effect of vaccine, initial encounter 4. Generalized weakness PT EVAL AND TREAT 5. Decreased strength, endurance, and mobility PT EVAL AND TREAT I suspect his falls and weakness are due to Covid-19 vaccine reaction. I think he has more baseline weakness than he realizes- recommended PHYSICAL THERAPY for strengthening and he agrees- already planning to see them for shoulder pain. Feeling better overall today. Recommended getting up every 2 hours to walk around, use walker for now. Call if more falls or continued extreme weakness.</p> |

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| 1041106 | 2/19/2021 | AR | 54 | F | 2/12/2021 | 2/13/2021 | Saturday morning passed out twice, stayed in bed and slept most of the day to avoid hitting my head again from passing out; Saturday night around 11:30 pm woke up having difficulty breathing-my airway was swollen-took 50 mg of benadryl every 3-4 hours until Monday morning; I was only able to move my left arm about 2 inches away from my body Saturday and Sunday; Monday morning I woke to a bottom swollen lip (felt like the size of a truck); no new reactions the remaining part of the week; my throat was extremely tender as well as my lip |
| 1040748 | 2/19/2021 | WI | 87 | F | 1/29/2021 | 1/30/2021 | Patient reported dizziness and a fainting episode the morning after her immunization. She knew she was getting dizzy and she attempted to get into her recliner, but fell into her recliner and injured her rib and possibly her 'tailbone'. She went to the Emergency Department where she was examined and scans were taken of her ribs. She was determined to have 'bruised' ribs and sent home with advice to take ibuprofen and acetaminophen alternately every 4 hours for pain relief. She has been at home since this episode. We only found out about this adverse event this week when we called her to confirm her second immunization. She reported this fall to us and was reluctant to get the second shot. I reported the event to her provider, and now to you at VAERS. |
| 1040728 | 2/19/2021 | NJ | 31 | F | 2/15/2021 | 2/16/2021 | Syncopal episode with head injury, concussion, chin laceration. At 4AM when walking back from the bathroom, suddenly syncopized with head strike on the floor. Subsequently required 6 stitches in the emergency room for her chin. Required CT head/neck and MRI head as well as she was confused and had amnesia. |

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| 1040673 | 2/19/2021 | OH | 79 | F | 1/28/2021 | 1/28/2021 | laid on the floor and does not know if passed out on the floor or fell asleep (thinks could not have fallen asleep with such a pain); horrible pain on left side (side of the injection); awful pain on left leg; could not raise leg; congestion in head, like a sinus infection; tiredness/fatigue; Headache; Chills; A spontaneous report was received from a consumer, a 79-year-old female patient, who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced laid on the floor and does not know if passed out on the floor or fell asleep (thinks could not have fallen asleep with such a pain), horrible pain on left side (side of the injection), headache, chills, tiredness/fatigue, awful pain in leg, could not raise leg, and congestion in head, like a sinus infection. The patient's medical history was not provided. Her allergies included sulfa, mycin, meloxicam and glycopyrrolate. Concomitant medications included blood pressure medication (name not reported). On 28 Jan 2021, approximately one day prior to the onset of events, the patient received her first of two planned doses of mRNA-1273 (Batch number: 028L20A) on the left side (anatomical location not reported) for prophylaxis of COVID-19 infection. On 28 Jan 2021, on the night of the vaccination, the patient woke up with a horrible pain on her left side (side of the injection), headache, chills, fatigue/tiredness, an awful pain on her leg, and congestion in her head, like a sinus infection. She got up thinking that walking would make the pain on her leg go away, but it did not. When the patient tried to go back to bed, she could not raise her leg so she laid on the floor and she did not know if she passed out on the floor or fell asleep (she thought she could not have fallen asleep with such pain). When the patient woke up, she could move her leg normally. Treatment information was not provided. Action taken in response to the events was unknown. The events, laid on the floor and does not know if passed out on the floor or fell asleep (thinks could not have fallen asleep with such a pain), horrible pain on left side (side of the injection), headache, chills, awful pain in leg, could not raise leg, and congestion in head, like a sinus infection were considered resolved on 29 Jan 2021. The event, fatigue/tiredness was considered not recovered/not resolved.; Reporter's Comments: This case concerns a 79 year old female subject, who experienced a serious unexpected event of loss of |

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| 1040613 | 2/19/2021 | CA | 30 | F | 1/26/2021 | 1/26/2021 | consciousness after first dose of mRNA1273 (Lot# 028L20A). Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Further information has been requested. |
| | | | | | | | She is a nurse and received her vaccine outside at the Vaccine Site. She had an immediate reaction to her first dose of the Pfizer Covid vaccine with acute hives within 15 minutes on 12/26. She had hives on her neck, arms chest, headache arm pain and mild dizziness. Symptoms resolved with Benadryl. She received her second dose of the Covid vaccine 12/26 with immediate symptoms within 30 minutes of respiratory symptoms, shortness of breath, hives, dizziness, fainting with treatment of epinephrine on site at the Vaccine Site by ambulance to the ER. She reports she was hypoxic with O2 sat 70 to 75%. Went to hospital and received 3 doses of epinephrine, IV Benadryl, IV fluids, Pepcid, and 7 days of prednisone. 1/26: c/o chest tightness had video visit with primarily MD, continued diphenhydramine and refer to allergy. She does have a history of vaccine reaction in the past to Gardasiln (contains polysorbate 80) given at age 16 with delayed hives 24 hours later. Allergist assessment: Covid vaccine 19 mRNA anaphylaxis with 2nd dose and acute hives with 1st dose of Pfizer vaccine S/p repeated doses of epipen With ongoing asthma, dizziness, light headed , nausea and fast heart rate 1.5 weeks after anaphylaxis but normotensive With prior history of delayed hives with gardisil --may be sensitive to polysorbate 80 in both vaccines. Added COVID vaccine to allergy list |

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| 1040554 | 2/19/2021 | PA | 16 | F | 2/2/2021 | 2/3/2021 | Went to sit down and passed out; felt dizzy; nauseous/nausia; sweaty; sick feeling; as she was ghost white; bad headache.; This is a spontaneous report from a contactable other Health Professional reported for herself. A 16-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN5318) via intramuscular on left arm on 02Feb2021 03:45 PM, at age of 16 years old at single dose for Covid-19 immunization. Patient was not pregnant at the time of vaccination. Medical history reported as allergies to medications, food, or other products was reported as none known. Prior to vaccination, patient was not diagnosed with COVID-19. Other medications the patient received within 2 weeks of vaccination included multivitamin and melatonin gummies. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL3248), via intramuscular at left arm on 12Jan2021 03:45 PM for Covid-19 immunization. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. It was reported morning after vaccine 03Feb2021 08:00 patient was felt dizzy and nauseous. Told her mom and her mom ran over as she was ghost white. Went to sit down and passed out. Patient experienced sweaty, nausea, sick feeling and bad headache. Patient went to the emergency room (ER), they gave fluids and blood work. No heart issues noted. Felt better around 3 hours after. Headache was bad and continued on 05Feb2021 (reported today). Also, still feel nauseous and had to lay down. All events occurred on 03Feb2021 08:00 AM. Patient was recovering. It was reported the adverse event result in emergency room/department or urgent care. The seriousness criteria were reported as not serious, no results in death, no life threatening, no caused/prolonged hospitalization, no disabling/incapacitating, no congenital anomaly/birth defect. Patient was received treatment for the adverse event included fluids and heart monitoring. The patient underwent lab tests and procedures which included blood work in Feb2021. Since the vaccination, patient had not been tested for COVID-19. Outcome of events bad headache and nauseous was not recovered, for felt dizzy, as she was ghost white, passed out, sweaty, sick feeling was recovering.; Sender's Comments: Based on the information provided and |

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plausible temporal association, a contributory of the suspect drug to the reported events cannot be completely excluded. Case will be reassessed when additional information is available. The impact of this report on the benefit/risk profile of the Pfizer drug is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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| 1040532 | 2/19/2021 | | | U | 1/28/2021 | 1/29/2021 | <p>Passed out and was unconscious for approximately 5 minutes; Nausea; Tightening or squeezing sensation of my chest; Tired; Vasovagal event; A spontaneous report was received from a healthcare professional who is the patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced tightening or squeezing sensation in my chest, passed out, unconscious for approximately 5 minutes, nausea, vasovagal event and tired. The patient's medical history was not provided. No concomitant product use was reported. On 28 Jan 2021, the patient received their second of two planned doses of mRNA-1273 (Lot number: not provided) for prophylaxis of COVID-19 infection. On 29 Jan 2021, at 01:30, the patient reported they started to feel a tightening or squeezing sensation in their chest. On 29 Jan 2021 at 02:30, the patient's symptoms worsened, they reported increased chest tightening and were nauseated. The patient went into their bathroom and "I passed out and ended up on the floor". The patient reported they were unconscious for approximately 5 minutes. The patient's wife called 911 due to chest pains and to rule out a mild heart attack. The patient stated, "all tests came back negative". The patient stated they had a vasovagal event while in the hospital with a blood pressure reading of 77/40. Patient feeling better now, but still tired". Treatment information was not provided. Action taken with mRNA-1273 in response to the events was not provided. The outcome of the events, tightening or squeezing sensation in my chest, passed out, unconscious for approximately 5 minutes, nausea, vasovagal event and tired, were considered unknown.; Reporter's Comments: This spontaneous report from a healthcare professional of unknown gender who experienced the serious events of unconscious, passed out and tightening or squeezing sensation in my chest and non-serious events of nausea, vasovagal event and tired. The events occurred 1 day after the administration of mRNA-1273 vaccine (Lot number: unknown, expiration date: unknown). Treatment given was not provided and outcome is resolved. Based on the information provided which shows a temporal association a causal association, between the reported events and the administration of mRNA-1273 vaccine cannot be excluded. The events of nausea and fatigue are consistent with the known safety profile of mRNA -1273</p> |

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| 1041411 | 2/19/2021 | MD | 60 | F | 2/1/2021 | 2/1/2021 | vaccine. day 1- shivering and cold, muscle aches day 2 loss of appetite, malaise, syncope episode with loss of consciousness |
| 1040533 | 2/19/2021 | CA | 72 | M | 1/24/2021 | 1/25/2021 | <p>Syncope; Diarrhea; Low pressure; Flu-like symptoms; A regulatory report was received from a consumer concerning a 72-years-old, male patient who received Moderna's COVID-19 Vaccine, and who experienced flu-like symptoms, head went back, eyes went white, jaw move left to right, made a last breath, thought he died, diarrhea and low pressure. The patient's medical history included high blood pressure. Products known to have been used by the patient, within two weeks prior to the event, included Metoprolol succinate. On 24 Jan 2021, approximately one day prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 (042L20A) intramuscularly in the right arm for prophylaxis of COVID-19 infection. On 25 Jan 2021, the patient reported flu-like symptoms. Treatment information was not provided. On 26 Jan 2021, the patient reported head went back, eyes went white, jaw move left to right, made a last breath, thought he died, diarrhea and low pressure. Treatment information was not provided. Action taken with mRNA-1273 in response to the events was unknown. The event, flu-like symptoms was considered recovered/resolved on 25 Jan 2021. The events, head went back, eyes went white, jaw move left to right, made a last breath, thought he died, and diarrhea was considered recovered/resolved on 26 Jan 2021. The outcome of the event low pressure was unknown.;</p> <p>Reporter's Comments: This case concerns a 72 year old male with medical history of hypertension on metoprolol, who experienced a serious unexpected event of syncope and non-serious unexpected events of flu-like symptoms, diarrhea, and low blood pressure. Event onset was 1 day after first dose of mRNA-1273. Flu-like symptoms resolved. Based on the current available information and temporal association between the use of mRNA-1273 and the start date of the events, a causal relationship cannot be excluded.</p> |

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| 1042412 | 2/19/2021 | FL | 83 | F | 2/5/2021 | 2/7/2021 | Days 3, 4, 5, 6: Inability to move head in any direction (up/down or L/R) without SEVERE pain. Neck unable to support head unless directly above shoulders. Leaning forward slightly to sit or stand up caused unbearable pain. Unable to lift head from pillow to roll over. Could only swallow food, if neck muscles held tightly with hand to prevent movement. Severe pain caused Vasovagal syndrome fainting. Asymptomatic fever 99.7-100.5 for Days 3, 4, 5. No chills, weakness or aching. Day 7: In A.M., slightly increased head movement possible for first time without pain. By P.M. even better, but still only very limited movement of a few inches possible. Improved daily thereafter. Day 15 (today): Mild stiff neck persists. |
| 1041454 | 2/19/2021 | | 22 | F | 2/7/2021 | 2/5/2021 | 2 days after vaccine, she fainted and later contacted her PCP. Patient may have been dehydrated with headaches after vaccine. Advised to seek medical assistance for ongoing issues. |
| 1041158 | 2/19/2021 | MI | 74 | F | 2/2/2021 | 2/2/2021 | Patient Syncope / Fainting unknown cause . Onsite EMS was called vitals were taken BP 132/90 HR 88. Patient refused evaluation/care. Left against medical advice. |
| 1042568 | 2/19/2021 | OH | 21 | F | 2/19/2021 | 2/19/2021 | Pt experienced a brief syncopal episode about 5 minutes after receiving vaccine. No other symptoms reported and episode quickly resolved. Pt stated that she has experienced syncope previously when getting a vaccine. |
| 1042382 | 2/19/2021 | CO | 56 | F | 2/17/2021 | 2/18/2021 | I woke up nauseous, when I stood up extremely nauseous. Went to feed dog and passed out without warning and woke up to my head slamming on floor. Stood up and immediately passed out again, again waking up to my head slamming on floor. Got a bunch of bumps and bruises on head but hurt my neck also. |
| 1042374 | 2/19/2021 | CA | 44 | F | 1/30/2021 | 1/31/2021 | Vasovagal syncope after getting up to urinate, hit head with loss of consciousness for 10-15 minutes, sustained concussion, admitted overnight for testing and observation. |
| 1041970 | 2/19/2021 | TX | 55 | M | 2/12/2021 | 2/16/2021 | vision skewed, balance off, speech slurred, syncope, |

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| 1041816 | 2/19/2021 | ID | 22 | F | 1/21/2021 | 1/22/2021 | I was vaccinated at 4PM on Thursday and the pain in my left arm was so severe the morning following (around 6AM) that I fainted on my bathroom floor. I was lightheaded and nauseous for the remainder of the day. I know pain is a typical side effect, but this was unusually intense pain and I felt I should report it. I quite literally felt delirious after coming-to on the floor. |
| 1041685 | 2/19/2021 | TX | 39 | F | 2/12/2021 | 2/13/2021 | Around midnight on 2/13/21, about 10 hours after pt received her second COVID19 vaccine, pt fainted and was found unconscious by her husband on the floor; pt regained consciousness and had cold sweats/nausea; out of precaution, pt went to the ER; per pt, she's had hx of fainting but it was a long time ago. At the ER, pt's BP was low at 90/56, and pulse was 85 which was usually in the 60s. Pt received NS and BP went back up to 113/70 |
| 1042703 | 2/19/2021 | AL | 41 | M | 2/18/2021 | 2/19/2021 | Woke up to use the restroom. Passed out and fell multiple (~5) times while trying to return to bed. I have never experienced that before. |
| 1041916 | 2/19/2021 | TX | 55 | M | 1/26/2021 | 1/31/2021 | syncope, headache, slurred speech 2 days |
| 1041477 | 2/19/2021 | FL | 28 | F | 2/17/2021 | 2/18/2021 | Pfizer-BioNTech COVID-19 Vaccine EUA injected into left arm at 10:15 am on 17 Feb. Soreness at the injection site was the only symptom immediately following the injection. At about 3:00 am the next morning, I experienced extreme nausea and chills. I fainted when I tried to get out of bed to go to the restroom. All of 18 Feb, I experienced the following symptoms: headache/migraine, fatigue, dizziness, loss of appetite, muscle aches/soreness, fever, and severe pain in my left arm. As of today, 19 Feb, I am experiencing headache, lightheadedness, and mild pain my left arm. |
| 1042578 | 2/19/2021 | NY | 37 | F | 2/18/2021 | 2/19/2021 | After 12 hours, extreme shakes and shivers, hot and cold, fainted and possible seizure for approximately 30-45 seconds- could not move or speak- was unresponsive and panting- cognitively aware but unresponsive. |

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| 1038763 | 2/18/2021 | FL | 66 | M | 2/18/2021 | 2/18/2021 | Patient became pale and felt faint while sitting in the observation area after receiving the vaccination. He was alert and talking but quickly reported the need to lay on the floor with dizziness and faintness. The patient began feeling better after laying down and wanted to then sit in the chair again. After sitting up a second time the patient fainted in the chair and was guided to the ground where he became alert again and waited until the medics arrived. After some time with the medics the patient began feeling better and declined to be taken for further medical treatment. |
| 1038488 | 2/18/2021 | WI | 60 | F | 2/12/2021 | 2/13/2021 | This 60 y.o. female with past medical history of CLL in clinical remission and depression was admitted to the hospital yesterday for observation after she had a syncopal episode during the night after her 2nd Moderna vaccination. Patient reported that she got her vaccine on 2/12 at 8am and by that night she was experiencing chills and nausea. She then went to get up in the middle of the night as she felt she needed to vomit and became lightheaded with syncope. |
| 1038493 | 2/18/2021 | NY | 84 | F | 2/11/2021 | 2/12/2021 | The morning after vaccination, she felt extremely and unusually fatigued. After getting up from bed and eating her usual breakfast, she was returning to her bedroom when she became dizzy and fainted, falling to the floor, hitting her head and suffering other effects, including rhabdomyolysis from being on the floor for a long time after the fall as she was unable to get up. She was transported to the ER and was admitted to the hospital for 3 days. She was treated with IV fluids, Tylenol and a short course of antibiotics. While hospitalized, she had a repeat of a rash/swelling at injection site that began about 48 hours after vaccination. The hospital treated the rash with some barrier cream and within 48, the redness, rash and swelling abated. |

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| 1038532 | 2/18/2021 | NC | 65 | M | 2/12/2021 | 2/14/2021 | Immediately after finishing a lunch meal on 2-14-21, I blacked out, without warning, and fell from my chair to the floor. I remained unconscious for approximately 30 seconds. My blood pressure reading was 136/82 approximately 10 minutes after the incident. This apparent vagal syncope was the first I have experienced. Had I been operating a motor vehicle, I would have crashed the vehicle as the blackout was instantaneous. I visited my PCP on 2-17-21. He checked my blood pressure and performed an EKG and both were normal. He has requested appointments with a cardiologist and a neurologist. |
| 1038571 | 2/18/2021 | ME | 24 | M | 2/18/2021 | 2/18/2021 | 5 minutes post injection patient became pale and unresponsive. lowered to floor, sternal chest rub, legs raised ice pack applied to neck. vitals signs done, patient aroused within 1 minute, assisted to sitting position. denied lightheadedness apple juice given continuously monitored, 15 minutes patient became diaphoretic and unconscious, lowered to floor again, sternal chest rub, patient regained consciousness, EMT notified ambulance on scene @0938, EMS resumed care, vitals signs, blood sugar done. Patient returned to baseline, refused transport to ED for further evaluation. Patient reported history of fainting after discussing medical history. Blood sugar 141 orthostatic vital signs done by EMS full assessment completed by EMS patient returned to baseline and allowed to discharge to home. |
| 1038728 | 2/18/2021 | CO | 23 | M | 2/18/2021 | 2/18/2021 | NEAR SYNCOPE, DIAPHORETIC, VOMITING, BRADYCARIA |
| 1038483 | 2/18/2021 | FL | 35 | M | 2/18/2021 | 2/18/2021 | Patient advised us of history of syncope after injections. We monitored closely after vaccination. Patient was fine for first several minutes, then began to feel lightheaded and nauseous. He never lost consciousness, but did vomit a small amount. Patient was monitored for approximately 30 minutes, felt recovered, and left with wife. Smelling salts were kept close at hand, but not needed. |

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| 1038029 | 2/18/2021 | IN | 55 | F | 1/5/2021 | 1/6/2021 | <p>FAINTED; vision impairment (blackout); DIZZINESS; spinning; NAUSEA; VOMITED; over heating; chills; FATIGUE; CHILLS; over heating; A spontaneous report was received from a consumer concerning a female 55 years-old, female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced fainted, vision impairment (blackout), spinning, chills, fever, fatigue, nausea, dizziness, and vomited. The patient's medical history was not provided. Concomitant product use was not provided by the reporter. The patient received their first of two planned doses of mRNA-1273 (Lot # 026L20A), intramuscularly (IM) (site not provided), on 05 Jan 2021. On 02-Feb-2021, the patient received their second of two planned doses of mRNA-1273 (lot #013M20A), IM (site not provided) for prophylaxis of COVID-19 infection. On 05 Jan 2021, the patient received their first Moderna vaccine. On 06 Jan 2021, patient experienced chills and overheating. On 02 Feb 2021 the patient received second dose of Moderna vaccine and experienced chills and fatigue on same day. On 03 Feb 2021, the patient experienced overheating, nausea and vomited, dizziness, spinning, vision impairment (blackout), and fainted. Treatment was not administered. The patient received both scheduled doses of mRNA-1273 prior to the events; therefore, action taken with the drug in response to the events is not applicable. Action taken with second dose of mRNA-1273 in response to the event was not provided. The outcome of all events was unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Further information has been requested. Chills, Pyrexia, nausea, vomiting and fatigue are listed events.</p> |

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| 1039228 | 2/18/2021 | CA | 78 | F | 2/6/2021 | 2/9/2021 | I had a room spinning dizzy spell on the 3rd day after the shot but didn't think too much of it after it passed. The 4th day I remember thinking I felt dizzy again, and the next thing I knew I was on the floor and hit my head really hard. I think I must have passed out for a nano second. (The first time in my life!) On the 8th day, Feb. 14th, I got a rash on the injection site. It was red, swollen, hot and shaped like a square about 2 inches diameter. I haven't had an event since. |
| 1038681 | 2/18/2021 | MN | 64 | F | 2/11/2021 | 2/11/2021 | Patient stated she "fainted when receiving vaccines." Received vaccine and walked to waiting area. Sat down and became faint at 8:45 am O2 sat 99%; BP 100/80; P 88. Laid down and was diaphoretic and clammy. Cool compress applied to forehead and back of neck. Drank juice and had some water. Patient . Stated she felt much better. 8:55 am walked to chair. BP 11/79 P 88. Stated she was fine. Left waiting area on her own at 9:00 am. |
| 1038429 | 2/18/2021 | MN | 21 | F | 2/11/2021 | 2/11/2021 | Patient stated she "fainted when receiving vaccines." Received vaccine and walked to waiting area. Sat down and became faint at 8:45 am O2 sat 99%; BP 100/80; P 88. Laid down and was diaphoretic and clammy. Cool compress applied to forehead and back of neck. Drank juice and had some water. Patient at u. Stated she felt much better. 8:55 am walked to chair. BP 11/79 P 88. Stated she was fine. Left waiting area on her own at 9:00 am. |

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| 1038368 | 2/18/2021 | MD | 45 | F | 2/14/2021 | 2/14/2021 | Got at the mass vaccination site, is a drive through site. Husband was driving. Pt herself was in passenger seat Reports she had her first covid vaccine 2/14/21 (pfizer) around 10:30am Placed in left upper arm about 10 min after the injection + pain at the site, and then felt tight in shoulder Then became nausea and her husband woke her up; and was about 15 seconds per her husbands report No seizure activity No rashes No throat swelling No swelling No n/v The vaccine staff then came over to her parked car Took her BP and reports was low, cannot recall how low Was starting to feel okay when the vaccine staff came over, reports was a national guard MD, who said he advised an epi pen due to her reaction, then to call 911. And then was given epinephrine and then called the ambulance Pt was feeling better when the EMT arrived, and was taken into the ambulance, she declined the ER Went home, husband drove home, and she rested on the couch the rest of the afternoon Has been feeling fine every since Feels well, eating drinking like normal, no syncope, no rash, no changes to skin, no arm pain |
| 1038343 | 2/18/2021 | NC | 69 | M | 2/17/2021 | 2/18/2021 | Extreme dizziness during the night, weakness and headache (took Tylenol 650 MG for headache). Around 6 AM got out of bed to use toilet. Wife heard a loud crash and found me in bathtub. I don't recall falling but shower curtain fell down and have minor neck and back discomfort at this time. Wife assisted me to crawl out of tub and she reported I "passed out" two more times for short durations as I crawled back into bed. Had profuse cold sweating episode for about 15 minutes. Much less weakness now at 10 am, no dizziness but still a mild headache. |

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| 1038258 | 2/18/2021 | NC | | F | 1/28/2021 | | Woke up on the floor, not sure if passed out or was unconscious; Cramps in hand; Hands shook; Dry heaving; Voice kind of changed; Urine was very bright; Chills; A spontaneous report was received from a female (age unknown) consumer who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced cramps in hand, hands shook/shaking of hands, dry heaving/dry heaves, voice kind of changed/distorted voice, urine was very bright/urine color abnormal, chills and woke up on the floor, not sure if passed out or unconscious. The patient's medical history was not reported. No relevant concomitant medications were reported. On 28 Jan 2021 prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On unknown date, patient started to experience cramps in hand, shaking of hands, dry heaving, voice kind of changed, urine was very bright, chills and woke up on the floor, not sure if passed out or unconscious. Treatment for the events were not provided. Action taken with the second dose of mRNA-1273 in response to the event was not reported. The outcome for the events, cramps in hand, hands shook/shaking of hands, dry heaving/dry heaves, voice kind of changed/distorted voice, urine was very bright/urine color abnormal, chills and woke up on the floor, not sure if passed out or unconscious was Unknown.; Reporter's Comments: The events developed after first dose of mRNA-1372. Very limited information regarding this events has been provided at this time. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |
| 1038229 | 2/18/2021 | NY | 75 | M | 2/16/2021 | 2/17/2021 | 26 hours after receiving the injection, I became very nauseous and had diarrhea. At one time I passed out and when I woke up I was covered in feces and vomit. The symptoms remained until about 3:00 a.m. on the 18th of this month. Today, the 18th, the vomiting and diarrhea subsided; but I remain very weak; and I have no appetite. |

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| 1038035 | 2/18/2021 | FL | | M | 2/1/2021 | 2/1/2021 | blacked out, passed out; could not move any part of the body; hard time breathing; sweating; A spontaneous report was received regarding a 73-year-old male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced sweating, blacking out, passing out, inability to move any part of his body. The patient's medical history was not provided. Concomitant medications were not provided. On 01 Feb 2021, prior to the onset of the events, the patient received one of two planned doses of mRNA-1273 (Lot number: 007M20A) intramuscularly for prophylaxis of COVID-19 infection. The injection took place in his car in a drive-in vaccination location. On 01 Feb 2021, approximately four minutes after the mRNA-1273 vaccine was given, the patient experienced sweating, blacking out, passing out, inability to move any part of his body. The patient reports that when he woke up he was out of his car on the grass and the emergency crew was working on him. They had given him a shot of an Epi-Pen. He had a hard time breathing and could not move any part of his body. He was placed in a wheelchair and taken into the emergency room. There, an EKG was done which had normal results. He was released from the emergency room approximately two hours later. Action taken with mRNA-1273 was not reported. The outcome of the events, sweating, blacking out, passing out, inability to move any part of his body, was considered resolved on 01 Feb 2021.; Reporter's Comments: Based on the current available information which indicates a strong temporal association between the use of the product and the onset of the reported events a causal relationship cannot be excluded |
| 1039245 | 2/18/2021 | HI | | 46 F | 2/3/2021 | 2/3/2021 | After receiving first dose of COVID-19 vaccine patient began experiencing jaw numbness on both sides and numbness of the arm. Was brought into ED where she denied any slurred speech, headache, chest pain, or shortness of breath. Denied any hives or itchiness, dizziness, or syncope. Blood pressure in the ED was 186/99 30 minutes after shot. |

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| 1037861 | 2/18/2021 | IL | 47 | M | 1/20/2021 | 1/23/2021 | I was dizzy all along and almost fainted; I was dizzy all along and almost fainted; migraine; This is a spontaneous report from a contactable consumer (patient). This 47-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose on 20Jan2021 for COVID-19 immunization. Medical history included sleep apnea; high blood pressure; high cholesterol; borderline diabetes. Concomitant medications included losartan; alirocumab (PRALUENT, injection) on 20Jan2021. Since 23Jan2021, patient was dizzy all along and almost fainted and was still having symptoms of mild migraine and he don't know like some light sensitivity. Doctor believed it was from vaccine. Patient was wondering how long was this going to be last as he had second shot coming out. He didn't think it was an adverse reaction and he thought he should get the second shot. But this was continuing to me and it had already been two weeks and patient still having symptoms of mild migraine. Patient was worried about taking the second shot as a result. He had never had a migraine before and was told it was probably from the vaccine and that was not something he wanted to hear. Patient wanted to know if this was normal to still be having this side effect for this long. Patient was taking acetaminophen (for migraine), it was not a TYLENOL, it was from a different brand. Patient did liver and cholesterol test and blood test in Jan2021 at Cardiologist and they came back fine, nothing was found there. The outcome of event migraine was not resolved. The outcome of rest events was unknown. Information on the lot/batch number has been requested. |

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| 1037842 | 2/18/2021 | FL | 79 | F | 1/22/2021 | 1/27/2021 | <p>may have had a mini stroke; Bell's Palsy/developed facial drooping/her eye was drooping; fell; This is a spontaneous report from a contactable consumer (patient). A 79-years-old female patient received bnt162b2 (BNT162B2, Pfizer COVID-19 Vaccine; Batch/lot number: EL9262), via an unspecified route of administration injection to right upper arm on 22Jan2021 14:00 at SINGLE DOSE for covid-19 immunisation. Medical history included ongoing she was a fainter (She was a fainter, she just faints so she has a hard time getting shots. Pfizer COVID-19 Vaccine administered to her by nurse while she was in her car seat. She just asked the nurse to let her lay down in the car seat when injection was administered so that if she fainted she would not fall far; she was still getting the wash cloth on her head preparing when the Nurse had already finished administering the injection.); ongoing depressed sometimes (she was depressed sometimes, was stressed. She was the primary caregiver for her 96 year old mother. She had seen something about stress and COVID and shots and everything); ongoing Very tired (She was almost 80 years old so she was very tired often. She was the primary caregiver for her 96 year old mother. By the time she comes home at night around 21:30 she was just wiped.); Obesity (She was really overweight but she did not like the term obesity.); thyroid disorder; hypertension; Cataract and glaucoma in left eye; family history of ongoing facial paralysis (Dad had Bell's palsy that might have been 30 years ago. He died at age 87 years.); diagnosed allergies, compromised immune status, respiratory illness, genetic / chromosomal abnormalities, endocrine abnormalities (including diabetes). Concomitant medication included Levothyroxine at 100mcg taken once daily in the morning early before she eats with Start date unknown, but at least 10-15 years ago for Thyroid. Enalapril at 10mg taken once daily (Caller initially reported product name as Vasotec, but clarified it is not Vasotec, it is drop for eye cataract and glaucoma) for High blood pressure. Brimonidine with Strength unknown, 1 drop in both eyes twice daily, started maybe 1 year ago. Specified cataract and glaucoma in left eye; but drop was administered to both eyes; and left eye was eye affected by Bell's palsy for Cataract and glaucoma in left eye. The patient previously took codeine and experienced allergy with</p> |

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onset maybe about 50 years ago, she was not sure; occurred during dental procedure; had bad headaches but no lasting effects so they assumed allergy to codeine; she did not know if still has allergy but says she does if asked. The patient experienced bell's palsy/developed facial drooping/her eye was drooping on 29Jan2021 with outcome of recovering, may have had a mini stroke on an unspecified date with outcome of unknown , fell on 27Jan2021 with outcome of unknown (reported date of end of reaction was 27Jan2021), she could not blink that eye on 29Jan2021 with outcome of not recovered. Five days later she fell and developed facial drooping. HCP suggested she may have had a mini stroke causing facial drooping and the fall. She went to the ER on 29Jan2021 and the ER believed it was Bell's Palsy. She was still experiencing facial symptoms but they are improving. This consumer was administered her first dose of Pfizer COVID-19 Vaccine 22Jan2021. She reported having fell 27Jan2021. She was diagnosed with Bell's palsy in 29Jan2021 after having been seen in the emergency room. She is supposed to have the second dose/booster of Pfizer COVID-19 Vaccine on 12Feb2021. She called to ask if she should or should not still get the second dose as scheduled; and if Bell's palsy could be a reaction to the Pfizer COVID-19 Vaccine. The emergency room staff did not know how she got Bell's palsy, but knew she had the Pfizer COVID-19 Vaccine and were kind of assuming the Bell's palsy was a reaction to the vaccine. She does not have Bell's palsy bad. The emergency room staff thought at first she had a stroke before diagnosing her with Bell's palsy. On Wednesday, 27Jan2021 she had a friend named (Name withheld) who came over for tea. Patient has an oriental rug, and around 15:00 patient fell face first on oriental rug. She was just fine after the fall initially. She wonders if her having fell has anything to do with the Bell's palsy. She thinks it was the night of 27Jan2021 or 28Jan2021 when she asked her son if her face looked funny, did she look ok, because her face felt a little funny. She was looking in the mirror and her smile was looking crooked, and her eye looked like it was drooping. When she got up Friday, 29Jan2021 she could see her eye was drooping, and she could not blink that eye. She called her Ophthalmologist who saw her the afternoon of 29Jan2021 around 13:30-13:55. The Ophthalmologist said yeah something is going on with

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that eye. Her friend called his friend who is a Pediatric Neurologist that advised her to go to the emergency room. She was seen in the emergency room of (Hospital name withheld) around 17:00 on 29Jan2021. She was not admitted to the hospital at that time; but was evaluated and treated. She Bell's palsy outcome: she is doing so much better. She still has a hard time blinking her left eye, she still cannot blink her bad eye: left eye, without also closing her good eye: right eye. She is not drooling, she can drink without drooling. Her smile is still just a little crooked. She was given 2 prescriptions in the emergency room which were Prednisone and Valtrex. On 29Jan2021 in the emergency room they did tests including testing her heart with EKG; X-ray of her heart or lungs or something; took blood tests; and continuously took her blood pressure. There were no notable or abnormal results of any of those tests. They wanted her to go see her doctor last week but she did not have a chance to do so. She has an appointment with her primary doctor on Monday coming up. She has not yet seen her primary doctor about this. History of all previous immunization with the Pfizer vaccine considered as suspect (or patient age at first and subsequent immunizations if dates of birth or immunizations are not available) was None. The event Bell's palsy require a visit to Emergency Room, no to Physician Office. The patient was not hospitalized. No Prior Vaccinations within four weeks prior to the first administration date of the suspect vaccine. The patient underwent lab tests which included her heart with EKG; X-ray of her heart or lungs or something; took blood tests; and continuously took her blood pressure, all with no notable or abnormal results of any of those tests on 29Jan2021.

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| 1037836 | 2/18/2021 | NJ | 19 | F | 2/4/2021 | 2/4/2021 | Patient fainted; This is a spontaneous report from a contactable pharmacist. A 19-years-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EL8982), intramuscular in the left arm on 04Feb2021 12:00 at single dose for covid-19 immunisation. The patient was not pregnant at time of vaccination. The patient medical history and concomitant medications were not reported. The patient fainted on 04Feb2021 12:00 with outcome of recovered in Feb2021. No treatment was performed due to the event. The patient did not have COVID-19 prior to vaccination and was not covid tested post vaccination.; Sender's Comments: Based on vaccine-event chronological association, a causal relationship between event syncope and BNT162B2 vaccine cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate. |
| 1037835 | 2/18/2021 | | | M | 1/28/2021 | 2/3/2021 | I practically passed out and couldn't stand up; I practically passed out and couldn't stand up; This is a spontaneous report from a contactable consumer (Patient). A 67-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 28Jan2021 at 10:45 at single dose for COVID-19 immunization. The patient medical history included ex-alcohol user (didn't drink anymore). Concomitant medications were not reported. The patient reported he practically passed out and couldn't stand up on 03Feb2021 at 15:15. Patient was pretty healthy and didn't drink anymore. Things like that used to happen when he drank but not now. He hoped it wasn't something neurologic going on with my body. The outcome of the events was unknown. Information on the Batch/Lot number has been requested. |

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| 1038079 | 2/18/2021 | | | F | 2/2/2021 | 1/4/2021 | Passed Out; flushed; sleeping all day; kind of like a fever; nauseated; Headache; A spontaneous report was received from a healthcare professional (HCP) concerning a 72-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced passing out (loss of consciousness), flushed, sleeping all day, kind of like a fever, nausea and headache. The patient's medical history was not reported. Concomitant products known to have been used by the patient, within two weeks prior to the event, included pantoprazole. On 02 Feb 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot number: 007M204) for prophylaxis of COVID-19 infection. The patient stated that on 04 Feb 2021, the patient got up in the morning and didn't feel very well. She stated that she was flushed, had a headache and a fever. She had a coffee and sandwich and talked to her husband and then they got up and passed out. They slept all day and did not feel well. The patient stated that she was nauseated and felt like she had a fever and a real, dull headache. Treatments for these events were not reported. Action taken with mRNA-1273 in response to this event was not reported. The outcome for the events passing out (loss of consciousness), flushed, sleeping all day, kind of like a fever, nausea and headache was unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Further information has been requested. |
| 1040355 | 2/18/2021 | NJ | 54 | F | 2/16/2021 | 2/17/2021 | 1:00 am (15 hours post injection) chills, fever, body aches, 4:00 am (18 hours post injection) nausea, vomit, dizzy, fainted 3 times 8:00 am(22 hours post injection) severe headache, fever lasting 8 hours |
| 1040428 | 2/18/2021 | NY | 25 | F | 2/6/2021 | 2/7/2021 | Collapsed twice, extremely low blood pressure (87/55), extreme dehydration, cramping of hands and feet, vomiting Most likely due to syncope Symptoms resolved approximately 12-18 hours first collapse |

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| 1039188 | 2/18/2021 | MI | 97 | F | 2/17/2021 | 2/17/2021 | Approximately 10 minutes after receiving her vaccination patient fainted, then once she gained consciousness she vomitted a small amount of water. Family that was present, said that this is a somewhat common occurrence as she's had several episodes similar to this within the past year. |
| 1040356 | 2/18/2021 | MO | 70 | F | 2/18/2021 | 2/18/2021 | Patient passed out for a couple of minutes. She was moved to a couch and her feet propped up. After 30 minutes, she was doing well. |
| 1039313 | 2/18/2021 | OH | 66 | M | 2/17/2021 | 2/17/2021 | Before given vaccine, patient stated he has passed out from vaccines before. He received the dose, stated that I provided good technique but would stay with his wife for the 15 minute period afterwards just in case. He started to feel lightheaded/dizzy and voluntarily laid down on the floor. We provided him water, and he was sitting up, standing up, and able to leave within the next ten minutes. |
| 1040288 | 2/18/2021 | IN | 24 | F | 2/18/2021 | 2/18/2021 | Vasovagal syncope after first dose of Moderna Covid-19 vaccine. After event patient informed staff she routinely has this reaction to medical procedures (lab draws, etc). |
| 1040157 | 2/18/2021 | WI | 16 | F | 2/18/2021 | 2/18/2021 | A minute after receiving vaccine, client lost consciousness for approximately 30 seconds paired with facial twitching. No history of seizures and history of syncope due to holding breath and anxiety with medical procedures and vaccinations in the past.EMS was called, client was evaluated by EMS upon arrival, parent was called and history verified. It was discussed with parent that PCP and client have a plan in place for these kinds of reactions to go home and continue monitoring, so client was driven home by friend. |
| 1040124 | 2/18/2021 | MT | 80 | M | 1/24/2021 | 2/8/2021 | Systemic: Confusion-Medium, Systemic: Fainting / Unresponsive-Medium, Additional Details: Patient found unresponsive sitting in recliner and breathing. Vitals normal. After 5min sternum rub patient became conscious and stated he could hear being spoken to but could not respond. Felt weak rest of the day. Although this occurred several days later there were 3 patients at same facility experiencing similar issues on same day |

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| 1040063 | 2/18/2021 | FL | 71 | M | 2/18/2021 | 2/18/2021 | Patient had a mild seizure and passed out for about a minute |
| 1039982 | 2/18/2021 | PA | 30 | M | 2/13/2021 | 2/13/2021 | Patient received IM injection of vaccine. He sat down for the 15 min observation period. After a couple minutes got up to go to the rest room. He came out of the rest room and stated he got dizzy and fell and hit his head. His head was bleeding. Refused 911 but convinced him to go to the ER down the street from our facility. He reported back after the ER visit that he was fine and told us that he has a history of fainting from injections. |

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| 1039942 | 2/18/2021 | VA | 36 | F | 1/15/2021 | 1/21/2021 | Fainting like episodes; Blurred vision; Severe vertigo; Chest pain; Fatigue; This is a spontaneous report from a contactable other health professional reported for herself. A 36-year-old female patient received first dose BNT162B2(PFIZER-BIONTECH COVID-19 VACCINE) Lot # EL8982, via an unspecified route of administration in right arm on 15Jan2021 12:00 at single dose for covid-19 immunisation. There were no relevant medical history or concomitant medications. The patient was not pregnant at the time of vaccination. The patient had no allergies to medications, food, or other products. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 21Jan2021, exactly "4 1/2 days" after vaccine the patient experienced fainting like episodes, blurred vision, severe vertigo, chest pain, fatigue. The patient has been out of work since the 20th and she still had blurred vision. The adverse event resulted in Doctor or other healthcare professional office/clinic visit and Emergency room/department or urgent care. No treatment was received. The patient was not recovered from the events. She has been to the ER, cardiologist for an echography, ultrasonography of thyroids, Magnetic resonance imaging (MRI) of her head, went to ENT dr and neurologist in 2021. All blood work in 2021 came back normal as well. The reporter considered the event as non-serious. The patient was not diagnosed with COVID-19 prior to vaccination. She had negative Nasal Swab Covid test post vaccination on 22Jan2021.; Sender's Comments: Considering the temporal association, a causal association between administration of BNT162B2 and the onset of fainting like episodes cannot be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate. |

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| 1039346 | 2/18/2021 | IL | 51 | F | 2/11/2021 | 2/12/2021 | 2/12/2021 - passed out upon waking up. Ongoing vertigo 2/13/2021 - low blood pressure (80/40) resulting in emergency room visit. Elevated d-dimer. No evidence of pulmonary embolisms. 2/14-2/18 - ongoing and severe vertigo |
| 1040405 | 2/18/2021 | TX | 47 | F | 1/15/2021 | 1/15/2021 | Tightening of throat as I was walking to waiting area, chest palpitations, dizziness, fainting, and vomiting. They were not prepared for this to happen. All people that where were calling anyone to come and help me and finally and ICU doctor came and took over my care asking for benadryl from the pharmacy, a stretcher to take me to ER. Stretcher arrived was put on it and an IV was put in my right arm and the benadryl was administer in which I felt I was burning and turn real red. They then proceeded to take me to ER, where they administered more medicine through the IV. I was there for about 4 1/2 hours. When i was released my throat was still very tight, felt very fatigue, muscle ached, shortness of breath and dizzy. I was sent home with an EPI PEN, Allegra, and pepcid. I also had a referral to see the allergist doctor who could see me on Tuesday 1/19/2021 because Monday was a Holiday. |

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| 1039939 | 2/18/2021 | CA | 87 | M | 1/21/2021 | 1/21/2021 | fainted; nauseated; vomited 4 times; dizzy; bad headache; extremely tired; This is a spontaneous report from a contactable consumer. An 87-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in Right arm (at age of 87-year-old) on 21Jan2021 at 12:00 PM as a single dose for COVID-19 immunisation, lot number: EL3247. Medical history was none. Patient had no allergies to medications, food, or other products. Concomitant medications within 2 weeks of vaccination included ibuprofen (ADVIL) and melatonin (minimal usage). Patient did not receive other vaccine in four weeks prior to the COVID vaccine. Prior to vaccination the patient was not diagnosed with COVID-19. It was reported that on 21Jan2021 at 02:45 PM (also reported as 2 1/2 hours after vaccine) patient became nauseated, he vomited four times, was dizzy, fainted, had bad headache and was extremely tired. Events resulted in Doctor or other healthcare professional office/clinic visit. Patient was treated for the events with nausea medications and ibuprofen (ADVIL). Since the vaccination patient had not been tested for COVID-19. Patient recovered with lasting effects from the events. |
| 1039315 | 2/18/2021 | AZ | 56 | F | 2/13/2021 | 2/13/2021 | From District Pharmacy Manager: Patient fainted after getting into the observation area (maybe about 3-5 minutes after receiving vaccine). Fire Dept was called. She did not go to hospital and did go home with her husband who was driving. |

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| 1039524 | 2/18/2021 | AK | 27 | F | 2/13/2021 | 2/13/2021 | At 8 pm the day I had the shot I started having a headache and muscle aches on both hips. The following day I was nauseous, light-headed, had a headache, muscle aches around my hips, pain at injection site, and was weak. I passed out for an unknown amount of time around 11 am that Sunday. I was unable to eat more than two pieces of pilot bread, but I kept drinking water and was hydrated. I kept rolling around trying to get comfortable, but the muscle pains in my hips would not let me until I used a heating pd. The following day I was weak, but no longer as nauseous or have as bad a headache. On Tuesday, I was able to get up, but both arms felt very weak and it was a strain to carry my bag and computer. Wednesday I was still very tired, but more like myself. No symptoms today February 18. |
| 1039538 | 2/18/2021 | WA | 66 | F | 2/6/2021 | 2/6/2021 | per patient report: "103.5 fever with heart rate of 100-120s. Farmer's Lung activated with profound coughing. O2 sats went transiently low to 85 but mostly 91-92%. Became very unsteady on feet, requiring support of walls, furnishings and counters. Horrible chiari headache with bad nausea Neuropathy in BLE flared, legs were buzzing and I was getting intense spasms of bilateral feet and ankles that made it hard to use them. Visual decline Passed out twice cold in the bathroom [found myself in bathroom, when "I came to"] In bed for 3 days except to use the restroom and make tea. Could not attend to any other ADLs. Injection site red from shoulder to elbow, swollen and itchy with axillary lymph swelling". Symptoms |

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| 1039908 | 2/18/2021 | MA | 53 | F | 1/15/2021 | 1/15/2021 | <p> Syncope; This is a spontaneous report from a contactable nurse. A 53-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date were not reported), via an unspecified route of administration on the right arm on 15Jan2021 12:00 at a single dose for COVID-19 immunization. Medical history included Crohns disease which is in remission (No immunosuppressants in 5 years) and shellfish sensitivity. The patient is not pregnant. Concomitant medication included duloxetine hydrochloride (CYMBALTA), trazodone, buspirone hydrochloride (BUSPAR), lisdexamfetamine mesilate (VYVANSE) and methylfolate. The patient experienced syncope on 15Jan2021. The event was assessed as serious (medically significant). The outcome of the event was recovering. Information on the lot/batch number has been requested.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the event syncope cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate. </p> |

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| 1039925 | 2/18/2021 | IL | 45 | M | 2/4/2021 | 2/6/2021 | fainted; nausea; left arm began to tingle; dizziness; Broke out in a cold sweat; chills; Lost control of my bladder.; This is a spontaneous report from a contactable consumer (patient). A 45-years-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL6269), via an unspecified route of administration in Left arm on 04Feb2021 15:00 (at the age of 45-years-old) at SINGLE DOSE for COVID-19 immunization. Medical history was reported as none. There were no concomitant medications. 51 hours after receiving the vaccine, the patient was sitting down watching a film. His left arm began to tingle, and he felt a wave of dizziness and nausea come over him. He stood up, walked a few steps and sat back down. He broke out in a cold sweat, chills, and saw stars. He leaned forward with his head in his hands, and apparently fainted for a moment and lost control of his bladder. All events started on 06Feb2021 06:00 PM. No treatment received for the events. The outcome of the events was recovered in Feb2021. No covid prior vaccination, no Covid tested post vaccination, no known allergies. |

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| 1039926 | 2/18/2021 | IN | 45 | F | 2/6/2021 | 2/7/2021 | Nearly passed out; Postural Orthostatic Tachycardia Syndrome; icy like pulsation through my blood occurred; fell to the ground; This is a spontaneous report from a contactable consumer reported for herself. A 45-year-old female patient (not pregnant) received the first dose of bnt162b2 (Pfizer-Biontech Covid-19 Vaccine), Lot number: EL9261, via an unspecified route of administration on 06Feb2021 12:30 at single dose in Left arm for covid-19 immunisation. Facility type Vaccine was Hospital. Medical history included anaemia, no known allergies. Patient had COVID-19 starting on 06Jan2021 and persisting through 16Jan. Her COVID symptoms were crushing chest pain, no fever, blood oxygen level never dropped below 98%. The patient's concomitant medications were not reported. There were no other vaccine in four weeks. Patient was experiencing Postural Orthostatic Tachycardia Syndrome. Nearly passed out going to the toilet when she first awoke. An icy like pulsation through her blood occurred first thing this AM, day after the vaccine. She fell to the ground and called for her husband to help her. He gave her 500mg acetaminophen and aspirin. She slept. Same thing happened with pulse 140+, he measured, as she showered. They stopped the shower, she laid down and recovered. When she got up immediately the pulse rises to 120+. Adverse events started from 07Feb2021 08:30 AM. Therapeutic measures were taken in response to the events. The outcome of the events was not recovered. Covid was not tested post vaccination. |

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| 1039927 | 2/18/2021 | CA | 71 | F | 2/5/2021 | 2/5/2021 | passed out; passed out when went into bathroom at 5 am, cut chin when fell; dehydrated; sweats; chills-shivers; Bad headache; Dizziness; Couldn't sleep; Neuropathy pain in hip/groin; This is a spontaneous report from a contactable consumer reporting for herself. A 71-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EM9809 and expiry date unknown) on 05Feb2021 08:30 at single does via an unspecified route of administration into her left arm for COVID-19 immunization. Medical history included known allergies to statins. The patient had received first dose of BNT162B2 (lot number EL3248) on 15Jan2021 16:00 for COVID-19 immunization (vaccine location=Left arm). The patient had not had COVID prior the vaccination, COVID not tested post the vaccination. Concomitant medication included gabapentin (GABAPENTIN), fish oil (FISH OIL), zinc (ZINC), cyanocobalamin (VITAMIN B 12), iron (IRON). No other vaccine received in four weeks. The patient experienced adverse events from 05Feb2021 at 20:30. She experienced chills-shivers, had bad head ache, dizziness, couldn't sleep, intense neuropathy pain in hip/groin when got out of bed and then passed out when went into bathroom at 5 am (06Feb2021), cut chin when fell. She felt dehydrated. Cold marble floor felt good as she had sweats, so she just layed there awhile. Her husband came to her rescue with water and cold compress for her head. She received lots of liquids and rest. She had good night's sleep on 06Feb2021. The outcome of the events was reported on 07Feb2021 as recovered. |

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| 1039936 | 2/18/2021 | IL | | M | 2/7/2021 | 2/7/2021 | The man walked approximately 30 feet and collapsed/fainted; Extremely diaphoretic; This is a spontaneous report from a non-contactable consumer (volunteer at a vaccination clinic) reporting for a patient. A male adult in his 30's received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number and expiry date unknown) via an unspecified route of administration on 07Feb2021 around 15:00 at a single dose for COVID-19 immunization. No information about the patient's medical history and concomitant drugs was provided. After receiving the vaccine, the man walked approximately 30 feet and collapsed. The onsite supervisor from the institute indicated that he was extremely diaphoretic and had "fainted" before he could reach the post-vaccination observation area. EMS (Emergency Medical Services) was stationed onsite and assisted the man. The man was placed in a chair for approximately 15 minutes. An electrocardiogram (ECG) appeared to have been performed. The man was then transported to the hospital for further evaluation of concussion as it was believed that his head might have impacted a table and/or the floor when he collapsed. It was not specified if the patient was admitted to the hospital. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained. |

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| 1035541 | 2/17/2021 | MO | 67 | F | 1/19/2021 | 1/19/2021 | syncope within 10 min. of injection, episode; BP 70/40 P 40-30 admitted to ICU; BP 70/40 P 40-30 admitted to ICU; Adrenal Crisis; patient with a medical history CVID (Immunodeficiency common variable) received bnt162b2; patient with a medical history CVID (Immunodeficiency common variable) received bnt162b2; This is a spontaneous report from a contactable nurse (patient). A 67-year-old female patient (not pregnant) received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot/batch number and expiration date unknown), via an unspecified route of administration in Left arm on 19Jan2021 at single dose for COVID-19 immunization in hospital; antilymphocyte immunoglobulins (reported as immunoglobulin infusion, concentrate for solution for infusion, lot/batch number and expiration date not provided) via an unspecified route of administration from an unspecified date at unknown dosage for an unspecified indication. Medical history included CVID (Immunodeficiency common variable), Addison Dx (diagnosis) and Pituitary Tumor. Prior to vaccination, patient was not diagnosed with COVID-19. No known allergies. The patient's concomitant medications were not reported. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient had syncope within 10 minutes of injection on 19Jan2021, episode, BP (blood pressure) 70/40, P (pulse) 40-30, admitted to ICU in Jan2021, determined adverse event maybe 2nd to immunoglobulin infusion received previous day leading to Adrenal Crisis, 2nd to Addison dx / Pituitary tumor which was unknown at time of vaccination. Events were resulted in doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care, Hospitalization, Life threatening illness (immediate risk of death from the event). Patient had been hospitalized for 6 days in Jan2021. Since the vaccination, patient had not been tested for COVID-19. The action taken in response to the events for antilymphocyte immunoglobulins was unknown. Therapeutic measures were taken as result of the events syncope, BP 70/40, P 40-30 and Adrenal Crisis. The outcome of the events "syncope, BP 70/40, P 40-30, Adrenal Crisis" was recovered in 2021. Patient then received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) on 08Feb2021. Pfizer is a marketing authorization holder of |

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antilymphocyte immunoglobulins in the country of incidence or the country where the product was purchased (if different). This may be a duplicate report if another marketing authorization holder of antilymphocyte immunoglobulins has submitted the same report to the regulatory authorities. Information on the lot/batch number has been requested.; Sender's Comments: Based on the compatible time association, the possible contribution of suspect vaccine BNT152B2 and antilymphocyte immunoglobulins to the events syncope, low BP and heart rate, adrenal crisis, cannot be excluded. The underlying Addison disease and Pituitary Tumor are major cofounders for the events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

Patient was pale and diaphoretic after receiving the vaccine. In the past, passed out when giving blood. Did not eat or drink before getting the vaccine. Given juice and water.

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| 1035541 | 2/17/2021 | MO | 67 | F | 1/19/2021 | 1/19/2021 | syncope within 10 min. of injection, episode; BP 70/40 P 40-30 admitted to ICU; BP 70/40 P 40-30 admitted to ICU; Adrenal Crisis; patient with a medical history CVID (Immunodeficiency common variable) received bnt162b2; patient with a medical history CVID (Immunodeficiency common variable) received bnt162b2; This is a spontaneous report from a contactable nurse (patient). A 67-year-old female patient (not pregnant) received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot/batch number and expiration date unknown), via an unspecified route of administration in Left arm on 19Jan2021 at single dose for COVID-19 immunization in hospital; antilymphocyte immunoglobulins (reported as immunoglobulin infusion, concentrate for solution for infusion, lot/batch number and expiration date not provided) via an unspecified route of administration from an unspecified date at unknown dosage for an unspecified indication. Medical history included CVID (Immunodeficiency common variable), Addison Dx (diagnosis) and Pituitary Tumor. Prior to vaccination, patient was not diagnosed with COVID-19. No known allergies. The patient's concomitant medications were not reported. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient had syncope within 10 minutes of injection on 19Jan2021, episode, BP (blood pressure) 70/40, P (pulse) 40-30, admitted to ICU in Jan2021, determined adverse event maybe 2nd to immunoglobulin infusion received previous day leading to Adrenal Crisis, 2nd to Addison dx / Pituitary tumor which was unknown at time of vaccination. Events were resulted in doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care, Hospitalization, Life threatening illness (immediate risk of death from the event). Patient had been hospitalized for 6 days in Jan2021. Since the vaccination, patient had not been tested for COVID-19. The action taken in response to the events for antilymphocyte immunoglobulins was unknown. Therapeutic measures were taken as result of the events syncope, BP 70/40, P 40-30 and Adrenal Crisis. The outcome of the events "syncope, BP 70/40, P 40-30, Adrenal Crisis" was recovered in 2021. Patient then received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) on 08Feb2021. Pfizer is a marketing authorization holder of |

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antilymphocyte immunoglobulins in the country of incidence or the country where the product was purchased (if different). This may be a duplicate report if another marketing authorization holder of antilymphocyte immunoglobulins has submitted the same report to the regulatory authorities. Information on the lot/batch number has been requested.; Sender's Comments: Based on the compatible time association, the possible contribution of suspect vaccine BNT152B2 and antilymphocyte immunoglobulins to the events syncope, low BP and heart rate, adrenal crisis, cannot be excluded. The underlying Addison disease and Pituitary Tumor are major cofounders for the events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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| 1036030 | 2/17/2021 | FL | | F | 2/2/2021 | 2/3/2021 | Pain in left arm; Passed out; Got dizzy; arm very swollen at the side of the injection; A spontaneous report was received from a consumer concerning her mother, a 52-year-old female patient, who experienced passed out (loss of consciousness), got dizzy (dizziness), arm very swollen at the side of the injection (vaccination site swelling), and pain in the left arm (vaccination site pain). The patient's medical history was not provided. Concomitant product use was not provided by the reporter. The patient received her first of two planned doses of mRNA-1273 (lot/batch number not provided) on an unknown date for prophylaxis of COVID-19 infection. On 02 Feb 2021, approximately 1 day and 6 hours prior to the onset of symptoms, the patient received her second of two planned doses of mRNA-1273 (batch number: 012M20A) in the left arm for prophylaxis of COVID-19 infection. On 03 Feb 2021, the patient got dizzy and passed out, her arm was very swollen at the side of the injection, and she had pain in her arm (at 6 to 7 in the morning). Treatment information was not provided. The patient received both scheduled doses of mRNA-1273 prior to the events; therefore, action taken with the drug in response to the events was not applicable. The outcome of the events, passed out, got dizzy, arm very swollen at the side of the injection, and pain in the left arm was unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the onset date of the events, a causal relationship cannot be excluded. |

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| 1035883 | 2/17/2021 | IA | 45 | F | 12/18/2020 | 12/18/2020 | <p>Throat and mouth "feels funny" following injection of Covid vaccine approx 1717. Slight chest burning. Patient ambulated. Drinking water without difficulty. Patient states tongue "feels funny" after getting covid vaccine. Patient states within minutes after the injection her tongue began to feel funny. She denies oral/lip swelling, numbness/tingling, difficulty swallowing, drooling, headache, nausea/vomiting, chest pain, shortness of breath. She also states her chest was burning just after receiving the vaccination however that has since resolved. No palpitations or syncope. No recent illness. No history of adverse reaction to vaccines. No known food/medication allergies. Patient is sitting comfortably on the exam table drinking water without difficulty. Patient states at this time her mouth feels better but "does not feel normal." Patient states she has a history of mitochondrial myopathy and has some esophageal motility issues at baseline. 1808: patient was given diphenhydramine 25 mg PO x 1. She reports mild improvement in symptoms. No headache, dizziness, nausea, oral edema, difficulty swallowing, chest pain, shortness of breath. 1830: patient states symptoms have resolved. She is sitting comfortably in the chair. No signs of distress. She states she thinks she got too anxious. No headache, dizziness, nausea, oral edema, difficulty swallowing, chest pain, shortness of breath. Patient states she feels comfortable leaving at this time. Discussed ED precautions. Patient verbalized understanding. Advised patient to follow up with her PCP to discuss second dose of covid vaccine. 1/15/21: Pt received 2nd dose of vaccine. About 10 minutes after, pt developed a rash at injection site. Rash spread up chest and onto back. Pt was taken to convenient care for further evaluation. At convenient care, pt stated she had no difficulty breathing but that something just didn't feel right. Rash spread to right arm and started to itch. Pt endorsed experiencing throat/tongue swelling but did not think it was closing off or actually swelling. Pt received epinephrine 0.3 mg IM x 1 and diphenhydramine 25 mg IM x 1. After treatment and about 1.25 hours of monitoring, pt felt well enough to go home. Pt was prescribed epinephrine 0.3 mg IM 2-pak kit. 1/15/21: Pt received 2nd dose of COVID vaccine and developed rash. Pt received epinephrine 0.3 mg IM x 1 and diphenhydramine 25 mg IM x 1. Discharged to home</p> |

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| 1035768 | 2/17/2021 | TX | 74 | F | 2/2/2021 | 2/2/2021 | <p>after treatment and monitoring with prescription for epinephrine 0.3 mg IM 2-pak kit.</p> <p>passed out; urinated on herself; could not sleep; chills; fever; A spontaneous report was received from a consumer concerning a 74 year old female patient who received Moderna's COVID-19 vaccine and experienced loss of consciousness, chills, pyrexia, urinary incontinence and insomnia. The patient's medical history was not provided. Concomitant medication included unspecified blood pressure medications. On an unspecified date, the patient received the first of their first planned doses of mRNA-1273 (lot number unknown) for prophylaxis of COVID-19 infection. On 02-Feb-2021 the patient received the second of their planned doses of mRNA-1273 (Lot number 041L20A) intramuscularly for prophylaxis of COVID-19 infection. On 02-Feb-2020, the patient experienced chills, some fever, and could not sleep. On the morning of 03-Feb-2021, the patient passed out twice and urinated on herself. No treatment information was provided. Action taken with the mRNA-1273 in response to the events was not applicable. The outcome of the events of loss of consciousness, chills, pyrexia, urinary incontinence and insomnia were was unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the onset date of the events, a causal relationship cannot be excluded.</p> |
| 1035658 | 2/17/2021 | PA | 67 | F | 2/16/2021 | 2/16/2021 | <p>Patient passed out in the middle of the night...not at site and hours after the dose was administered.</p> |

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| 1036032 | 2/17/2021 | IL | 71 | F | 2/3/2021 | 2/3/2021 | <p>Passed out; Unsteady; Slurring her words; Fell into a deep sleep; Tingly in her upper right arm; Feels like equilibrium is off; Legs feel heavy; Fatigue; A spontaneous report was received from a consumer who was also a 71-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced passing out (loss of consciousness), unsteadiness (gait disturbance), slurring words (dysarthria), fell into a deep sleep (hypersomnia), tingly feeling in her upper right arm (paraesthesia), felt like equilibrium was off (balance disorder), legs felt heavy (limb discomfort), and fatigue. The patient's medical history included epilepsy. Concomitant products known to have been used by the patient, within two weeks prior to the event, included clonazepam. On 03 Feb 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. The patient was slurring her words and fell into a deep sleep. It took three individuals to wake her up. The patient wondered if she passed out. She felt tingly in her upper right arm and it felt like her equilibrium was off, and legs were heavy. The patient was very fatigued. Treatments of these events were not provided. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events, passing out, unsteadiness, slurring words, fell into a deep sleep, tingly feeling in her upper right arm, felt like equilibrium was off, legs felt heavy and fatigue, was unknown.; Reporter's Comments: This case concerns a 71 year old female subject, with history of epilepsy, who experienced a serious unexpected event of loss of consciousness after first dose of mRNA1273 (Lot# unknown). Concomitant medication included clonazepam. Very limited information has been provided at this time. Further information has been requested.</p> |

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| 1035518 | 2/17/2021 | PA | 48 | M | 2/2/2021 | 2/2/2021 | passed out; terrible headache; still some body aches; general bad feeling all over; nausea/tremendous chills and nausea; tremendous chills and nausea; low grade fever 99.5; This is a spontaneous report from a contactable consumer (patient). A 48-year-old male patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in Left arm (at age of 48-year-old) on 02Feb2021 at 10:30 AM as a single dose for COVID-19 immunisation, lot number: EL9262. Medical history included high cholesterol and allergies to some seaweeds. Patient received first vaccine dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 14Jan2021 via an unspecified route of administration in Left arm (at age of 48-year-old) for COVID-19 immunisation, lot number: EL3246. Concomitant medications in two weeks prior to the vaccination included atorvastatin and multi- vitamin. Patient did not receive other vaccine in four weeks prior to the COVID vaccine. Prior to vaccination the patient was not diagnosed with COVID-19. Patient started about 12 hours after getting vaccinated (reported as 02Feb2021 at 10:00 PM) with a general bad feeling all over, 15 hours after (03Feb2021 at 01:00 AM) patient got out of bed because of nausea and passed out, his wife found he on the floor. Patient had tremendous chills and nausea with a low grade fever 99.5 for several more hours, maybe 6 hours, (onset date 02Feb2021) the next morning patient had a terrible headache and still some body aches. Patient was treated with extra strength paracetamol (TYLENOL) and ondansetron (ZOFRAN). Since the vaccination patient had not been tested for COVID-19. Patient was recovering from the events, at the time of the report. |

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| 1035514 | 2/17/2021 | | | U | | | <p>feelings of fainting; high blood pressure in the 160s, normally <120s systolic); severe headaches; dizziness; This is a spontaneous report from a contactable pharmacist. A patient of unspecified age and gender received first dose of BNT162B2 (Lot number and expiry date not provided), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history concomitant medications were not reported. On an unspecified date, the patient developed severe headaches, dizziness, high blood pressure (in the 160s, normally <120s systolic), and feelings of fainting 5-10 minutes after receiving the first dose of the vaccine. This adverse event was reported already, but the pharmacist was wondering if it is still recommended to get the second dose after a reaction like this. Stated "This reaction doesn't meet your definition of anaphylaxis or allergic reaction which is why I am reaching out to see if you have any recommendations on this". The patient underwent lab tests and procedures which included blood pressure: high blood pressure (in the 160s, normally <120s systolic). The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.</p> |

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| 1035507 | 2/17/2021 | WA | | F | 1/28/2021 | 1/28/2021 | 3 episodes of fainting; Flu like symptoms; Chest tightness; Sore and tender upon swallowing food; Muscle aches on right arm; fever; fatigue; A spontaneous report was received from a consumer concerning a 45-year old, female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced fatigue, fever, fainting, muscle aches, flu-like symptoms, chest tightness, and sore throat. The patient's medical history, as provided by the reporter, included childhood asthma and seasonal allergies. No relevant concomitant medications were reported. The patient received their first of two planned doses of mRNA-1273 on an unknown date. On 28 Jan 2021, the patient received their second of two planned doses of mRNA-1273 (042L20A) intramuscularly in the right arm for prophylaxis of COVID-19 infection. On 28 Jan 2021, the patient had fatigue by the end of the day following vaccination. On 29 Jan 2021, the patient presented fever and 3 episodes of fainting. She had muscles aches on her right arm, flu-like symptoms, chest tightness, and sore/tender throat area upon swallowing food. No treatment information was provided. The patient received both scheduled doses of mRNA-1273 prior to the events, therefore action taken with the drug in response to the events is not applicable. The outcome of the events was not reported.; Reporter's Comments: Further information has been requested as there is limited information regarding the events, particularly the event of syncope and chest discomfort. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. |

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| 1035010 | 2/17/2021 | OH | 45 | F | 1/13/2021 | 1/16/2021 | Fainting; shortness of breath; hand spasms; nausea; vomiting; This is a spontaneous report from a contactable other health care professional (HCP) reporting for herself. A 45-year-old female patient not pregnant received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in Left arm (at age of 45-year-old) on 13Jan2021 at 01:00 PM as a single dose for COVID-19 immunisation, lot number: EL3249. Medical history included penicillin allergy. Patient did not receive any other medications within two weeks prior to the vaccination. Patient did not receive other vaccine in four weeks prior to the COVID vaccine. Prior to vaccination the patient was not diagnosed with COVID-19. On 16Jan2021 at 06:00 PM patient experienced nausea, vomiting, shortness of breath, fainting and hand spasms. Events resulted in Emergency room/department or urgent care. Patient was treated at emergency room (ER) with diphenhydramine hydrochloride (BENADRYL), Steroid and Anti nausea. Patient was not tested for Covid post vaccination. Patient recovered on unknown date in 2021 from the reported events.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate. |

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| 1035006 | 2/17/2021 | NC | 74 | F | 2/1/2021 | 2/2/2021 | Passed out and fell to the floor before daylight; Passed out and fell to the floor before daylight; Dizziness; This is a spontaneous report from a contactable consumer (patient's spouse). A 74-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EL9265) on 01Feb2021 at 13:15 at single dose intramuscular COVID-19 immunization. Relevant medical history included Alzheimer's disease diagnosed about 5-6 years ago, seizure (diagnosed 40 years ago) and ongoing high blood pressure. Concomitant medications were not reported. On 02Feb2021 patient passed out and fell before daylight morning, it may be around 06:00-07:00 (as reported). Patient's spouse informed that got up early and was already up when she called him to tell him she had fallen. She sleeps a lot anyway, so she was just put back to bed. Reporter didn't know exactly when she was up again. It was also informed that several of the medications that she took have side effects like dizziness (as reported). At the time of the reporting event outcome was unknown. |
| 1036237 | 2/17/2021 | PA | 30 | F | 2/12/2021 | 2/17/2021 | fever, near syncope throat and lymph node swelling |

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| 1035008 | 2/17/2021 | AZ | 26 | F | 1/17/2021 | 1/17/2021 | <p> Syncope; Passed out within minutes of second dose.; Urination and emesis upon waking up; Urination and emesis upon waking up; This is a spontaneous report from a contactable Pharmacist (patient). A 26-year-old female patient not pregnant received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in Left arm (at age of 26-year-old) on 17Jan2021 at 09:30 AM as a single dose for COVID-19 immunisation, lot number: EL1283. Medical history was not provided. Patient had no known allergies. Patient received first vaccine dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 27Dec2020 at 09:30 AM via an unspecified route of administration in Left arm (at age of 26-year-old) for COVID-19 immunisation, lot number: EH9899. Patient did not receive any other medications within two weeks prior to the vaccination. Patient did not receive other vaccine in four weeks prior to the COVID vaccine. Prior to vaccination the patient was not diagnosed with COVID-19. On 17Jan2021 at 09:45 AM patient experienced syncope. Passed out within minutes of second dose. Urination and emesis upon waking up. Brought to hospital, given 1L nacl and 1 dose of ondansetron (ZOFTRAN). Events considered serious due to hospitalization. Events resulted in Emergency room/department or urgent care. Patient was treated with fluids and ondansetron (ZOFTRAN). Patient was not tested for Covid post vaccination. Patient recovered from the events on unknown date.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate. </p> |
| 1037066 | 2/17/2021 | MI | 24 | M | 2/17/2021 | 2/17/2021 | patient fainted, passed out for 10 seconds |
| 1037077 | 2/17/2021 | CA | 73 | M | 2/16/2021 | 2/17/2021 | Syncope, weakness, thirst Severe neck pain after falling on floor |

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| 1037058 | 2/17/2021 | FL | 23 | M | 2/17/2021 | 2/17/2021 | Patient fainted right after receiving the vaccine. He waited 30 minutes after and drank water, then was fine. |
| 1037033 | 2/17/2021 | WA | 69 | M | 1/30/2021 | 2/5/2021 | fever chills uncontrollable tremors/shakes; recurrent near syncope/onset over 90 min; lasted 11hrs, then cleared as fast as it came on. Unable to converse clearly much of that time |
| 1036981 | 2/17/2021 | ID | 70 | F | 2/12/2021 | 2/13/2021 | Arm pain, diarrhea, syncope, fatigue, rash. |
| 1036967 | 2/17/2021 | OH | 64 | F | 2/13/2021 | 2/14/2021 | Passed out twice, for a few seconds each time, during trip to bathroom in attempt to vomit. Nausea, low grade fever, cold sweats following. Did not vomit. Arm soreness at site, other muscle soreness, headache, fatigue continued for six hours. Symptoms lessened and continued for 24 hours at lesser extent. |
| 1036925 | 2/17/2021 | TX | 64 | M | 2/17/2021 | 2/17/2021 | After vaccination, patient was okay until the 8 minute remaining mark. At this point patient became lethargic, clammy and passed out. Patient was revived with smelling salts, for a few seconds and the faded in and out of consciousness. Sternal rub was performed in order to attempt to keep patient awake and present. Vital signs where taken, BP was elevated at 155/ 115. Patient was still not coherent at this point patient was team lifted to wheel chair and taken to the ER. Patient remains in the hospital at this time admitted for observation. |
| 1036711 | 2/17/2021 | NY | 72 | F | 2/17/2021 | 2/17/2021 | SOB, sweating, dizziness, itching. After the 2nd dose of vaccine I had itching in arms and neck . This was followed by dizziness, high BP, SOB, and nausea. The 2nd shot triggered post itching my neurocardiogenic syncope. |
| 1036707 | 2/17/2021 | CA | 67 | F | 2/13/2021 | 2/13/2021 | Patient experienced syncope, dizziness, respiratory distress, palpitations. BP 132/67, pulse 60. |

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| 1036486 | 2/17/2021 | IN | 82 | M | 2/12/2021 | 2/13/2021 | 2/13 0800 Post second vaccine. Weak, dizzy, unable to walk per self as usually does. SBP 80 when getting up to use commode with diarrhea. Syncope lasting approx 15 seconds. Came to et was oriented X3 at that time but having times of confusion. Staff reports pt felt weak and same way after first Covid vaccine. Encouraged hydration, bed rest, use of stand aide for use of BR. Gave Claritin 24 hour tablet. Held lisinopril. 2/14 @ 10 am. Feeling some better, mostly oriented with episodes of intermittent confusion. Drank lots of fluids over past 24 hrs. SBP 99. Continued with some diarrhea. Held lisinopril et gave another Claritin 24 hr. Tablet and encouraged hydration. Monday 2/15. SBP. 114/51. Gave Claritin 24 hour tablet and held lisinopril. Encouraged fluids. Feeling some better. Not as weak. Denies dizziness. Able to walk some per self. In evening used stand aid. 2/16 dayshift. BP 123/47 et heart rate 78. lisinopril held. Able to ambulated in room with supervision. Mentation at baseline. 2/17 dayshift.: lisinopril held. Ambulation per self in room and hall with supervision. BP 114/59 with heart rate of 57. No confusion. Mentation at baseline. |
| 1036418 | 2/17/2021 | IL | 85 | M | 1/21/2021 | 1/25/2021 | ER visit 1/25/21 patient walked into a prompt care and collapsed, witnessed and pulseless CPR with ROSC after 6-7mins, no shock no meds. Awake and speaking upon arrival to ER. 2 plus pitting edema ble ER diagnosis Anasarca, cardiac arrest, hypotension, elevated troponin I levels, Acute kidney injury and syncope. ER notes reveal a syncopal episode in the shower prior to collapse at prompt care. Central line placed and plan to ship to another facility, patient continued to decline despite dopamine and dobutamine expired in ER prior to transfer. |
| 1037105 | 2/17/2021 | AL | 58 | F | 2/17/2021 | 2/17/2021 | pt fainted |

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| 1036361 | 2/17/2021 | MA | | F | 1/4/2021 | 2/2/2021 | Patient passed out without warning (fell) and hit ceramic floor; Patient passed out without warning (fell) and hit ceramic floor; Black eye; bruised extremities; Been "out of it" since then; A spontaneous report was received from a consumer concerning a 59 year old female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and passed out and hit a ceramic floor causing a black eye, bruised extremities, and the patient was been out of it since the event (feeling abnormal). The patient's medical history was not provided. No relevant concomitant medications were reported. On 01 Feb 2021, approximately one day prior to the onset of the events, the patient received their second of two planned doses of mRNA-1273 (lot number 028L20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. The patient passed out without warning and hit a ceramic floor, which cased a black eye, bruised extremities, and the patient has been out of it since the event. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not provided. The outcome of the events passed out and hit a ceramic floor causing a black eye, bruised extremities, and the patient was been out of it since the event (feeling abnormal) were unknown.; Reporter's Comments: This case concerns a 59 year old female subject, who experienced a serious unexpected event of loss of consciousness after second dose of mRNA1273 (Lot# 028L20A). Very limited information has been provided at this time. Further information has been requested. |
| 1036769 | 2/17/2021 | CO | 19 | F | 2/12/2021 | 2/12/2021 | Patient fainted in the chair shortly after vaccine administration. Patient regained consciousness 4 or 5 seconds later. She was nauseated for a short time, then was completely recovered. She had a friend with her because she has fainted before after a vaccination. She waited with her friend for 30 minutes outside the pharmacy. She was feeling fine when she left. |
| 1036111 | 2/17/2021 | RI | 24 | M | 2/16/2021 | 2/16/2021 | syncope/vomit/vaso vagal |

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| 1032777 | 2/16/2021 | OH | 35 | F | 2/5/2021 | 2/5/2021 | She passed out a couple hours after the second dose of the vaccine was received. The employee was contributing it to the vaccine, but she has been to 3 emergent/urgent visits since then for continued episodes of syncope. She has not returned to work since the vaccine she works in a Dr.'s office. |
| 1033211 | 2/16/2021 | NC | 57 | F | 2/9/2021 | 2/10/2021 | Fainting/syncope, drop in blood pressure. BP lying down after syncope 80/59, pulse 88. Patient unable to rise up for 20 minutes without experiencing faintness. After consuming 32 ounces of water, blood pressure came back to normal limits. Patient was not dehydrated at time of event. Pt did not fall or sustain injury. Upon recognizing symptoms, pt. immediately tried to get to sofa, but had to sit on floor then lie down. LOC very brief. After 10 minutes, BP 97/61 standing. After 30 minutes, BP 116/69, pulse 78 sitting. After 50 minutes, BP 96/65 standing, pulse 94. at 60 minutes, BP 102/67, pulse 92. Pt. able to stay up and move around. Total episode lasted about 1 hour. |
| 1033193 | 2/16/2021 | | 74 | F | 2/12/2021 | 2/12/2021 | About 15 minutes after vaccination, patient began to experience acute pyrexia and nausea. No vomiting. No syncope. Vital signs within normal limits. Borderline tachy. No hypertension, but some shortness of breath and some lightheadedness.. After 1st vaccination , developed body aches and wrist burning on 2nd day. Taken to ED where BP 129/77, HR 80, O2 sat 97%. EKG showed NSR. Symptoms resolved on own. |
| 1033113 | 2/16/2021 | MA | 58 | F | 2/2/2021 | 2/2/2021 | I fainted almost immediately but I was extremely anxious and crying/hyperventilating. I also had nausea and retching. My blood pressure went up. A couple of hours later I had a sever head ache, chills and sweats with body aches that lasted through the next morning. |
| 1033075 | 2/16/2021 | MO | 60 | F | 12/19/2020 | 12/19/2020 | 12/19/2020 130 vaccination. When got up to leave, near syncope episode. Monitored for 15+ more minutes. Left after. Later that evening, I felt like I was on 'speed'. Chills, HA, couldn't sleep. HR was increased. I wasn't able to eat; no appetite. Symptoms lasted for several days. Don't think I ran a fever. I was very dizzy, double vision, extreme fatigue. Did what i could with work online. *HX of aura migraines and happened during this episode. Within that week, saw NP. |

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| 1033063 | 2/16/2021 | WI | 66 | F | 2/12/2021 | 2/12/2021 | 02/12/2021, 9.15 pm Chills so intense that I was shaking uncontrollably. Then intense headache later on that night, 3.30 am 02/13.2021, Got out of bed to take some tylenol, so weak I passed out, twice in the bathroom. I have no memory of passing out. My husband called 911 and I was taken by ambulance to the local hospital. Vital signs remained good through out. Large bump on my forehead and brushing on my chin as a result of passing out. |
| 1033022 | 2/16/2021 | IN | 20 | F | 2/15/2021 | 2/15/2021 | Pt. fainted roughly 30 seconds after vaccine administration - had some jerky motions in chair, but did not fall. Pt. loss of consciousness less 2 minutes. |
| 1032943 | 2/16/2021 | IL | 37 | F | 1/26/2021 | 1/27/2021 | pt c/o fatigue, SOB, weakness, presyncope, fever, chills, bowel urgency, tingling, HA dizziness, tachycardia |
| 1032927 | 2/16/2021 | CT | 25 | F | 2/15/2021 | 2/16/2021 | Fever 100.8 Fainting upon standing 5:30am: stood slowly, took a few steps and began to have loud ringing in ears, sweating, nausea, then vision went black but was able to guide myself to the floor before becoming unconscious. Moderate pain at injection site Headache Weakness, fatigue, malaise |
| 1032891 | 2/16/2021 | PA | 19 | F | 2/15/2021 | 2/15/2021 | Fainting, 11:30 PM |
| 1032727 | 2/16/2021 | FL | 43 | F | 2/13/2021 | 2/13/2021 | Right arm became very painful and unable to move due to the stiffness of the upper arm. Could NOT use or lift arm at all for 24 hours. At 10:30pm on the 13th, my husband and I decided to try and move my arm slowly up and down to help "loosen the stiffness" when my husband lifted my right arm to about shoulder height, the pain was so bad I fainted. I have never fainted before in my life. I was out for about 2-3 minutes. |
| 1033396 | 2/16/2021 | ME | 84 | M | 1/27/2021 | 1/31/2021 | Admitted to Medical Center with syncopal event that occurred at home. Cause of syncope unclear at discharge |

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| 1033420 | 2/16/2021 | CA | 50 | F | 1/14/2021 | 1/15/2021 | From occupational health note: patient was asked by her supervisor to call. Received vaccine on 1/14, had dizziness, seeing spots in her eyes, lethargy and was sent to to ED and discharged. Generalized itching the next day. All sxs have resolved since yesterday. Scheduled to work on Friday, 1/22. From ED note: 50 yo f c/o mild dizziness and light-headedness today, worse with standing up. No n/v/d/f/c. Describes sx as typical early flu like sx today but slightly worse than her usual feeling from flu vaccines. Received the covid vaccine yesterday and friend experienced same symptoms. Felt "difficulty concentrating at work", which was very busy. No weakness, pre-syncope, numbness, cp, SOB. No unsteady gait, vision changes. Occ vision spots assoc with standing up. H/o anemia, h/o gastric bypass 2005. Often gets routine labs q 6 months but has not had any yet since COVID. |

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| 1032920 | 2/16/2021 | MI | 73 | F | 1/22/2021 | 1/22/2021 | Heart rate at 107; Stomach issue; Nausea; Chills; Passed out; Dizzy; Temperature; Hands were shaking; Sweating profusely; A spontaneous report was received from a consumer who is a 73 year old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced chills, dizzy(dizziness), temperature(temperature abnormal), hands were shaking(tremors), passed out(loss of consciousness), sweating profusely(hyperhidrosis), nausea, heart rate at 107(heart rate increased) and stomach discomfort(abdominal discomfort). The patient's medical history, as provided by the reporter included breast cancer. No concomitant medications were reported. On 22 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: 029L20A) intramuscularly for prophylaxis of COVID-19 infection. On 22 Jan 2021, the patient experienced chills, dizzy, temperature, hands were shaking, passed out and sweating profusely. The treatment for the events included paracetamol. On an unknown date, the patient experienced, nausea, heart rate at 107 heartbeats per minute and stomach discomfort. The treatment for the events included paracetamol. Action taken with mRNA-1273 in response to the events was not provided. The outcome for the events, chills, dizzy, temperature, hands were shaking, passed out, sweating profusely, nausea, heart rate at 107 and stomach discomfort was unknown.; Reporter's Comments: This case concerns a 73-year-old female patient, who experienced serious event of loss of consciousness and non-serious events of chills, dizziness, temperature abnormal, tremors, hyperhidrosis, nausea, heart rate increased, and abdominal discomfort. The reported events occurred on the same day after first dose of mRNA-1273, (lot # 029L20A) with the exception of nausea, heart rate increased, and abdominal discomfort which occurred at unknown date. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. |

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| 1033850 | 2/16/2021 | IA | 46 | F | 1/7/2021 | 1/7/2021 | By minute 5, I had numbness in the arm, numbness and tingling in the lips and tongue. By minute 12, I had flushing and passed out. I came back and all of the sudden my words started not making sense and I couldn't move my arms or legs. My speech got better but it continued to be slurred, lost use of my legs 3 different times. |
| 1034418 | 2/16/2021 | CA | 23 | F | 2/5/2021 | 2/6/2021 | sudden onset of nausea, dizziness, body aches, chills, fatigue x 24 hrs post vaccine along with soreness and pain to left arm (site of injection). One episode of what felt as near syncope and cold sweating that lasted for approx 10 mins and resolved. Tylenol and ibuprofen was taken with some relief of pain. Pain to left arm lasted about 3 days and all sx resolved within 24 hrs of onset. |
| 1033234 | 2/16/2021 | VA | 30 | M | 2/16/2021 | 2/16/2021 | Patient was administered the 2nd dose of the vaccine series, previously no reaction to the first dose. Upon standing up, the patient experienced syncope and was caught by the administering pharmacist. Administering pharmacist called for help from the other pharmacists and 911 was called. The patient was set to the ground and administered epinephrine in case of anaphylaxis. The patient was monitored for 3 minutes at which point he seemed to start aspirating. He was then rolled to his side for prevention. Approximately 5 minutes later, the patient came to as EMS arrived on scene. |
| 1034270 | 2/16/2021 | CA | 69 | F | 2/11/2021 | 2/11/2021 | Syncope, dizziness. BP 145/64, pulse 73, O2 sat 100%. 2 L Oxygen via nasal cannula given. |

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| 1033950 | 2/16/2021 | MN | 46 | F | 2/10/2021 | 2/11/2021 | At 4:00 am on Thursday morning (12 hours after vaccination), I got up to use the bathroom and when I was finished, I fainted. My mom heard the loud noise and found me on the bathroom floor and could not arouse me. She called 911 and I came to when she was on the phone with them. She helped me up and I felt weak and flush. She gave me some cold towels and I felt better soon after. She then took me to ER because I had a gash on my chin and my jaw was very sore. I asked the ER doctor if my fainting could have something to do with the vaccine and he didn't think so. He did a CT scan to check my jaw and an EKG and they were both normal. I told him that I have been very busy at work the last week or so and I know that I haven't been eating or hydrating properly. |
| 1033724 | 2/16/2021 | NJ | 25 | M | 2/15/2021 | 2/15/2021 | Patient, who was staff member, passed out about 10 minutes after vaccination. Was administered oxygen and given water. Blood pressure was a little elevated. Oxygen saturation was normal. Refused to go to hospital. Was observed for 30 minutes then allowed to go home. |
| 1033697 | 2/16/2021 | OH | 28 | F | 1/5/2021 | 1/6/2021 | Blindness (loss of vision); Neurocardiogenic syncope; Tingling in hands and feet/lower legs; Panic attack/unable to breathe; Nausea; Vomiting; Dehydration; Tiredness; Body aches |
| 1033689 | 2/16/2021 | KS | 23 | F | 2/15/2021 | 2/15/2021 | Patient experienced light-headedness and syncope 5-10 minutes following administration. Patient began feeling normal again shortly after. Vitals checked normal by EMS personel and patient was released. |
| 1033660 | 2/16/2021 | CA | 67 | F | 2/11/2021 | 2/11/2021 | Patient reported numbness of the left vaccinated arm, "passed out" for a few seconds and became diaphoretic. Cold packs applied. (BG = 126, BP180/100, T 97.2, HR 60, R 18, 18:16 time O2 was 94% room air, EKG Normal Sinus Rhythm Alert and Oriented. Repeat BP 98/78. Patient taken to ER or Clinic for further observation unknown if was a ER or clinic |
| 1033583 | 2/16/2021 | WA | 62 | F | 2/16/2021 | 2/16/2021 | Syncope after getting vaccine |
| 1033571 | 2/16/2021 | IL | 28 | F | 2/16/2021 | 2/16/2021 | first pregnancy. 24 weeks. Felt very dizzy and almost passed out. |

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| 1033506 | 2/16/2021 | GA | 78 | F | 2/13/2021 | 2/14/2021 | Day after injection-Chills, headache, nausea, body aches, diarrhea, dizziness, fainting, temperature. 2nd - 3rd day- headache, fatigue, slight temperature, tightness in chest |
| 1033429 | 2/16/2021 | SC | 49 | M | 1/6/2021 | 1/6/2021 | 1/6/2021 vaccination; Later that afternoon, I started to go into a 'fog', tired, HA. I could function but nothing seemed 'clear' or 'sharp', 1/7/2021 fatigue, arm sore. The 'fog' was worse; 1/8 fog was really bad; forgetting conversations. 1/9 2:45 in morning. Went to bathroom. Walking, about 1/2 way there, felt like a 'spike' and instant HA. I went to bathroom, door closed, I got sick/vomiting. The shiver, shakes, and fever spiked. I bent down to throw up and I cant relieve. I fell into the wall, pushed self to stand up. Was back in bedroom, laying on floor and passed out. Wife woke me, I was bleeding. Don't know how long I was on the floor. BP144/78, 133 blood sugar, O2 was 98%, temp 98.1. 3:45 I decided to go to hospital, EKG, CT scan, Xray, etc. 'Just fainted' *PCP stated it was due to shot / vaccine. **busted lip, ER bill ***2nd vaccine; minor side affects (slight HA,) |
| 1034013 | 2/16/2021 | NY | 43 | F | 2/16/2021 | 2/16/2021 | fainted after injection |
| 1029837 | 2/15/2021 | MI | 68 | F | 2/12/2021 | 2/13/2021 | Maybe 5:00 a.m. woke up and needed to use the restroom, got up slowly and walked to the Bathroom slowly; I passed out and fell on the floor; not sure if my head hit the floor or just the trash barrel. I fell on my right side and the bathtub was at my back. When I realized where I was, I knew I still needed to use the restroom; I meneuvered myself slowly and carefully; I did use the restroom and then I carefully went back to bed. |

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| 1030614 | 2/15/2021 | CA | 34 | F | 2/12/2021 | 2/12/2021 | 11:40am - received 2nd Moderna vaccine at Vaccination Superstation 3:00pm - started to feel queasy (this was also felt with first vaccine) 5:00pm - ate dinner 11:00pm, 2:00am, and 6:00am - vomited 7:00am - tried a small piece of toast for breakfast 9:00am - vomited and immediately had to defecate, while on toilet started to feel dizzy, got up to walk to bed and collapsed on my way, blacked out for a few seconds and hit my face on the carpet. Husband was nearby, he helped me turn over onto my back, I laid there for about 30 minutes resting and then called nurse line who recommended I go to ER. Arrived at ER around 10am. While in waiting room at ER, began to feel dizzy, nurse immediately checked BP and it was low, brought me to room to lay down. Started IV fluids. Doctor consulted, suggested it was likely a vasovagal syncope episode. Ran EKG, CT scan, urinalysis, CBC, chest and finger radiographs- all normal. Received 2 bags of LRS fluids and was able to eat some crackers, discharged around 3pm. I was tired and nauseous the rest of the day but was able to eat small amounts of bland food. No further vomiting. The next day, 2/14, I was still tired and nauseous but ate small meals and rested a lot. Today, 2/15, feeling stronger but not 100%, still a little bit queasy but better than I've been the last few days. |

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| 1031482 | 2/15/2021 | NY | | F | 1/17/2021 | 1/18/2021 | Patient fainted; Migraine; Shortness of breath; Felt very tired; Fever; A spontaneous report was received from a consumer who was also a 34-year old female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and who experienced fainting (syncope), migraine, shortness of breath (dyspnoea), fever (pyrexia), and felt very tired (fatigue). The patient's medical history was not provided. Products known to have been used by the patient, within two weeks prior to the event, included fexofenadine hydrochloride and birth control. On 17 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (Batch number: 026L20A) intramuscularly in right arm for prophylaxis of COVID-19 infection. On 18 Jan 2021, the patient fainted. She felt very tired, had migraine, fever, and shortness of breath. The symptoms continued on and off. Treatment for the event included paracetamol. Action taken with mRNA-1273 in response to the events was not provided. The outcomes of the events fainted, migraine, shortness of breath, fever, and felt very tired, was not reported.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the onset of the reported events, a causal relationship cannot be excluded. Fever and fatigue are consistent with the known safety profile of the vaccine. |
| 1030873 | 2/15/2021 | CO | 51 | F | 2/12/2021 | 2/13/2021 | Disoriented, confused, dizzy and resulted in fainting and was unresponsive for 2 minutes |

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| 1030850 | 2/15/2021 | NE | 23 | F | 12/30/2020 | 12/31/2020 | <p>Twitching of the face; Syncope; Weakness; A spontaneous report was received from a pharmacy intern, concerning a 23-year-old, female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced syncope, weakness, and twitching of the face. The patient's medical history was not provided. No relevant concomitant medications were reported. On 30 Dec 2020, approximately 1 day prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot number 025J20-2A) intramuscularly in the right deltoid for prophylaxis of COVID-19 infection. On 31 Dec 2020, the patient was working and experienced syncope and weakness. On 06 Jan 2021, the patient reported experience twitching of the face beginning on an undisclosed date and she also continued to experience weakness. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the event, syncope, was unknown. The events, weakness and twitching of the face, were considered not resolved.; Reporter's Comments: This case concerns a 23-year-old, female, who experienced serious unexpected event of syncope, and non-serious unexpected events of asthenia and muscle twitching. The events of syncope, asthenia occurred 2 days after mRNA-1273 (Lot# 025J20-2A), while the event of muscle twitching occurred on an unspecified date after mRNA-1273 (Lot# 025J20-2A). Treatment details were not provided. Based on temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Additional information has been requested.</p> |
| 1030699 | 2/15/2021 | MD | 37 | M | 2/12/2021 | 2/13/2021 | <p>At the time of the incident (3:00 A.M.) I was experiencing chills, a fever, and nightmares. When I went to the bathroom I fainted. Once I regained consciousness and got to a standing position I fainted a second time after I took a few steps.</p> |
| 1030645 | 2/15/2021 | MI | 30 | F | 1/15/2021 | 1/15/2021 | <p>Patient reported Syncope/Fainting on site EMS was required. BP 112/72 Oximetry 100 HR 72. Refused care released against medical advice.</p> |

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| 1031612 | 2/15/2021 | TN | 85 | F | 2/1/2021 | 2/10/2021 | 2nd vaccine ?2nd day Blood pressure dropped to 88/55 Fainted Hit head. Couldn?t get up Bruised, sore Early evening 2 days later Raynauds developed on finger on left hand |
| 1030541 | 2/15/2021 | KS | 67 | F | 2/12/2021 | 2/13/2021 | Woke up with sore left arm, weak and had chills. Passed out in the bathroom at 9 pm 2/13/21, hit head and injured shoulder. Did not feel faint-like prior tp passing out. |
| 1030442 | 2/15/2021 | ME | 72 | F | 2/15/2021 | 2/15/2021 | Patient became lightheaded and pale. No syncope. No symptoms/signs of anaphylaxis. Vital signs remained stable. Symptoms resolved within 45 minutes with laying supine, water, and carbohydrate. Completely asymptomatic before leaving building. |
| 1030439 | 2/15/2021 | MI | 47 | M | 1/13/2021 | 1/13/2021 | Patient reported Syncope/Fainting on site EMS was required. SBP 118, Oximetry 98, EMS/on site physician decided No treatment was needed transported to local hospital. |
| 1030338 | 2/15/2021 | MD | 25 | M | 2/12/2021 | 2/13/2021 | Dizziness, fainting, headache, sweating, joint pain |

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| 1030016 | 2/15/2021 | AR | | M | 1/30/2021 | 1/31/2021 | Faint; Shortness of breath; Dizzy; Headache; A spontaneous report was received from a consumer who is a 34-year-old, male patient, who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced fainting, dizziness, shortness of breath and headache. The patient's medical history was not provided. Concomitant medications were not reported. On 30 Jan 2021, the patient received their second dose of two planned doses of mRNA-1273 (Batch number: 029L20A) intramuscularly in his right arm for the prophylaxis of COVID-19 infection. On 31 Jan 2021, 14 hours after the second dose, the patient experienced fainting, dizziness, shortness of breath and headache. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not reported. The outcome of events, fainting, dizziness, shortness of breath and headache, were unknown.; Reporter's Comments: This case concerns a 34-year-old male patient, who experienced medically significant unlisted event of Syncope, non-serious listed event of Headache, and non-serious unlisted events of Dyspnea and Dizziness. The events occurred approximately 14 hours after receiving their second of two planned doses of mRNA-1273 (Lot #029L20A). Based on the current available information and temporal association between the use of the product and the onset of events, a causal relationship cannot be excluded and the events are considered possibly related to the vaccine. |
| 1030578 | 2/15/2021 | | 30 | F | 2/11/2021 | 2/12/2021 | Woke up at 5 am on 2/12/2021 with a 102.8 degree fever, nausea and chills. Got up to get Tylenol and experienced a vasovagal syncope episode with Loss of consciousness lasting 5+ seconds resulting in a closed head injury requiring and emergent visit for approximated head wound, needing 4 staples. |
| 1031620 | 2/15/2021 | KY | 22 | F | 2/8/2021 | 2/8/2021 | Fever (highest- 102.5 F), dizziness, muscle aches/soreness, chills, fatigue, chest pain, shortness of breath, muscle weakness, night sweats, vomiting, fainting |
| 1030332 | 2/15/2021 | NY | 85 | F | 2/14/2021 | 2/14/2021 | Appears to have had a vasovagal response, vomiting and syncope approx. 7pm same day of 2 vaccine. Hit head causing head injury. |

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| 1032148 | 2/15/2021 | OK | 75 | F | 2/11/2021 | 2/13/2021 | 48 Hours after receiving vaccine I woke up with sever vertigo and passed out briefly. Felt dizzy most of Saturday. Sunday morning about 1:00, I woke up with severe vertigo and could not sit up or stand up to go to the bathroom. My husband had to help me. I then experienced severe, repeated vomiting that lasted until 5:30 AM. I was sick and dizzy all day Sunday. Began feeling better that evening. Next day (today) I am much better. But I was desperately ill all Saturday night. |
| 1031669 | 2/15/2021 | PA | 59 | F | 1/28/2021 | 1/29/2021 | I woke up feeling ok just a little tired. When I got into the office I had low back pain, chills, abdominal pain, pain behind left ear, head ache. nausea. I got up and tried to shake it off, I got this sensation of weakness like I was going to pass out and laid myself on the floor everything got a little foggy and I don't remember everything because I passed out. The Doctors I worked with helped me up and called my husband, he took me to the ER and kept me there for a while, my BP was really low. They gave me Tylenol and IV fluids until my BP got better. I went home and felt wiped out, I was able to walk with assistance. The following day I was fine almost like it didn't happen or I was faking it. I didn't get an arm rash like the first dose. |
| 1342666 | 2/15/2021 | IL | 40 | F | 1/12/2021 | 1/13/2021 | 01-13-2021 C/o syncope and collapse Body aches- Transported per EMS. to ER. Sometime around 10:00 am. Arrival ER . 10:39 |
| 1032601 | 2/15/2021 | CA | 29 | M | 2/15/2021 | 2/15/2021 | Moderna COVID-19 Vaccine EUA. Patient came to get his first dose of the vaccine. He fainted while sitting at the post-vaccine observation area. I called 911 to ask for paramedics while the nurses from MinuteClinic checked up on the patient. After a few minutes, the patient's alertness came back, his color returned to normal. When paramedics arrived, patient could verify his infomation and whereabouts. He denied help from the paramedics. Immunization pharmacist recommended him to be observeed for at least 30 mins, and check in with the ER or primary care physician for check-up for any delayed response. Patient said he will follow up with his primary care physician. After 30 mins, his wife came to get him. |

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| 1032152 | 2/15/2021 | NY | 26 | F | 2/13/2021 | 2/13/2021 | 2/13/2021 @11:20pm- fainting episode with vomiting. Convulsing chills for 24 hours post vaccine. Arm heaviness with headache for 24 hours. Morning of 2/15/21- butterfly like rash bilaterally on cheeks and nose resolved with 25mg diphenhydramine. |
| 1032110 | 2/15/2021 | CA | 40 | F | 2/11/2021 | 2/13/2021 | Fainted twice! Causing massive head trauma & wounds. It happened 35 hours after the vaccination & I was given no warning that this could happen. |
| 1032060 | 2/15/2021 | CA | 58 | F | 1/11/2021 | 1/11/2021 | Had feeling of euphoria. Then not feeling well at 1545. Then passed out at 1930, fever, chills, and general malaise began. Worsened on 1/12/2021. Had fever 102 F. Had rigors even with Acetaminophen and Ibuprofen. Then develop. resp. issues, using advair/albuterol/singulair. |
| 1032025 | 2/15/2021 | MO | 72 | F | 2/15/2021 | 2/15/2021 | As I was administering the vaccine, the patient stated: "I feel" and then fainted on me. Her husband and I kept trying to get her to talk to us, she was squeezing my hand as we talked, I ran an alcohol pad under her nose. We got her to open her eyes a few times and decided to call 911. She was breathing and I could feel her pulse. 911 had us lay her on the floor where she started to come to and mentioned how bad her vertigo was before I gave the shot. She also said her blood pressure was really low this morning and didn't want us to call the news as she didn't want to be on the news |
| 1030483 | 2/15/2021 | VA | 53 | F | 2/13/2021 | 2/14/2021 | Nearly blacked out/passed out after I woke up on 2/14 Sluggish with chills and aches the rest of the day Noticed enlarged lymph node in the left arm pit region on 2/15 |

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| 1031707 | 2/15/2021 | CA | 71 | F | 2/15/2021 | 2/15/2021 | Patient verbalized history of dizziness with fainting/falling to floor after receiving flu vaccine. At 1056, Pt complained of dizziness. Placed into wheeled chair, and brought to private holding room. transferred to gurnee. At 1057, B/P 146/71, heart rate 68bpm, Pulse ox 98%. Pt stated Dizziness 8 out of 10, with mild pain to forehead. Seated with head of bed up at 30 degrees. Offered both juice and water to drink At 11: 02, BP 148/76. Heart rate 71 bpm, 95% pulse ox. Pt states dizziness now 6 out of 10. At 11:18, B/P 135/74, Heart rate 65 bpm, 96% pulse ox. Dizziness 4 out of 10 At 11:29 BP 129/76. Heart rate 64 bpm, 95% Pulse ox. Dizziness one out of 10. Patient states minimal pain to forehead. Sat to edge of bed, without incident. Patient brought to standing position, shifted weight from side to side multiple times, and ambulated around holding room without incident. Stated feeling able to return home, and dizziness gone. Left to home with husband at 11:31 |
| 1032188 | 2/15/2021 | CA | 72 | F | 2/1/2021 | 2/9/2021 | Almost fainted 24 hours post injection mild dizziness for about 20 minutes Redness, swelling and itching day 8 post injection |
| 1031682 | 2/15/2021 | MI | 64 | F | 2/12/2021 | 2/12/2021 | Patient received Moderna vaccine on 2/12/21 at 3pm. She sat in our waiting area under observation for 15 minutes (she reported no allergies, prior issues with vaccination such as fainting/anaphylaxis). Once she was home, she started feeling nauseous (and vomiting), severe joint and body pain, headache (reports feeling like, "her head is going to explode). These issues were worst over Friday/Saturday but improved over Sunday and today, Monday. Patient stayed home over the weekend and did not contact emergency services. Patient contacted her doctor on Monday to report the events of the weekend. At this time, her doctor has not recommended any treatments or issued prescriptions, and their plan is to have the patient follow up with the office should things worsen or change. |

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| 1032024 | 2/15/2021 | OH | 54 | F | 2/6/2021 | 2/6/2021 | 1533 Lightheaded post shot pt passed out. BP 182/120, 1540 148/108 pt lying on the floor, responding to nurse. Son was called to meet her at Hospital. 1542 911 called and squad arrived. 1545 Sitting in chair with EMS present. Oriented x3. 1548 Pt ambulated to squad with EMTS. Pt agreed to go to ER. Pt states she passes out after shots. She was advised to inform her PCP. |
| 1031719 | 2/15/2021 | OH | 50 | F | 2/12/2021 | 2/12/2021 | - Got the vaccine in the afternoon and by evening her arm was sore for several hours, about 6-7 hours post her shot she was fatigued. -She then experienced light headedness and headache roughly 10 hours or so after the shot, she had chills but no fever. She went to sleep. - Pt went took Tylenol around 11pm for headache and joint pain. Woke up the next morning and took Tylenol again, she had some severe dizziness around 0730 next day that was made her feel like she was fainting and panicking, she took her BP and it was 76/40. She then took it 20mins later it was back to normal at 116/80. She spoke with her PCP over the phone and they advised her to continue to observe herself at home and go to hospital if it happens again. -On 2/14/2021 at 2pm, her joints are still aching and hands are swollen/itchy/red on the backs of her hands. Followed up later on 2/14/2021 Follow up attempt: Spoke with patient and she is doing better, symptoms are resolving. Ibuprofen taken recently, just managing joint pain and headache with OTC meds. Hand swelling resolved. Advised caller to call us back with further questions or concerns as needed, seek medical attention if dizziness or hypotension occurs |
| 1031739 | 2/15/2021 | FL | 76 | M | 2/12/2021 | 2/13/2021 | About 1:35 am I was experiencing acid reflux, I prepared some alka-seltzer. As I was beginning to drink it I started to feel faint, My legs started to give out, my glass dropped into the sink, and a was flat on my back on the floor. I got up and went to bed. As I lay there uncovered I began to perspire, but that soon stopped. After 10 minutes I pulled the sheet over me and 30 minutes later I pulled the blanket over me. At about 2:30 am I was feeling normal except for the reflux. I took a full dose of alka-seltzer and have had no more problems since then. I believe the acid reflux was from eating and drinking wine that evening. I don't know of the fainting was from the vaccine or a touch of flu for one hour. |

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| 1031814 | 2/15/2021 | MA | 70 | F | 2/10/2021 | 2/15/2021 | I had a bad headache on the first day getting the shot and had a mild headache for the few days. on Feb. 14th I had stomach ache and diarrhea and vomiting, and then I felt dizzy and fainted. |
| 1031888 | 2/15/2021 | CA | 67 | F | 2/13/2021 | 2/14/2021 | I was feeling a bit dizzy upon awakening the day after the vaccination. Once in the bathroom I became very dizzy and started sweating profusely. I tried to walk back to the bedroom but fainted. I came to sitting on the floor. My husband brought me some water and stayed with me. It took quite a while for those symptoms to subside enough that I could get up and go back to bed. For the next 7 or 8 hours I felt chilly and somewhat tired. Normal by late afternoon and evening. |
| 1032012 | 2/15/2021 | WA | 70 | F | 2/1/2021 | 2/1/2021 | Extreme fatigue, weakness, muscle aches, steady headache, from 2 pm until next day. Still fatigued and some dizziness and weakness on second day. Headache diminished. Slight queasy feeling. On third day, one incident of weakness almost to point of fainting. Improved after lying down for 15 minutes. Sore arm. Almost 10 days after injection, raised welt and itching area at injection site. Still itchy 14 days after shot. No other symptoms. |
| 1029316 | 2/14/2021 | NJ | 54 | M | 2/11/2021 | 2/13/2021 | Fainted at 9am with little warning, fainted again at 2:30pm with little warning. |
| 1029624 | 2/14/2021 | MA | 32 | F | 1/22/2021 | 1/22/2021 | 1/22 - near syncope 2/7 - right axillary lymphadenopathy 2/8 - petichiae to right earlobe |

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| 1028990 | 2/14/2021 | TX | 66 | F | 2/12/2021 | 2/13/2021 | After beginning to not feel well--upset stomach, nauseous, lethargic , about 6 hours after shot, I had trouble sleeping and felt bad during the night. I woke up about 6am and when I was brushing my teeth I felt nauseous and very weak, and then I passed out. I hit floor hard and have a good size bump on the back of my head. For the rest of the morning (day after my 1:30 second shot), I continued to feel weak and a little nauseous. I never had a fever. I'm sending this report the morning of the second day after my second dose, and I'm feeling much better--more energy and no nausea. ---But i was pretty sick annd passing out indicates a severe reaction. I'm small--only 4 ft 11 in and 95 pounds. For my retired friends and neighbors who have been vaccinated, the smaller ladies are having much worse side effects. |
| 1029033 | 2/14/2021 | MO | 73 | F | 2/12/2021 | 2/13/2021 | Day of vaccine headache, fatigue, soreness 2nd day 2/13/21 Had issues sleeping and felt uncomfortable. In early a.m. hours, felt dizzy, feeling of sick stomach, and fainted in the bathroom. Paramedics were called by my spouse and they worked with me, then was transported by Ambulance to emergency room where they ran tests and released me the same day. I was told by the doctor that apparently my blood pressure decreased too fast causing me to faint. |
| 1029052 | 2/14/2021 | NY | 54 | F | 2/10/2021 | 2/10/2021 | I got the second does of the Pfizer. I had a massive headache and chills overnight. I had a fever of 100.1 at 7.10am the next morning. I was leaving my ground floor bathroom and I woke up on my basement floor. I fainted and fell down a flight of stairs. I passed out again, when I tried to get back up the stairs. I crawled back up the stairs and phoned my husband to come home, He did and helped me into the bathroom to wash my teeth. I fainted again and he caught me and carried me back into the sofa. I spent the rest of the day in bed. I am bruised and scraped all over. I am sore all over. I went to Urgent Care on 2/13/21 and got x-rays done. I have a fracture in my right thumb and may have a dislocated left shoulder. I have to see more doctors tomorrow. I sill don't fell well and I have no appetite. I fell really weak. I have dizziness when lying down, that may be related to the fall. |

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| 1029222 | 2/14/2021 | NY | 33 | M | 2/11/2021 | 2/12/2021 | woke at 3:30 am on Feb 12, 2021 with severe vertigo that caused him to fall with no injury, he could not get up crawled back to bed. Awoke again at approximately 7:00am with feeling feverish, shills fatigue with no vertigo. At 5:00pm patient stood to walk to bathroom, felt chills and flushed and "passed out" and fell hitting his chin on the kitchen table awoke on the floor did not remember passing out or hitting his chin. He stood up did not feel dizzy, just tired continued to the bathroom. No episodes after that just tired. Patient had been taking fluids throughout the day and eating. |
| 1029239 | 2/14/2021 | NJ | 69 | M | 2/12/2021 | 2/13/2021 | achy upon waking up on 2/13 (approx 7a). At laundromat, started to get clammy, and sweaty. Sat down, and next thing I knew I has fainted (approx 7:45-8a). Police were called, then First Aid Squad. Very pale, sweaty and nauseous (threw up 2x). Went to Hospital. Was evaluated in the ED for approx 6 hrs, then transferred to a room for overnight observation. |

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| 1029296 | 2/14/2021 | PA | 39 | M | 2/12/2021 | 2/12/2021 | THE PATIENT RECEIVED VACCINE. DISCUSSED SIDE EFFECTS AND APPOINTMENT FOR DOSE 2. EVERYTHING WAS FINE, PATIENT DIDN'T HAVE ANY OTHER QUESTIONS/CONCERNS. I SAID I WILL CHECK ON HIM IN A FEW MINUTES. WITHIN MAYBE 1-2 MINUTES, HIS WIFE CAME TO THE COUNTER AND SAID HE IS OUT, PASSED OUT. I WENT TO CHECK ON HIM. YELLED TO MY TECH TO CALL 911. PATIENT WAS SLUMPED OVER IN THE CHAIR. HE WAS BREATHING AND HAD A PULSE, BUT NOT AWAKE. TRIED TO AROUSE HIM BE CALLING HIS NAME AND SHAKING HIS ARM TO WAKE HIM. HIS WIFE THEN WAS TAPPING THE SIDE OF HIS FACE TO WAKE HIM UP. SKIN WAS GRAY IN COLOR. SHE STATED HE IS GOING TO VOMIT AS HE WAKES UP AND NEEDED A GARBAGE CAN. I WENT TO GRAB CAN FROM PHARMACY AND RETURNED. SHE PUT CAN IN BETWEEN HIS LEGS AS HE CAME TO AND IMMEDIATELY STARTED TO VOMIT. HE WAS AWAKE BUT OUT OF SORTS. AT THAT TIME THE EMT ARRIVED AND WENT TO WORK. PATIENT BP WAS LOW AND THEY STARTED IV FLUIDS. THE PATIENT WAS ABLE TO SPEAK TO EMT AND ANSWER THEIR QUESTIONS. THEY PREPPED HIM FOR TRANSPORT TO THE EMERGENCY DEPT FOR FURTHER EVALUATION. BY THE TIME THE PATIENT WAS BEING TRANSPORTED, HIS BP WAS BACK UP CLOSE TO NORMAL. I SPOKE TO BOTH THE PATIENT AND HIS WIFE AROUND 5PM THAT DAY. THEY WERE LEAVING THE HOSPITAL AT THAT TIME. THE PATIENT WAS FEELING MUCH BETTER. HIS BP WAS BACK TO NORMAL, HIS COLOR WAS BACK, AND HIS VOICE WAS STRONG. THEY BOTH PLAN ON RETURNING FOR THE COVID 19 DOSE #2. |
| 1029305 | 2/14/2021 | MD | 48 | F | 2/12/2021 | 2/12/2021 | Soon after my arm got painful into my fingers and in my armpit that subsided. Friday night I had a high fever with chills, soaking through my sheets. Saturday I got up to go to the bathroom and my daughter found me on the floor. I am not sure how long I was passed out for. Today I feel a lot better, sore from falling. I did not hit my head because I fell on laundry basket. I do have some numbness and tingling in both hands today and low energy. |

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| 1028779 | 2/14/2021 | MI | 25 | F | 2/11/2021 | 2/12/2021 | Arm soreness began 7PM on 2/11. Vasovagal syncope episode at 2:25AM on 2/12; triggered by combination of arm soreness, body aches, and low-grade fever. Senses returned back to normal within 5-10 minutes. Consistent low-grade fever from 1AM on 2/12 until 6PM on 2/13. Treated with 1000mg liquid acetaminophen every 6 hours per manufacturer instructions. Notable ache in legs (akin to Restless Leg Syndrome) from 3AM on 2/12 until around 9AM on 2/13. Urge to move calmed by acetaminophen. Highest recorded fever: 99.5°F at 9AM on 2/12. Fever subsided as of 6PM on 2/13. |
| 1029731 | 2/14/2021 | OH | 64 | F | 2/10/2021 | 2/11/2021 | Fever, Headaches, nausea, bodyache. Became very weak, fainted and fell on the floor. lost all her memory about the incident. |
| 1029468 | 2/14/2021 | WI | 67 | F | 1/29/2021 | 1/29/2021 | One of our Greenfield patients called today (2/12/21) to discuss the adverse effects she experienced following her first dose of the COVID vaccine (received last Friday, January 29). The patient indicated that several hours after receiving her vaccine, she experienced pronounced dyspnea and tachycardia. She stated these symptoms lasted throughout the weekend and were severe enough to prevent her from conducting her daily activities. The patient mentioned that, at one point, she nearly passed out while showering from not being able to catch her breath. The patient reported that she contacted her PCP for guidance, who instructed her to visit the ER for a thorough workup; however, the patient stated she did not follow these orders due to concerns of having a high copay. When speaking with her today, the patient assured me that her symptoms have since resolved. |
| 1029783 | 2/14/2021 | DE | 90 | F | 1/21/2021 | 1/21/2021 | Shortly after receiving the Moderna COVID-19 vaccine, patient complained of chest and stomach pain, then became very sleepy and fainted. RN was unable to obtain a manual BP; Apical pulse 36. Pulse Ox in the 70s. She was placed in bed and eventually regained consciousness. Her pulse ox improved to the 90s. BP 92/55. Her only complaint was that her hands were cold. Medical Director believes it was vasovagal syncope due to receiving the vaccine. Patient died on 1/28/2021, due to progressive dementia. |
| 1029342 | 2/14/2021 | HI | 20 | F | 12/30/2020 | 1/4/2021 | Severe hot flashes Syncope episodes |

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| 1029675 | 2/14/2021 | | 35 | F | 2/1/2021 | 2/2/2021 | At 12 hours after the vaccination, the patient became feverish and nauseous. The patient sat down and became dizzy and lightheaded and passed out / fainted briefly, waking up with head on the floor several seconds later but no obvious head injury. These symptoms gradually improved over the next 12-16 hours and the patient did not pass out again. |
| 1029645 | 2/14/2021 | NY | 49 | F | 2/8/2021 | 2/9/2021 | I had nausea and dizziness and then passed out. I hit my forehead on a blunt object so I had a gash over my eyebrow. It was stitched up. CAT scan was normal. |
| 1029633 | 2/14/2021 | NJ | 33 | F | 2/13/2021 | 2/13/2021 | Severe chills, sweating, nausea, dizziness, headache, near syncope event |
| 1029484 | 2/14/2021 | CO | 67 | M | 1/26/2021 | 1/27/2021 | Spouse woke at 3am got up for a drink of water and fainted - fell on a tile floor damaging lips and teeth. I got up to help, cleaning up blood and checking injury. After a while I got dizzy and fainted, got up too soon and fainted again. I fainted a third time, had convulsions and lost bladder control. Visited my PCP a week later. Now have a neurologist appt scheduled, a month out. Currently, I have no apparent issues. |
| 1029451 | 2/14/2021 | GA | 69 | F | 2/9/2021 | 2/9/2021 | Severe muscle pain, severe weakness, slight shortness of breath. Was unable to sleep because of severe muscle pain. I passed out when I went to the bathroom at 3:53 am from the pain I came to on the floor at approximately 3:57 and had hit my head just below my eyebrow on the sink counter. I was bleeding from a wound and sustained a black eye. |
| 1029448 | 2/14/2021 | OH | 49 | F | 12/22/2020 | 1/4/2021 | 12/22 Vaccination Unknown dates; around the holidays 1.5.2021 - missed 2 weeks of work. I started the propranolol. I ended up with extreme HA, vomiting, syncope, Stomach pain, couldn't keep anything down. Lasted for 2 weeks. *2nd shot - same symptoms |

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| 1028602 | 2/13/2021 | IL | 24 | F | 2/11/2021 | 2/11/2021 | Around 5 pm on 2/11 (day of vaccination) I began to notice a very sore arm and dry mouth/dehydration. Drank water and continued as normal. Around 2 am of 2/12 I woke up with chills and had been sleeping very restlessly. I had body aches in my arm, legs and back. Around 3am my temperature was 100.2. I also felt very faint when standing and thought I may pass out. 3 times when standing, I had to quickly sit down to avoid it. I do suffer from vasovagal syncope so this may be unrelated to vaccination. I took Tylenol and drank more water. Temp rose to about 100.6 before beginning to drop at around 4 am. I continued to take Tylenol every 4 hours and it helped keep temp below 100 but towards the end of the 4 hours, it would start to rise again. I ate normally and drank extra water due to feeling dehydrated still. Around 1 PM 2/12 I started to feel nauseous and had an upset stomach. I was still have a general body aches and elevated temperature around 99.5. My normal temp is usually about 98.0. Nausea led to diarrhea 1 time. Symptoms continued until approximately 8 pm when very quickly the body aches, nausea, fever and soreness in injection arm all went away. None of these symptoms have returned and it is now 2/13 at 8 pm. I did test positive for Covid-19 on December 28, 2020 but have been fully recovered with no symptoms since 1/8/2021. |
| 1028017 | 2/13/2021 | OH | 46 | F | 2/10/2021 | 2/12/2021 | Woke up nauseous, clammy, passed out but never vomitted, Chills all day and achy all over. |
| 1027753 | 2/13/2021 | OH | 26 | F | 2/10/2021 | 2/10/2021 | Passed out after receiving |

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| 1027476 | 2/13/2021 | WA | 66 | F | 2/9/2021 | 2/10/2021 | 18 hours after 2nd dose, severe cramping, diarrhea, sweating. Passed out while on toilet. Came to with nose bleeding from both nostrils, goose egg on forehead. Husband helped me back on commode, more diarrhea, then threw up 3 times. After 15 minutes, helped back to bed, chills, shakes, fatigue. May have broken/cracked nose and slight concussion - was slightly confused for 24 hours, headaches, unable to wear eyeglasses due to swelling and bruising on nose. Ice pack on nose 4x day for 15 minutes. Tylenol and Ibuprofen for pain. At 60 hours (after injection) welt is fading and not hot, beginning to feel better, although still fatigued, and headaches continue. This description was sent to my doctor. |
| 1027771 | 2/13/2021 | PA | 26 | F | 2/12/2021 | 2/13/2021 | Around 11 pm on 2/12/2021 patient had sever body aches that required Motrin OTC , I woke at 5 am on 2/13/2021 and had sever body aches and chills, I went to the bathroom and woke up on the floor and had passed out. |
| 1027773 | 2/13/2021 | PA | 27 | F | 2/12/2021 | 2/13/2021 | I became suddenly very dizzy, passed out, and woke up on the floor. I don't remember falling. When I woke up I had bladder incontinence, was very dizzy, and became nauseous. I threw up over night from dizziness. Today I am still dizzy. |
| 1027780 | 2/13/2021 | OH | 34 | M | 2/13/2021 | 2/13/2021 | Passed out in his chair and hit the floor. Possible seizure for 5 seconds. He was the conscious over the next hour but would get light headed and need to lay down. |
| 1027816 | 2/13/2021 | KS | 51 | F | 2/6/2021 | 2/7/2021 | 2nd COVID vaccine 2/6/21 @10:02am. Episode of vasovagal syncope 2/7/21 @5:00a. Also side effects of fever, N/V, diarrhea and weakness of approx. 1 hour. Unable to eat/drink. Presented to the ED 2/8/21 @1:30p. Rec 1L LR, Tylenol, benadryl and compazine @5:25p. CT head @6:00p. I was d/c from the ED 2/8/2021 @7:47p. Severe vertigo 2/7 @5:00a-2/9 @4:00p. Profound hearing loss noted @11:30a 2/10/21. Appt with audiologist 2/12/2021 @8:00a, ENT 2/12/2021 @1:50p. Hearing test X2 shows near 100% hearing loss in R ear. Rec steroid injection behind R eardrum 2/12/21 @2:30p. PO steroid taper 2/12/21 @5:30p. |

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| 1027866 | 2/13/2021 | SC | 22 | F | 2/12/2021 | 2/13/2021 | Was having body aches everywhere so I got out of bed at 2:30am to take some ibuprofen. I started to feel lightheaded and started to get the cold sweats. Next this I know I?m waking up on the ground. I had passed out. I went to the ER and was diagnosed with syncope. I wasn?t given any treatment after they identified my EKG and vitals were normal and was discharged quickly. I feel fine right now. |
| 1027615 | 2/13/2021 | NY | 45 | F | 2/11/2021 | 2/12/2021 | left arm pain and swelling with a small red circular rash that is not indurated. At the time pt was in office she became dizziness and fainted |
| 1028311 | 2/13/2021 | MD | 21 | F | 2/3/2021 | 2/12/2021 | Event:Loss of Consciousness, Fainting, Falling Outcome: possible concussion |
| 1028324 | 2/13/2021 | CA | 40 | F | 2/11/2021 | 2/11/2021 | Lightheaded (almost fainting for 24 hours) 103 temp, body aches like nothing I?ve ever felt. Extreme pain at injection site. Chills. Joint and sling pain. Earlobe pain. Headache. Worst flu-like experience ever. |
| 1028354 | 2/13/2021 | LA | 65 | F | 1/4/2021 | 1/6/2021 | On the 01/06/2021 I noticed that I had a fever of 100.9 I was really fatigued . I Thinking I was okay . I went to visit the nail shop and fainted.. I was rushed to the hospital . My heart was fluttering and racing . My blood pressure was also low . |
| 1028454 | 2/13/2021 | OH | 45 | F | 1/25/2021 | 2/6/2021 | 10 days after second dose awoke at 11:30 at night with nausea then after a few minutes began to itch and break out into hives then proceeded to get chest pressure and unable to breath until I passed out. Husband able to revive me 3 times until 911 came then went to urgent care Nausea with vomiting and chest pain, back pain, heart burn, and urinal incontinence. Sent to MC for NSTEMI work up of echo and cardiac stress test. Cardiologist said NSTEMI from low oxygen and hypotension. |

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| 1028476 | 2/13/2021 | AR | 79 | F | 1/21/2021 | 1/22/2021 | She started having breathing problems/heart attack appearance. on 1/22/21 and went to the ER. Upon admittance was told it was an anaphylactic shock from the Covid shot. They kept her in ICU and released her 1/23/21. At 12:45 am on 1/24/21 she passed out and we called the ambulance. Hospital admitted her and worked through multiple organ failure issues and thought her numbers were under control. She was released on 1/27/21 and was driving on 1/28/21 around 4:15 pm and appears to have had heart failure and had a wreck. She passed away that day. |
| 1028558 | 2/13/2021 | | 53 | F | 2/12/2021 | 2/1/2021 | 12 hours after receiving my booster I got up to go to the bathroom at 2 a.m. and fainted. My husband caught me. I collapsed. After coming to I immediately had to take a bowel movement and broke into an intense sweat. Followed by chills for 2 hours/. I could not get warm. The next day I had a fever of 102. |
| 1028566 | 2/13/2021 | CA | 29 | F | 2/13/2021 | 2/13/2021 | Patient felt faint and she sat on the ground on her knees. She was pale and clammy. VS normal. No LOC. Patient has history of fainting when getting blood drawn. She felt better after resting and water. |

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| 1031115 | 2/13/2021 | | 66 | M | 2/11/2021 | 2/11/2021 | syncope, c/o itchy throat Narrative: Patient was seen prior to administration of the Moderna COVID-19 vaccination. He has allergies to bees/egg and a h/o anaphylaxis 2/2 receiving an injection of penicillin in the past. Discussed that prior h/o anaphylaxis to PCN injection was not a contraindication to this vaccination, but is a precaution. Discussed risks of receiving the vaccination vs benefits of the vaccine, which patient states "I already had this discussion with Dr.!" He has multiple comorbidities which place him at a higher risk for more severe illness from COVID-19. Again received the risk vs benefit discussion. Patient stated understanding and desire to proceed with the vaccination. He will be monitored for at least 30 minutes in area where staff can directly observe him. Patient received the COVID vaccination at 13:00. At 45 minutes later, staff alerted that he was c/o palpitations. Due to confusion and weakness, we were unable to transport him to an examination room. Oxygen, water, and vitals machine were brought to him. He presented with SOB, confusion, lightheadedness. Exam demonstrated acute distress, speaking in staccato sentences. HR in 80s, with lungs CTAB and no stridor - despite increased RR to 20s. Vitals with HR in 70s, SpO2 remained 97% or greater on RA. BP was initially 140/72. A code blue was called and Drs. presented to the area. Patient c/o itchy throat and still p/w confusion/combativeness, loss of orientation, and SOB. No visible swelling noticed. At around 13:58, patient syncopized. HR and SpO2 remained 70-80s and >98% on room air respectively. Pulse remained palpable. At that time, an epipen was administered. Patient woke up. During the entire episode, he was able to recognize a staff member with whom he was previously familiar. EMS arrived, vitals remained stable. EMS transported patient to the ER for further monitoring and f/u. Concern for immediate allergic reaction 2/2 vaccination. After event, patient in need of referral to allergy provider for evaluation prior to consideration of 2nd dosage. |
| 1028559 | 2/13/2021 | AZ | 48 | M | 2/12/2021 | 2/13/2021 | Two episodes of syncope within 15 seconds of one another. |
| 1028290 | 2/13/2021 | FL | 37 | M | 2/8/2021 | 2/9/2021 | Diarrhea, fever, chill, severe exhaustion, vomiting sweating and passed out. Residual sweating and difficulty sleeping |

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| 1026254 | 2/12/2021 | VA | 54 | F | 1/27/2021 | 1/27/2021 | Received Moderna COVID-19 vaccine on 1/27/21 in the am. At 11:30 pm, pt started to feel sweaty and went to the bathroom. She passed out and fell to the floor. Woke up on the floor. Incontinent of stool. Had scratches on forehead and nose from the fall. Called her daughter who took her to emergency room. She was not admitted. She was not given any treatment. Stated they checked her vitals and drew some blood work. She stated that she was told it was due to her blood pressure dropping. Discharged home with no further problems. Reported this on 1/12/21. |
| 1026007 | 2/12/2021 | | | M | 1/17/2021 | | Had a syncopal event; A spontaneous report was received from a health care provider who is also the patient, a male of unreported age, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced a syncopal episode. The patient's medical history was not provided. No relevant concomitant medications were reported. On 17 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (Lot number: unknown) intramuscularly for prophylaxis of COVID-19 infection. On 17 Jan 2021, after receiving the vaccine, the patient had a syncopal episode. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not reported. The outcome for the event, syncopal episode, was considered unknown.; Reporter's Comments: This case concerns a male patient of unknown age. The medical history is not provided. The patient experienced a medically significant and unexpected event of Syncope occurred one day (same day) after receiving their first of two planned doses of mRNA-1273 (Lot unknown). Based on the current available information and temporal association between the use of the product and the onset of the event, a causal relationship cannot be excluded and the event is considered possibly related to the vaccine. |

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| 1026008 | 2/12/2021 | CT | 47 | F | 1/8/2021 | 1/8/2021 | New sensitives to face cleansers; Anaphylactic shock; A spontaneous report was received from a consumer, concerning herself, a 47-year-old female patient, who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced anaphylactic shock and "newsensitives to face cleansers". The patient's medical history was not provided. Concomitant product use included face cleansers. On 08-Jan-2021, the patient received the first of two planned doses of mRNA-1273 (lot number unknown) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 08-Jan-2021, approximately five minutes after receiving the vaccine, the patient experienced anaphylactic shock as evidenced by throat warm and tingling, arms was bright red and warm to touch, trouble breathing, felt like choking, and nausea. Hence, she was treated with "epinephrine quite a few times along with steroids and ranitidine". On 09-Jan-2021, the patient went to the hospital two more times for "breathing issues", however she was not admitted. On 10-Jan-2021, in the morning, the patient had "passed out" and was given another epinephrine injection as she went into anaphylaxis shock again. On-29 Jan-2021, the patient also reported her arm, legs and chest are "bright red" and "burns". The patient also experienced new sensitivities to the face cleansers she has used for over 12 years. Action taken with mRNA-1273 in response to the events were unknown. The events, anaphylactic shock, was considered newsensitives to face cleanser" were considered not resolved.; Reporter's Comments: This case concerns a 47-year-old female patient, who experienced serious event of anaphylactic shock and non-serious event of sensitive skin. The event of anaphylactic shock occurred on the same day and re-occurred again approximately 2 days after first dose of mRNA-1273, lot # unknown. Based on the current available information and temporal association between the use of the product and the onset date of the events, a causal relationship cannot be excluded. |

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| 1026012 | 2/12/2021 | CA | 21 | F | 1/1/2021 | | Fainted; A spontaneous report was received from a 21-year-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced fainted (syncope). The patient's medical history was not provided. Concomitant product use was not provided by the reporter. The patient received her first of two planned doses of mRNA-1273 (lot/batch number unknown) in the left arm in approximately January 2021 for prophylaxis of COVID-19 infection. In approximately January 2021 (a few days later after vaccination), the patient experienced fainted. Treatment information was not provided. The action taken with mRNA-in response to the event was unknown. The outcome of the event fainted was unknown.; Reporter's Comments: This case concerns a 21-year-old, female, patient, who experienced a serious unexpected event of syncope. The event occurred at unknown date, reported as few days later, after first dose of mRNA-1273, lot # unknown. Treatment information is not provided. Based on the current available information and temporal association between the use of the product and onset of the event a causal relationship cannot be excluded. |

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| 1026024 | 2/12/2021 | MO | 32 | F | 1/26/2021 | 1/26/2021 | passed out and almost broke her arm; started salivating really bad/it's lot of drool; Heart rate started pounding; This is a spontaneous report from a contactable consumer (patient). A 32-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EL9261, expiration date May2021), via an unspecified route of administration on 26Jan2021 at single dose for COVID-19 immunisation. Medical history included: Allergy. Concomitant medication included drospirenone, ethinylestradiol (YASMIN) for Birth control, chlorphenamine maleate (PIRITON) for Allergy. The patient was perfectly fine up until about the 3 hours after the vaccine, she started salivating really bad, she was not throwing up or nauseas or anything, it's just that it's lot of drool, like she even had just go over sink as just salivating so much it was weird, and her heart rate started pounding and she passed out and almost broke her arm, so and then she kind of like blacked out and don't remember anything for rest of the evening. The events onset date was on 26Jan2021 08:30. No treatment was received. The outcome of events was recovered in Jan2021. |
| 1026060 | 2/12/2021 | GA | 65 | F | 2/10/2021 | 2/10/2021 | Severe flu like systems with nausea and cramping. Lightheaded, clammy, cold to the touch. No fever. Passed out 3 times - per my husband trying to go the bathroom. These systems lasted from 10.30 pm till 8.00am the next morning. Severe nausea continued and my doctor prescribe ondansetron. This is the sickest I can remember being in my life. I am very concerned about me passing out. |
| 1026126 | 2/12/2021 | PA | 24 | F | 1/6/2021 | 1/6/2021 | Around 12 hours post-vaccine experiences severe chills for a couple of hours. Woke up around 8AM with headache, took an advil, passed out for an hour and have been fine since. |

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| 1025689 | 2/12/2021 | DE | 70 | M | 2/10/2021 | 2/10/2021 | Client sitting in his wheelchair after 1st COVID 19 vaccination, arrived in observation room 1:57pm. Client with complaint of headache. He reported rating as 5 and said headache usually followed by syncope. He then lost consciousness and aroused by a nurse present in the room. He was maintained in his wheelchair. He was breathing on his own and has a pulse. He noted headache still present, again lost consciousness and was aroused by a nurse in the room. EMS arrived and assisted client to the floor. He aroused. EMS assessed the client, and brought paramedic assessed EKG. Client was transferred to stretcher, awake responsive. Client |
| 1026252 | 2/12/2021 | NM | 75 | F | 2/9/2021 | 2/11/2021 | Received dose on Tuesday, felt fine besides sore arm and body aches. Then on Thursday evening between 7 and 9pm, patient fainted with no warning signs. Patient was talking to sister on the phone and sister states she was confused. Patient is not sure how long she was unconscious for. Patient hit the back of her head and hurt her left arm. Her head bled a little bit. She denies headache. She is sore from the fall, she still has a sore arm and body aches. She checked her blood pressure this morning, 2/12/21, is was 139/88 and pulse 95. Patient has not gone to an urgent care yet to get checked out. Recommended patient contact doctor and be seen right away. She will contact urgent care as soon as we are off of the phone. |
| 1025434 | 2/12/2021 | NY | 33 | F | 1/27/2021 | 1/28/2021 | Patient reported syncopal episode at 2AM on 01/28/21. Per patient, she woke up feeling nauseas went to bathroom became faint when she turned on the light and passed out. Per patient she believes she hit her head on the bathroom since. 1x1.5 inch bruised are noted to left forehead. Per patient she was seeing a bright spot and blurry vision to left eye for 45 minutes following the fall. At time of assessment patient experiencing mild headache and fatigue. Patient took 600mg ibuprofen at 4AM. |
| 1026210 | 2/12/2021 | CA | 69 | F | 2/9/2021 | 2/9/2021 | syncope (in setting of chills) about 12 hrs after vaccine given |

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| 1025673 | 2/12/2021 | NY | 53 | F | 1/28/2021 | 1/28/2021 | PATIENT REPORTED SYNCOPE TO CHILDHOOD IMM., BUT NOT RECENT FLU SHOT. PATIENT WAS OBSERVED TO BE FINE FOR 20 MINUTES POST-VACC. SHE WAS ON HER WAY HOME AT 50 MINS. POST-VAC WHEN SHE BECAME UNCONSCIOUS, UNRESPONSIVE, & PRESENTED W/HIVES. SHE WAS TREATED AT EMERG. DEPT. AFTER 90 MIN, SHE IS CONSCIOUS & IMPROVING. |
| 1025614 | 2/12/2021 | TX | 52 | F | 2/10/2021 | 2/10/2021 | Body aches, not just in injection site, dizziness, nausea, fainting. Lasted 30 hours after beginning of symptoms |
| 1025539 | 2/12/2021 | CT | 35 | F | 2/11/2021 | 2/11/2021 | At about 7-8pm the day of vaccination I started to experience body aches, chills, low grade fever. I was so cold that my fingers turned blue and I looked very pale. In the middle of the night, when going to the bathroom, I felt nauseous and dizzy and fainted hitting my head hard on the floor . Today I have a bad headache and still feel slightly cold. |

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| 1025005 | 2/12/2021 | | | F | 1/27/2021 | 1/28/2021 | Fainted during the night; I had chills with a high fever; A spontaneous report was received from a female consumer, age not reported who experienced "chills with a high fever", and "fainted during the night" after receiving the second dose of mRNA-1273. The patient's medical history was not reported. Concomitant product use was not reported. On 27-Jan-2021 prior to the onset of symptoms, the patient received her second dose of mRNA-1273, route, site and Batch number not reported, for prophylaxis of Covid-19 infection. The patient reported a bad reaction approximately after ten or eleven hours after her immunization, she had chills with a high fever and then fainted during the night. She reported that she did come to a moment later. On 29-Jan-2021 she reported that she is feeling fine that day. The patient stated that she felt it was an unusual reaction that should be reported. Treatment for the event was not reported. Action taken with the study drug due to the events "chills with a high fever", and "fainted during the night" was not reported. The events "chills with a high fever", and "fainted during the night", were considered recovered/resolved on 29-Jan-2021.; Reporter's Comments: This case concerns a female patient, who experienced events of chills with a high fever, and fainted during the night. The events occurred 10-11 hours after the second and last dose of mRNA-1273 vaccine administration. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded and the events are assessed as possibly related. |
| 1026321 | 2/12/2021 | NJ | 47 | F | 2/11/2021 | 2/12/2021 | Fever, aches, nausea, chills, headache, pains, fainting |
| 1025406 | 2/12/2021 | NY | 26 | F | 2/12/2021 | 2/12/2021 | Patient reports that she has a history of near syncope following immunization's. Patient was walked to recovery as per protocol, when she suffered a period of near syncope. Patient was moved to wheelchair and placed in fowlers position, Cardiac Monitor applied, BG was 133 at time of reaction. Patient is closely monitored in clinic with improving conditions after about 10 minutes of care. Patient reports that she now feel well and was advised to seek further medical treatment as needed and to advise Clinic of any change in condition. |

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| 1025365 | 2/12/2021 | NJ | 21 | F | 2/2/2021 | 2/2/2021 | Patient fainted after injection, possible seizure (she had rapid eye movement) lasted approximately 1 minute. Patient woke up saying she was ok then fainted again lasted approximately 2 minutes . After she woke up she wanted and received ice pack behind her neck . We asked her to stay 30 minutes for observation. She stated she was fine after the 30 minutes. |
| 1025239 | 2/12/2021 | MA | 58 | F | 2/4/2021 | 2/4/2021 | Started with a low grade fever, that evening into the next day severe headache, body aches, chills and temperature. Friday afternoon fever was 104, very severe body aches and headache. I was brought to the ED at 2:30 in the afternoon. Upon arrival I was vomiting and passed out. After being treated and discharged home I continued with headache and nausea, which continues until today (Tuesday) the 9th. |

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| 1025007 | 2/12/2021 | NJ | 21 | F | 2/2/2021 | 2/2/2021 | Rapid eye movement like "having a mini-seizure"; Fainted; Feeling warm; A spontaneous report (United States) was received from a pharmacist concerning a 21-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and fainted and experienced to have rapid eye movement like "having a mini-seizure" and feeling of warmth. The patient's medical history included historical seizures. Concomitant product use was not provided by the reporter. On 02 Feb 2021, the patient received their first of two planned doses of mRNA-1273 (Batch number:026L20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 02 Feb 2021, a few minutes after the injection, the patient fainted then recovered but again fainted and was noted to have rapid eye movement like "having a mini-seizure". HCP managed her with ice pack as patient complained of feeling warm and she recovered in less than 30 minutes. Treatment information was not provided. The outcome for events fainted, rapid eye movement like "having a mini-seizure~~" and feeling warm were resolved.; Reporter's Comments: This spontaneous report concerns a 21-year-old, female patient with historical seizures. who received experienced the patient fainted then recovered but again fainted and was noted to have rapid eye movement like "having a mini-seizure." The event occurred a few minutes after the administration of mRNA-1273 vaccine (Batch number: 026L20A, expiration date: unknown). Treatment administered include Icepak and outcome is resolved. Based on the information provided which includes a strong temporal onset between the vaccine administration and the event, a causal association cannot be excluded. However, event is confounded by the subject's history of seizures. Feeling warm is consistent with the safety profile of the product. |
| 1027304 | 2/12/2021 | IN | 43 | M | 2/10/2021 | 2/11/2021 | Woke up the next morning feeling a little weak, muscle soreness, and slight sore throat. About 30 minutes after waking up I passed out and fell while taking a shower. I have no history of passing out for any reason and have had no side effects with any other prior vaccinations. |

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| 1025458 | 2/12/2021 | ME | 27 | F | 2/11/2021 | 2/11/2021 | Please note, vaccine was not administered at doctors office. Not clear what was being asked in previous page for address - of doctor or vaccination site. I had vaccine at 730-740am and by 430pm, I had heavy onset symptoms of body aches, chills, fever etc. I took 1000mg of Tylenol and began feeling better. Still exhausted so I went to bed around 630pm but because I was pushing so much fluid, I kept getting up to pee. I was still freezing. Around 940pm, I woke up to pee and again freezing still. I sat on the toilet and started having full body convulsions and the next thing I remember is waking up on the floor. My husband found me passed out, face first on the tile floor with my pants still down. I hit the left side of my face very hard. My husband helped me to bed where I took more ibuprofen and tremored for the next hour before I fell asleep. I woke up completely drenched and sweat and with a headache. |
| 1027394 | 2/12/2021 | WA | 30 | M | 2/11/2021 | 2/12/2021 | Fainting/ dizziness heavy perspiration |
| 1027238 | 2/12/2021 | WI | 41 | F | 1/23/2021 | 1/23/2021 | Itchy, redness, swelling, for 10 days. fatigue, dizziness, presyncope ongoing 3 weeks later |
| 1333037 | 2/12/2021 | WI | | F | 2/12/2021 | 2/12/2021 | Reactive Anxiety secondary to medical procedure acute on chronic + pallor , diaphoresis - syncope |
| 1027362 | 2/12/2021 | NJ | 58 | F | 2/11/2021 | 2/11/2021 | 1120 S/p almost immediately following vaccination reports "feels really dizzy", witnessed loses balance and assisted to floor (left side) by vaccinator; coherent at this time, oriented x 3 at this time, informs "ate a full breakfast" and continues to answer questions on prompt; Vitals assessed: BP 115/65 P 84 RR16 O2 sat 98% RA; 1125 verbalizes increased dizziness "be still room is spinning", client attempts to lift head and sit up w/ immediate episode of syncope, soon recovering and responds to verbal stimuli and questions "I'm ok"; sits up with assistance, offered and consumes sips of H2O. 1130 BP 119/ 89 P 84 RR 16 O2 Sat 99%; EMS dispatched for transport to hospital for further evaluation / treatment |

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| 1027311 | 2/12/2021 | CA | 55 | F | 1/29/2021 | 1/29/2021 | Almost passed out within 5 minutes of receiving vaccine. Had 2 more waves of significant dizziness within first 30 minutes after receiving vaccine. Vital signs taken with elevated blood pressure initially. No other treatment given except for a drink of water. Sent home. 2 more instances of severe dizziness with almost losing consciousness after leaving the medical office (All within 1 hour after vaccination). Unable to swallow within 15 minutes of leaving the medical office where I received the vaccine. I went to ER and stayed for 1 hour where inability to swallow subsided. Dizziness subsided with oral Benadryl, although I've had a few dizzy spells since then. February 5, I started having severe left arm pain that was not there previously. I went to Urgent Care 2/12/21 when left arm pain radiated into chest, and I started having elevated blood pressure. My blood pressure was previously under control. My blood pressure was elevated in Urgent Care. I was placed on short-term Isosorbide 10 mg twice daily. My ECG was normal. I was also placed on Flexeril 10 mg 3x daily for severe left arm pain. |
| 1027288 | 2/12/2021 | PA | 23 | F | 2/11/2021 | 2/12/2021 | Had normal immune reaction symptoms going to sleep, work up at about 12:30 and went downstairs to get water. Felt very weak and was walking out of kitchen when I felt extremely nauseous for about 10 seconds then started to stumble and dropped my water as I fell. Got back up and tried getting more water and then I fully fainted and woke up slightly confused on the floor. Felt slightly better after and called my PCP's on call doctor who told me I did not need to go to the ER. Woke up with body aches/mild fever still and a headache from hitting my head |

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| 1027210 | 2/12/2021 | CA | 62 | F | 2/2/2021 | 2/3/2021 | At 2pm I was at work and packed my things like I was going home. A friend saw me and told me it wasn't time to go home. At this time she took me to my office and I realized I was confused. When I got home on the 3rd of February I had a fainting spell. I had headache on the left parietal and temporal lobe. The headache was the worst headache of my life. It lasted for 7 days. It was throbbing and pulling constantly. It felt better when I was sleeping. The left side of my head was warm. Upon waking up, my headache would return. On day 7 all symptoms resolved. I went to my physician (Via phone visit) and she has ordered me an MRA w/o contrast head which is now pending. |
| 1027201 | 2/12/2021 | NY | 71 | F | 2/12/2021 | 2/12/2021 | Patient called staff over and told him she was going to faint. staff got senior nurse to help assess. Other nurse which was at pt site. Patient leaning forward and then sat back head tilted backwards, eyes opened and non-responsive. Sternal rub performed and other noxious stimuli performed. Continued until pt became responsive. app less than a minute late patient became responsive. Alert and Oriented X 4, Vital signs obtained. encouraged Patient to drink water and take deep breaths. Patient stated incident of fainting occurred prior in dermatologist office. No follow-up care was given after the doctors visit. patient became nauseas and vomited. She was clammy and pale. Patient was encouraged to go to the hospital and would not let us call EMS. Said she would not take public transportation home. She will take a cab and call her PCP in the morning and follow-up care. Staff verbalized that it was unsafe for her to go home rather than the hospital. patient denied any further dizziness, nausea or respiratory distress. Stated she just felt unwell and needed to rest. Staff made her sign "Refusal of Immediate Care Against Medical Advice". Patient then called uber and staffed member escorted pt into cab at 7.12pm. We attempted to call patient multiple times between 7.23 pm - 7.30 pm. |

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| 1027169 | 2/12/2021 | MN | 23 | F | 2/12/2021 | 2/12/2021 | Patient passed out and fell to the floor. She was very dizzy and nauseous. She may have also hit her head on the floor when she fell. She stayed laying down until she felt better and then sat up. She said her neck also her, and she used an ice pack. A nurse was with me, helping with paper work and she helped to monitor her. Patient called a friend to take her home once she was feeling better so she wasn't left alone. |
| 1027135 | 2/12/2021 | CA | 68 | F | 2/12/2021 | 2/12/2021 | Pt received vaccine @ 2:50 PM. Pt reported feeling dizzy, hot and sweaty. Pt has a history of anxiety/fainting when dealing with needle sticks. VS 122/80 HR: 72 O2: 94. Patient later reported feeling back to normal. Pt denied feeling dizzy, hot, and sweaty. Pt was d/c home with her husband. |
| 1027112 | 2/12/2021 | IN | 81 | F | 2/10/2021 | 2/11/2021 | Fever, chills, body aches, fatigue, fainting through first night. Body aches and fatigue next day and night. Still have some aching and fatigue on fri, second full day after vaccination |
| 1026575 | 2/12/2021 | WV | 72 | M | 2/9/2021 | 2/9/2021 | Patient came to the Health Department on afternoon of 2/12/21 to report incident. He received the vaccine approximately 4:20pm. According to the patient, he felt at his normal all evening. At 9:15pm, he reports he started having chills and was very cold. He rested with a blanket until he got up at 9:30pm to get a drink of water and check his temperature. Per the patient, he remembers checking his temperature, which was 97.6F, then awoke on the floor. He had passed out, believes he was "out" for no more than a minute. Patient reports he felt well when he awoke and has felt at his baseline ever since. He has abrasions to bilateral hands, as well as his chin. His upper lip was busted. He did not see his doctor in regards to this. He admittedly does not see a doctor often. Encouraged patient to follow up with is doctor, as he states he has a history of a stroke and heart attack. |
| 1026381 | 2/12/2021 | NY | 69 | M | 2/12/2021 | 2/12/2021 | Pt became faint 10 minutes or so after dosing of cv19 vaccine. Per EMS pt passed out for about 1 minute. Pt came to stated he felt ok. Decreased blood pressure 80/40. pt states he had not eaten anything since 0700 blood sugar 125, pt loaded on to stretcher and transported via EMS to local hospital St. Lukes for fluids and monitoring. |

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| 1027098 | 2/12/2021 | AK | 35 | M | 2/12/2021 | 2/12/2021 | With in a few minutes of receiving the injection patient said he felt like he was going to faint. HCP stood next to patient and he remained upright in the chair but his head rolled back, he became pale and sweaty and passed out. Patient recovered and 10 minutes later repeated the episode. Patient recovered and 5 or 10 minutes later he repeated the episode. BP was 90/50, 89/53 and 109/76. He received 25mg of benedryl. An ambulance transported him to the hospital for further observation. |
| 1026393 | 2/12/2021 | AZ | 73 | F | 2/11/2021 | 2/11/2021 | Severe pain in the R arm vaccinated fainting almost 3 hours after receiving vaccine |
| 1026666 | 2/12/2021 | CA | 37 | F | 2/11/2021 | 2/12/2021 | I became light headed, then passed out, then woke up and started vomiting, vomited/dry heaved about a dozen times, then had severe chills and could not feel my feet and hands for about 2 hours. I have had vasovagal events in the past and this was exactly like them, only normally they are triggered by an event, and there was no event so I assume it was the vaccine. After sleeping it off under multiple blankets for a couple hours I seem to be recovered and just have a headache. |
| 1026700 | 2/12/2021 | GA | 37 | F | 2/11/2021 | 2/11/2021 | Patient was on observation area after receiving vaccine. Patient fainted falling face first onto the floor from seated position. Patient denied history of anaphylactic reaction to any inject-able medication. EMS was called and patient left with EMS. |
| 1026796 | 2/12/2021 | | 42 | F | 2/12/2021 | 2/12/2021 | pre-syncope, no n/v. no tru syncope. observed pt in car. 98ra. put feet up on dashboard. q10min checks and given juice. she felt much better after 30min obs and husband drove her home. |
| 1026837 | 2/12/2021 | FL | 74 | F | 2/2/2021 | 2/3/2021 | on 2/3/21 middle of the night was dizzy and fainted. Had cold sweat and weak to stand. had upset stomach. Flu like aching, but not fever. As of 2/11/Still weak and light headed. Off balanced noticed. No fever though. |
| 1026966 | 2/12/2021 | PA | 73 | F | 2/12/2021 | 2/12/2021 | Chest pain radiating to arm pits, shortness of breath, fast heart rate, fainting, loss of vision |

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| 1026994 | 2/12/2021 | MO | 80 | M | 1/26/2021 | 1/27/2021 | Patient began feeling ill within 24 hours of getting second COVID19 vaccination. Presented to our hospital the evening of 1/28/21 with generalized weakness, fevers, near syncope. Extensive workup revealed likely hemophagocytic lymphohistiocytosis syndrome attributed to reaction to vaccine. Patient treated with blood transfusions, corticosteroid (dexamethasone 20mg) and folic acid 1mg daily. Patient also developed rectus sheath hematoma attributed to vaccine/reaction. Patient continues to remain hospitalized 15 days later. Clinically stable, yet critically ill with no significant / some worsening of laboratory results. |
| 1027039 | 2/12/2021 | CT | 49 | F | 2/11/2021 | 2/11/2021 | I am the patient and within five minutes I got extremely hot my hearing started to leave me and then I passed out I don't know how long I was out for but staff that were there said I was having a seizure shaking and making gurgling sounds in my throat when I came to I could see people but my hearing took longer to come back. I was then brought to Midstate hospital via ambulance at Midstate I had an EKG and blood work done as well as blood pressure monitored and blood oxygen levels |

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| 1023365 | 2/11/2021 | | | U | 1/27/2021 | 1/27/2021 | When got up I passed out; blood pressure shoot up to 180 over 100; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiration date were not reported), via an unspecified route of administration on 27Jan2021 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that the patient took the covid dose yesterday and after he/she took it, he/she sat there for few minutes and then when he/she got up he/she just passed out. The patient mentioned that they called the code blue in the hospital, they tried to, they were going to, he/she doesn't know what they were going to do but they ended up taking the patient to the emergency room where they ran every test possible blood work they did chest X-ray, they did EKG. The patient stated that the only thing that was consistent was that after the vaccine his/her blood pressure shot up to 180 over 100 and they were trying to get it down, they gave the patient some fluid (unspecified) which stayed for over two hours. The patient added that he/she have never had any blood pressure issues, as he/she was not even on any medications. The patient mentioned that he/she was now afraid to take the second dose. The events occurred on 27Jan2021 with outcome of unknown. Unknown results for blood work, EKG and chest X-ray. The reporter considered the events serious per hospitalization on 27Jan2021. Information on the lot/ batch number has been requested. |

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| 1021918 | 2/11/2021 | CA | 58 | F | 1/13/2021 | 1/21/2021 | Flushed; Body aches; Red rashy spot; Fatigued; The site on my left arm got to a baseball size; Headaches; Felt like I would throw up; Ended up fainting/ went down for a second time; Diarrhea; Light headed; Discombobulated; A spontaneous report was received from a 58 year old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced diarrhea, felt that she would throw up, light headed, fainted, discombobulated, site on her left arm got to a baseball size, and in the middle was a red rashy spot, flushed, fatigued, had body aches and headaches. The patient's medical history included high blood pressure. Relevant concomitant medications included unknown blood pressure medication. On 13 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (Lot: 011J20A) intramuscularly in left arm for prophylaxis of COVID-19 infection. On 21 Jan 2021, around three, the patient experienced diarrhea, she thought it was food poisoning. While on the "pot" with diarrhea she felt that she would throw up. She mentioned that she became lightheaded but did not throw up and ended up fainting. She fell off the pot and decided to lay down in her bed. She got lightheaded again and went down for a second time. She stated she had a difficult time getting up; she crawled to the bed. When she attempted to stand up, she could feel she was lightheaded again. The patient mentioned that maybe she was down 45 minutes before getting to lay on her bed. She felt discombobulated. She felt very clumsy when trying to dial her sister's number; she left a message on the machine and was struggling to get her words together. The site on her left arm got to a baseball size, and in the middle was a red rashy spot. On Friday evening, 26 Jan 2021, the patient stated she started feeling better. She mentioned that she was flushed, fatigued and had body aches. The patient stated she hasn't tried any treatments but took paracetamol for headaches and tried to rest. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events, diarrhea, felt that she would throw up, light headed, fainted, discombobulated, site on her left arm got to a baseball size, and in the middle was a red rashy spot, were resolving. The outcome of the events, headaches, flushed, fatigued and body aches, were unknown.; Reporter's Comments: This case concerns a 58 year old female patient with medical |

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| 1022754 | 2/11/2021 | MO | 46 | F | 1/8/2021 | 1/8/2021 | history of high blood pressure, who experienced a serious unexpected event of Syncope and NS unexpected events of diarrhea, nausea, dizziness, confusional state, injection site swelling, rash erythematous, flushing , fatigue, pain and headache. The events occurred approximately 8 days after first dose of the study medication administration. she only took paracetamol for headaches and tried to rest without any other treatment. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. |
| | | | | | | | After 10 min receiving the second dose I passed out during observation at the vaccination site, was rushed to the ER. They monitored me, gave me fluids and performed an EKG. |

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| 1023358 | 2/11/2021 | CA | | F | 12/19/2020 | 12/19/2020 | encephalitis-like symptoms; Hearing loss; memory loss; paresthesias; visual disturbances; taste disturbances; dizziness; L-sided chest pain; staggering; elevated SBP 190-200; severe L-sided chest tightness; pre-syncope; elevated BP; DDimer was elevated; fell; intermittent memory lapses; nausea episodes; cant smell that last 1-2 hrs; L neck /head pain; L neck /head pain; Left axilla lymphadenopathy; rhinitis; lightheaded/lightheadedness; had an episode of pain all over; SOB; This is a spontaneous report from a contactable physician (patient). A 46-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot/batch number and expiration date were unknown), via an unspecified route of administration from on 19Dec2020 at a single dose for COVID-19 immunization. Medical history included ovarian cancer at age 29, food allergy to clams and escargot, and allergy to sulfa. The patient's concomitant medications were not reported. The patient previously took bactrim and experienced allergies. On 19Dec2020, immediately after vaccine had rhinitis, lightheaded, given Zyrtec and water and observed for a duration of 30 min. Three hours postvaccination on 19Dec2020, at home had an episode of pain all over and SOB (shortness of breath). 3 days later (22Dec2020), patient had L (left) neck /head pain and left axilla lymphadenopathy. On 23Dec2020, she fell in the shower. On the same day (23Dec2020) the patient had intermittent memory lapses, lightheadedness, nausea episodes, can't smell that last 1-2 hours a few times a day. Symptoms worsened on 03Jan2021, with severe L-sided chest tightness, pre-syncope, was seen in the ER with elevated BP. DDimer was elevated, CT Scan of Chest/Abdomen showed L axilla lymphadenopathy, negative for PE. CBC, Electrolytes WNL (within normal limits), still on 03Jan2021. Observed in ER for 7 hrs. and then discharged home. Intermittent symptoms continued. On 08Jan2021, patient had another severe episode while at work. She was noted to be staggering, and again was complaining of left-sided chest pain. She was taken to the ER by her colleagues on 08Jan2021 and noted to have elevated SBP 190-200. On 08Jan2021, patient underwent CT head negative, MRI negative, w/u (workup) for pheochromocytoma negative and COVID negative. She was started on prednisone and Norvasc |

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and discharged home. She continues to have intermittent episodes however they have decreased in intensity and last for about 1 hour. She described her symptoms as encephalitis-like symptoms. These include memory loss, paresthesia, visual disturbances, hearing loss, taste disturbances, and dizziness. These symptoms when severe have been incapacitating. She had been hospitalized for a neurological and infectious work up (including Brain MRI and multiple COVID tests) but no diagnosis has been yet identified. This symptom complex (unspecified) has persisted to now. She has not received the second dose of vaccine. She is asking how long mRNA, the lipid nanoparticles and the protein spike lasts in the body. Outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the limited information currently available, a possible contributory role of the suspect drug in the reported events cannot be completely excluded given the implied temporal association. However, underlying medical conditions may provide the alternate explanations. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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| 1023345 | 2/11/2021 | HI | 89 | F | 1/26/2021 | 1/26/2021 | Got sick; Headache; Shortness of breath; Passed out; Dizzy/ Dizziness; Tightness in her chest; This is a spontaneous report from a contactable consumer. An 89-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number and expiration date unknown, first dose, intramuscular on 26Jan2021 at single dose on right arm for COVID-19 immunization. Medical history included mastectomy, surgery for metaplastic carcinoma. She received 4 units of blood and reacted to the blood and itched from her head to toe and they treated her with prednisone for that. She said that the metaplastic carcinoma was 10 inches big and half of her front was removed. Other medical history and past drugs included allergic to Bactrim, Sulfa drugs, Cortisone, Zocor, Keflex, Macroclantin, Penicillin, Vicodin (took three times and thought she was going to die; coughed for a year and couldn't even sleep because she developed Pericarditis), Benazepril, Levaquin, Losartan, Niaspan (whole body turned red), Pravastatin. On 07Jan2021, she had an appointment with her doctor who first advised her not to take the vaccine because of all of her allergies but she said there is an antidote if she has a reaction so she said she could take it. She had the first dose of the vaccine on 26Jan2021 and had a bad reaction. She was very dizzy and got sick. They didn't catch it at the vaccination site because they only had the patients wait 15 minutes. Her drive home takes 10-15 minutes. She thought she couldn't drive home because of the dizziness. She got a tightness in her chest and started getting so dizzy that she ran into the living room and slept on the sofa because she couldn't handle it anymore. It was reported that she passed out from about 12:00-15:00. She was completely out. She took a Tylenol right after the shot for dizziness and sick because when she told her healthcare professional about the symptoms, she said to take a Tylenol. She also had shortness of breath on 27Jan2021. This morning (28Jan2021) she had a headache but she was feeling much better. The caller asked if she should get the second dose due to her reaction. The patient stated she has a whole list of allergies that she gave the other agent. The patient stated that she doesn't think she will take the second shot. She also stated she takes Tylenol after the Flu shot so she doesn't get so sick. The patient mentioned that her physician does not know about any of this and said |

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that she received the vaccine at a hospital. She said that she only contacted her doctor to notify her that she was dizzy. She was directed to take Tylenol. She said that she did take Tylenol as directed by the people administering the vaccines too and she did get sick. The patient said that it helped a little and she knows that it was not the Tylenol that caused this. She does not want to get the second shot if she gets sick like this. The patient said that the fact sheet said to call 911. The shot did not hurt her at all, and she did not know that she even received it. She said that the person who administered the vaccine was very good. The outcome of the event headache was recovering, dizziness, shortness of breath recovered on 27Jan2021, Tightness in her chest, passed out was recovered on 26Jan2021 and sick was unknown. Information about Lot/ Batch has been requested.

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| 1023343 | 2/11/2021 | MN | 41 | F | 1/27/2021 | 1/27/2021 | Fainted; blacked out; This is a spontaneous report from a contactable nurse (patient). A 41-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EL1283), intramuscular on 27Jan2021 10:15 at a single dose on right arm for COVID-19 immunization. Medical history included low iron. The patient was not diagnosed with COVID-19 prior to vaccination. The patient was not pregnant at the time of vaccination. The patient had no allergies to medications, food or other products. Concomitant medications included ferrous sulfate, vitamin c [ascorbic acid] (VITAMIN C), chondroitin sulfate, glucosamine sulfate (GLUCOSAMINE CHONDROITIN SULFATE). The patient previously received first dose of BNT162B2 on 06Jan2021 for COVID-19 immunization (brand: Pfizer, lot number: EK9231, administration time: 04:30 PM, route: intramuscular, vaccine location: right arm, dose number: 1). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 27Jan2021 23:45, the patient fainted and blacked out. No treatment was given for the adverse events. The events resulted in doctor or other healthcare professional office/clinic and emergency room/department or urgent care visits. It was unknown if the patient has been tested for COVID-19 since the vaccination. The patient was recovering from the events.; Sender's Comments: Based on the compatible time association, the events fainted and blacked out are possibly related to suspect vaccine BNT162B2 administration. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate. |

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| 1022804 | 2/11/2021 | NC | 38 | M | 1/26/2021 | 1/26/2021 | He states he received the vaccine and within 2-3 minutes he experienced dizziness, chest tightness affecting breathing, tunnel vision, disorientation. He asked for help and first they walked him to a chair and then laid him down. He recalls the MD taking his pulse and reporting it as 140. He states his awareness was blurred, but he remembers receiving the epi pen and then feeling better. He recalls sweating but not sure if it was before or after epinephrine. EMS arrived, started an IV and transported him to ER. He denies recalling pruritis, urticaria, oral face throat or tongue swelling, watery eyes, chest pain, cough, wheeze, nausea or emesis. ER observed him several hours. His discharge diagnosis was syncope. He denies recent use of antihistamines or H2 blockers. Per chart review, provider at the event recorded patient c/o hot dizzy, tachycardia, erythema bilat arms, chest with extension to the neck, diaphoresis, difficulty responding (single word only); treated with epinephrine with improved response. |
| 1022798 | 2/11/2021 | | 42 | F | 2/2/2021 | 2/4/2021 | Tiredness pain in injection site. Burning joints lightheaded to the point of fainting and vomiting |

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| 1023360 | 2/11/2021 | GA | 38 | M | 1/27/2021 | 1/27/2021 | blood pressure (1:10 PM): 143/92; Syncopal episode; Patient was pale; Diaphoretic; feeling light-headed; This is a spontaneous report from a contactable nurse. A 38-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot: EL8982), intramuscularly into the left arm on 27Jan2021 13:00 at a single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. On 27Jan2021 13:05 patient had a syncopal episode but regained consciousness immediately and was assessed for injury and other reactions. The patient was pale, diaphoretic and reported feeling light-headed on 27Jan2021 13:05. The patient underwent lab tests and procedures on 27Jan2021 which included blood pressure measurement (units unspecified): 143/92 (1:10 pm), 125/90 (1:15 pm), 131/89 (1:20 pm), 135/81 (1:25 pm) and 130/89 (while standing upright); body temperature (unit unspecified): 98.6 (1:10 pm), 99.0 (1:25 pm) and 98.6 (oral; while standing upright); heart rate (unit unspecified): 74 (1:10 pm), 81 (1:15 pm), heart rate: 85 (1:20 pm), 79 (1:25 pm), 72 (while standing upright); oxygen saturation: 96% (1:10 pm), 99% (1:15 pm), 97% (1:25 pm), 96% (while standing upright); respiratory rate (unit unspecified): 20 (1:10 pm), 20 (1:15 pm), 20 (1:20 pm), 20 (1:25 pm), 18 (while standing up). Outcome of events recovered on an unspecified date.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the event syncope cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate. |
| 1022724 | 2/11/2021 | MD | 79 | F | 2/9/2021 | 2/10/2021 | fainting day after vaccination chills and flu=like symptoms |

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| 1022695 | 2/11/2021 | WV | 61 | F | 2/10/2021 | 2/11/2021 | The patient felt fine immediately after the vaccine which was at 3pm 2/10. She reports having difficulty sleeping and awoke with a headache. When she got out of bed, a few after getting up, she felt dizzy and decided to get back in bed however she fainted and fell onto the floor. She also reports nausea. |
| 1022391 | 2/11/2021 | IL | 42 | F | 2/10/2021 | 2/11/2021 | MODERNA COVID-19 vaccine EUA Received first shot yesterday (2/10/21 @ 2:42pm) had chills off and on overnight and sore arm. Got up at 6:30 am today (2/11/21), used the bathroom, felt very dizzy and lightheaded, started sweating profusely, tried to make it back to bed, took 4 steps and passed out, hitting my face on dresser. This has only happened one other time, 16 years ago when I was pregnant, flying on vacation and hadn't eaten, blood sugar dropped and I passed out momentarily. No history of fainting, not diabetic, no health issues whatsoever. Healthy weight, fit and in shape. |
| 1022389 | 2/11/2021 | MI | 77 | F | 1/21/2021 | 1/22/2021 | I was sleeping, then woke up and my whole body felt numb. I got up to go to the bathroom and fainted. I fell on the floor and got a bloody nose, cut lip and cut and bump on my head. I had stiff neck for a week afterward. |
| 1022047 | 2/11/2021 | WA | 62 | F | 1/26/2021 | 1/27/2021 | collapse and passed out; Woke up at midnight with severe leg cramps; I turned white as a ghost and sweats; I turned white as a ghost and sweats; Got the chills after sweating; This is a spontaneous report from a contactable 62-year-old female consumer reported for herself that she received 1st dose of bnt162b2 (BNT162B2; lot number EL9261) on 26Jan2021 04:30 PM at left arm for COVID-19 immunization in Public Health Clinic. Medical history and concomitant drugs was none. The patient woke up at midnight with severe leg cramps, tried walking it out, collapse and passed out (according to husband). He stated that the patient turned white as a ghost and sweats. After coming too, drank electrolytes and water. The patient got the chills after sweating. It took a while for her to warm up and go back to sleep. Event start time was reported as 27Jan2021. The outcome of the event was resolved. |
| 1021731 | 2/11/2021 | MO | 37 | M | 2/8/2021 | 2/9/2021 | Bloody nose, fainting spells, sore arm, insomnia. |

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| 1023375 | 2/11/2021 | IA | 35 | F | 1/29/2021 | 1/29/2021 | Became unresponsive; Looked like having a seizure; Felt light headed; BP extremely low; Profusely sweating; Heart rate extremely low; A spontaneous report was received from a pharmacist, concerning a 35-year-old female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced felt light headed, became unresponsive, looked like having a seizure, BP extremely low, heart rate extremely low, and profusely sweating. The patient's medical history, as provided by the reporter, included high blood pressure. Products known to have been used by the patient, within two weeks prior to the event, included hydrochlorothiazide/lisinopril. On 29 Jan 2021, five minutes prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot Number: 025L20A) intramuscularly in the right arm for prophylaxis of COVID-19 infection. On 29 Jan 2021, the patient felt light-headed five minutes after receiving the vaccine. He then became unresponsive but was breathing and had a pulse. The reporter stated it looked like the patient was having a seizure; his eyes rolled upward, his left arm shook, and he did not respond to touch or voice. It was reported that 911 was immediately called and responded within a couple of minutes. The patient's blood pressure and heart rate were extremely low, and he was profusely sweating. The reporter stated that the patient came to and still felt very light-headed. The patient was then taken to the emergency department. Medical tests and laboratory results were unknown, but the reporter stated that a magnetic resonance imaging (MRI) was possibly performed. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not provided. The outcome for the events, became unresponsive and looked like having a seizure, were resolved on 29 Jan 2021. The outcome for the events, felt light headed, BP extremely low, heart rate extremely low, and profusely sweating, was unknown.; Reporter's Comments: This case concerns a 35-year-old, female, with medical history of high blood pressure, who experienced a serious unexpected event of syncope, seizure, and non-serious unexpected events of dizziness, hypotension, hyperhidrosis, and heart rate decreased. The events occurred 1 day (5 min) after mRNA-1273 (Lot# 025L20A). Treatment information was not provided. |

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| 1022037 | 2/11/2021 | TN | 50 | F | 1/25/2021 | 1/25/2021 | <p>Concomitant medications included: hydrochlorothiazide/lisinopril. Based on temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Additional information has been requested.</p> <p>felt near syncopal; very short of breath; heart was pounding hard; felt tachycardic; BP was 160/100; irregular HR with PVCs; HR 40; This is a spontaneous report from a contactable healthcare professional (patient). A 50-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; lot number EL1283) on 25Jan2021 08:15 given intramuscular (left arm) single dose for COVID-19 immunization. Medical history included was reported as none. The patient was not pregnant at the time of vaccination. Concomitant medication included estradiol, testosterone, lorazepam (ATIVAN). The patient previously received ultram/ Zofran ad experienced drug allergies, and first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number EL1284) on 04Jan2021 08:15 intramuscular single dose for COVID-19 immunization. The patient was not diagnosed with covid prior vaccination and the patient was not tested for covid post vaccination. On 25Jan2021 at 08:45 AM, 30 minutes after injection,-the patient felt horrible described as her heart was pounding hard and felt tachycardic. BP was 160/100 and HR 110 and felt near syncopal. Then PVCs started/ very short of breath, and HR went from 112, 69, 40, then 80. The patient went to ER. The patient was monitored and given was IVFs and O2, and labs checked. The patient was discharged 7 hours later and continued having irregular HR with PVCs. Outcome of the events was recovering at the time of the report.; Sender's Comments: Based on the available information, a possible contribution of the drug to the event syncope cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p> |

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| 1022385 | 2/11/2021 | AR | 42 | F | 1/15/2021 | 1/15/2021 | 5 minutes after receiving vaccine became very dizzy, and flushed with fast heart rate , dropped to the floor near syncope. Laid down and took off mask for air. Was offered water and Benadryl. Drank some water then felt better.. Refused the Benadryl. 10 minutes after someone noticed a possible rash on my forehead. Went ahead and took some Benadryl. Later that night had same feelings.. fast heart rate and dizziness. The next day development flu like symptoms with fever up to 102.9. Took a half Tylenol. The next day just felt achy . The day after that had diarrhea. |
| 1024562 | 2/11/2021 | ID | 32 | F | 2/11/2021 | 2/11/2021 | Patient experienced likely vasovagal syncope. Felt "woozy, dizzy," then momentary syncopal episode, then slight nausea and dizziness. VS monitored Q 5 mins x 35 mins, incl orthostatics. Patient assisted to gurney with head raised, given bottle of H2O to drink. Pt states had eaten Taco Bell immed prior to vaccine appt and was well-hydrated. Pt states that she experienced a similar event in Oct 2020 after a blood draw. Pt felt back to normal within 10-15 minutes, this RN continued to monitor and provide support for an additional 20 mins. Pt reported feeling "completely normal" at discharge. Conversing and ambulating well. |
| 1023711 | 2/11/2021 | CA | 46 | F | 12/28/2020 | 12/28/2020 | Describe adverse reaction: vasovagal syncope several hours after vaccine. Sent to ED via ambulance. Vasovagal symptoms: dizziness; vertigo; lightheadedness; near syncope and weakness. Sent to ED via ambulance from work. ED gave IV fluids and mescaline. Studies performed: EKG; CBC; and BMP. From ED MD note DC instructions: You came to our ER with concerns of dizziness after getting your covid vaccine. We evaluated you with labs, and provided you with meclizine and fluids. The results of our evaluation were reassuring, and we believe that the causes of your symptoms are not immediately life threatening and safe to follow up with your clinic doctors. We've prescribed you meclizine, take it as needed for dizziness. Administration error: no Clinic called No; Transferred to Emergency Department from workplace several hours after vaccine was administered. |

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| 1021917 | 2/11/2021 | NY | 90 | M | 1/26/2021 | 1/26/2021 | <p> Syncope; Shaking; Struggling to breathe; A spontaneous report was received from a consumer concerning a 90-year-old, male patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and developed syncope, shaking, and struggling to breathe. The patient's medical history was not provided. Concomitant medications reported included warfarin, ezetimibe, bupropion, finasteride, tamsulosin, furosemide, potassium chloride, rosuvastatin, and nitrofurantoin. On 26 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (Lot # 032L20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 26 Jan 2021, after vaccine administration, the patient stayed at the vaccination site for fifteen minutes to watch for any reaction, he had none, so he left. Later that night the patient began shaking and struggling to breathe, so 911 was called. At the hospital, the patient was diagnosed with syncope. He spent overnight in the hospital and had an echocardiogram the following day. No results were provided for the echo, but the patient was cleared to go home after a sixteen-hour hospital stay. No treatment information was provided. Action taken with mRNA-1273 in response to the event was unknown. The outcome of the events, syncope, shaking, and struggling to breathe, was resolved.; Reporter's Comments: This case concerns a 90 year-old, male patient, who experienced events of syncope, shaking, and struggling to breathe. The events occurred the same night after the first and last dose of mRNA-1273 vaccine administration. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded and the events are assessed as possibly related. </p> |
| 1024684 | 2/11/2021 | | 35 | M | 2/11/2021 | 2/11/2021 | <p> PT fainted post vaccination. He was sitting in chair looked nervous conscious. He then fell out of chair and hit his head on the ground. When assessed he was rigged, eyes were flickering in head and was not responsive. Lasted for about 30 seconds. He then regained consciousness and was AxO times four. Felt cold and shaken. </p> |
| 1024867 | 2/11/2021 | HI | 75 | M | 2/10/2021 | 2/11/2021 | <p> near syncope </p> |

| <u>VAERS_ID</u> | <u>RECVDATE</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1024669 | 2/11/2021 | AZ | 31 | F | 2/11/2021 | 2/11/2021 | Got dizzy and light headed. Passed out 5 minutes after vaccine. Heart rate dropped to 39. Threw up once after waking up. |
| 1024752 | 2/11/2021 | OR | 74 | F | 2/8/2021 | 2/9/2021 | Patient reports she got up out of bed early the next morning after receiving her COVID vaccine and took 2 of her morning pills and then had an episode where she passed out for a few minutes and spilled the water down her clothing. She felt weak and tired after this episode and so went back to bed for several hours. Later that day she had another episode of feeling lightheaded as if she might pass out, while sitting at a hair salon waiting for her appointment, but did not actually pass out, just felt a wave of heat and slight nausea, but did not faint. She had one further near syncopal episode at home later that night when she also noticed she was a little "jittery" and noted a strange smell that the rest of her family did not notice. She also reports that she has had near syncopal episodes in the past and thinks she may have been a little dehydrated the day these incidents occurred. |
| 1024557 | 2/11/2021 | CA | 43 | F | 1/1/2021 | 1/9/2021 | Presyncope 15 min post vaccination |
| 1024457 | 2/11/2021 | NV | 24 | F | 2/9/2021 | 2/10/2021 | I had on-and-off insomnia starting around 10pm. I woke up every thirty minutes on the minute with a feeling like there was a fifty pound vest on my body. At 3:30, I felt nauseous. I walked from my bedroom to downstairs to the kitchen. My knees buckled several times en route. When I ate one bite of a protein bar, my nausea increased tenfold. I ask drank water at the time. I walked back upstairs to my room to sleep where remained awake until ~five am. I slept from ~five am until approximately 8:10am. I felt faint as I walked into the bathroom where I felt my faintness increase by the second. My knees buckled and I passed out on the bathroom floor tile for ~five - ten seconds. I layed there for a few minutes until I felt stable to stand. This morning, 45 hours after the injection and 22 hours after blacking out, I felt a goose egg on the back of my head. It has hurt all day at a level 4/10 on the pain scale. |

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| 1023915 | 2/11/2021 | FL | 73 | F | 1/28/2021 | 1/28/2021 | Syncope and collapse. 10 minutes after injection, while sitting, I got very dizzy and hot. Apparently I passed out and had to be given two nose sniffs with ammonia to get me awake. Was told by nurse that she had to rub my sternum to get me awake. This lasted a few minutes after which I was clammy all over, but feeling better. |
| 1023728 | 2/11/2021 | FL | 66 | F | 2/8/2021 | 2/8/2021 | Within 15-minutes of vaccination, the patient reported dizziness and feeling faint. EMS evaluated patient, no respiratory distress and no sign of increase work of breathing. Patient was hypertensive (158/78) with FSBG of 84. EMS transported the patient to the Medical Center emergency department. Patient was discharged from the ED with vasovagal syncope. |
| 1024675 | 2/11/2021 | TX | 42 | F | 2/9/2021 | 2/10/2021 | 2/10-Chills around 2:30 am (did not take temperature); fainting spell around 7:00 am and temp of 100.1; chills, fluctuating temperature (99.5-100.1), sore arm, redness at injection site, and fatigue all day. 2/11-mild arm soreness, redness at site injection, and temperature between 98.4-99.6 (higher than normal for me. I take my temp every day for work and am usually 97.3-97.8). |
| 1023810 | 2/11/2021 | PA | 38 | M | 1/30/2021 | 1/30/2021 | FOLLOWING SECOND DOSE, RAPID ONSET OF SEVERE PAIN IN LEFT ARM AND SHOULDER, PAIN OF NECK, UPPER BACK, RIGHT SHOULDER. THE FOLLOWING DAY, 01/31, FEVER VARYING FROM 101 TO 105 FOR FOUR DAYS. ABDOMINAL AND CHEST PAIN, RUNNY NOSE, HEADACHE AND MIGRAINE SYMPTOMS. DIAHRREA, NAUSEA AND VOMITING. LOOSE STOOLS PERSISTED FOR ELEVEN DAYS FOLLOWING INJECTION OF SECOND DOSE OF THE MODERNA 030L20A. AFTER EVERY MEAL, UNDIGESTED STOMACH CONTENTS PASSED VIA RECTUM, WITH WATERY MUCOUS. LOSS OF APPETITE, GENERAL MALAISE. ON DAY 3, NEAR SYNCOPE COUPLED WITH HYPOTENSION AND HYPOGLYCEMIA WITH DEHYDRATION. CONSUMED 1L OF PEDIALYTE/DAY, WITH 2L OF WATER/DAY. COVID-19 RAPID TEST WAS NEGATIVE. |

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| 1024411 | 2/11/2021 | WA | 82 | F | 2/11/2021 | 2/11/2021 | PATIENT VACCINATED AT 10:10AM, WAITED FOR 15 MINUTES. FELL AT 10:42 AM WHILE ENGAGED IN RECREATIONAL ACTIVITY. NO ANAPHYLAXIS. NO FAINTING. AMBULANCE CALLED AND PATIENT TRANSPORTED TO HOSPITAL. |
| 1023923 | 2/11/2021 | VA | 64 | F | 2/11/2021 | 2/11/2021 | HPI: reports feeling ?woozy? 30 minutes after getting Moderna COVID-19 vaccine, 2nd dose in series. Reports she became lightheaded when she stood up to leave. No syncope. No chest pain or SOB. No airway complaint. No headache. Reports she did not eat breakfast or lunch. PMH: HTN Allergies: tree nuts, some fruits, latex Meds: triamterene/hctz 37.5/25mg, Epipen as needed ROS: otherwise negative. PE: Constitutional: No acute distress. Able to sit in a chair without difficulty. Skin w/d. Respiratory: No increased WOB. Cardiac: radial pulses strong and regular. A/P: Lightheaded. Likely secondary to not eating any meals today and then receiving IM injection, mild vasovagal response. No allergic reaction evident. Given graham crackers and juice, which she ate without difficulty. Felt completely fine within 10 minutes and preferred to leave in order to attend a meeting. Encouraged to seek attention for new or worsening. Will report. |
| 1024146 | 2/11/2021 | MA | 37 | F | 2/10/2021 | 2/11/2021 | I experienced early morning subjective fevers and documented fever (99.8) and chills. Mild to moderate myalgias. I also experienced acute weakness and lightheadedness and suffered a vasovagal syncope that morning. I now have a tension headache throughout the day. |
| 1024155 | 2/11/2021 | DC | 23 | F | 1/19/2021 | 1/19/2021 | After being vaccinated and while waiting in the observation area, I began to feel hot and light headed. I fainted about 15 minutes after sitting down in the waiting area and upon fainting hit my head on the floor. I regained consciousness while laying on the floor getting my vitals taken by staff. Because of the minor head injury and proximity to getting the vaccine, I accepted being taken to the ER. |
| 1024175 | 2/11/2021 | MD | 93 | F | 2/10/2021 | 2/11/2021 | Patient felt dizzy, lightheaded and fell. She reported that she could have "passed out" she lives alone. She remembers getting up off the floor. |

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| 1024178 | 2/11/2021 | MS | 24 | F | 2/11/2021 | 2/11/2021 | Patient was given second dose. 30 minutes later she sat down on a couch and was breathing short and shallow. She was not responsive and mildly shaking. I gave her an EpiPen shot and in less than a minute she was a wake and feeling much better. She drank some water. 911 was not called because her mother was a nurse and was nearby. She came and picked her up and took her to a doctor. I checked on the patient this afternoon and she is feeling fine other than feeling tired. She has a medical history of weight loss surgery and not dieting properly. The administrator of the home said she has a history of not feeling well and almost fainting from not eating properly after her weight loss surgery. |
| 1020214 | 2/10/2021 | TX | 51 | M | 2/10/2021 | 2/10/2021 | Patient's wife reported shaking for a few seconds and passed out. Patient reports lightheadedness. EMS performed EKG, HR = 40s to 60s; blood pressure = 99/58. Refused transport to ambulance |
| 1020664 | 2/10/2021 | KS | 46 | M | 2/8/2021 | 2/9/2021 | Per patient, woke up on the morning after the day following his vaccination (2/9/21) with chest pain, shortness of breath, and feeling light-headed. He tried to sit up, saw red dots, and "passed out" momentarily. He had severe headache upon awakening, ringing in ears, and blurry vision. Went back to bed and slept all day. Symptoms worsened every time he tried to get up. Woke up this AM, with symptoms persisting. Came in for OV, BP noted to be elevated at 150/106. Patient was sent to hospital via ambulance for further work-up and management. |
| 1020300 | 2/10/2021 | NC | 36 | F | 2/10/2021 | 2/10/2021 | Patient stated that she felt hot and short of breath. Patient was offered an ice pack and a pulse oximeter was placed on finger for obtaining O2 sat. Patient stated she felt flushed and that tongue and throat were tingling. EMS was called. Attempted to transfer patient to a wheelchair to relocate patient to clinic emergency area. Patient passed out and onsite MD consulted. Epi pen administered at 1021 via R arm and vitals monitored until EMS arrived. O2 sat 99%. BP 180/86 and HR 126. EMS arrived on site at 1040 |
| 1020253 | 2/10/2021 | NY | 37 | F | 2/9/2021 | 2/10/2021 | Passed out approximately 24 hours after second dose of vaccine. |

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| 1020250 | 2/10/2021 | IN | 28 | F | 1/11/2021 | 1/11/2021 | dizziness, light headedness, fainting (loss of consciousness for a few seconds) 5 hours after receiving the first dose of Moderna |
| 1020215 | 2/10/2021 | CA | 36 | F | 2/9/2021 | 2/9/2021 | female presenting with dizziness, nausea, vomiting, shortness of breath after receiving her second Covid vaccination, Pfizer. She had no adverse reactions with the first vaccination. She reports that approximately 10 minutes after the vaccination, she started to feel dizzy and "drunk". She felt that the room was spinning. She then became very nauseated and started dry heaving. No emesis but she arrives dry heaving. She reports that she started having shortness of breath after the nausea and dry heaving but feels like it is more because she is feeling very panicked. No cough. No wheezing. She has some throat soreness. No syncope or fall. She does have several allergies and carries an EpiPen for coconut allergy |
| 1020668 | 2/10/2021 | NC | 73 | F | 2/10/2021 | 2/10/2021 | She showed up at the hospital today and received her Covid shot. She had no reaction to the first shot. About 14 minutes after the shot she felt mildly short of breath. Reportedly there was no signs of increased work of breathing. She had no throat swelling or change in voice. Patient reports these symptoms were different from her baseline asthma so the decision to call a Code 44 was made and she was brought to the ED. Since that event her symptoms have improved. She denies any chest pain or pressure. She denies any recent illness prior to the event. She denies any lightheadedness or syncope. |
| 1019937 | 2/10/2021 | WA | 88 | F | 2/9/2021 | 2/9/2021 | Systemic: Chills-Severe, Systemic: Fainting-Severe, Systemic: Other- High heart rate, 121 BPM, high anxiety, body shaking chills, passed out for about 30 seconds, was able to speak and breath normally |
| 1019933 | 2/10/2021 | PA | 53 | F | 1/22/2021 | 1/23/2021 | fainted approximately 12 hours after vaccinated and injured my nose. |
| 1019927 | 2/10/2021 | CA | 47 | F | 2/9/2021 | 2/9/2021 | Systemic: Fainting-Medium, Systemic: Other- High BP |

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| 1019847 | 2/10/2021 | MA | 77 | M | 2/9/2021 | 2/9/2021 | I had my (Moderna) first dose yesterday. Within ~6 hour the soreness level of the shoulder joint (but not especially the site of the jab) zoomed up to intense. So much so, that simply lifting my arm slow-motion to the level of my eyes caused intense pain spasms. Last night and this morning were equally severe. Within the last hour or so, the pain level has diminished a bit. NOTE: I know how people rate pain is super subjective. In my case working as a geologist in a quarry a number of years ago, I was struck and pinned by a large boulder. The ER crew would not give me a pain killer, so that they could monitor how the Jaw of Life was working (it broke, the boulder was too heavy), so I not surprisingly passed out several times from the pain level before being extricated. Needless to say, this compound fracture of the tibia and fibula accident was a 10 of 10 pain level. Yesterday's CV-19 jab pain level was an 8-9 of 10. Nothing I read before yesterday's jab, Fauci et al, prepared me for this pain level. So, is this normal??? My POV is, I think, atypical in this matter of pain. Should I be concerned about a return to normalcy right now (today / tomorrow) as well as for the second dose?? I HOPE THAT A MEDICAL PERSON WILL RESPOND TO THIS EMAIL - NOT SOME BOILER PLATE WORDS. If you want more details, feel free to phone me |
| 1019664 | 2/10/2021 | CO | 75 | F | 2/5/2021 | 2/8/2021 | 75-year-old woman who presented to the emergency room 2 days after vaccination with chest tightness, fatigue and was found to have pericardial effusion without tamponade. It was noted that patient has had intermittent syncope since August of 2020 and clinical interpretation is likely that pericardial effusion pre dated vaccination. In her workup for dizziness and syncope she had not previously undergone EKG, chest x-ray or echocardiogram therefore pericardial effusion could have been missed. I elected to report the pericardial effusion to be on the side of caution. |
| 1019558 | 2/10/2021 | IN | 47 | F | 2/7/2021 | 2/9/2021 | Fever 102.4 onset 2am. Followed by severe right side and abdominal pain radiating from Right hip up through shoulder and head. Vomiting for 13 hours and syncope X2. |

| <i>VAERS_ID</i> | <i>RECVDATE</i> | <i>STATE</i> | <i>AGE_YRS</i> | <i>SEX</i> | <i>VAX_DATE</i> | <i>ONSET_DATE</i> | <i>SYMPTOM_TEXT</i> |
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| 1018849 | 2/10/2021 | CA | 31 | M | 2/9/2021 | 2/9/2021 | Syncope right after injection given. Of note, he has a history of fainting episodes with injections. BP 131/83, pulse 79. Laid on floor with legs elevated. Given water, juice, and crackers. Resolved. |

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| 1018328 | 2/10/2021 | FL | | F | 1/11/2021 | 1/12/2021 | Headache; Collapsed on the floor; Left arm injection site red; Rash; A spontaneous report was received from a consumer, who was also a 80-year-old, female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced syncope, injection site redness, rash, and headache. The patient's medical history, as provided by the reporter, included high blood pressure. Concomitant product use reported included atenolol and atorvastatin. On 11 Jan 2021, one day prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Batch number: 039K20A) intramuscularly in the left arm for the prophylaxis of COVID-19 infection. On 12 Jan 2021, the patient noticed her left arm was getting redder and redder at the injection site. When she turned to look at the clock, the patient collapsed on the floor. She went to the medical center and was prescribed prednisone and diphenhydramine. On 21 Jan 2021, the patient reported she now had a headache that began on an unspecified date, and that her injection site redness and rash were still present, but getting better. Action taken with mRNA-1273 in response to the events was not reported. The outcome of event, syncope, was unknown. The events, injection site redness and rash, were considered resolving. The event, headache, was considered not resolved.; Reporter's Comments: This spontaneous report concerns an 80-year-old, female patient with medical history of high blood pressure who experienced serious event of syncope and non-serious events of injection site redness, rash and headache. The events of syncope rash and injection site redness occurred 1 day after administration of mRNA-1273 (Batch number: 039K20A, expiration date-unknown). On an unspecified date on the event of headache began. Treatment provided for the events included prednisone and diphenhydramine and the outcome is not resolved. injection site redness, rash and headache are consistent with the known safety profile of the mRNA-1273 Vaccine and hence, based on the temporal association between the events and the vaccine administration, a causal association cannot be excluded |
| 1020742 | 2/10/2021 | WI | 36 | F | 1/19/2021 | 1/22/2021 | Passed out from standing/leaning on her bed, awoke, nausea, vomited, fatigue for two days. |

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| 1018381 | 2/10/2021 | NY | 30 | F | 12/30/2020 | | Injection sight tenderness; Fatigue; Severe headache; This is a spontaneous report from a contactable other HCP report for self. This 30-year-old not pregnant female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL0140) intramuscular at left arm on 30Dec2020 at single dose for COVID-19 immunization. Medical history included Asthma, anxiety, allergies to Acetaminophen (seizure like activity and fainting). No COVID prior vaccination. No other vaccine in four weeks. Concomitant medications include Fluoxetine, lorazepam, and Ibuprofen. Patient experienced injection sight tenderness, severe headache for 5 days, fatigue for 7-10 days after first dose. The outcome of events was unknown. |
| 1021136 | 2/10/2021 | WI | 35 | F | 2/1/2021 | 2/2/2021 | Slight headache day after first injection. First Covid vaccine on 1/4/2021. Made sure to use my right arm so there was minimal soreness. Second Covid Vaccine on 2/1/2021 Headache 15 minutes after receiving 2nd vaccine. Made sure to use my right arm to help prevent some soreness in my right arm. Moderate Soreness, swelling at injection site day after 2nd injection. Large red area at injection site on day 2 after 2nd injection. Went to MD who though it could be cellulitis. Redness went away on day 3. Today is day 9 and there is bruising and it is still slightly swollen. General Fatigue Chills Fever Dizziness Lightheadedness Continuous headache since 2nd vaccine. Will come and go, but gets severe to point of causing nausea and feeling like fainting at times. |
| 1020697 | 2/10/2021 | NY | 23 | F | 2/4/2021 | 2/5/2021 | headache and fatigue at 3:30pm day of dose; 3:00am the next day vasovagal syncope, shaking, nausea, EXTREME weakness/fatigue, stomach pains |
| 1020714 | 2/10/2021 | OH | 25 | M | 2/10/2021 | 2/10/2021 | Patient fainted after COVID-19 vaccination,. Clinic personal assessed and EMS on site. Patient refused transfer to medical facility. |
| 1023091 | 2/10/2021 | CA | 37 | F | 2/3/2021 | 2/3/2021 | 2 min after receiving my 2nd dose I. Started feeling dizzy, tightness in my chest my heart was beating to fast and last thing I remember was telling one of the nurses that I felt very dizzy and fainted after that. I was given epinephrine X2 twice and Oxygen. |

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| 1021473 | 2/10/2021 | CA | 59 | F | 2/10/2021 | 2/10/2021 | dizzy- passed out while in chair. Blood sugar-92, Patient given fluids, feet elevated After 15 minutes patient able to sit safely. Monitored additional 30 minutes without issue |
| 1021213 | 2/10/2021 | PA | 26 | F | 2/9/2021 | 2/9/2021 | Patient lost consciousness (fainted) and was helped to the floor. Regained consciousness within 1 minute and was monitored for 45 minutes |
| 1021073 | 2/10/2021 | NY | 19 | F | 2/10/2021 | 2/10/2021 | Sat down post vaccination, was emotional. Sipping water. patient fainted in the chair . came around within 5 minutes. Attended by EMS and Doctor. |
| 1021031 | 2/10/2021 | NH | 27 | F | 2/10/2021 | 2/10/2021 | Pt developed lightheadedness, tingling of tongue and mild nausea 1-2 minutes after injection. She suspects that she may have passed out momentarily. BP was 105 systolic. HR: 98, SP02: 100%. She was given snacks and a drink and improved without intervention. She left appx 45 minutes after injection and noted that she felt back to normal. |
| 1020996 | 2/10/2021 | | 23 | F | 2/9/2021 | 2/9/2021 | 2/9 at 4:00pm: moderate headache and ear pressure, arthralgia and myalgia from hips to ankles, moderate chills, moderate injection site pain 2/10 at 8:45am: vasovagal syncope episode, consciousness retained but lost vision and balance; needed fluids and to lay down for about 15 minutes Initial symptoms from 2/9 are still presiding except for the injection site pain (it's now 2/10 at 6:30pm) |
| 1020782 | 2/10/2021 | IL | 39 | F | 2/5/2021 | 2/5/2021 | Headache, neck stiffness and pain, body aches, nausea, fever, chills, dizziness, fainting, fast heart rate, low BP |

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| 1021270 | 2/10/2021 | MO | 28 | M | 1/28/2021 | 1/28/2021 | Immediately after I administered the vaccine, the patient passed out. He fell onto the floor and we witnessed some oral seizure like type movement . The patient was unconscious for approximately 1.5-2 minutes. Our Chief Medical Officer was on site and walking into the room as the patient fell. We immediately placed him on his left side, protected his head, and stayed with him. We called 911 immediately due to the uncertainty of health issues. Once conscious, the patient explained to us that he experiences such every time he receives a vaccine. He was assessed by the CMO as well as the EMTs that arrived on scene. His vitals were taken. He was moved into a comfortable position and monitored. He was alert and orientated x 3. We requested he have someone pick him up instead of him driving himself home which he did. This gentleman is also an employee and we were able to see him and verify all was well in the following days. We also recommended he tell all vaccinators that he experiences LOC post vaccination. When he receives his second dose we plan to have him lying down and our CMO will be present. We recommended he follow-up with his PCP. |
| 1020778 | 2/10/2021 | MA | 22 | F | 2/10/2021 | 2/10/2021 | vagal response post vaccination while seating in post vaccine observation area. Fainted with loss of consciouness approximately 10 seconds then arousable but foggy mentation that progressively cleared. She did not eat breakfast this morning. Vital signs stable, oxygen stauration 98-99% on room air. Brought from Vaccine Clinic to Emergency Department via stretcher. Examined, recovered, able to eat discharged to home. |
| 1020986 | 2/10/2021 | TX | 68 | F | 2/9/2021 | 2/9/2021 | Aching, fever, chills, fainting |

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| 1020803 | 2/10/2021 | AK | 63 | F | 1/29/2021 | 1/29/2021 | Fever to 101 beginning about 5 hours after injection. Followed that evening by nausea. Fever and nausea persisted all night. Sat AM 1/30/2021 fever had broken, nausea persisted. After a couple sips of tea, returned up stairs to go back to bed: Sudden complete loss of consciousness (syncope), striking right forehead on wooden chair as falling to the floor. Completely unresponsive for 5-10 minutes. Then confused but responsive to voice. Amnesia for events for at least the next hour. Taken via ambulance to ER for evaluation. Trouble with concentration and dexterity for nearly a week. Bruising and tender forehead for more than a week. Left arm injection site became red and itchy 1/31/21, for several days. |
| 1020960 | 2/10/2021 | MO | 31 | F | 1/6/2021 | 1/6/2021 | Syncope and passing out;admitted and received potassium chlorid 40 mEq tablet, for hypokalemia and DVT prophylaxis with subcutaneous heparin. Was discharged after admission for overnight (from 01/07/21 to 01/08/21. Admitted for electrolyte abnormality. Of note, patient had one other syncope event a long time ago from a blood draw. |
| 1020970 | 2/10/2021 | MO | 28 | F | 1/20/2021 | 1/20/2021 | Syncope. Per ED note, patient has experienced syncope epsoides before Diagnosis:Syncope and collapse, Injury of head, initial encounter Vasovagal episode |
| 1020972 | 2/10/2021 | | 32 | F | 2/7/2021 | 2/7/2021 | Moderna COVID-19 Vaccine EUA. Side effect symptoms experienced 2/7/21 pm through 2/9/21: Moderate to severe muscle pain entire left arm, Moderate to severe muscle pain entire right and left legs and feet, Joint pain, low back pain, chills, fever, fatigue, headache. One instance of dizziness/pre-syncope on 2/7/21 pm. |
| 1020981 | 2/10/2021 | OH | 61 | F | 2/9/2021 | 2/10/2021 | Approximately 24 hours after given 2nd covid vaccine injection patient was sitting at bedside of a family member that came to hospital ED. She passed out and fell to floor. Lost her pulse and ED staff began CPR. She got her pulse back and woke up and said I am okay. Doctor seeing her ordered labs, EKG, Echocardiogram , chest xray, cardiac enzymes. All tests were normal. ED doctor told patient the only thing they could contribute this to was her covid vaccine she got the day before. She was admitted to the facility for further observation for the next 24 hours. |

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| 1016105 | 2/9/2021 | MD | 69 | F | 2/8/2021 | 2/9/2021 | Patient states she received the Moderna second vaccine around noon. Around 2 am she sent and drank some warm milk. As she walked up the stairs, she felt like vomiting and also felt like she could not move. Tried to crawl to the bathroom when she passed out. woke up with clothes full of vomit. Feeling better today. |
| 1016938 | 2/9/2021 | OR | 28 | F | 1/31/2021 | 2/1/2021 | 02-01-2021 patient syncope x 2 with loss of consciousness. Chest heaviness, dizziness, lightheaded, increasing fatigue. Went to ED - diagnosed with new onset Right Bundle Branch Block and hypophosphatemia. Elevated D-Dimer. |
| 1016686 | 2/9/2021 | CT | 41 | F | 1/21/2021 | 1/21/2021 | As I was leaving the clinic, roughly 20 minutes after receiving the vaccine, I became very nauseous and returned to tell the nurse I didn't feel well. I then had an episode of syncope and was unconscious for around 40 seconds. I was transported to the hospital via ambulance. In the ambulance I had a second syncopal episode while the EKG monitored that my HR dropped to 30 bpm. I was unconscious the 2nd time for around 1 minute. Upon arrival to the ER I vomited uncontrollably for a few minutes. For the last 3 weeks following the vaccine I've had a fever of 99.8, headaches, mild diarrhea and nausea. For 10 days following the vaccine I had trouble with thinking clearly and "brain fog". Beginning 2 days post-vaccination my left supraclavicular lymph nodes became very swollen and hard and have remained that way since. |

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| 1016622 | 2/9/2021 | VA | 45 | F | 1/15/2021 | 1/15/2021 | faint; feeling off; feel dizzy/light headed; dry mouth; hard to swallow; They took my BP upon arrival and it was 141/93; chills; low grade fever 100 degrees; This is a spontaneous report from a contactable 45-year-old female other health professional reported for herself that she received 1st dose of bnt162b2 (lot number EL8982) on 15Jan2021 08:00 AM at left arm for Covid-19 immunization. Medical history included hereditary angioedema from unknown date (last episode 2015). The patient had not received other vaccines within 4 weeks prior to COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination. Concomitant drug included caffeine, paracetamol (ACETAMINOPHEN AND CAFFEINE). The patient reported that after waiting the 15 minutes, she walked to her car, and started feeling off. She thought about sitting in the hospital parking lot, but started to drive home. She started to feel dizzy, light headed, faint, dry mouth, hard to swallow so she drove herself to the fire station. They took her blood pressure (BP) upon arrival and it was 141/93 and blood sugar was 90 on 15Jan2021. She was 120 pounds and her normal BP was 116/63. The event onset time was reported as 15Jan2021 08:30 AM. Later on 15Jan2021, the patient had chills and low grade fever 100 degrees. Treatment was received for the events. The events were resolved on unknown date. Events were reported non-serious. Since the vaccination, the patient has not been tested for COVID-19.; Sender's Comments: Based on temporal association, the causal relationship between bnt162b2 and the event syncope cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate. |

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| 1016617 | 2/9/2021 | NY | 70 | M | 1/22/2021 | 1/1/2021 | <p>He almost passed out a couple times; Fever; weak; Awful shakes; Sweating; Chills; Stomach like on fire; Diarrhea; He lost about 4 pounds; has autoimmune disease, lupus; has autoimmune disease, lupus; he thinks he was almost dehydrated; This is a spontaneous report from a contactable consumer (patient). A 70-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; lot number and expiry date not reported) via an unspecified route of administration at right arm, on 22Jan2021 14:30, at SINGLE DOSE for COVID-19 immunization. Medical history included autoimmune disease, systemic lupus erythematosus diagnosed in 2018 (over 3 years ago). Concomitant medication included baricitinib taken in a clinical trial, a study, unknown if 2 or 4mg plus placebo for lupus. On 25Jan2021, at 14:30 in the afternoon, the patient was sweating and it was awful shakes and chills, and it lasted over three hours, and on 26Jan2021 he was weak. The patient lost about 4 pounds on 25Jan2021, with all the water running out of of him. The sweating and shakes happened so suddenly and stomach felt like it was on fire on 25Jan2021. The stomach feeling like it is on fire has gone away, he almost passed out a couple times on an unspecified date, he had diarrhea on 25Jan2021, it was unbelievable. The sweats with awful shakes has gone away on 25Jan2021, but it was horrible, he has recovered with a lasting effect, he is a little weak, but he can move he had to take his dog to the beautician. Diarrhea: the is not eating (had no breakfast this morning) however it was also reported that the patient had a little slice of roast beef and blackberries not many, and he has been drinking, he thinks he was almost dehydrated in Jan2021, he drank about a quart of water so far today. On an unspecified date, the patient had fever. His doctor called the day before and said it was alright; his rheumatologist said it was ok. Outcome of the events he almost passed out a couple times, fever, chills, weak, Diarrhea, He lost about 4 pounds, he thinks he was almost dehydrated was unknown; the events sweating, awful shakes recovered on 25Jan2021 with sequaleae, while Stomach like on fire recovered in 2021. Information on the lot/batch number has been requested.</p> |

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| 1016616 | 2/9/2021 | GA | 25 | F | 12/28/2020 | 12/28/2020 | syncopal episodes; Vomited 40+ times; blood pressure dropped to 70/40; Elevated bilirubin; elevated liver enzymes (ALT, AST); elevated liver enzymes (ALT, AST); This is a spontaneous report from a contactable other health professional (patient herself). A 25-year-old female patient (non-pregnant) received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EL0142), via an unspecified route of administration on 28Dec2020 12:30 in right arm at single dose for covid-19 immunization. The patient had COVID prior vaccination. Concomitant medication in two weeks included levothyroxine sodium (SYNTHROID), amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL). The patient experienced vomited 40+ times, syncopal episodes, blood pressure dropped to 70/40, elevated bilirubin, elevated liver enzymes (ALT (alanine aminotransferase), AST (aspartate aminotransferase)) on 28Dec2020 19:30. Events resulted in emergency room/department or urgent care. IV fluids were received for events. The patient was not tested COVID post vaccination. Outcome of elevated bilirubin was recovered on an unspecified date, and outcome of other events were recovering.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported syncope cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate. |

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| 1016610 | 2/9/2021 | AL | 45 | F | 1/25/2021 | 1/25/2021 | <p>Syncope; passed out; This is a spontaneous report from a contactable pharmacist reported that a 45-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN5318), intramuscular on the left arm on 25Jan2021 15:00 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient previously received flu vaccine on an unspecified date for immunization and experienced fever. On 25Jan2021, the patient was experienced syncope and passed out. She woke up within the next couple of minutes and was monitored. The patient eaten food. The outcome of the events was unknown.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported events, syncope and passed out, and the administration of COVID-19 vaccine, BNT162B2, based on the reasonable temporal association, and lacking alternative explanations. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.</p> |

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| 1015631 | 2/9/2021 | NY | | M | 1/23/2021 | 1/23/2021 | Passed out; Hypotensive; Lightheaded; Heart rate dropped to 50; Arm soreness; A spontaneous report was received from a consumer concerning a 43-year old, male patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced passed out, hypotensive, lightheaded, heart rate dropped to 50 and arm soreness. The patient's medical history was not provided. No relevant concomitant medications were reported. On 23 Jan 2021, approximately 0 days prior to the onset of the events, the patient received a dose of mRNA-1273 (Batch number 011L20A) intramuscularly for prophylaxis of COVID-19 infection. On 23 Jan 2021, 6 minutes following vaccination, the patient experienced lightheadedness, became hypotensive, heart rate dropped to 50, and he passed out. Following the events, ambulance came and he was rushed to a health clinic. They gave him an Epinephrine shot and his vitals stabilized quickly. The patient also had arm soreness. Treatment for the event included epinephrine. Action taken with mRNA-1273 in response to the events was not reported. The events passed out, hypotensive, lightheaded, heart rate dropped to 50, were considered resolved on 23 Jan 2021. The outcome of the event arm soreness was unknown.; Reporter's Comments: Company comment: This spontaneous report concerns a 43-year old, male patient who experienced serious event of passed out and nonseries events of hypotensive, lightheaded, heart rate dropped to 50 and arm soreness. The events occurred on the same day, 6 minutes after the administration of the first dose of mRNA 1273 (lot number 011L20A, expiration date unknown). Treatment included epinephrine and outcome of all events except arm soreness are resolved. Based on the information provided, which indicates a temporal association of the reported events with the administration of mRNA-1273 vaccine, a causal association cannot be excluded. |
| 1016693 | 2/9/2021 | MS | 81 | M | 2/9/2021 | 2/9/2021 | Near syncope Patient states he "felt dizzy and equilibrium was off~~ |

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| 1016598 | 2/9/2021 | NC | | M | 1/27/2021 | 1/27/2021 | Vasovagal syncope; I suffered incontinence; Blood pressure dropped; A spontaneous report was received from a 29-year-old male patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced vasovagal syncope, blood pressure dropped, and incontinence. The patient's medical history was not provided. Products known to have been used by the patient, within two weeks prior to the event, included multivitamin and fish oil. On 27 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 intramuscularly in the left arm for prophylaxis of COVID-19 infection. Approximately five minutes after receiving the vaccine, the patient experienced vasovagal syncope. The patient reported his blood pressure dropped too much and he passed out for about ten seconds. He also suffered incontinence. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not reported. On 27 Jan 2021, the outcome of the events, experienced vasovagal syncope, blood pressure dropped, and incontinence, were considered resolved.; Reporter's Comments: This case concerns 29-year-old male patient, who experienced non serious unexpected events of blood pressure decreased with vasovagal syncope and incontinence. The events occurred 5 minutes after the first dose of mRNA-1273 vaccine. No treatment was reported, and outcome of reported events was reported as resolved. All events were assessed as related to mRNA-1273 vaccine due to temporal association. |
| 1015978 | 2/9/2021 | SC | 41 | F | 2/8/2021 | 2/8/2021 | I immediately felt nauseated and fatigued, but severe reaction occurred at 10 pm. Extreme weakness and tingling on lips and tongue with difficulty breathing. Migraine and body aches not resolved with OTC meds. Lower back pain was notable and prevented me from sleeping. I passed out in the bathroom when trying to get Tylenol. |
| 1015772 | 2/9/2021 | TN | 36 | M | 2/7/2021 | 2/8/2021 | Vagal response, passed out due to low blood pressure, , low blood oxygen level saturation 83 |

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| 1015759 | 2/9/2021 | IN | 73 | M | 2/7/2021 | 2/8/2021 | A. Shoulder Injury Related to Vaccine Administration (7 days) sore at spot next day AM but less in PM. Today no pain at spot. B. Vasovagal syncope (7 days) Today feel light headed before meal. Had good night sleep 10 PM to 7 AM |
| 1015675 | 2/9/2021 | AR | 91 | M | 1/1/2021 | 1/1/2021 | I faint anf fell twice hurt my back once; I faint anf fell twice hurt my back once; hurt my back once; Dizzy spells; Constipation; This is a spontaneous report from a contactable consumer (patient). A 91-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL1284) via an unspecified route of administration in Jan2021 (a week before reporting) at single dose in left shoulder for COVID-19 immunisation. Age at vaccination was 91 years. The patient's medical history and concomitant medications were not reported. About 24 hours after shot he started having some dizzy spells and then fainted and fell a couple of times and hurt his back once. He stated he also had had constipation since the shot and do not know if that is related or not. The patient wanted to talk to see if he could get his second shot. He is taking some pain killers for his back. With regards to Physician Office/ Emergency Room: patient stated, 'This for my back and nothing else of that'. The outcome of the events was unknown. The information on the lot/batch number has been requested. |

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| 1015667 | 2/9/2021 | NY | 30 | F | 1/20/2021 | 1/20/2021 | diarrhea (7+ loose stools each day starting on this day); headache; severe nausea; worsened muscle pain; new joint pain morning after (Included in aforementioned, but significant stiff neck.); new joint pain morning after (Included in aforementioned, but significant stiff neck.); fatigue/malaise; fatigue/malaise; This is a spontaneous report from a contactable other HCP report for self. This 30-year-old not pregnant female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL3302) Intramuscular at left arm on 20Jan2021 at single dose for COVID-19 immunization. Medical history included Asthma, anxiety, allergies to Acetaminophen (seizure like activity and fainting). No COVID prior vaccination. No other vaccine in four weeks. Other medications in two weeks includes fluoxetine, lorazepam, and Ibuprofen. Patient received first dose of bnt162b2 (lot number: EL0140) on 30Dec2020 and experienced injection sight tenderness, severe headache and fatigue. On 20Jan2021 5:00 PM after the second dose, patient experience headache, severe nausea, diarrhea (7+ loose stools each day starting on this day), worsened muscle pain several hours later, new joint pain morning after (Included in aforementioned, but significant stiff neck), fatigue/malaise. Patient received Ibuprofen and rest, supportive care due to events. The outcome of event was not recovered. Rapid Nasal Swab tested Negative on 21Jan2021.; Sender's Comments: The reported event diarrhea was likely causally related to the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) due to temporal relationship, and considering no alternative cause reported currently. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics committees and Investigators, as appropriate. |

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| 1015656 | 2/9/2021 | AR | 48 | F | 1/7/2021 | 1/7/2021 | Bilateral arm weakness/dysesthesia; Bilateral arm weakness; Severe fatigue; Pretty bad swelling in the shoulder joint that she had the shot in; stiffness in her neck and joints, and in both of her hands, fingers, and elbows.; stiffness in her neck and joints, and in both of her hands, fingers, and elbows; her neck and joints, and in both of her hands, fingers, and elbows; stiffness in her neck and joints, and in both of her hands, fingers, and elbows.; She also had pain in both biceps; Within 20 minutes she had a really weird sharp pain in her upper back the size of a cantelope; This is a spontaneous report from a contactable Nurse. A 48-Year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection) on 07Jan2021 at single dose via an unspecified route of administration in right deltoid for COVID-19 immunization. Relevant medical history included Multiple sclerosis/Diagnosed in 1991 or 1992. She also had 2 previous reactions to a pneumonia vaccine two years in a row. About 30-45 minutes after she had fainting episodes. On 07Jan2021 within 20 minutes she had a really weird sharp pain in her upper back the size of a cantelope. On the same day she complained pretty bad swelling in the shoulder joint that she had the shot in, along with stiffness in her neck and joints, and in both of her hands, fingers, and elbows. She also had pain in both biceps. On 08Jan2021 the patient experienced severe fatigue and 10Jan2021 Bilateral arm weakness/dysesthesia. They were floppy noodles and she could hardly use them. She could not hold her purse in her hands. She has not had this issue before with her Multiple Sclerosis. This took about a full week and a half for that to go away. It was like weakness/dysesthesia. She talked to her doctor and he said he felt like the shot had exacerbated her Multiple Sclerosis potentially. At the time of the reporting the patient was recovering from Bilateral arm weakness/dysesthesia. She recovered from fatigue on 09Jan2021, from 'Within 20 minutes she had a really weird sharp pain in her upper back the size of a cantelope' on 10Jan2021 and from other reported events on 12Jan2021. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information currently available, a possible contributory role of the suspect BNT162B2 in triggering the onset of bilateral arm weakness/dysesthesia cannot be excluded. The events are confounded by underlying multiple |

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sclerosis. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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| 1015651 | 2/9/2021 | WV | 67 | F | 1/21/2021 | 1/22/2021 | Rash on torso; Passed out; Laceration to back of skull requiring staples; Severe chills; Feeling unwell; Difficulty sleeping; Dizziness; Weakness; Joint pain neck; Joint pain neck; Mild injection site pain; This is a spontaneous report from a contactable nurse reporting for self. A 67-year-old female patient received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL9261), via an unspecified route of administration on 21Jan2021 at single dose for covid-19 immunisation. Medical history included Covid, Hypothyroidism, Arthritis, Chronic Neck R shoulder pain, Migraines, Submaxillary gland removal, Tubal ligation. Concomitant medication included amitriptyline, ibuprofen, levothyroxine sodium (LEVOTHYROXIN), ibuprofen (MOTRIN [IBUPROFEN]), vitamin d3. Patient received first dose of bnt162b2 on 30Dec2020 and experienced injection site pain. Patient had allergies to Amoxicillin, Duricef, Mobic, Nexium. The patient experienced severe chills, feeling unwell, difficulty sleeping, dizziness and weakness, passed out, laceration to back of skull requiring staples, joint pain neck, mild injection site pain, on 22Jan2021 01:00 AM, 24 hours later rash on torso. Patient underwent CT head neck, EKG, Chest XRAY, Labs, results all unknown. Events resulted in Emergency room/department or urgent care. Outcome of event rash was unknown, of other events was recovering.; Sender's Comments: Based on temporal association, a possible contributory role of BNT162B2 cannot be excluded for passed out and chills. Laceration is subsequent to passed out. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate. |

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| 1015653 | 2/9/2021 | MD | 65 | F | 1/18/2021 | 1/1/2021 | She felt same the way but worst; Lack of appetite; Passed out; Chills; Aches; Headache; Had no energy; Tired; Feeling sick; She was shaky, cold; She was shaky, cold; She had the flu; This is a spontaneous report from a contactable consumer reporting for herself. A 65-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EL1284), via an unspecified route of administration left arm single dose on 18Jan2021 17:30 for covid-19 immunisation. Medical history was none. There were no concomitant medications. No other vaccine was received in four weeks. The patient experienced passed out on 20Jan2021 14:00, tired on 18Jan2021 21:00, feeling sick on 18Jan2021 21:00, chills on 19Jan2021 09:00, aches on 19Jan2021 09:00, headache 19Jan2021 09:00, had no energy on 19Jan2021 09:00, lack of appetite on 22Jan2021 09:00, she was shaky in Jan2021, cold in Jan2021, she had the flu on Jan2021, she felt same the way but worst on an unspecified date. The outcome of the events was recovered on 22Jan2021 |
| 1018125 | 2/9/2021 | NY | 25 | F | 2/6/2021 | 2/7/2021 | Fever & chills starting at 9/10 pm on the day of the vaccine. Body aches, headache & joint pain by midnight . Fainted around 5:30 the following morning within 24 hours of the vaccine. |
| 1016084 | 2/9/2021 | PA | 50 | M | 1/19/2021 | 1/19/2021 | About 5 minutes post vaccine, reports vasovagal syncope. Was taken to ED and treated with Zofran for nausea. EKG showed HR of 30's but sinus rhythm. Hydrated with PO fluids and discharged home. |
| 1022299 | 2/9/2021 | VA | 52 | F | 2/5/2021 | 2/6/2021 | Extreme pain at injection site and shoulder. Felt very hot and nauseous; fainted; chills for about 4-5 hours after. Fatigued for following two days. |

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| 1018127 | 2/9/2021 | TX | 44 | F | 2/9/2021 | 2/9/2021 | While PT was in her 15 minute observation period PT began to experience weakness with a near syncope, later complaining of chest pain. PT was found to be hypertensive BP 200/100. PT advised she has a PMH of HTN but did not take her prescribed medication in the morning. PT remained hypertensive and was found to have an irregular heart rhythm with no history of cardiac issues. IV was established, 325 mg of aspirin via PO was and 0.4 mg of nitroglycerin was administered via sublingual with PT chest pain improving from 8 of 10 chest pain to pain completely subsiding. Run #21-0766 |
| 1017079 | 2/9/2021 | CA | | U | 1/23/2021 | 1/23/2021 | Fainted; Had a seizure; A spontaneous report was received from a physician concerning a patient who received Moderna's COVID-19 vaccine (mRNA-1273) and fainted and had a seizure. The patient's medical history was not provided. No relevant concomitant medications were reported. On 23 Jan 2021, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On 23 Jan 2021, after vaccine administration, the patient fainted and had a seizure. No treatment information was provided. Action taken with mRNA-1273 in response to the event was not reported. The outcome of the events, fainted and seizure, were unknown.; Reporter's Comments: This case concerns a patient, who experienced events of fainted and seizure. The events occurred the same day after the first and last dose of mRNA-1273 vaccine administration. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded and the events are assessed as possibly related. |
| 1018095 | 2/9/2021 | MI | 45 | F | 2/9/2021 | 2/9/2021 | Patient claimed felt lightheaded about an hour after vaccinated. Around 3 hours after vaccine administered she fainted and EMS came. |

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| 1018007 | 2/9/2021 | CA | 56 | M | 2/9/2021 | 2/9/2021 | Patient received vaccine then passed out a few minutes later. Patient was sitting so did not fall and was observed by multiple people. Patient came too shortly after in a matter of 5-10 seconds. Patient sat for another 15 minutes and was being constantly observed and was fine. BP was monitored and was 115/76 pulse was 52. I followed up with at 2:43 pm and he reports to be fine. Patient thinks he suffered from a panic attack. Note at the beginning of the incident we called 911, but subsequently cancelled it. |
| 1017885 | 2/9/2021 | CA | 25 | F | 2/7/2021 | 2/7/2021 | Syncope/fainting 14 hours post vaccine. Fever began around 9 hours post vaccine and was 4 degrees above my normal temperature. Extreme chills and shaking, became dizzy and fainted, out for about a minute. Laid on ground for a while, returned to bed and took Advil for fever |
| 1017882 | 2/9/2021 | OH | 55 | F | 1/5/2021 | 1/6/2021 | 1/5 vaccine. Twelve hours later, I woke up around 3am. My arm was really hurting. I got up and was sitting in bathroom, wave of nausea. I was standing, brushing teeth, felt weak from the inside out. I was leaning over the vanity, I hit the floor. My husband came in, I tore my non displaced fracture of clavicle; partial tear of rotator cuff and AC sprain. It took me a bit to 'come to', laid there for a little bit. I felt weak, shoulder pain. I had a HA for 3 weeks, neck injury. Don't know if due to vaccine or injury from syncope. |

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| 1017080 | 2/9/2021 | | | F | 1/26/2021 | 1/1/2021 | fainted; body aches; fever; Chills; A spontaneous report was received from a consumer who is a female patient, who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced fainting, body aches, fever and chills. The patient's medical history was not provided. Concomitant medications were not reported. On 26 Jan 2021, the patient received their second dose of two planned doses of mRNA-1273 (Batch number: unknown) for the prophylaxis of COVID-19 infection. On 26 Jan 2021, the patient experienced body aches, fever and chills and she got up in the middle of the night and fainted. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not reported. The outcome of events fainting, body aches, fever and chills, were considered not resolved.~; Reporter's Comments: This case concerns a female patient, who experienced events of fainting, body aches, fever and chills. The events occurred the same day after the second and last dose of mRNA-1273 vaccine administration. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded and the events are assessed as possibly related. |
| 1017729 | 2/9/2021 | NC | 41 | M | 1/19/2021 | 1/19/2021 | Mild symptoms - cold chills, achy on the night of vaccine. At about 24 hrs after vaccine administration, developed high fever(102), rapid heart rate, low o2 sat, eventually passed out and EMS had to be called. Was not transported to hospital per pt request. |
| 1017505 | 2/9/2021 | ME | 47 | F | 2/6/2021 | 2/6/2021 | ADR- Chills, sweats, body aches, tachycardia with near syncope and a fall in the shower this am. |
| 1017431 | 2/9/2021 | CA | 29 | F | 2/9/2021 | 2/9/2021 | One hour 10 minutes after dose employee was at work station, stood up, felt faint and fell to the ground. Regained consciousness in less than 30 seconds and asked for help from nearby co worker. She was taken by ambulance to Hospital due to recent hip injury and fall to insure no further injury occurred. Pt has previously passed out while receiving flu vaccine. Pt is currently using a knee scooter to assist with mobility. |
| 1017407 | 2/9/2021 | TX | 49 | F | 2/6/2021 | 2/6/2021 | Chills, nausea, possibly passed out, red and hot to the touch rash on chest and back |

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| 1017328 | 2/9/2021 | MA | 90 | F | 2/5/2021 | 2/5/2021 | Systemic: Fainting; symptoms lasted 1 day. |
| 1017309 | 2/9/2021 | MA | 90 | F | 2/5/2021 | 2/5/2021 | Systemic: Fainting; symptoms lasted 1 day. |
| 1017138 | 2/9/2021 | CA | 87 | F | 2/8/2021 | 2/8/2021 | Systemic: Other- Fainting only |
| 1017822 | 2/9/2021 | NY | 72 | F | 2/4/2021 | 2/5/2021 | Syncope, Migraine, Blood Test, Urinalysis, CT scan, chest xray. IV. Discharge condition stable. |
| 1018558 | 2/9/2021 | WA | 64 | F | 2/3/2021 | 2/5/2021 | 37 hours after Pfizer injection, experienced severe abdominal pain that caused me to have vasovagal syncope. Started sweating, and I lost my vision, then must have fallen on the floor. When I came to, felt very headachy and nauseous. went to urgent care - they ordered an abdominal scan for 2/8/21 but scan did not reveal the cause of the pain. 8 hours later on 2/5/21, started feeling asthma like symptoms. Throat felt tight, voice became hoarse, kept having to cough because airway was starting to feel thickened. went to ER, they took vitals and told me that i wasn't having an allergic reaction because my symptoms were outside the time frame for an allergic reaction. After 3 hours there, they sent me home. Next morning felt like I was having heart palpitations. that feeling eventually went away if I walked around. But the following two mornings, I had the same feeling. |

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| 1011581 | 2/8/2021 | MN | 41 | M | 2/4/2021 | 2/4/2021 | <p>Patient screened for first dose of Pfizer vaccine. He checked no history of allergies or reactions to medications or vaccines. In the initial screening he informed me he had a phobia of needles but this is usually with blood draws. He reported he should be fine with vaccinations. I inquired on previous reactions and he denied any allergic reaction just that he does not like them. I asked him how I can help give the vaccine. We had him look away and to think of a different situation. I asked him if he would like to know when I am administering or just use distraction. He chose to be informed when he would feel a slight poke. Vaccine was administered with no issues. Within the minute following the vaccine patient started to feel dizzy. Hung his head a bit but was responsive. I requested staff assistance to help the situation including RN to prevent any episodes of syncope. We provided water which he was able to drink. He was still seated and we suggested putting head between legs. This was not comfortable for him so we moved him to the floor. About 3-4 min in he began to sweat a bit more and appeared Pale. We obtained a BP and pulse. BP was 112/60 and pulse around 60. When he felt hot, sweaty and appeared pale we all decided to call EMS to be cautious. He maintained BP, no SOB, did not lose conscious. EMS evaluated him, med list provided and vitals. He was on medications for anxiety. They released him after about 30min and reported a panic attack and not related to the vaccine. Patient walked out of the clinic with his partner and was stable. He is requesting 2nd dose of the vaccine. I informed him nurse would review and would have a plan for future injection.</p> |

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| 1011749 | 2/8/2021 | MI | 72 | F | 1/21/2021 | 1/24/2021 | 1/21/2021, 4 pm, Covid-19 first shot, Pfizer, Lot EL3246 On 1/24/2021 at 5 am I had bad heartburn so I got out of bed, took a couple of TUMS and sat in chair , At 6 am I went to get in bed and felt nausea and started to go to the bathroom but ended up fainting. When I came to I started vomiting., Then my husband had to help me off the floor and get to the bathroom. I was vomiting and had Diarrhea. My temperature was normal. When symptoms subsided in about a half hour time I realized my right foot, leg and knee hurt. At approximately 1 pm my daughter insisted that I go to the ER, where I was treated.They ran a bunch of test but did not find anything seriously wrong with me and sent me home. |
| 1011754 | 2/8/2021 | CA | 43 | F | 2/2/2021 | 2/2/2021 | Approximately 12 hours after the vaccine felt nauseated, and then she passed out. She got really cold to the point that she was layered up with blankets, shivering with 4 layers, teeth shattering, possibly going into shock, took Tylenol, her temp was 100. She went to sleep and was just trying to get warm. The next morning she still had a fever of 100. She continued to take Tylenol and by Friday 2/5/21 was okay. She is 4'11 and weighs 85#, wondering if the dose was too strong for her body frame, otherwise healthy person. |
| 1011920 | 2/8/2021 | CA | 47 | M | 2/4/2021 | 2/5/2021 | Nausea, low blood pressure, fainted, body pain, adverse reaction to cosmetic filler. |
| 1012022 | 2/8/2021 | IN | 83 | F | 2/6/2021 | 2/7/2021 | Started with intense abdominal pain and need to evacuate/nearly fainted Started to run a fever accompanied bu aching in joints, muscles, head. The fever has continued for two days (low grade 100.8 plus or minus No appetite for two days so far |
| 1012048 | 2/8/2021 | FL | 71 | F | 2/3/2021 | 2/3/2021 | About 14 hrs later Severe dizziness , chills, some nausea They persisted for about 18 hrs. I don't know if I passed out the next morning but I was dizzy fell and sprained my ankle. |
| 1012050 | 2/8/2021 | KY | 59 | F | 2/3/2021 | 2/5/2021 | Severe nausea and diarrhea, so severe I was dehydrated within two hours of onset. I passed out 3 times and taken to the ER. At the ER I got IV fluids and 3 doses of nausea meds It was at the ER I tested positive for covid. |

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| 1012381 | 2/8/2021 | MA | 24 | F | 1/25/2021 | 1/25/2021 | felt herself losing consciousness; Low blood pressure following event (50/20); My vision went blurry first; This is a spontaneous report from a contactable consumer (patient). A 24-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in the left arm on 25Jan2021 at 09:30 at a single dose in the workplace clinic for COVID-19 immunization. Medical history included asthma and history of vasovagal syncope following vaccinations; this adverse reaction to the vaccination directly aligns with other episodes that have occurred to her following vaccinations/interactions with needles (ie. blood draws). The patient had no COVID prior to vaccination. The patient is not pregnant. Concomitant medication included levonorgestrel (MIRENA). On 25Jan2021 at 09:30 (after getting the vaccine), the patient felt herself losing consciousness, her vision went blurry first and she was able to brace herself by lying down against a wall, and low blood pressure following event (50/20). Blood pressure and pulse rose over the next 25 minutes. 15 minutes more of observation was completed. The patient did not receive treatments for the events. The patient was not tested for COVID post vaccination. The patient recovered from the events. Information on the Batch/Lot number has been requested. |
| 1012647 | 2/8/2021 | TX | 24 | F | 1/4/2021 | 1/4/2021 | Patient walked over to post-observation area and had a near syncope episode. Patient's vital signs taken and was observed for an additional 30 minutes. Water and snacks were offered. Patient left with companion who was driving the patient home. |
| 1011519 | 2/8/2021 | PA | 33 | M | 2/3/2021 | 2/3/2021 | pt fainted post vaccination- caught by paramedic. treated and monitored by paramedic. BS 70, BP 99/40, HR 52. given ginger ale and H2O, assessed and monitored by paramedic- helped to sit/stand- initially felt well then dizzy and helped to sit, HR dipped to 40s/50s after each time of sit/stand attempt- pt was advised on benefit of further eval @ ER- he agreed and ambulance was called. |
| 1012645 | 2/8/2021 | NM | 89 | F | 2/5/2021 | 2/6/2021 | I became nauseous, light headed then fainted. Had mild fever. Recovered after reclining. |

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| 1011502 | 2/8/2021 | LA | 68 | F | 2/7/2021 | 2/7/2021 | Patient experienced fever of 100.4, chills, diarrhea, vomiting, nausea, dizziness, and joint/body pain. Patient also passed out and suspects hit head on toilet. There is a scratch on her forehead but no bump. |
| 1011469 | 2/8/2021 | NY | 51 | F | 2/5/2021 | 2/6/2021 | 12 hours after getting vaccinated, I woke up with vicious chills. I took my temp and it was 102.5 F. I became nauseated and then fainted, smacking the back of my head on the bathroom floor. I took naproxen (220mg) for the fever and returned to bed. At around 8am I got up and my fever was 101F and stayed at that temp for 24 hours. I fainted again and blacked out for about 30 seconds. I stayed in bed all day. My fever broke by Sunday morning and I started to feel better by midday. |
| 1011317 | 2/8/2021 | NC | 83 | F | 1/25/2021 | 2/5/2021 | 12 days after first vaccination: Dizziness; high blood pressure; nearly passed out; right arm numbness; inability to grip or pick up items with fingers; feeling of "lopsidedness"; unsteady on feet, requiring assistance to walk. Primary care physician recommended ER visit where possible stroke was diagnosed. Hospital MRI confirmed: " Left acute arterial ischemic stroke, MCA (Middle cerebral artery)" . Spent 2 days in hospital with high blood pressure, dizziness. Residual right finger numbness upon release. |
| 1011297 | 2/8/2021 | MI | 96 | F | 2/4/2021 | 2/6/2021 | syncope 2 days later after taking nitroglycerin |
| 1011215 | 2/8/2021 | IN | 55 | F | 2/6/2021 | 2/7/2021 | I had a headache during the night and on waking the following morning after the vaccine. I passed out twice whilst making breakfast. Not sure how long I was out each time but don't believe it was very long. Took some tylenol and laid down. I experienced chills after taking the tylenol but otherwise felt well enough to get up and fix myself something to eat after about 30 minutes. Stiff and sore the rest of the day from the falls - sore/pain around coccyx/lower back area, right elbow and left shoulder bruise. Ongoing soreness/pain today (Monday) |
| 1011210 | 2/8/2021 | PA | 23 | M | 2/5/2021 | 2/5/2021 | Patient reported feeling lightheaded and dizzy minutes after receiving vaccine. Some diaphoresis. No overt fainting. VS: BP 110/66; P82; RR 16; Pulse Ox: 98% |
| 1011189 | 2/8/2021 | GA | 66 | M | 1/18/2021 | 1/19/2021 | Fever, dizziness, passed out. |

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| 1012697 | 2/8/2021 | OH | 37 | F | 1/29/2021 | 1/29/2021 | Nausea, headache, fatigue, chills, body aches, dizziness, near fainting, palpitations, shortness of breath. |
| 1011093 | 2/8/2021 | NY | 56 | F | 2/5/2021 | 2/5/2021 | lightheaded ,dizzy feeling of passing out . sweating drop in blood pressure 90 over 40. Was given an IV with fluids plus benadryl and a steroid. was taken to the ER for observation. was given an EKG and it was normal. the outcome was presyncope. |
| 1010901 | 2/8/2021 | FL | 72 | F | 1/20/2021 | 1/1/2021 | Passed out; Little bit sore arm; I woke up, was not able to sleep; My heart was doing kind of flip floppy; Dizzy/ had the dizziness which was severe; Falling; This is a spontaneous report from a contactable consumer (patient). A 72-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Batch/lot number: EL1283), via an unspecified route of administration on 20Jan2021 at 08:00 AM at single dose because she would like to not get Covid 19. Medical history reported as no. Concomitant medication included levothyroxine. The patient reported that she had bnt162b2 shot on Wednesday the 20Jan2021 about 8 O'clock in the morning, no real problem when she had it, had little bit sore arm but this morning (in Jan2021) about 2 O'clock she woke up, was not able to sleep, moved around a bit, her heart was doing kind of flip floppy, was not thinking much, the next thing she knew, she was extremely dizzy and she passed out, patient was asking could that be a side effect of Covid 19, it was about 36 hours after she had the shot. Patient also stated falling and passing out kind of get you off key. She had the dizziness which was severe and did pass out in Jan2021. No investigation assessment. No treatment was received for the events. The outcome of the events was unknown. |

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| 1010692 | 2/8/2021 | LA | 46 | M | 1/15/2021 | 1/15/2021 | tired; not feeling well; nausea; dizziness/almost passed out; This is a spontaneous report from a contactable nurse and a consumer. A 46-year-old male patient received the first dose of BNT162B2 (lot number: EL3247, expiry date: 31May2021), via an unspecified route of administration in left deltoid on 15Jan2021 12:56 at single dose for COVID-19 immunization. Medical history included had allergies as a child and carried as an epi pen. Concomitant medications were not reported. Reported to the waiting area for 15 minutes observation and left then came back to facility at 14:05 was not feeling well, reported dizziness and nausea. RN assessed patient, vital signs 122/84, pulse was 78 and O2 97 on room air, respiratory rate was 20, alert and oriented, was monitored for 30 minutes, reassessed at 14:25 188/76, heart rate 76, respiratory rate 18, O2 sats 98% on room air, encouraged patient to follow up with PCP or ER. Patient walked out with companion and stated he was feeling better. On 18Jan2021, patient was called for follow up, only complained he was as still tired, all other side effects had resolved. Stated he almost passed out upon coming back to the observation unit on 15Jan2021. Reporter stated it was noted that when patient returned for 2nd dose, would monitor for 45 minutes. Outcome of the event tired was not resolved, of event not feeling well was unknown, and of other events was resolved. |
| 1011129 | 2/8/2021 | KY | 77 | M | 1/28/2021 | 2/7/2021 | . Syncope and collapse 2. Respiratory arrest ADMITTED TO ICU |
| 1014404 | 2/8/2021 | NY | 24 | F | 1/24/2021 | 1/24/2021 | Symptom onset within 10 hours after vaccination: Swelling >5cm at injection site, significant pain and throbbing in extending down the arm of the injection site, swelling extending down to the forearm. Syncope and loss of consciousness occurred with trauma to the forehead and nose causing nose bleed. Unable to determine how long patient lost consciousness. When patient woke up, she was laying in a pool of blood from nose bleed and patient described shaking/rigors that were only relieved by taking Ibuprofen 800mg Q8H for 6 days. Denies fever. Due to syncope and head trauma, patient suffered concussion with symptoms of HA, blurry vision, difficulty concentrating, and fatigue. |

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| 1012749 | 2/8/2021 | FL | 60 | F | 12/22/2020 | 12/22/2020 | 12/22 Vaccination 4 hours later, chest pain. Felt heavy. Got extremely sleepy. I tried to lay down, episode of syncope. Chest discomfort. ER for observation |
| 1010690 | 2/8/2021 | NY | 28 | F | 1/22/2021 | 1/23/2021 | Passed out; fell; became disoriented and weak; became disoriented and weak; could not control her body, all muscles felt heavy and weak; could not control her body, all muscles felt heavy and weak; Felt tingles in feet and lower legs; This is a spontaneous report from a contactable consumer(patient). The 28-year-old female patient(not pregnant) received first dose BNT162B2(COVID 19, lot number: EL9262), via an unspecified route of administration at left arm on 22Jan2021 13:00 at single dose for COVID-19 immunization. Medical history included none. She had no known allergies. Concomitant medication included spironolactone, amfetamine aspartate/amfetamine sulfate/ dexamfetamine saccharate/ dexamfetamine sulfate (ADDERALL), vitamin b complex (VITAMIN B), ergocalciferol (VIT D), ZINC, omeg(omeprazole). There was no other vaccine in four weeks. About 11 hours after receiving(23Jan2021), she very quickly became disoriented and weak, could not control her body, all muscles felt heavy and weak. She fell once and then presumably passed out - she came to after falling again. She felt tingles in feet and lower legs. After sleeping about 9 hours, she felt better. There was no treatment received, no covid prior vaccination, covid tested post vaccination. Events were assessed as non-serious. Outcome of events was recovering. |
| 1016126 | 2/8/2021 | IL | 29 | M | 2/6/2021 | 2/6/2021 | Patient fainted and fell to the floor. EMS administered first Aid and ref pt to hospital. Refused to be transported by Ambulance car. Brother tranport pt to Hosp. |

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| 1015227 | 2/8/2021 | OR | 28 | F | 2/7/2021 | 2/8/2021 | -Nausea, episode of vomiting - occurred about 11 hours post-vaccination (1st dose), vomiting episode lasted half an hour. Nausea improved afterwards and was barely there in the next 16 hours. -Significant chills/shivering - started about 11 hours post vaccination and lasted about 2 hours. Improved after taking Tylenol and managed for the next 16 hours with Tylenol. -Low-grade fever. - Dizziness/lightheadedness/near syncope episodes- started about 11 hours post-vaccination at time of vomiting episode (middle of the night) and lasted about 6 hours. Systolic BP was in the high 80's, usual systolic BP is in the 120's. Managed by increasing fluid intake & drinking caffeinated beverages to increase BP. |
| 1015092 | 2/8/2021 | MI | 46 | F | 2/3/2021 | 2/4/2021 | Fainted , fever of 102.5 and ached all over for 24 hours |
| 1014817 | 2/8/2021 | ID | 44 | F | 2/5/2021 | 2/5/2021 | I felt fine after the vaccination at 11AM. Between 1-3:30PM, I got a pedicure and drank two 5.4% alcohol beverages. I drove home, made dinner, and ate. Shortly after eating, around 7:00PM, the soreness in my arm got intense, I began feeling nauseous and disoriented. I went to the bathroom and got on my hands and knees because I thought I was going to vomit. My boyfriend helped me get up on the edge of the bathtub, but I quickly passed out and fell forward. He said I was out for approximately 30 seconds. I came to long enough to tell him to call my mom then passed out again. for about 15 seconds Within minutes my mom, sister and daughter arrived, followed by first responders. First responders had to keep me from passing out for about 10 minutes, during which time I broke into a cold, soaking sweat, had involuntary muscle convulsions, extreme nausea, disorientation, slurred speech, and loss of ability to get up or walk on my own. I was admitted to the emergency room around 7:45. It took another hour for me to regain muscle control, speech and total coherency. I was released and went home. My arm was severely sore until Monday morning, but I also experienced severe fatigue, nausea, headache and muscle aches until late Sunday. |

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| 1014672 | 2/8/2021 | MI | 29 | F | 1/21/2021 | 1/22/2021 | Moderna COVID-19 Vaccine EUA 8-9 hours after my vaccine I fainted. I got up in the middle of the night, used the bathroom and fainted. I was not having stomach issue nor did I have a fever. I had eaten and drank enough fluids before and after the vaccine. I could feel that I was going to faint and started to sit down, luckily I did not fit my head only had a bruise on my forearm and hip. I woke up quickly and family members were nearby to help me slowly sit up. I did not faint anymore after this. I was very fatigued for the next 2 days. I contacted my health care provider, but did not need to be seen or treated. Medical History with fainting: I have fainted before, once in my teens when I had a very high fever and once after my first pap smear (vagal response). |
| 1014625 | 2/8/2021 | MD | 22 | F | 2/8/2021 | 2/8/2021 | fainted felt lightheaded nautious weird and weak |
| 1014486 | 2/8/2021 | WA | 44 | M | 2/2/2021 | 2/7/2021 | Near vasovagal syncope 5 days after 2nd dose. 5 days after my second COVID vaccine, I was outside in snowy, cold weather about a mile from my car. I had stopped moving to rearrange some items. While stopped, I started to feel lightheaded, develop tunnel vision, and feel faint, almost to the point of blacking out. I put my head down and legs up and felt somewhat better. I then attempted to return to my car. I could go 100-200 yards at a stretch, before having to purposefully fall down and elevate my legs. I traveled the mile back to my car like this (slowly). I could not check my pulse because my hands were too cold; my respiration rate was elevated. At the car, I drank fluids and warmed up and began to recover enough to get home. |
| 1014402 | 2/8/2021 | NY | 56 | F | 1/22/2021 | 1/22/2021 | This was my first vaccine. I had Covid last March. As of Jan 2021 i still had some antibodies in my body. After 12 hours i began to get chills and my skin was very achey. I took advil because when i was very sick with covid and too tylenol every 6 hours it didn't lower my temperature or take away any of my pain. two hours later, i had a stomach ache. While having a bowel movement i fainted onto the floor and ended up with a black eye. i do not pass out from having bowel moments otherwise. My cheekbone was sore to the touch for a week. |
| 1013341 | 2/8/2021 | FL | 74 | M | 2/8/2021 | 2/8/2021 | Patient had a syncope episode. |

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| 1013015 | 2/8/2021 | TX | 55 | F | 2/1/2021 | 2/2/2021 | Fatigue, syncope sensation, Arm pain - scale 10, arm swelling, fingers numbness, tingling, and swelling. Nausea. GI - Diarrhea. Swollen Lymph nodes, chills, fever, no appetite. |
| 1012764 | 2/8/2021 | FL | 73 | M | 1/25/2021 | 1/26/2021 | Approx. 24 hrs after vaccine, Felt sore arm, general weakness, lightheadedness,. Fainted. Hospitalized, Couldnt speak and eventually went into a coma type sleep for approx. 24-48 hours. Hospital Diagnosis was: Encephalopathy, History or intracranial hemorrhage, hypertension, stroke like symptoms, hepsis. 5 days in hospital. Medicines after discharge added: Norvasc 5mg 1 day, Plavix 75 mg, 1 day, Lisopril 1 day 5mg. |
| 1012803 | 2/8/2021 | ME | 43 | F | 2/4/2021 | 2/5/2021 | Vaccinated 2/4/21. On 2/5/21 in the AM, she developed a dull headache, sore throat and injection site pain/swelling. She felt that the pain went into the lymph nodes and into her back. The headache, pain and sore throat worsened over the afternoon. By the time she got home at 4:30pm she had whole body aches and was feeling really bad. She developed facial and eyelid swelling. She applied ice. Her eyelids swelled so much that they cracked. Her face has a dry, red rash. She later got up to take bedtime medications and she passed out. She began vomiting. She declined an offer to call the ambulance or to go be seen by a doctor. She took tylenol for pain and zofran for vomiting. On 2/6/21, she developed diarrhea. She was |
| 1014508 | 2/8/2021 | | | F | 2/2/2021 | 2/3/2021 | Resident received second dose of COVID -19 ON 2/2/21 on 2/3/21 resident had a fall after an episode of syncope |

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| 1012964 | 2/8/2021 | NH | 61 | F | 2/3/2021 | 2/4/2021 | 2/4/21 slight headache during day, tired. Cold on and off, cold feet throughout the day. 5:30pm got home from work had shaking chills, unable to get warm for 2 hours. Finally got warm but it was a hot warmth. No fever. Took Tylenol 500mg. The warmth continued and had mild headache. Took 500mg Tylenol at bedtime 11pm. I was hot throughout the night (no sweats) woke at 6am feeling light headed and dizzy, body aches, still hot. Felt like I had the flu. I went into the bathroom to void. I remember thinking - I am too sick to go to work. My husband said I was standing holding onto the door, white in color, said "i'm sick" he came to stand beside me to help me walk and I passed out. I had loss of consciousness. I do not know how long - he said he tried to shake me to wake me up about 30 seconds. He yelled to my son sleeping upstairs a few times, they got the phone and called 911. He said I vomited a few times and would not wake up. I remember coming to - sitting on the floor with him talking to 911 . I woke up enough to get up and walk to the living room couch with assist and gradually starting feeling better. The paramedics came and took my vital signs. Blood pressure (120/69), heart rate (84) oxygen saturations were all good. Blood glucose 116. I declined ER transport. I had continued light headedness, dizziness 2/6, 2/7/21. Arm soreness gone at injection site on 2/7/21. I believe the dizziness is a mild concussion. I have a provider appointment 2/9/21. |
| 1013246 | 2/8/2021 | AZ | 28 | F | 2/6/2021 | 2/6/2021 | Chills were the first symptom. The next day, I also experienced feeling very cold and some chills. I passed out briefly after getting out of bed and threw up right after that. I had body aches. I was nauseous but was able to take ibuprofen in the late morning. After the ibuprofen wore off, my body aches returned as well as a lethargic feeling. The next morning, I experienced nausea again until in the afternoon. |
| 1013058 | 2/8/2021 | | 56 | U | 2/5/2021 | 2/5/2021 | Syncope after vaccination requiring medical intervention to treat symptomatic hypotension. Patient also complaining of nausea. Initial vitals 90/50, HR 65, RR 16, SPO2 100. Given IV fluids, 50mg Benadryl and Solumedrol 125mg . BP recovered to 140/90. Transferred to local hospital via EMS. |

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| 1013138 | 2/8/2021 | IL | 68 | F | 2/8/2021 | 2/8/2021 | 10 minutes after vaccination patient became unresponsive, staring forward with stiff body, arms flexed and hands fisted. She required sternal rub without response. She was incontinent. Episode lasted 1-2 minutes. She had no recollection of the episode. Paramedics assisted, with Temp 97.1, HR 80, B/P 122/80, pulse ox 98%, fingerstick 101. She was transported by ambulance to Hospital. Laboratory assessment was unremarkable for for CMP, CBC, Troponin, Lactic acid. EKG, CXR and CT head were also unremarkable. She was discharged with diagnosis of possible vasovagal syncope episode and instructed to follow-up with her pcp. |
| 1013173 | 2/8/2021 | AZ | 60 | F | 1/2/2021 | 1/13/2021 | Fever 102.4, feeling of nausea, vomiting, diarrhea, dizzy, joint pain in back mostly, syncope. |
| 1013190 | 2/8/2021 | FL | 70 | M | 2/5/2021 | 2/5/2021 | Heart racing, lightheaded and passed out causing a traffic accident on the way home. Just as quick as it came on it went. Under regular care for years with no problems that would of caused this. The only thing that was different on the day of the reaction was the 2nd Covid shot. No problems at all with the first one. |
| 1013191 | 2/8/2021 | PA | 27 | U | 2/6/2021 | 2/6/2021 | Patient felt dizzy and fainted for 10 to 15 seconds. came to and was pale and felt nauseas |

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| 1012846 | 2/8/2021 | KS | 34 | F | 1/8/2021 | 1/8/2021 | <p>34 y.o. female who was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. She denied any history of previous adverse reactions to vaccines. She was given the Moderna vaccination in the right deltoid muscle. During her 15 minute waiting period after the injection, the patient began to experience dizziness and diaphoresis. She denied difficulty breathing, throat tightness and facial swelling. This provider was notified of patient reaction and she was then assessed in the emergency bay area. Monitored patient for severe reaction symptoms, including but not limited to blood pressure abnormality , rapid progression of symptoms and syncope. Patient states she last ate an apple with PB around 1pm today, but has not had much else today. Denies drinking much water today. She was working in surgery a majority of the day. ALLERGY REVIEW OF SYSTEMS: Patient complains of dizziness Patient denies chest tightness, shortness of breath and rash + diaphoresis: Previous Reactions: Denies. Got the flu vaccine this year without adverse reactions.</p> <p>Objective Vitals Vitals: 01/08/21 1506 01/08/21 1520 01/08/21 1529 BP: (!) 147/92 132/86 (!) 130/90 Pulse: 69 69 75 SpO2: 100% 100% 100% Physical Exam Constitutional: Appearance: Normal appearance. HENT: Head: Normocephalic. Mouth/Throat: Mouth: Mucous membranes are moist. Pharynx: Oropharynx is clear. No posterior oropharyngeal erythema. Comments: No swelling or lips or tongue. Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Pulmonary: Effort: Pulmonary effort is normal. No respiratory distress. Breath sounds: Normal breath sounds. No wheezing or rales. Skin: General: Skin is warm and dry. Neurological: General: No focal deficit present. Mental Status: She is alert and oriented to person, place, and time.</p> <p>Assessment/Plan Treatment included: no therapy. Patient was given a snack and water. Follow up response to treatment: good. Patients symptoms completely resolved before she was discharged. Encouraged her to drink water at home. Her BP improved throughout her visit. Patient discharge: Stable to go home and follow up with PCP. ons After Visit Summary (Automatic SnapShot taken 1/8/2021) Additional Documentation Vitals: BP 130/90 Pulse 75 SpO2 100% More Vitals Encounter Info: Old Enc Report, History, BestPractice</p> |

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| 1009467 | 2/7/2021 | OR | 35 | F | 1/20/2021 | 1/21/2021 | <p>Advisories, OB History Report</p> <p>The first night, 1/20. I had chills, but manageable. 1/21 I was fatigued, but also manageable. By the evening of 1/21 I could not stop shivering as I was sweating through 3 outfits a day (this lasted 4 days). By 1/22 my temperature was up to a 103 and I couldn't stand more than 10 minutes without fainting/passing out. Fever was gone by 1/25 but still have extreme fatigue/dreams where I'm almost hallucinating to this day 2/7. Did a virtual doctors visit on 1/29 where I was put on 3 days of bed rest, but still struggle to make it through a normal work day.</p> |

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| 1020134 | 2/7/2021 | | 61 | M | 1/28/2021 | 1/29/2021 | <p>anxious, restless, weak, dizzy, felt "horrible". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, "shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease." No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got "that shot" he hasn't felt well. When asked what shot pt replied "COVID shot." Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above</p> |

VAERS_ID RECVD STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 1009182 | 2/7/2021 | MI | 56 | F | 2/5/2021 | 2/6/2021 | information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped. |
| 1009192 | 2/7/2021 | IN | 37 | F | 2/5/2021 | 2/5/2021 | Episode of syncope at 12 pm resolved in a few minutes 2/6/21. Had to lie down for 2 hours. Did not require medical treatment. |
| | | | | | | | 9pm had chills then a hot flash, slight stomach ache. Went to go use the restroom and passed out and fell. Woke up and was stood up by friends and passed out again. I do have a history of vasovagal syncopy but it hasn't happened in over 10years |

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| 1009402 | 2/7/2021 | NY | 57 | M | 2/1/2021 | 2/6/2021 | Fainted twice. During the second faint had a mild shaking (seizure) he was out for about about 10 seconds then came awake. Sweating and hot. He slept for an hour, then was able to stand, and take the stairs up to bed. I'm calling his doctor tomorrow (Monday). |
| 1009419 | 2/7/2021 | WA | 30 | F | 2/6/2021 | 2/7/2021 | Vasovagal syncope upon waking and sitting up in bed. |
| 1009439 | 2/7/2021 | IN | 86 | F | 2/5/2021 | 2/5/2021 | general body aches, chills first- went to bed- then body shaking-during night had nausea, more of body issues and felt hot- took Tylenol PM-apparently passed out coming from bathroom. took one Tylenol and one Ibuprofen. stayed in bed until late morning. tried to hydrate but probably not enough. stayed up most of day- late afternoon chills returned and temperature 100.1 - took 2 Tylenol. went to bed 8:00- woke during night sweating and nightclothes drenched. got up this morning - 02/07- feeling better- some body aches and fatigue which could be from inactivity. |
| 1009665 | 2/7/2021 | TX | 64 | M | 2/6/2021 | 2/7/2021 | Vertigo Fainting Nausea Diarrhea |
| 1009741 | 2/7/2021 | TX | 81 | F | 2/6/2021 | 2/7/2021 | patient said on 2.7.21 around 12 pm she got light headed and black out/fainted for a few minutes and blood pressure dropped to 93/56, she felt like it could be vaccine related, no treatment, patient feeling better |
| 1009907 | 2/7/2021 | TX | 42 | F | 2/6/2021 | 2/6/2021 | Patient received vaccine in left deltoid at 3:40PM. During observation she became dizzy and fainted in seated position at 3:50PM. She came to immediately with the pharmacist talking to her and grasping her shoulders. Her BP at 3:51PM was 120/83 with HR of 60. Patient admitted to fasting for two days prior. She was administered Glucose gel sublingually at 3:54PM and BP was 107/81 with HR 69. She began to feel less faint with color returning within 2 minutes of administration of the glucose. She was observed until 4:10PM without any further incident. She was released with pharmacist's recommendation to go to the ER if any other symptoms are experienced. |
| 1010082 | 2/7/2021 | CA | 56 | F | 2/5/2021 | 2/6/2021 | I passed out about 24 hours after the vaccine and fell on the kitchen floor. I passed out a second time about 5- 10 min later when my husband was helping me sit up. |

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| 1010105 | 2/7/2021 | | 38 | M | 1/14/2021 | 1/25/2021 | Eleven days after the vaccination the patient developed 2 days of heartburn followed by a worsening nonproductive cough, substernal chest pain, diaphoresis, palpitations, and an episode of near syncope. These worsened over about 6 days and then slowly decreased. During this time he was referred to the ED and then admitted to a civilian host nation hospital. Echocardiogram and CT scan were performed and a pericardial cyst was discovered measuring 7.4 cm. He was then referred to another facility for evaluation. The pericardial cyst was confirmed, now 6.5 cm and laboratory tests were performed on 4 FEB, but there was at that time no elevation in inflammatory markers. Cardiology and Cardiothoracic Surgery consultations were obtained, but the consultants and the attending physician (who is an infectious disease physician by training) did not think that the crescendo-decrescendo symptoms could be explained by the pericardial cyst, which was likely an incidental finding. A milder cough may have preceded these events by up to a year, and this may possibly be related to the cyst. The heartburn, chest pain, tachycardia, diaphoresis, palpitations, and near syncope may well be adverse reactions of the vaccine. |
| 1009503 | 2/7/2021 | NJ | 34 | F | 2/5/2021 | 2/5/2021 | Sleepiness right after the dose. Extreme muscle cramps/spams in leg and lower back about 20 after the shot. Tiredness, sore arm, and dizziness the first 12hrs 12hrs mark fever 101.9 and fainted, loss of consciousness for about 5-10 minutes. Dry heaving while unconscious. Woke up from fainting with a lot of dry heaving and proceeded to throw up and sweat vigorously. A headache set in right after the vomiting. Intense headache, teeth pain and sore neck. Now, after almost 48 hrs tremors in hands and blurred vision but all the other symptoms are gone. I took Tylenol pm, and my regular Meloxicam and baclofen for the day. |

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| 1010138 | 2/7/2021 | | 44 | F | 1/29/2021 | 1/29/2021 | 1408 Numbness and tingling of bilateral cheeks and swelling of fingers. Denies SOB, dysphagia,cough,dizziness,syncope,Vital 120/82,82,96%. Given Benadryl 50mg po. 1419 Reports symptoms calming down less sensation of swelling and calming down. 1433 spoke with husband and notified of situation. 1515 Patient exited in stable condition. Agreed and understands of what to do if symptoms worsen or continue. |
| 1007692 | 2/6/2021 | IL | 25 | F | 2/5/2021 | 2/5/2021 | felt fine besides soreness after vaccine. My 9pm I felt dizzy, had a headache, and started feeling nauseous I took some Tylenol and ibuprofen and a snack (can?t take it on an empty stomach when nauseous Was able to fall sleep but woke up at 2am very shaky, nauseous, and with extreme joint pain. I went to get a snack so I could take more pain reliever and I passed out and briefly blacked out my vision. When I came to, all the lights in my apartment were on but I had to use my hands to feel where my bed was so I could get back in. My TV was on but I realized that I couldn?t hear it. All I could hear was a buzzing/wooshing sound and realized my hearing was gone and when I scratched my head and I couldn?t hear the sound on my scalp. It came back about 30 minutes later but happened again the next time I stood up. By around 4am I was in so much joint pain I couldn?t lie down anymore and had to run a bath so I could relieve some of the pain. I?m still in a lot of pain but I don?t have the nausea anymore as strongly. |
| 1008160 | 2/6/2021 | FL | 72 | F | 2/2/2021 | 2/3/2021 | About 1/2hour after I got up, I started feeling off with vision issues. Next thing I knew I had passed out and was laying on the floor. Then severe sweating with a headache and tiredness. My left arm was quite sore. |

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| 1008155 | 2/6/2021 | MI | 66 | M | 2/6/2021 | 2/6/2021 | Patient stated they were becoming dizzy and lightheaded. Immediately had patient come into vaccine room to see what else was happening. Patient stated they were also having breathing difficulties. Immediately tested patients bloods pressure. Tested twice and came to 220/120 with heart rate 80. Was an emergent situation. Informed patient I was contacting 911 to have them take him to the hospital as this is an emergency situation. Went and made phone call. Had staff bring patient into waiting area so that we could monitor him if something worsened. 911 advised to just monitor the patient. If he began vomiting or passed out to have him on his side, so he doesn't choke from vomit. We monitored patient until ambulance arrived. They asked for current medications we knew of (listed in report) and that he had received Pfizer Covid vaccine 0.3ml resulting in emergency BP readings of 220/120 after receiving. Ambulance took patient to Hospital. Current condition unknown or if anything even occurred after that point. Whole event lasted about 1 hour before patient left with medical personnel. |
| 1008062 | 2/6/2021 | NJ | 59 | F | 1/4/2021 | 2/4/2021 | Felt suddenly faint. Have hx of vasovagal syncope and when I faint my blood pressure goes very, very LOW. I moved to a armchair near the window thinking if I fainted I would not fall on floor and I mentioned to a nurse that I was feeling off and have a hx of vasovagal syncope and if my BP dropped very low to not worry, I'm fine and it will readjust. They sent medic over and took BP which was 200/120. I have NO hx of high blood pressure. He took it repeatedly and it remained at least 200/120 and he wanted me to get it checked out so I was taken by ambulance to hospital. Pressure normalized a short time later w no intervention. Purchased good BP cuff and that night BP was average 118/84 and now 99/68 (it tends to run low to normal in general) |
| 1008731 | 2/6/2021 | NY | 43 | F | 2/4/2021 | 2/5/2021 | 2/5/2021 extreme exhaustion, dizziness, weakness, extreme sweat lightheaded passed out at work, fever, body aches, red irritated swollen extreme pain at injection site. 2/6/2021 fatigue, dizziness, weakness, muscle joint pain slight fever, red irritated swollen pain tingling arm electric shock like pain sporadically at injection site. |

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| 1007966 | 2/6/2021 | WA | 30 | F | 2/5/2021 | 2/5/2021 | Vaccine started at 4. Roughly 5 minutes after, I raised my hand in the waiting for for the male nurse to come over due to symptoms of dizziness, loss of consciousness, ?blacking out?, and confusion. The male nurse came over and started seeing signs of profuse sweating as water began dripping from all over my body. 5 minutes after that I started heaving and gasping for air unaroused next to the nurse as he took my blood pressure. Blood pressure dropped to 85/76. I started breathing heavy, sweating uncontrollably and couldn?t talk or stand. I remained hardly alert and almost passed out due to weakness. |

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| 1007398 | 2/6/2021 | NY | 24 | F | 1/21/2021 | 1/28/2021 | <p>On January 21 I received my first dose of Moderna vaccine on my left arm. After the vaccine I had a red lump that was hot and a bruise that only lasted 2 days. Everything was fine until the January 28th when I developed a large red lump during the day while at work that was severely itchy and hot. When I got home from work I had a low grade fever. I made an appointment with my primary care for the next day which was Friday the 29th. My doctor told me she believes I had cellulitis. I was given an antibiotic 2x a day for 7 days. She drew a purple circle around the area and told me that if it goes outside the marked area or I feel any new symptoms, to go to the emergency room. Saturday morning on the 30th i woke up to my entire arm red and hot. I felt like I had a huge sunburn. I couldn't put my sweatshirt on because it was so hot. The emergency room doctor told me I was fine and to keep taking the antibiotics that were given to me yesterday from my primary care doctor. After the emergency room I went to work and started to feel dizzy and nauseous. My hands became sweaty but the rest of my body was cold. I started having a butterfly feeling in my chest. My Apple Watch alerted me that my heart rate was over 100 bpm. That night before bed I had another low grade fever. On Sunday the 31st I noticed the red area was gone but instead it was a dark purple. I felt okay Sunday besides a rapid pulse. Monday February 1st I woke up out of a dead sleep sweating, butterfly feeling in my chest and dizzy. I tried to take my pulse while laying down but it was so fast I couldn't keep up with it. I put my Apple Watch on which alerted me immediately that my pulse was 152 bpm. I slowly got up but then I passed out falling off of my bed. I couldn't get any words out because my heart was beating so fast that I couldn't breathe. I was sweating horribly and had a hard time walking. Had absolutely no strength in my left hand, my arm was purple/red, cold and numb. My arm felt like someone punched me repeatedly and gave me a dead arm. I called my primary doctors office and they were able to get me in that afternoon. All morning my pulse was spiking and then drastically dropping. About an hour and a half before I went to the doctor everything was fine. I was able to talk but still struggled with breathing while talking. The doctor ordered an EKG which came back clear. My pulse and blood pressure was also fine. The doctor told me she believed all of the</p> |

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symptoms I had were from the medication I take at night (doxazosin-to relax my muscles and help with sleep.) She also told me she believed some of it was my mental health issues taking over. She told me the cellulitis looked fine and sent me home. Later that day I felt exhausted and when I woke up from a nap, I had a fever of 100.5. Took Tylenol and it dropped to 99.5 but wouldn't go any lower. February 2nd I woke up to a large red ring outside of the purple marker, numb finger tips and butterfly feeling in my chest. All day I received alerts that my pulse was falling and spiking. I sent my primary doctor an email and she told me she didn't think it was cellulitis anymore, maybe a hematoma but she wasn't sure. Since January 28th I still struggle everyday with the butterfly feeling in my chest, blurry vision, low grade temps, alerts of pulse, dizziness and breathing difficulties. My arm is always hot, my finger tips are numb and sometimes the strength in my hand is gone. The top of my arm is always a dark purple with red blotches and other times my entire arm is red and hot. When my pulse is very fast, I have a hard time talking, remembering what I was going to say and focusing. I've had multiple coworkers ask me if I'm okay because I'll randomly stop talking and stare off and then I'm alerted that my pulse has either spiked or dropped drastically after spiking. My pulse is never consistent. It is always ranging from 57-155bpm. I realized at first I may have what they call "COVID arm" but my symptoms haven't gotten any better. No answers have been given to me or a diagnosis. The first diagnosis that they thought was cellulitis. Then it was "in my head and behavioral." Then it was a hematoma. Now it's an "I don't know." I have tried Benadryl for the itching, ice packs for the days that I'm swollen, Tylenol for the fevers and pain but I never have any relief.

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| 1007788 | 2/6/2021 | CO | 61 | F | 2/4/2021 | 2/5/2021 | Immediate soreness in arm after shot. Some light headedness. Took 2 tylenol after and then again before bed. Felt fine until waking at 2am to muscle soreness. At 4:30am chills and horrible headache, horrible flatulence. 8:30am stomach cramps, almost passed out. More chills, sweats and body shakes. Diarrhea and staved off vomiting. Could not eat most of the day until evening. Drank tons of fluids and Gatorade. Slept most of the day. Woke at 2am the morning of Feb 6th with continued muscle ache. Took more Tylenol. 9:15am as I write, I am feeling better, just exhausted. |
| 1007441 | 2/6/2021 | CA | 44 | F | 1/22/2021 | 1/22/2021 | Approx. 14 hours after receiving the 1st part of Covid vaccine my arm became so sore I couldn't move it. It was sore from my neck down to just below my elbow. I began having chills and a low grade temp shortly after that. by 0130, I was dizzy, experiencing diarrhea, with episodes of diaphoresis, and acute nausea. I felt that I had some postural hypotension, was very pale and every time I would get up to walk I felt like I was going to end up on the ground. I remained in bed for approx. 16 hours before I felt like I comfortable even getting up and going to restroom. I still have intermittent dizziness, with syncope to this date. I had to leave work early as well as calling in sick for the next shift. |
| 1008185 | 2/6/2021 | OH | 33 | F | 2/5/2021 | 2/6/2021 | Flu like symptoms, nausea, light headed, fainting |
| 1007801 | 2/6/2021 | NY | 48 | F | 2/5/2021 | 2/5/2021 | After shot one (left arm) on 01/08/2021 I had severe joint and muscle pain, fevers, chills, exhaustion, nausea and shooting pain down my left arm and up to my neck and back of skull from afternoon of injection on Friday to Sunday night. I slept all weekend. After shot two (right arm) on 02/05/21 I had all of those same reactions by early Friday afternoon. I woke up at 10:00 pm with the need to vomit. While sitting on the edge of my bath tub waiting to vomit, I fainted and fell backwards into the bathtub, hitting me head and wrenching my neck as I was wedged into the tub sideways. My son found me and roused me. I then urinated all over myself, had extreme diarrhea and vomiting x 2 rounds. I fainted a second time while sitting on the toilet with diarrhea and vomited 2x more into my bathtub. |

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| 1008833 | 2/6/2021 | CA | 47 | M | 2/6/2021 | 2/6/2021 | Vasovagal post vaccination. Pt passed out and lost consciousness. |
| 1008288 | 2/6/2021 | | 37 | F | 1/21/2021 | 1/21/2021 | 5 hours after second injection had injection site pain, fever, dizziness and syncope. Referred to PCP for further evaluation. |
| 1008689 | 2/6/2021 | NJ | 44 | F | 1/18/2021 | 1/21/2021 | Thursday, 2/21 - started feeling, overall, exhausted, and having lots of aches and pains. My chest and back (near area where I have costochondritis (xiphoid process) was in a great deal of pain. My heart rate also kept jumping around between 65 and 105 without exertion. Tuesday, 1/26/2021 - I was feeling exhausted and got out of breath with minimal exertion. Heart rate jumped up with minimal exertion (e.g. just standing, heart rate climbed about 110). I also started feeling dizzy and , ultimately, fainted, which put me in the emergency room, where they ruled out a PE and all cardiac emergencies. My blood pressure spiked with a systolic around 165 (my usual is 90-95). Labs indicated everything was fine. The only thing different than usual was the vaccine. This was also the day I realized I developed extreme cold feet and also cold fingers, ears, and nose. My cold feet is still an issue - they get so cold, it?s actually painful. I now have to have a heating pad around my feet at home. This has never happened to me before the vaccine in my, now, 45 years alive. I?m still a bit fatigued, have sporadic aches and pains, sometimes get a little dizzy, and have extremely cold feet...two and a half weeks later. |
| 1011757 | 2/6/2021 | | 58 | F | 2/4/2021 | 2/4/2021 | Dizziness, Headache, Myalgia, HYPERTension, Syncope, Bradycardia, had flulike symptoms and rash with 1st dose, 2nd dose: during 15min observation period, felt weak, tingling all over body and felt weak on her right side and dizziness. lightheadedness, dizziness, and generalized weakness. slow to respond to questions, co Narrative: Other Relevant History: |

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| 1008792 | 2/6/2021 | VA | 28 | F | 2/5/2021 | 2/6/2021 | The second dose was very painful, compared to no pain when the first dose was given one month ago. My arm was immediately hot and tender after administration. The area around the injection site had less feeling than the rest of my arm - it felt almost numb. My arm was very sore and warm the rest of the evening. I began having fatigue, muscle aches, and joint pain last night as well. I woke up around 6 this morning and the room was spinning. I was also nauseous. I tried to roll over in bed but was unable to feel my arms and legs. I was also temporarily unable to see. Right after, I passed out and lost urinary continence. I regained consciousness a minute later and had normal functioning again. I have not had any more dizziness today but am still sore and fatigued. |
| 1008736 | 2/6/2021 | IL | 67 | M | 2/5/2021 | 2/6/2021 | Not sure if it was related but wanted to let someone know in case others have experienced. Patient has Parkinson?s and gets low blood pressure. However, his blood pressure and temp were taken immediately after incident and both were normal. At 8:30 this morning, he went into the kitchen to make breakfast and blacked out, grabbed the counter and made it to the floor. Never fully fainting. He was extremely pale and had to call for help to get up. The remainder of the day, he has taken it easy but felt fine and normal. |
| 1008695 | 2/6/2021 | OR | 37 | M | 1/31/2021 | 2/1/2021 | Nausea, vomiting, syncope, headache, myalgia, fatigue |
| 1008641 | 2/6/2021 | OH | 27 | F | 2/6/2021 | 2/6/2021 | Patient had a hot/cold sensation. She felt both hot and cold at the same time. She had chills and felt "off." This occurred less than three minutes after receiving the Pfizer vaccine. These symptoms lasted for approximately 30 minutes. A couple of years ago she passed out after receiving the HPV vaccine. |
| 1008596 | 2/6/2021 | FL | 24 | F | 2/6/2021 | 2/6/2021 | I felt dizzy and light headed. Then my body felt very heavy and I passed out. I woke up in the ground and my mom and brother put a wet rag on my forehead. I felt faint for 30 minutes afterwards. |
| 1008475 | 2/6/2021 | KY | 23 | F | 2/6/2021 | 2/6/2021 | Patient fainted. Pharmacists, nurses and EMS responded. Took blood pressure, blood glucose and stabilized patient. She was transported by ambulance to local ER. |

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| 1006123 | 2/5/2021 | VA | 25 | F | 2/3/2021 | 2/3/2021 | Client fainted after COVID-19 vaccination completed. Client fell out of chair onto floor. EMS called and assessed patient's vitals, confirmed no injury or illness. Client reported this happened before after receiving shot. Client monitored x 30 min with no further issues. The initial VAERS report filled out by vaccinator . Given to me by clinic nurse lead. Attempted to fax but unable to get through due to fax busy. |
| 1005563 | 2/5/2021 | ME | 40 | F | 2/3/2021 | 2/4/2021 | Pt states felt poorly, chills fatigue, body aches day after vaccine. Pt experienced fever and a "foggy Head". Pt left work place early, does not remember driving home and states she fainted in her garage, her husband found her. Pt is uninjured, has hx of moderate aortic regurgitation. Pt did go to work today, states feeling much better, pt will see PCP today for follow up |

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| 1005350 | 2/5/2021 | MD | | F | 12/28/2020 | 1/25/2021 | <p>Passed out, loss of unconsciousness; Aching; Felt unwell, very sick; Shaky; Feverish; Fatigue; Nauseated; A spontaneous report was received from a 49-year-old, female consumer who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced loss of consciousness, aching, fatigue, felt unwell, very sick, shaky, feverish, and nauseated. The patient's medical history was not provided. Concomitant medication was Loratadine. On 28 Dec 2020, the patient received their first of two planned doses of mRNA-1273 intramuscularly in the right arm for prophylaxis of COVID-19 infection. On 25 Jan 2021 prior to the onset of the events, the patient received their second of two planned doses of mRNA-1273 (Lot Number: 013L20A) intramuscularly in the right arm for prophylaxis of COVID-19 infection. On 25 Jan 2021, after receiving the vaccine the patient experienced loss of consciousness, aching, fatigue, felt unwell, very sick, shaky, feverish, nauseated. On 29 Jan 2021, the patient was experiencing fatigue. Treatment for the event was not provided. Action taken with the mRNA-1273 was withdrawn. The outcome for the events, loss of consciousness, aching, shaky, feverish and nauseated was Unknown and the outcome for the events, fatigue, felt unwell, very sick was considered Not resolved.;</p> <p>Reporter's Comments: This case concerns a 49 year old female patient experienced a serious unexpected event of loss of consciousness and NS unexpected events of aching, fatigue, felt unwell, very sick, shaky, feverish and nauseated. The events occurred after first dose of the study medication administration on the same day. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.</p> |
| 1005491 | 2/5/2021 | WA | 67 | F | 2/3/2021 | 2/4/2021 | Loss of consciousness - fainted 18 hours after dose |

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| 1005525 | 2/5/2021 | IL | 46 | F | 2/4/2021 | 2/4/2021 | Became nauseous and started vomiting approximately 20 minutes after the vaccine. She initially refused to go to the emergency room by ambulance. The vomiting continued and she then passed out and became diaphoretic. 911 was called and she was transported to the emergency room. I later spoke with a nurse at the ER and tests were being ran. She said they did not feel it was vaccine related. She did say the doctor said she had a panic attack. |
| 1005347 | 2/5/2021 | FL | | M | 1/21/2021 | 1/21/2021 | Fainted; Unconscious; A spontaneous report was received from a consumer who was also a 73-year-old, male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced fainting and unconscious. The patient's medical history was not provided. Concomitant medications were levofloxacin, metformin, amlodipine and lisinopril. On 21 Jan 2021, prior to obtaining his vaccination, the patient took levofloxacin, metformin, amlodipine, and lisinopril. On 21 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: 012L20A) intramuscularly for prophylaxis of COVID-19 infection. On 21 Jan 2021, within minutes of receiving the vaccine, the patient fainted with his eyes open and was unconscious. His health care provider told him he was dehydrated and that might be why he fainted. Action taken with the second dose of mRNA-1273 in response to the event was not reported. The outcome for the events, fainting and unconscious, was considered resolved on 21 Jan 2021.; Reporter's Comments: This case concerns a 73-years-old male patient, who experienced medically significant unexpected events of Syncope and Loss of consciousness. The events occurred within minutes after first dose of mRNA-1273, lot # 012L20A. Concomitant medication included levofloxacin, metformin, amlodipine and lisinopril. Treatment details were not provided. Based on the current available information and temporal association between the use of the product and onset of the events a causal relationship cannot be excluded. Of note, dehydration was reported as potential contributing factor. |

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| 1005734 | 2/5/2021 | PA | 44 | F | 2/4/2021 | 2/4/2021 | 15 min after vaccine administered patient stated she had a frontal headache radiating to her right side of head and tingling around her lips. She was instructed to stay for an additional 15 min for observation. She was placed on a stretcher to lie down. She was conversing and her S/S went unchanged. At approx 1 pm she became unresponsive, she did not wake with touch or verbal command Her eyelids were fluttering as if she was experiencing a seizure. A condition was called. Pulse ox 100 % blood sugar 90. Monitor NSR. She remained unresponsive and was taken to the ED. Upon arrival to the ED at approx 1:17 pm, the ED nurse stated she was awake. Evaluated by physician, labs and CT head ordered. Patient stated all lab work and CT scan was normal. Employee was discharged with a diagnosis of vasovagal near syncope. |
| 1006015 | 2/5/2021 | | | F | 1/23/2021 | 1/24/2021 | headache; had chills; freezing; body aches; got really hot; passed out; This is a spontaneous report from a contactable consumer (patient) received via Medical Information Team. A female patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 23Jan2021 at 13:15 at single dose for COVID-19 immunization. The patient medical history included COVID-19 from Mar2020 to an unknown date. The patient's concomitant medications were not reported. On 24Jan2021, the patient experienced at 4:00 she was freezing and had chills and body aches. At 7:15, she felt body aches and a bad headache. Things started spinning and she passed out. After that, she got really hot and she went back to bed and stayed in bed until 14:00. It seemed very severe. She didn't have a fever, but her body hurt like she did. The patient outcome of the events was unknown. The information on the batch number has been requested. |

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| 1004205 | 2/5/2021 | NC | 74 | F | 1/20/2021 | 1/21/2021 | <p>Passed out-was totally out for a couple of second; UTI; PVCs; very very dizzy; Vasovagal reaction; Arm was sore-not hurting much; A spontaneous report was received from a 74-year-old female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced dizziness, passed out, vasovagal reaction, urinary tract infection, premature ventricular contractions and arm pain. The patient's medical history included back problems with osteoarthritis in the spinal column neck and lower back. Products known to have been used by the patient, within two weeks prior to the event, included celecoxib and nortriptyline. On 20 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot 028L20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 21 Jan 2021, the patient reported she got very dizzy and passed out. Her husband relays that she was totally out for a couple of seconds. She went to the emergency room and was diagnosed with a vasovagal reaction and urinary tract infection. Premature ventricular contractions were also discovered and was not known prior to this event. Patient reports a normal blood pressure of 114-120/75. Patient also stated her arm was sore the day after vaccine but not hurting much during her usual four mile walk. Treatment for the event included intravenous medications in the emergency room, cephalexin, and a heart monitor. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events passed out, dizziness, vasovagal reaction and arm pain were resolved. The outcome of the events, urinary tract infection and premature ventricular contractions were unknown.; Reporter's Comments: This case concerns a 74 year-old, female patient, who experienced events of dizziness, passed out, vasovagal reaction, urinary tract infection, premature ventricular contractions and arm pain. The events occurred the next day after the first and last dose of mRNA-1273 vaccine administration. Based on the current limited available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded and the events are assessed as possibly related. Further information have been requested.</p> |

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| 1006093 | 2/5/2021 | KY | 55 | F | 2/3/2021 | 2/3/2021 | Chills started the night of the vaccine. Chills got so bad my entire body was shaking. Then would started sweating so bad the sheets were wet. Extremely tired. Lighted headed, slept off and on all day the next day. Passed out the day after the shot. |
| 1005033 | 2/5/2021 | TX | 25 | F | 2/2/2021 | 2/2/2021 | Patient arrived at 12:14PM. Observation nurse noticed patient with eyes closed with hand raised on top of head. Patient was lethargic and weak, AOX3. Patient stated "I am not able to see anything." while patient's eyes were open. Apical pulse very faint. Patient felt the urge to vomit and suddenly appeared flushed in the face. Patient stated "I feel better." immediately after experiencing nausea. 12:25PM - BP 97/67 Patient reiterated her experience stating: "I felt lightheaded and felt like I was about to faint.", "I felt heavy and foggy." Patient was given water to drink and a cookie. 12:35PM - Patient reported pressure on both sides of head and "weird" (as per patient) visual changes. Patient stated "Everything has a glare." Patient reported prior reactions to past vaccinations: Flu and Tetanus - experienced lightheadedness, fainting and visual changes. Indicated reactions were "more worse" than prior reactions. 12:45PM - BP 115/78 HR 64 SPO2 98% Patient was asked to sit closer to nurse an was able to ambulate with no issues and steady gait. 1:15PM Patient reports to feel "Back to normal." denied any symptoms including visual changes. Patient contacted her parents to be driven home. 1:37PM Walked patient to her parent's car outside the convention center. Instructed to go to ER/Call 911 if symptoms persist or get worse. 2/3/21 The next day patient texted nurse observer that she is feeling much better from yesterday after resting and taking Advil. |
| 1006144 | 2/5/2021 | KY | 31 | F | 2/3/2021 | 2/4/2021 | Felt sick, within 10minutes of feeling nausea, I passed out while teaching class. 23 hours after injection. |
| 1006165 | 2/5/2021 | MD | 39 | M | 2/4/2021 | 2/5/2021 | Patient began to feel nauseous and dizzy about 12 midnight after 11AM vaccine. Patient fainted in the bathroom. Wife reported the patient became disoriented for 2-5 minutes. Patient became re-oriented but continued to have fever/chills. Headache persists through time of this report. |

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| 1006072 | 2/5/2021 | MI | 66 | M | 2/3/2021 | 2/4/2021 | lightheadedness and syncopal episode. States "all of the sudden he felt hot and passed out" He was hypotensive with b/p 75/51 HR 65. EKG NSR. sent to the ER for further evaluation. |
| 1005227 | 2/5/2021 | AZ | 35 | M | 2/4/2021 | 2/4/2021 | Systemic: Fainting-Medium |
| 1006181 | 2/5/2021 | GA | 43 | F | 2/2/2021 | 2/3/2021 | At or around 2:00 am I became very restless, got out of bed and walked into the bathroom. I became nauseous, had a slight headache, dizzy, a cold sweat and began having intense stomach cramps. Within 1 minute I passed out in my bathroom and was found face down in my bathroom. It was clear that I hit my head and lost a tooth. I was taken via ambulance to a local hospital. |
| 1005208 | 2/5/2021 | IL | 25 | F | 2/4/2021 | 2/4/2021 | 10:50 am: received vaccination, no adverse events immediately afterwards, went back to work. 9pm: felt ill, took temp., temp was 98.6. Then felt nauseous, went to the bathroom to vomit. Felt faint, sat with head between legs for 1 minute, then passed out on the floor. Woke up 30 seconds later and vomited. Still felt lightheaded 10 minutes after adverse event. Called EMS and went to Emergency Room. |
| 1005066 | 2/5/2021 | | | F | 1/4/2021 | 1/5/2021 | 1/5/2021 @0718 Pt received 2nd COVID vaccine 1/4/21. Oral temp 100.6, near syncope, muscle aches and head aches. Per EMS NSR, denies SOB, and chest pain. 500 ml bolus received in route. In ED, Pt c/o nausea. Pt anxious, sweating and uncomfortable. 0855 Pt resting comfortably, reports decrease in pain/body aches 4/10. 1043 Discharge disposition: home. Accompanied By: self. Mode: walk. |
| 1004857 | 2/5/2021 | PA | 54 | F | 1/27/2021 | 1/28/2021 | Palpitations, fever, near syncope, nausea, tremors |
| 1004854 | 2/5/2021 | PA | 16 | F | 2/2/2021 | 2/3/2021 | Systemic: Fainting-Severe |
| 1004806 | 2/5/2021 | NY | 32 | F | 2/3/2021 | 2/3/2021 | 12 hours post injection, my blood pressure dropped, I almost passed out and my hands and feet turned blue. Chills lasted for about an hour and a half. |

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| 1004520 | 2/5/2021 | | | F | 1/20/2021 | 1/21/2021 | passed out; This is a spontaneous report from a Pfizer sponsored program from a non-contactable consumer. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 20Jan2021 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient woke up next morning on 21Jan2021 to go to bathroom and passed out. The outcome of event was unknown. No follow-up attempts are possible, information about lot/batch number cannot be obtained. |
| 1004464 | 2/5/2021 | OH | 27 | F | 1/23/2021 | 1/23/2021 | Pain at injection site; muscle pain; fatigue; dizziness; This is a spontaneous report from a contactable healthcare professional (patient). A 27-year-old female patient (unknown if pregnant at the time of vaccination) received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL8982), via an unspecified route of administration on left arm on 23Jan2021 13:15 at single dose for covid-19 immunisation. Medical history included Migraines with aura, vasovagal syncope, PCOS, environmental allergies/hay fever, eczema. Prior to vaccination, the patient was not diagnosed with COVID-19. Concomitant medication included cefixime (FLEXERIL), ibuprofen (ADVIL), montelukast sodium (SINGULAIR), cetirizine hydrochloride (ZYRTEC), inositol. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced pain at injection site, muscle pain, fatigue, dizziness, all on 23Jan2021 1400. The events were assessed as non-serious. Since the vaccination, the patient has not been tested for COVID-19. No treatment was given for the events. The outcome of the events was recovering. |

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| 1004455 | 2/5/2021 | MO | 25 | F | 1/22/2021 | 1/22/2021 | <p>Passed out; Pulseless for 30 seconds; Feel dizzy and nauseous; Feel dizzy and nauseous; This is a spontaneous report from a contactable Other Health Professional (patient). A 25-year-old female (not pregnant at the time of vaccination) patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot number and expiration date unknown since not available/provided to reporter at the time of report completion), via an unspecified route of administration at left arm on 22Jan2021 11:45 at single dose for COVID-19 immunization at a Nursing Home/Senior Living Facility. The patient's medical history included known allergies: Sulfa and poppy seed. No other known medical history/conditions. For concomitant medications, the patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient previously took amoxicillin, clarithromycin (BIAXIN) and cefaclor (CECLOR), and experienced drug allergy. The patient was not diagnosed with COVID-19 prior to vaccination, and had not been tested for COVID-19 since the vaccination. After receiving the vaccine, the patient was sitting in the observation area for about 10 minutes when she started to feel dizzy and nauseous. She raised her hand up and called for the nurse to come over. She passed out. She was pulseless for 30 seconds and they had to begin giving her CPR chest compressions. She woke up lying on the ground and was taken to the emergency room (ER) where they ran tests to see how she was doing and for observation for several hours. The patient was "discharged" this afternoon and was doing better. The events result in emergency room/department or urgent care. Treatment was received for the events, ER observation and care, and CPR chest compressions. The patient underwent lab tests and procedures which included test on 22Jan2021: unknown results. The outcome of events at the time of last observation was recovering. The reporter's assessment of the events was non-serious, no results in death, no life threatening, not causing/prolonging hospitalization, no disabling/incapacitating, no congenital anomaly/birth defect. Information on the lot/batch number has been requested.; Sender's Comments: The reported passed out and pulseless for 30 seconds were likely related to the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) due to temporal relationship. However,</p> |

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considering the clinical course and medical history, other cause(s)/confounding factors cannot be excluded. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics committees and Investigators, as appropriate.

She passed out.; This is a spontaneous report from a contactable consumer (parent). A 17-year-old female patient (daughter) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number=EL1284) on 22Jan2021 11:45 AM at left arm at single dose for COVID-19 immunisation. Medical history and concomitant medications were none. No known allergies. Patient was not pregnant. Patient did not have COVID prior vaccination, and did not have other vaccine in four weeks, did not other medications in two weeks. The patient experienced passed out on 22Jan2021 12:00 PM. Treatment included they had her lay on the ground with her knees up and cold compresses. Patient did not test COVID post vaccination. The outcome of event was recovering.

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| 1004432 | 2/5/2021 | MO | 22 | F | 1/21/2021 | 1/22/2021 | Fainted; Dizziness; Heart racing; This is a spontaneous report from a contactable consumer reported for herself. A 22-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 21Jan2021 15:45 at single dose in left arm for COVID-19 immunisation. The patient medical history was not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not pregnant at the time of vaccination. Concomitant medication included lisdexamfetamine mesilate (VYVANSE), escitalopram oxalate (LEXAPRO), spironolactone and Birth control product. The patient experienced fainted morning after 1st dose with dizziness and heart racing on 22Jan2021 06:45 - had to go to ER. The patient received anti-nausea and heart monitor as treatment for the adverse event. Events outcome was unknown. Information on the lot/batch number has been requested. |

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| 1006831 | 2/5/2021 | MS | 43 | M | 2/5/2021 | 2/5/2021 | Patient had vasovagal syncopal event. This event was not a vaccine side effect but a vasovagal response (previous history of syncope with vaccinations/procedures). Patient received 1st dose of Pfizer vaccine around 11am today. Within 2 minutes of receiving the vaccine, he started to feel dizzy and passed out for around 45 secs. He had cold extremities, looked pale and was sweating. He was immediately transferred from chair to floor and his legs were raised. Cold towel was placed on his head. He regained consciousness but was confused for less than a 1min. Vitals were checked and his BP was 95/50's and HR was around 56. Pulse O2 was 99% during entire event. He was able to converse well after that and was oriented. He informed having anxiety/panic attacks, had taken his medication that morning. He reported similar syncopal episodes in the past. He was monitored in same posture. He was gently hydrated orally with water and soda. He was given sublingual zofran due to nausea and retching. He did not vomit. We continued to monitor his BP on regular intervals. He had slow improvement in BP and after 2 hrs while sitting his BP was 104/65, pulse 56/min (reports being an athlete and previous records show baseline bradycardia). He denied any symptoms and was awake, alert, oriented. As he was not accompanied by anyone, his wife was contacted who came to clinic in 10mins and helped to drive him home. He was transported by wheelchair till entrance of clinic. He reported feeling better and thanked for helping. He does not have any contraindications to receive 2nd dose of vaccine. |
| 1005085 | 2/5/2021 | IL | 22 | M | 2/5/2021 | 2/5/2021 | Pt had the vaccine at 7:15 a.m. today, sat at the facility where he received the vaccine for 15 minutes, pt was with his mother who was driving. Pt then went to his mom's car, they were driving when pt had a syncope episode, per his mother his hands were shaking, pt's mother then drove him to our ER facility. |

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| 1007217 | 2/5/2021 | CA | 47 | F | 1/27/2021 | 1/27/2021 | Severe chills, body aches- particularly legs, dizziness, beginning 9 hours post-injection. Worse than ever experienced, even during the flu. These progressed until awakened around 10:30pm and fainted on floor after urinating. Woke up several minutes later vomiting. Nausea and severe body aches continued until the following morning, when they started to subside. Resolved completely the following day, around 48 hours post injection. Mild fatigue in the following days. |
| 1006226 | 2/5/2021 | IA | 30 | F | 2/3/2021 | 2/3/2021 | Head ache; sweaty; Got into elevator to go back to work and passed out. Assessed by physicians assistant and was released, sent home for the day. |
| 1006779 | 2/5/2021 | IA | 41 | F | 1/29/2021 | 1/29/2021 | Patient felt extremely lightheaded, nervous, experienced syncope approximately five minutes after administration. |
| 1007244 | 2/5/2021 | CA | 67 | F | 2/1/2021 | 2/1/2021 | I was hospitalized with a severe reaction to my first dose of the Pfizer vaccine given 2/1/21 @ 9:45. I was discharged Tuesday evening 2/2/21. Dr., my internist, agrees that what happened was not a vasovagal syncope (hospital's diagnosis). My Experience: Within say 7 minutes of the injection I felt woozy, the wooziness intensified, I got intense pins and needles in my lower legs, fore arms and hands, and less so in my face. My speech became very slowed down, slurred and I had a lot of difficulty forming words. It was as if I was extremely drunk. After they called the paramedics, I was not able to get myself out of my car or walk. I lost motor coordination/control in hands and feet. I was cold, never felt faint, and had slightly evaluated blood pressure for me(normal is 110/64 paramedics got it at 152/94). |
| 1007172 | 2/5/2021 | WV | 32 | F | 2/5/2021 | 2/5/2021 | I got sudden sob, had trouble swallowing my water was driving on way back to work. Got pulled over. Heart was racing. Got hot starting shaking. Sob. Hands feet and face started to get numb. And almost passed out. |
| 1007160 | 2/5/2021 | IL | 31 | M | 2/5/2021 | 2/5/2021 | Near Fainting and stiff neck. He was assisted from the chair to the bed and laid down. Vitals monitored for 30 min. No other complaints or reactions. Alert entire time and related to feeling much better after water and the time monitored. He did not want any further assistance and left under his own ability. |

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| 1007113 | 2/5/2021 | MN | 57 | F | 2/1/2021 | 2/2/2021 | I woke up in the middle of the night with a headache and body aches. I got up to take ibuprofen and when I was in my bathroom, I collapsed. I do not remember actually falling but I heard the thud when I hit the floor. I tried to get up and had absolutely no strength in any part of body. My husband came to help me up but I could not even lift up my head. He was finally able to help me up and I took a few steps and collapsed/fainted again. This has never happened to me in my life. |
| 1007076 | 2/5/2021 | MD | 61 | F | 2/2/2021 | 2/3/2021 | Syncope and hypotension. No previous history of syncope. Syncopal episode 20 hours after injection . Other symptoms were chills, low grade fever, headache. No allergic rxn, no rash. Hypotension lasted for several hours. |
| 1007068 | 2/5/2021 | CO | 78 | F | | | I did not feel particularly lightheaded or dizzy, but I passed out in my kitchen while preparing breakfast at approximately 7:30 AM on the morning following my vaccination |
| 1006891 | 2/5/2021 | MD | 58 | F | 1/25/2021 | 2/3/2021 | Syncope 5 - 10 seconds , Nausea, slight head ache, weakness after syncope 2/3 @ 10:15 am Hospitalized on 2/3 @ 11:30 am on 2/3/2021 2/5 @ 4 :30 pm Primary Care visit @ 3:30 pm on 2/5/2021 |
| 1006883 | 2/5/2021 | NY | 72 | F | 2/5/2021 | 2/5/2021 | 72 y/o Female with sudden onset of "hot" feeling with flushed feeling. No shortness of breath, wheezes, stridor, nausea/vomiting, or near syncope. Pt was placed in chair and observed. Vital signs: BP 138/84, HR 72, Resp. 16, Room air O2 99%. Symptoms resolved spontaneously. Pt observed x 30 min. |
| 1006861 | 2/5/2021 | VA | 22 | F | 1/20/2021 | 1/20/2021 | Client reported history of fainting from shots. Staff was already monitoring patient specifically due to previous history of fainting from receiving other vaccinations. Client passed out in the 15 minute wait time and was observed by EMS in a squad where she recovered. At 17:55 BP 103/68 and pulse 68, at 18:02 BP 106/70 and pulse 98. At 18:06 BP 115/72 and pulse 100. No other adverse reactions reported at the time of this event. |
| 1006859 | 2/5/2021 | MI | 24 | F | 1/23/2021 | 1/23/2021 | Passed out the day of, numb and tingling face and body for over a week, shortness of breath, dizziness, fast heart beat |

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| 1006814 | 2/5/2021 | PA | 59 | F | 2/4/2021 | 2/4/2021 | Symptoms started a few hours after vaccination. Initial symptoms were injection site pain and tiredness. I later developed a mild headache, moderate muscle and joint pain, to which I applied a heating pad. I then developed a low fever and chills. Temp was 99.7 11:30pm on Feb 4, and 99.9 at 10:20 on Feb 5. I then began to feel nauseous and generally terrible, so I went to the bathroom, where I fell and may have passed out. |
| 1006342 | 2/5/2021 | TX | 20 | M | 2/5/2021 | 2/5/2021 | After receiving vaccine, pt walked into the post vaccine observation room located outside the door of the vaccination room. Pt. sat down in chair, went to put his head down towards his knees, then patient slid out of chair and onto the floor. This RN was immediately at the patients side, and pt. immediately responded to his name. Pt. insisted on standing up against this RN's advice, and got back into the chair. Pt stated he didn't know what happened, so I explained to him that he had fainted. His mother and father were present. Pt stated he ate no breakfast today. Pt. states he has no health concerns, allergies, or issues. Pt.s stated that he is very afraid of needles and thinks he was just nervous. BP readings: 09:45 90/75 HR 60, 09:50 90/75 HR 60 10:00 BP 113/72 HR 65. Pt stated he was feeling fine. Pt. released to go home w/Parents at 10:30. This RN called this pt. to f/u at noon today, and patient stated he was feeling good and thinks he was just really nervous. Pt. thanked this RN for the phone call and call was ended. |
| 1007295 | 2/5/2021 | WA | 65 | F | 2/3/2021 | 2/3/1921 | INTENSE CHILLS, BODY ACHES, NAUSE, FATIGUE, SLEEPINESS,LOSS OF APPETITE. FAINTED-YES FAINTED FALLING BACK AND HITTING MY HEAD ABOUT 3 AM IN MORNING. I AM ON WARFARIN FOR BLOOD CLOTS |
| 1006655 | 2/5/2021 | NY | 44 | F | 2/5/2021 | 2/5/2021 | Pt received first Moderna injection and stated she had an episode an hour or so later when she almost passed out but started to feel better within a few minutes. Later in the day after she had went home she notified the office at 16:30 that she was having some numbness and tingling sensations and not feeling well. She was instructed to go to the ER for further evaluation. |

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| 1006255 | 2/5/2021 | IL | 32 | F | 2/5/2021 | 2/5/2021 | 5 minutes after shot, patient passed out for 10-15 seconds. Nurse woke up patient. Patient reports vomiting about 1 minutes later. Patient states they had a migraine before getting the vaccine today. Patient reports a history of getting anxious and passing out with shots or blood draws. |
| 1006337 | 2/5/2021 | IN | 84 | F | 2/3/2021 | 2/4/2021 | I just got done going to the bathroom (2-4-2021) and was zipping up my pants when I fainted. I fell backwards into the bathtub knocking down both shower doors. My legs were hanging over the edge of the tub. One shower door fell on my upper right chest area. This happened just over 24 hours from when I received the vaccine. I had not felt bad at all from the vaccine. Didn't sleep too well that night (2-4-2021) because I hurt due to the fall. I called my doctor on 2-5-2021 to let her know I fainted 24 hours after receiving the vaccine and wondered if that was due to it. I do feel weak today (2-5-2021). |
| 1006356 | 2/5/2021 | CT | 53 | F | 2/3/2021 | 2/3/2021 | pt states later in the day after the vax she noticed her neck, arm and upper back was sore. She went to bed since she wasn't feeling well. She woke up feeling a little dizzy and foggy. Pt got up next day but fainted after getting out of bed. After coming to she stood up and then passed out again. She had intense fatigue and headache. Pt states that she is better but still has fatigue but has not appetite. Pt has not contacted her PCP since her symptoms were getting better. |
| 1006375 | 2/5/2021 | MA | 25 | M | 2/1/2021 | 2/4/2021 | Severe vasovagal response ~9 hours after injection. Got chills, 15 minutes later got up to get water. Made it about ~20 feet before getting severely lightheaded where I had to sit on the floor for 15+minutes. My roommate reported I was white as a ghost. I was on the cusp of fainting for roughly 15minutes. |
| 1006637 | 2/5/2021 | NV | 78 | F | 1/28/2021 | 2/1/2021 | high fever for three days fainting feeling dizzy and unwell |

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| 1006440 | 2/5/2021 | | 22 | U | 2/2/2021 | 2/2/2021 | Got vaccine 02/02/21 starting feeling fatigued immediately 11am, around 5pm started feeling fever, at 7pm started having chills, fever and pain and keep getting worse, by 11pm or 12am fever was 102.6 with lower back pain and all muscles felt weak even with tylenol continued, 3-4 am started getting headache and fever starting going down after tylenol and pain reduced and chills stopped. Now pt continued tylenol and is feeling better tried eating breakfast almost passed out, does not have appetite |
| 1006463 | 2/5/2021 | IN | 50 | M | 2/3/2021 | 2/3/2021 | I became extremely ill about 12 hours after vaccination. I slept about (10pm to 6:30 am) 8.5 hours, and then I woke for work the next morning. I felt a little off, but I thought I was ok. I entered my shower, and then I was found unconscious on the floor of my shower by my wife about 5 minutes later. I passed out 2 more times while attempting to stand and exit the shower. I was extremely fatigued at this point. I went back to bed and slept until 10 pm that night. I woke for about 2 hours, ate some food and drank some water and soda pop. I then went back to sleep until 7:30 am the next morning. I was awake for 3 hours, and then I slept for 3 more hours. I have been awake for about 2 hours, and I am now typing this adverse event document. The entire time I have had temperature regulation issues, severe headache, muscle and joint aches, and fatigue. |
| 1006550 | 2/5/2021 | MA | 37 | F | 2/4/2021 | 2/5/2021 | Vasovagal syncope while walking after getting out of bed at night. This occurred approximately at the onset of chills/rigors. |
| 1006570 | 2/5/2021 | NC | 50 | F | 1/29/2021 | 1/30/2021 | About 18 hours after vaccine, became very hot and felt odd. and fainted. At day 7 after vaccination, still have 2" of redness around perimeter of vaccination site. A little tender still but not bothersome. |
| 1006422 | 2/5/2021 | | 61 | F | 2/4/2021 | 2/4/2021 | I experienced muscle aches the spread across my entire back starting at about 8 PM on 2/4/21. At 2:30 AM on 2/5/21, I passed out three times after rising from the toilet, resulting in a split lip. I was covered with sweat the third time I "came to" and soon got the chills. |
| 1006651 | 2/5/2021 | | 29 | F | 2/4/2021 | 2/5/2021 | Syncope, fever, chills, myalgias |

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| 1001404 | 2/4/2021 | MI | 33 | F | 1/26/2021 | 1/26/2021 | Patient passed out after receiving vaccine. She regained consciousness without any intervention. She reports she frequently passes out after vaccinations. |

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| 1001444 | 2/4/2021 | TX | 38 | M | 12/30/2020 | 12/31/2020 | headache; sweating; neck was stiff; passed out for about 5-10 seconds; body ache; really bad chills; fever 100.4; unable to sleep; This is a spontaneous report from a contactable Consumer (patient). A 38-years-old male patient started to receive 1st dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EL0142, Expiry Date: 01Mar2021), via an unspecified route of administration at Left arm on 30Dec2020 18:17 at SINGLE DOSE for covid-19 immunisation. Patient's Medical History (including any illness at time of vaccination) was none. There were no concomitant medications. Prior Vaccinations (within 4 weeks) was reported as 'None' and AEs following prior vaccinations was reported as 'None'. AE(s) following prior vaccinations was reported as None. The patient experienced really bad chills, body aches, fever, unable to sleep on 31Dec2020 with outcome of recovered on 01Jan2021, passed out on bathroom floor for 5-10 seconds, sweating and neck was stiff on 01Jan2021 with outcome of recovered on 01Jan2021, headache on an unspecified data with outcome of unknown. Details were as follows: the patient received the Covi-19 vaccine 30Dec2021. He had a reaction to the vaccine. 24 hours after getting the vaccine he had really bad chills, body aches, fever 100.4. He didn't take any medication for a bit. He then took acetaminophen (TYLENOL). He had a headache, he was unable to sleep. The acetaminophen worked and he went to bed. At 5:00 am he started having a bad headache and took Ibuprofen. He woke up to go to the bathroom. He passed out for 5-10 seconds in the bathroom. His head was leaning in the wall by the door. He was sweating and was stiff all over. He went to the Emergency Room on 01Jan2021. They did an X-ray and a CT scan. They gave him 100ml of saline and some pills. They also did some lab work. Everything was negative. They assumed his body couldn't handle the vaccine. He was supposed to have received the second shot yesterday (20Jan2021). Employee Health said his Primary Care Physician would have to make the decision on him taking it or not. His doctor said he would have to do more research with Pfizer before he says if he can take it or not. Emergency Room visit required due to event passing out. |

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| 1001556 | 2/4/2021 | KY | 59 | M | 1/18/2021 | 1/27/2021 | I have had a weekly routine of fasting one day a week for the last 20 years. Sometimes I would extend this to 3 days, water only. I am healthy, 6'1" weight 170-180 all of my adult life. Resting HR <56. 9 days after having my first vaccination, I did a 24 hour fast. I woke at 2 am to go to the bathroom. I became lightheaded and passed out while standing over the toilet. I layed on the floor for over 5 minutes with my head spinning. I then realized I was hypoglycemic. I have never had this issue. I took some orange juice and recovered my strength. I hit my head on the top of the toilet which required my to have 5 sutures in my chin at the ER that night. Today I was working out for 30 minutes on an elliptical. I work out 4 to 5 times weekly. 10 minutes after returning to my room I noticed I was dizzy and checked my pulse from my watch. My HR was 210. this lasted for over 10 minutes. I have never had this issue. I believe it would not be in my best interest to take the second vaccination. |
| 1001571 | 2/4/2021 | TX | 21 | F | 2/3/2021 | 2/4/2021 | After receiving the second dosage of my COVID vaccine at 2 PM on 02/03/21, I only had left arm pain near the site of the injection. However, I went to sleep and at 2 AM on 02/04/20, I started having fever, a severe HA, and myalgia that hindered my sleep. I took 500 mg Tylenol at 6 AM and went back to sleep. When I woke up at 8:30 AM, I went to use the restroom and felt dizzy with hot flashes. Immediately afterwards, I noticed that I had fainted and my mother helped me to my bed. After drinking soup and juice and having a bowel movement, I felt normal and alerted my PCP. |
| 1001924 | 2/4/2021 | OR | 55 | F | 1/11/2021 | 1/12/2021 | CG received 2nd Covid Vaccine 1/11/2021; S/Sx Vertigo,,dizzy,,foggy feeling,generalized malaise on 1/12/21. on 1/13/21 felt near normal. Then 1/14/21 ,almost passed out on way to work,foggy feeling,vertigo,dizzy & therefore called in sick for today,1/14/21. . Vertigo, loss of balance, extreme malaise, near syncopal episodes. . I continued to have neurological symptoms both days. Vertigo, loss of balance, extreme malaise, near syncopal episodes. . 1/20: I continued to have neurological symptoms both days. Vertigo, loss of balance, extreme malaise, near syncopal episodes on 1/15. |

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| 1002202 | 2/4/2021 | WA | 72 | M | 2/3/2021 | 2/3/2021 | PATIENT SAID HE FELT LIKE FAINTING SENSATION FOR A FEW SECONDS AND TINGLING SENSATION IN HIS ARM FOR A FEW SECONDS. HE SAID HE WAS FINE AFTER THOSE FEW SECONDS. |
| 1002178 | 2/4/2021 | WA | 66 | F | 1/8/2021 | 1/10/2021 | 7:00 PM onset of chills and fairly severe body aches - concentrated in lower back and hips. Went to bed early - slept to 8:00 PM. Woke up so got up to take evening meds and brush teeth. Had vertigo and moderate nausea. While brushing teeth, I fainted. Came around quickly - was on bathroom floor. Took only one of my medications - the one to prevent migraines and went back to bed. Continued with body aches and chills on and off through the night. In the morning I had worsened vertigo and nausea, but this is typical of my vestibular migraines and I think that was what was going on. I called in sick to work, took one of my pills for treating migraines and basically slept all day. I do not get migraines often - usually |
| 1001071 | 2/4/2021 | CO | 45 | M | 1/27/2021 | 1/27/2021 | Approximately 12 hours after my 2nd injection of the Moderna COVID19 vaccine, I experienced severe nausea and ended up having an episode of syncope where I passed out on the stairs in my home. |

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| 999906 | 2/4/2021 | MA | | M | 1/11/2021 | 1/11/2021 | <p>Syncopal episode while driving; Crash; Became extremely warm; Sweaty; Right flank pain; A spontaneous report was received from a nurse concerning her husband, a 53-year-old, male patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced became extremely warm, sweaty, right flank pain, a syncopal episode while driving, and crash. The patient's medical history was not provided. No relevant concomitant medications were reported. On 11 Jan 2021, approximately two and a half hours prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On 11 Jan 2021, the patient felt fine for approximately two and a half hours after receiving the vaccine, then became extremely warm, sweaty, developed right flank pain, and had a syncopal episode while driving. The nurse mentioned that the patient was not seriously injured in the crash, nor was anyone else. No treatment information was provided. It was also reported that the patient had followed up with his PCP and seen a cardiologist, some diagnostics were scheduled, and plans to see a neurologist. Action taken with mRNA-1273 in response to the event was not reported. The outcome of the events, became extremely warm, sweaty, developed right flank pain, syncopal episode while driving, and crash, was unknown.; Reporter's Comments: This case concerns a 53-years-old male patient, who experienced serious unexpected events of syncope and non-serious unexpected event of road traffic accident, feeling hot, hyperhidrosis, and flank pain. The events occurred 1 day (approximately 2.5 hours) after first dose of mRNA-1273, lot # unknown. Treatment details not provided. Very limited information regarding these events has been provided at this time. Based on the current available information and temporal association between the use of the product and onset of the event a causal relationship cannot be excluded.</p> |
| 1002207 | 2/4/2021 | CA | 52 | F | 1/27/2021 | 1/28/2021 | chill body aches almost fainted in the bath tub |

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| 1002131 | 2/4/2021 | FL | 46 | F | 2/2/2021 | 2/2/2021 | No adverse event at 1st shot. After second shot I felt dizzy driving home. Within 2 hrs my joints hurt and I had extreme fatigue. 24hrs later I almost fainted while taking hot shower and then vomited. The fatigue, joint pain, hot/cold feeling lasted till about 6pm the day after shot. The injection site is still red, swollen and itchy 2 days later. Appears to growing in diameter. As of this morning I feel much better and almost back to normal. |
| 1000922 | 2/4/2021 | GA | 39 | F | 1/15/2021 | 1/15/2021 | After the first shot on 12/26/20 I had dizziness, facial flushing, elevated blood pressure, and tachycardia within minutes. It lasted about an hour. I had no issues after that. I received the 2nd shot on 1/15/21, I had the exact same reaction however it only lasted 20 min. I then went to my car and started driving home, about 10 minutes later and while on the freeway I had dizziness, flushing, tachycardia, , shakiness, and facial numbness. I took an exit and was able to pull over in a parking lot. It lasted about 20 minutes. Since that time I have had frequent episodes of dizziness, facial flushing, tremulousness, facial numbness/tingling, and presyncope. The worst episodes were on 2/1/21 and 2/3/21. I was unable to work because of these symptoms. |
| 1000873 | 2/4/2021 | FL | 49 | F | 2/1/2021 | 2/1/2021 | Systemic: Anaphylaxis-Severe, Systemic: Fainting-Severe, Systemic: Seizure-Severe |
| 1000756 | 2/4/2021 | KY | 60 | F | 2/3/2021 | 2/3/2021 | Chills (extreme) vertigo, nausea - started at 1030pm. Passed out- when I came to began vomiting - bile lasted approximately 4 hours. 1030 pm - began intense shaking - cold - I went to get Tylenol but found myself extremely dizzy and nauseous. I took 4mg Zofran and 1000mg Tylenol & tried to make it back to bed. I passed out - my husband witnessed and said my legs simply collapsed, He was yelling my name and he said I moaned. He is 1 wk post op TKR so he was going to call 911. I came to and began vomiting thick yellow bile. By 2:30 I felt somewhat better. Today I am achy - my back & head hurt but I am still nauseous. Fever 99.0 |
| 1000677 | 2/4/2021 | MA | 23 | F | 2/3/2021 | 2/4/2021 | Vasovagal syncope intermittent for 45 minutes, still present but remaining in a laying position |

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| 1000527 | 2/4/2021 | MN | 30 | F | 1/19/2021 | 1/19/2021 | I was so faint/nearly passed out; so hot; very chilled for about 15 or 20 minutes; feeling sort "off"; weak; fatigued/very drained/exhausted; This is a spontaneous report from a contactable consumer (patient). A 30-year-old female patient (not pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EK4176), via an unspecified route of administration on 19Jan2021 at 08:15 AM at single dose in right arm for COVID-19 immunisation. Patient age at time of vaccination was years 30 years. No other vaccine was given within 4 weeks prior to the COVID vaccine. The patient has no known allergies. The patient had no relevant medical history and received no concomitant medications. The patient reported the following: 'About 5 minutes after receiving the vaccine I was so faint I nearly passed out and was so hot I was given an ice pack to try and cool me down. It took about 45 minutes for me to be able walk across one room. I then was very chilled for about 15 or 20 minutes, and very drained. The rest of the day I was back and forth between feeling sort "off" and feeling like I was weak, exhausted, and fatigued'. Adverse events onset date was reported as 19Jan2021 at 08:15 AM. No treatment was received for the events other than ice pack for feeling hot. The patient was recovering from the events. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, has not been tested for COVID-19. |

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| 1000228 | 2/4/2021 | NV | 40 | M | 1/21/2021 | 1/21/2021 | <p>dead; Collapsed; bnt162b2 was given to patient with immunocompromised w/ reportable conditions; bnt162b2 was given to patient with immunocompromised w/ reportable conditions; This is a spontaneous report from a contactable nurse. A 40-year-old male patient receive first dose of bnt162b2 (Lot number: EK9231, Brand: Pfizer), intramuscular in left arm on 21Jan2021 15:15 at single dose for COVID-19 immunization. Medical history included immunocompromised w/ reportable conditions from an unknown date and unknown if ongoing, positive for Covid in September from Sep2020 to an unknown date. The patient's concomitant medications were not reported. The patient experienced dead, collapsed on 26Jan2021. Therapeutic measures were taken as a result of collapsed. The outcome of collapsed was unknown. The patient died on 26Jan2021. It was not reported if an autopsy was performed. Received Covid vaccine here on 21Jan2021, was at work on 26Jan2021 and collapsed, no known complaints at the time, CPR (cardiopulmonary resuscitation) was initiated immediately, transported to ER (Emergency room) and pronounced dead. Unknown if other vaccine in four weeks. The patient had COVID prior vaccination. Unknown If COVID tested post vaccination.; Sender's Comments: Based on the information currently provided, the patient was immunocompromised and had prior COVID infection. The death and syncope more likely are associated with the patient underlying medical conditions. More information such medical history, concomitant medications, treatment indication and event term details especially death cause and autopsy results are needed for fully medical assessment. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Dead</p> |

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| 999904 | 2/4/2021 | CA | 36 | M | 1/14/2021 | 1/14/2021 | Fainted; Disoriented and didn't know what was happening; Feels a little dizzy; Lethargy; Tenderness in the arm; A spontaneous report was received from a consumer who was a 36-year-old, male, patient, who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced fainted, tenderness in the arm, lethargy, disoriented and didn't know what was happening, and feels a little dizzy. The patient's medical history was not provided. No relevant concomitant medications were reported. On 14 Jan 2021, prior to the onset of events, the patient received the first of two planned doses of mRNA-1273 (Lot number: 25L20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On the evening of 14 Jan 2021, the patient had tenderness in the arm and felt lethargic. On 15 Jan 2021, the patient fainted when he woke up in the morning. The patient's legs gave out and he fell into the wall. The patient was disoriented and didn't know what was happening. The patient reported the event as happening pretty quick and described it as "like he had very low blood sugar". The patient reported that sometimes when he gets up too quickly, he feels a little dizzy. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events, fainted, tenderness in the arm, lethargy, disoriented and didn't know what was happening, and sometimes when he gets up too quickly, was unknown. The event, feels a little dizzy, was considered not resolved.; Reporter's Comments: This spontaneous report refers to a case of a 36-year-old male patient who experienced events of fainted, tenderness in the arm, lethargy, disoriented and didn't know what was happening, and feels a little dizzy. The events developed on the following day after the administration of the mRNA-1273 vaccine (Lot # 25L20A, expiration date-unknown). No treatment was reported, and outcome is resolved for dizziness and unknown for all other events. Based on the information provided which includes a temporal association, a causal association cannot be excluded |
| 999434 | 2/4/2021 | AK | 22 | F | 2/3/2021 | 2/3/2021 | Within 2 minutes patient sank in chair and passed out |

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| 1002397 | 2/4/2021 | IN | 27 | F | 2/2/2021 | 2/3/2021 | I had severe coldness, severe body aches where it hurt to move at all, severe vertigo to where just standing slowly made the room around me spin, severe migraine where it made my vision red, nausea and vomiting, fainting several times when attempting to go to the bathroom as slowly as possible, high fever of 101.9, swelling of the injection sight, and extreme fatigue |
| 1000917 | 2/4/2021 | MA | 46 | F | 2/4/2021 | 2/4/2021 | Fainted, possible Vasovagal reaction. |

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| 1000524 | 2/4/2021 | FL | 72 | F | 1/18/2021 | 1/19/2021 | tends to have low blood pressure; Dizziness; she lies down and then gets up she is dizzy; tired; she might have almost fainted as the room was spinning; This is a spontaneous report from a contactable consumer, the patient. A 72-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Lot number EL1284, expiration date 0Apr2021), via an unspecified route of administration in the left arm on 18Jan2021 at 09:30 (at the age of 72-years-old) as a single dose for COVID-19 vaccination. Medical history included Reflux esophagitis, COPD and a root canal on 14Jan2021. Historical vaccinations included the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) on 28Dec2020. Past drug history includes sore arm after COVID-19 vaccination on 28Dec2020. It was unknown if the patient has any allergies to medications, food, or other products. The patient's concomitant medications included oral famotidine (FAMOTIDINE) 20mg twice daily for reflux, (tiotropium bromide) SPIRIVA 2.5mcg, two puffs once daily by mouth for COPD, latanaprost (LATANAPROST)125mcg; one drop each eye at night for Glaucoma, (TIMOLOL) 5% one drop twice daily to each eye and (LORATADINE) 10mg; take once daily by mouth as needed for allergy. The patient did not receive any other vaccine within four (4) weeks prior to the vaccine. The vaccine was administered to the patient at the hospital. On 19Jan2021 the patient experienced dizziness and feeling tired. The patient further described that she had the vaccine on Monday and since yesterday, when she woke up, she has a lot of dizziness; and again this morning when she woke up. Also, when she lies down and then gets up she is dizzy. Mentions she didn't see dizziness on the list of side effects. She knows that is a side effect of COVID. She is asking is dizziness is a side effect of the vaccine wants to know if she should call her doctor. She continued and mentioned that she noticed when she was waking up on 19Jan2021 she was so dizzy that she couldn't get out of bed. Adds she thinks she might have almost fainted as the room was spinning. Mentions she tends to have low blood pressure but this is not typical. As far as side effects from the vaccine she mentions she is tired. The tiredness started after the second dose and has continued through today but not as bad. The clinical outcome of dizziness |

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| 1003598 | 2/4/2021 | FL | 34 | F | 2/3/2021 | 2/3/2021 | was reported as not recovered, the outcome of fatigue was recovering and the outcome of almost fainted and low blood pressure was unknown. |
| 1000804 | 2/4/2021 | NY | 41 | M | 2/2/2021 | 2/2/2021 | 20 min after receiving vaccine. I almost passed out, blood pressure low, heart racing, face flushed and hot, head squeezing and foggy, fingers tingling, nausea. Did not resolve with snacks or drinks. Lasted for approximately eight hours after receiving vaccine. I had to call off of work for the rest of the day. |
| 1013023 | 2/4/2021 | | 21 | F | 1/3/2021 | 1/4/2021 | Syncopal event after shot given . Clammy and diaphoretic , ashen appearance and announced he was about to pass out before he passed out . Has had between 15-20 similar episodes describable and recallable in his lifetime . Awoke after a brief 10 sec loss of consciousness. Felt immediately better and no different than any other episode that occurred after seeing needles and getting shots. Drank some water and dc home after observation . Drove himself home . No sequelae. |
| 1003683 | 2/4/2021 | CA | 73 | M | 1/27/2021 | 1/28/2021 | Pt got pfizer covid vaccine on 1/3 (approx 48 hrs PTA) where she a CNA. She got the vaccine in the afternoon. Pt felt well on the day of the vaccine, but yesterday (1/4, one day after vaccine), pt syncoped at work in the evening. She had eaten normal meals that day. After syncopal episode, her blood sugar was normal. Her blood pressure was 76 / 56. Pt felt very lightheaded prior to syncope. No chest pain, dyspnea, no palpitations. Pt was unconscious just briefly. Pt states she did have some tingling in her R arm, R foot, and entire tongue. Pt is still having a HA. No other sxs. Has not taken anything for these sxs. When pt syncoped, she landed on soft bed, did not hit head on anything hard. Pt syncoped once previously at age 9. Pt has soreness at injection site, but no swelling or erythema. |
| | | | | | | | Dizzy with loss of consciousness /fainting x2. Minor closed head injury secondary to fainting. |

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| 1002504 | 2/4/2021 | | 22 | F | 1/4/2021 | 2/4/2021 | 1/4/2020 vaccine few hours later, started to experience dizzy, SOB. I passed out on the floor, still conscious. Felt weak, sat up. Sweating profusely. Migraine. I went home from work. Couldn't move arm; extreme soreness. Body aches, chills, fever at nights. Peaked within 24 hours. 2-3 days, 2nd day being the hardest. Within couple days, I felt fine. |
| 1003605 | 2/4/2021 | MD | 35 | F | 2/3/2021 | 2/4/2021 | In addition to the normal side effects of the Moderna vaccine (chills, fever, muscle aches, headaches) I also experienced syncope; I completely blacked out and fell on my face. |
| 1003581 | 2/4/2021 | NJ | 27 | F | 2/3/2021 | 2/3/2021 | I received the second dose of my Moderna covid vaccine at 10 am on Wednesday February 3rd. Around 8:30 pm I experienced extreme chills and had a 100-101 F fever all night. I woke in the morning still feeling weak because I spent the whole night uncomfortable from the fever and flushed face I had. I walked towards another part of my house and fell down and fainted. I was unconscious for a few seconds before a family member was able to shake me and wake me up. I take no medications and am a generally healthy individual with no prior medical history or underlying Heath conditions. I also do not have a history of falls or issues from taking any past vaccines. I also am not allergic to anything or have experienced any allergic reactions in my life. It?s the second day now and I am still experiencing a 100 Degree fever and face flushing. I am currently self medicating at home with Tylenol every 4-6 hours. I have not gone to see a health care professional yet. |

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| 1003549 | 2/4/2021 | CA | 41 | M | 1/27/2021 | 1/27/2021 | Patient received 2nd dose of Pfizer-BioNTech COVID-19 Vaccine EUA at 2:04pm , <5 minutes after vaccine administration he developed hypotension with loss of consciousness for few seconds. He was sitting in a designated chair for the protocol 15 min observation and fell from the chair to the ground, hitting the right side of his temporal - redness noted around area with skin intact. Clinic staff immediately moved patient to be lying down on the ground with cervical spine precaution and lifted his legs up on a chair. Vitals: HR 78 and BP 118/72 taken in supine position on ground with legs elevated. Patient was transported by EMS to the ED at 2:45pm. ED note: Patient has Hx of vasovagal syncope in the past with similar symptoms after blood draws..Exam and workup shows well-appearing young man, nonfocal neuro exam, normal gait, cardiopulmonary exam unremarkable, no signs of trauma other than a small hematoma to the right forehead. After evaluation, their Canadian Syncope Risk Score is -3 indicating very low risk for 30 day serious adverse events (<1%). Telemetry monitoring during their ED stay has not captured any events. Discussed next steps with patient: given their low risk for 30 day serious adverse events (including death, serious arrhythmia, MI, PE, ICH), they would prefer to be discharged to continue their workup as an outpatient, rather than admission for observation. Patient was deemed stable to discharged from the ED at 5:57pm with counseling to follow up with PCP in the next 2 days and to return to the ED with any persistent or worsening symptoms. |
| 1003507 | 2/4/2021 | DC | 80 | F | 2/4/2021 | 2/4/2021 | Pt fainted, and fell forward out of her chair onto the floor during post vaccination observation. |
| 1003503 | 2/4/2021 | PA | 16 | F | 2/2/2021 | 2/3/2021 | Approximately 20 hours after vaccination patient felt faint, lost all color and fainted. She was in and out of responsiveness. Patient was transported to the ER. Patient was treated with fluids and discharged after observation. According to patient's mom the EKG and lab work were unremarkable. Patient has fully recovered. |

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| 1017647 | 2/4/2021 | | 52 | F | 2/2/2021 | 2/3/2021 | Dizziness, Headache & Syncope Narrative: 2nd dose received 0830 on 2/2/21. At 1900 hours body aches & chills. At 2400 hours awoke with abdominal discomfort, became dizzy, then loss of consciences for few seconds and fell to kitchen floor injuring head. Next morning on 2/3/21, syncope in bathroom and loss of consciousness for few seconds and fell to floor. While on floor being held by husband, 2 more episodes of syncope. Went to ER admitted. |
| 1002701 | 2/4/2021 | CO | 73 | F | 2/2/2021 | 2/2/2021 | As soon as I got the shot I felt ?strange? . all over. We waited a bit and then the nurse took my BP. It was sky high. 210/180 They took it a couple of times and even changed machines. Then the took me in a wheelchair to the ER. On the way I could not answer some questions or my answers were slow. According to my husband I slumped a bit. And answered questions in my native tongue. In the room they did all kinds of tests. BP was still high, but came down . After a few hours my ?fog? in my head cleared and I felt ? normal ? again. They let me go around 11 pm. The doctor said it was NOT the vaccine, but I disagree with her. I felt good till I got the shot. She says I had a syncope vasovagal. But that occurs with low BP. I had high BP. |
| 1003658 | 2/4/2021 | MD | 27 | F | 2/3/2021 | 2/3/2021 | I had severe dizziness and fainting for two days after shot, and shortness of breath. |
| 1003484 | 2/4/2021 | CA | 35 | F | 2/4/2021 | 2/4/2021 | Patient felt faint & "tingly" with some mild anxiety post-administration. No true syncope. BP 114/68 sitting, 112/64; no orthostatic hypotension. Remained in an upright position. c/o suborbital ocular twitch x 20 seconds which was observed by this writer. Visual onset of mild swelling L upper cheekbone. Treated with cold pack to area, Benadryl 25mg IM PRN to RD, decrease in environmental stimuli, reassurance, and direct observation x 15 mins. Interventions effective; no further swelling, no s/sx anaphylaxis, anxiety & other symptoms relieved. Client observed with steady gait "I'm better~~ |

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| 1002630 | 2/4/2021 | TX | 41 | F | 1/20/2021 | 1/22/2021 | Pt. stated that she received the COVID vaccine on 1/20/21. On 1/21/21 she felt tired, had loss of appetite. She reported that she went to a store, and apparently "passed out." Employees of the store told her that she had a seizure. Pt. was transported to local ER, where she states that she had a CT of brain, blood work and was told "everything is normal." Stated that she had COVID testing both in the ER and at work, both reportedly negative. This clinic, has thus far been unable to obtain the individuals medical records from the ER. When seen in our clinic on 2/3/21, pt. stated that she is feeling better, but fatigued. No other loss of consciousness reported by pt. |
| 1002692 | 2/4/2021 | OR | 18 | F | 1/18/2021 | 1/18/2021 | 11:40 Vasovagal response-fainted. VS: 107/72, HR 65 , RR 16, O2 100%. Laid down. juice, water and ice packs offered. Patient left observation area with her mom at 11:50. |
| 1003016 | 2/4/2021 | MO | 44 | F | 1/28/2021 | 1/29/2021 | Dizziness, nausea, Fainting, extreme headaches, brain fog, impacted depth perception, extreme muscle pain, knots in large muscles, diarrhea. |
| 1003134 | 2/4/2021 | UT | 45 | F | 1/22/2021 | 2/1/2021 | 10 days after getting the first dose, I experiences a severe headache in the forehead and front/top crown area. It lasted for over 24 hours. At 2:45 AM on 2-1-21, the pain was so bad that I fainted. |
| 1003356 | 2/4/2021 | MO | 31 | F | 2/3/2021 | 2/4/2021 | Symptoms started middle of night. 2am woke up to shivers, fever, headache, body aches, nausea and vertigo. Went to bathroom because of nausea and passed out. Woke up in tub. Continued to shiver, fever for remainder of night. Restless. Fatigue faded around 8am. Nausea remained till 4pm on 2/4/2021 |
| 1002626 | 2/4/2021 | IL | 27 | F | 2/4/2021 | 2/4/2021 | about 5 minutes after receiving her covid Pfizer vaccine pt fainted. her blood pressure was 90/50, blood sugar 74, pulse 82. she was taken to the hospital and discharged without issues. |

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| 1003395 | 2/4/2021 | NY | 55 | F | 2/1/2021 | 2/1/2021 | Fever of 101.5 with shaking chills, sweats, headache, body aches started 2/1 at 9:45pm. Nausea, with vomiting every 15 minutes started at 11:50pm through 2:30am on 2/2/2021. Very dizzy and fainted on the bathroom floor at 12:15 am 2/2. Dizziness, fever, headache, body aches and chills continued through entire day 2/2 . Fever through the night with sweating 2/3. Continue now with some fatigue. Was unable to work 2/2 or 2/3 due to symptoms. |
| 1003398 | 2/4/2021 | TX | 42 | M | 2/3/2021 | 2/4/2021 | Fever of 103 Body aches Syncope |
| 1002688 | 2/4/2021 | | 76 | F | 1/30/2021 | 1/30/2021 | Evening of vaccine patient felt chills that lasted through out the night. Patient got up Sunday morning and passed out, fell to floor. Patient reports that once she woke up it was about 15 mins before she could get off the floor. All day Sunday felt very fatigued and rested. Then felt "foggy" on Monday. |
| 997877 | 2/3/2021 | | 90 | M | 1/31/2021 | 2/1/2021 | AS (aortic stenosis); Cardiac syncope; Pancytopenia; Severe aortic valve stenosis; Symptomatic anemia; Syncope; Syncope, unspecified syncope type |

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| 996742 | 2/3/2021 | MI | 49 | F | 12/18/2020 | 12/1/2020 | Severe headache; malaise; fatigue; syncope and collapse - orthostatic hypotension; Orthostatic hypotension; This is a spontaneous report from a contactable nurse (patient). A 49-year-old female patient (non-pregnant) received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJ1685), via an unspecified route of administration on 18Dec2020 at single dose at right arm for covid-19 immunization. Medical history included chronic fatigue, hypothyroidism, allergic rhinitis from an unknown date and unknown if ongoing. The patient's concomitant medications were not reported. Patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine, patient didn't receive other medication within 2 weeks of vaccination. The patient previously took promethazine hydrochloride (PHENERGAN) and experienced allergies: phenergan. After 1st dose, patient had severe headache for five days, malaise, fatigue on 19Dec2020 09:45 PM, day 6 syncope and collapse - orthostatic hypotension in Dec2020. The adverse events resulted in emergency room/department or urgent care. Adverse events treatment included CT head, carotid doppler, echocardiogram, lab work. It was unknown if the patient was not diagnosed with COVID-19 prior to vaccination. Covid test type post vaccination included nasal swab on 24Dec2020: negative. Patient received second dose of bnt162b2 (lot number: eI0142) on 08Jan2021 10:00 at single dose at left arm for covid-19 immunization. Outcome of events was recovered on unspecified date.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of syncope, orthostatic hypotension and other events due to temporal relationship. However, the events may likely possibly represent concurrent medical conditions in this patient. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including head CT/MRI, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of |

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aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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| 997566 | 2/3/2021 | GA | 36 | M | 1/4/2021 | 2/19/2021 | ~~Moderna COVID-19 Vaccine EUA" Had Covid infection on Nov 29 2020 - Moderate severity (chills, fever, cough, loss of taste/smell, muscle aches, burning chest and nose) 4 day duration of fever, 10 day duration of reported symptoms SINCE THEN - Chronic Fatigue, foggy brain, shortness of breath, chest burning, elevated heart rate, inability to function at normal routine, cough, Symptoms wax and wane, but persist to this day. Severe enough to cause near fainting episodes during routine work day, inability to work Symptoms were the same before and after Moderna Vaccination, but are persistent through time to get the next booster |
| 997833 | 2/3/2021 | TX | 68 | M | 1/27/2021 | 1/27/2021 | Systemic: Fainting-Severe |
| 997776 | 2/3/2021 | IN | 45 | F | 1/30/2021 | 1/31/2021 | 24 hours at the shot, I got up and went to the bathroom, took my dog out, came inside, and was so nauseated, and weak, I passed out in my kitchen, for several minutes, crawled to my bed. Had a fever 101 all day, very fatigued and weak, for almost 36 hours |
| 997761 | 2/3/2021 | TX | 62 | F | 2/2/2021 | 2/2/2021 | Systemic: Fainting-Medium, Systemic: Other- Increase Blood Pressure |
| 997606 | 2/3/2021 | MI | 39 | F | 1/28/2021 | 1/29/2021 | I woke up at 1:30 am with a sore arm and went into the bathroom to get some motrin for the soreness. I started to feel dizzy and a bit nauseous...suddenly I woke up on the floor. I had passed out while standing at the counter. |

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| 997303 | 2/3/2021 | FL | 34 | F | 1/5/2021 | 1/6/2021 | Patient reported on 2-2-21 that she had a "seizure" during the night following the vaccine. Patient reports that around 12 hours after the injection (which would have been around 2 am on 1-6-21) that she woke up with her arm sore and with nausea. Reports that she went to the bathroom because she thought she was going to be sick but husband reports she passed out and had "seizure like" activity. Husband reports that she "was out" for about 1 minute. Patient was evaluated by ER staff with labs, CT, urine specimen. Per the patient everything came back ok except wbc and tsh were slightly elevated. She is establishing care with primary MD and he is desiring MRI. Patient has not had MRI to date due to insurance requirements. Patients stated that she had COVID in September 2020 and since October 2020 she has been having dizziness and that it has been increasing over the last few months. |
| 997295 | 2/3/2021 | NY | 34 | F | 2/2/2021 | 2/2/2021 | Systemic: Chills-Severe, Systemic: Nausea-Severe, Systemic: Vomiting-Severe, Systemic: Fainting-Severe, Systemic: Other- elevated blood pressure and heart rate |
| 997262 | 2/3/2021 | ME | 73 | F | 1/26/2021 | 1/27/2021 | Had shot at 4:26pm Ate a light dinner(lentil soup and omelette) Woke up around 2:30 am feeling nauseas and had diarrhea and chills which continued through the night and following day. Very weak and passed out briefly when feeding my dogs.Ate a bland diet and drank plenty of water for the next few days. Felt better on Saturday January 30th |

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| 997228 | 2/3/2021 | TX | 53 | M | 1/13/2021 | 1/16/2021 | <p> Syncope/a complete syncopal episode while standing. Then a 2nd one on return; unconscious approximately 30 seconds each time; chills; fatigue; muscle aches; joint aches; headaches; extreme dizziness and nausea; extreme dizziness and nausea; injure a knee when my legs pretzeled on the 2nd syncopal episode.; This is a spontaneous report from a contactable consumer. This consumer reported for self that the 53-year-old male patient received second dose of BNT162B2 (COVID-19 Pfizer/Biontech, Lot#: EL3248), via an unspecified route of administration on 13Jan2021 11:00 AM on Left arm at single dose for COVID-19 immunisation. Medical history included Controlled hypertension and known allergies: Hypersensitive to narcotics. Concomitant medications included Amlodipine, Irbesartan and Atoravastin. The patient previously took first dose of BNT162B2 (COVID-19 Pfizer/Biontech, Lot#: EK9231), via an unspecified route of administration on 23Dec2020 11:00 AM on Left arm at single dose for COVID-19 immunisation. Facility type Vaccine was Hospital. No Other vaccine in four weeks. The patient experienced Syncope. He had the most common severe reactions (chills, fatigue, muscle aches, joint aches, headaches). But when he walked to bathroom, he had extreme dizziness and nausea, then a complete syncopal episode while standing. Then a 2nd one on return. His wife said he was unconscious approximately 30 seconds each time. EMS was called but refused transport since ERs full. The patient did also injure a knee when his legs pretzeled on the 2nd syncopal episode. The events started from 16Jan2021 01:30 AM. The outcome of th events was recovered. No treatment received. No Covid prior vaccination. No covid tested post vaccination. </p> |
| 996809 | 2/3/2021 | MA | 35 | F | 2/1/2021 | 2/2/2021 | <p> 15 weeks pregnant, expected date of delivery is July 24, 2021. Dizziness to the point of almost fainting, sudden chills, low grade temperature of 99, muscle aches, no appetite, severe tiredness. Lasting from noon 02/02/2021 until time of form submission. Have been resting, drinking liquids, and taking Tylenol every 4-6 hours since symptom onset. </p> |

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| 998385 | 2/3/2021 | CA | 37 | F | 2/2/2021 | 2/2/2021 | Patient had first dose of Moderna COVID vaccination on 1/5/21 and experienced a syncopal episode approximately 10 minutes post administration. She was found to have a low blood sugar (approx. 70) at the time of the syncope. She had her second dose of Moderna COVID vaccination on 2/2/21. Her starting blood sugar displayed on her pump (type 1 diabetic with insulin pump and continuous glucose monitor) was 172 after approximately 20 minutes her blood sugar had dropped to 92, she ate approximately 100 grams of carbs starting at 10 minutes after the 2nd dose of vaccine. Her blood sugar stabilized and remained in the mid nineties after 45 minutes. Her vital signs were stable and she left stating she didn't feel any signs of low blood glucose. Her pump also indicated that her blood sugar was no longer dropping. |
| 996582 | 2/3/2021 | CA | 30 | F | 1/27/2021 | 1/27/2021 | After taking the vaccine around 9:45 am, 1/27, I started feeling mild pain so took ibuprofen. -after an hour or less, I started getting itchy, burning hives all over my face and scalp. - hives disappeared by the end of the day. - next morning there was bad headache, almost passed out, threw up. -entire body pain for atleast 3 days - have been getting hives on face on and off till this date 2/2. |
| 997108 | 2/3/2021 | FL | 52 | F | 2/2/2021 | 2/3/2021 | Left arm pain, swelling at sight of injection, dizziness, passed out,bump on head |
| 999293 | 2/3/2021 | NJ | 29 | F | 1/13/2021 | 1/22/2021 | Some fever and fatigue first two days, subsequently subsided. 1/22 dizziness and near fainting while driving and heart palpitations (no prior history). Went to urgent care for ekg and bloodwork all normal. 1/28 near fainting again, dizziness and heart palpitations went to er, followed up with cardiologist got halter monitor, monitor showed supraventricular tachycardia (no history prior to vaccine), went to er again following another episode the same day, hasneuro exam, followed up with electrophysiologist who detected no arrhythmia but cited possible vaccine effects. |

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| 997911 | 2/3/2021 | | 74 | M | 2/1/2021 | 2/1/2021 | Narrative: Patient received Moderna COVID-19 vaccine via drive thru clinic. The patient was in his vehicle with his wife, when he became diaphoretic and passed out for a couple minutes. Rapid response was called. Patient was removed from the vehicle. He was becoming obtunded and was placed on the pavement. 911 was called. He was given EpiPen at 10:41. His vital signs at 1042 were: saturation 98% on room air, pulse 59, blood pressure 138/80. Patient received Solu-Medrol 125 mg IM a couple of minutes after EpiPen. After the EpiPen the patient became more alert, denied shortness of breath or wheezing, he was nauseated without vomiting. His saturation at that point dropped to 88% on room air, he was started on oxygen with nonrebreather mask. Rescue truck arrived at approximately 1047, and the patient was taken to emergency room. Discharged same day. |
| 998111 | 2/3/2021 | KS | 48 | F | 1/29/2021 | 1/30/2021 | Fever, body aches, vomiting, passed out, tremors |

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| 999369 | 2/3/2021 | FL | 73 | M | 2/1/2021 | 2/1/2021 | Moderna COVID-19 Vaccine EUA I received a Moderna covid-19 vaccination (Lot # 007M20A) at 10:20 AM on Monday 02-01-2021 at the VA Clinic . Between 3 and 4 minutes later I began to experience difficulty breathing, sweating and feeling warm, and then I passed out behind the steering wheel of my parked car, while sitting with my wife. I came to after few minutes as people were attempting to get me out of my car and into a wheelchair, but I had difficulty breathing, couldn't move, and had to be pulled out. After being put in the wheelchair, I passed out again and came to after I had been taken out of the wheelchair and laid on my left side on the ground by Fire Dept. EMT's. I then began to retch, but did not vomit. My wife said that one of the EMT's pumped my chest a couple of times. They lifted me onto a gurney and put me in an ambulance, hit me with an EPI pen, and placed an oxygen mask on my face, as I was having great difficulty breathing. I was unable to move or lift my arms to help them place a blood pressure cuff on my arm, a pulse monitor on my finger, and lift my shirt to help them attach EKG pads. At that point I realized that I had also lost control of my bladder at some point. I continued to have difficulty breathing, and started to experience extreme shivering all the while to emergency Room. Once in the Emergency Room, I could not move myself off the FD gurney, and they had to lift the sheet that I was laying on in order to move me onto the hospital gurney. I had great difficulty helping the technicians remove my shirt so that they could administer another EKG and start an IV (LR 1,000ml bolus). I continued to have difficulty breathing and kept shivering and sweating for some time. I was advised that the EKG's both appeared normal. After a lengthy period of I gradually reached a point where I stopped shivering and sweating, and returned to almost normal breathing. I was finally released around 1-1:30 PM. |
| 999174 | 2/3/2021 | IL | 37 | F | 12/29/2020 | 12/30/2020 | Daily dizzy spells, frequent near syncope episodes, headaches, swollen inguinal lymph nodes, loss of appetite, fatigue |

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| 999074 | 2/3/2021 | NY | 25 | F | 2/3/2021 | 2/3/2021 | Brief Syncopal episode immediately following vaccine administration. Patient regained consciousness within 30 sec. she had some sweating immediately following but no other symptoms. Medical and EMS responded. BP 98/50 P 70 Patient has a history of syncope when ever she gets a shot. |
| 998854 | 2/3/2021 | TX | 82 | F | 1/29/2021 | 1/30/2021 | Dizziness, severe headache, fainting |
| 998833 | 2/3/2021 | MA | 56 | M | 1/28/2021 | 1/29/2021 | Fever, beginning on day after shot, lasted 2 days. The second day after shot he fainted upon standing up and hit the wall, nausea, fever, fatigue, chills. |
| 998535 | 2/3/2021 | NJ | 58 | F | 2/3/2021 | 2/3/2021 | Patient c/o dizziness, flushed feeling, and syncope 10 min post-vaccine. Hx of same related to vaccines/venipuncture in past. Epi-pen given prior to obtaining vasovagal syncope hx. Patient awoke and symptoms improved. |
| 998752 | 2/3/2021 | MI | 65 | F | 2/1/2021 | 2/2/2021 | Syncope 20 hrs after vaccine. Swollen glands 32 hrs after vaccine. Rash on right upper arm 48 hrs after vaccine. |
| 998720 | 2/3/2021 | NY | 26 | F | 2/3/2021 | 2/3/2021 | 15mins after the injection " reported feeling faint and stated her vision began tunneling" BP 86/55 temp 98.2 O2 sat 97% HR 63 Lay down with water and snack 10 min after 105/72 5min 112/78 , denied feeling lightheaded, dizzy or any other symptoms when she left .stated almost fainting in the past from injections~~ |

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| 998598 | 2/3/2021 | | 98 | F | 1/6/2021 | 1/26/2021 | On 1/15/21, resident fell during the night while getting up without assistance and hit her head. She did not have any neurological impairment after fall and remained at facility to be monitored. 1/26/21, resident had sudden loss of consciousness with hypotension and tachycardia. This resolved slowly after resident was put in trendelenberg position. She has not had similar events in the past. She was sent to ED without a distinct underlying cause of the event identified, differential included cardiac arrhythmia, ? orthostatic hypotension, vasovagal syncope, stroke She had a similar event occur on 1/27 after she had returned to the facility from the ED. The family elected not to pursue further evaluation for second event and she was placed on hospice as she had been experiencing some gradual decline before these events occurred. |
| 998549 | 2/3/2021 | VA | 23 | M | 2/3/2021 | 2/3/2021 | Patient presented with a no health hx except for hives to PCN as a child and "passed out" with a childhood vaccine x 7 years ago. Vaccine given without incident, doctor present to distract patient while I gave vaccine. 3-5 min post vaccine patient c/o of nausea and trash can provided. Patient became silent while talking, head fell forward and clonic tonic posturing noted in upper extremities. Called to doctor and patient lowered to floor and placed in recovery position, MSE lasted approximately 30 seconds, EMS called. Post seizure: Patient very pale and diaphoretic, oriented to person quickly, no signs of facial swelling, resp distress or symptoms of a severe allergic reaction. B/P 134/50 HR 80 and regular, patient at this time shares that he had a MSE 3 or 4 years ago with friends. States came around after eating and drinking. States he did not share this information with his health care provider. Patient was AA&O x3 but with dismissed LOC from pre-vaccine state. 1200-EMS arrived, B/P 110/7, glucose 88/EMS, attempted to sit patient up/EMS, became dizzy and pale. Lowered to recovery position and waited for second team. Attempted to sit patient up again when second team arrived and again he became pale and dizzy. 1212- patient consented to be transported to hospital at this time/EMS. |

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| 998754 | 2/3/2021 | NC | 45 | F | 1/27/2021 | 1/28/2021 | Following day was hypotensive with blood pressure 70/65 and had syncope with fall and laceration to face. Received CT scans, IV fluids in ER . Had another episode of syncope in ER. On days 2 severe pain abdomen with bloating, myalgia and fatigue that lasted fir 2-3 days. |
| 1001616 | 2/3/2021 | | 38 | M | 12/29/2020 | 12/29/2020 | Myalgia, CoughWheeze, Syncope, Chills Narrative: covid tested positive 1/1/21. symptoms resolved 1/2/21. |
| 998530 | 2/3/2021 | WA | 28 | F | 1/13/2021 | 1/13/2021 | 'Had second dose of Pfizer vaccine on 1/13 at 4:30PM. The following morning (1/14), I experienced nausea and light headedness. This resulted in fainting multiple times and be transported to via ambulance. After receiving fluids, symptoms decreased but continued to have fever/body aches until following day (1/15).' |
| 994899 | 2/2/2021 | | 52 | F | 1/18/2021 | 1/18/2021 | passed out; hit chin on the sink; vomited; Fever; chills; This is a spontaneous report from a non-contactable consumer (patient). A 52-year-old female patient (non-pregnant) received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Jan2021 at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. Patient previously received first dose of bnt162b2 at single dose on unspecified date for covid-19 immunization. Patient had one of the worst nights, fever/chills on 18Jan2021. Got up at 1:30 on 19Jan2021 to use the bathroom, passed out and hit chin on the sink. Then vomited. Still low fever. Patient didn't receive treatment for events. Outcome of all events was recovering. The adverse events resulted in neither doctor or other healthcare professional office/clinic visit, nor emergency room/department or urgent care. The report was considered as non-serious. No follow-up attempts are possible; information about lot/batch number cannot be obtained. |

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| 995039 | 2/2/2021 | AZ | 40 | M | 1/30/2021 | 1/30/2021 | About 2 to 3 minutes after receiving the injection I felt light headed and passed out. My wife said my eyes were open but glazed over. I also started shaking. When I woke up I was confused and felt nauseated. A few minutes after I woke up the EMTs ran my vitals. My heart rate was in the 40s and my blood pressure was in the 90s. I have never had a reaction like this to any other shot/vaccines. |

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| 995141 | 2/2/2021 | IL | 54 | F | 1/18/2021 | 1/18/2021 | kind of fainted; Body feels tender and skin feels tender to touch; dizziness; Weakness; Fatigue; Headache; Chills; Left arm hurting really bad; A 54-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular on 18Jan2021 07:15 at single dose in left arm for covid-19 immunisation. Medical history included menopause from May2020 and ongoing (She is going through menopause, which started 7 months ago). There were no concomitant medications. Received call from consumer regarding the Pfizer BioNtech COVID vaccine. She had first vaccine yesterday morning and is experiencing some side effects. It looks like it was prescribed by a pharmacist, but she is not able to see the name and does not have any contact details to provide. She signed up at the online thing for reporting. Her arm is much better this morning. She woke up at 03:00 with the headache and still has it. Dizziness and weakness started 06:30 this morning. She kind of fainted. She was walking from one room to the next and she just gave out. It has improved and she is not really dizzy any more. She is having a little fatigue though. Chills began at 06:30 and they come and go. She is going through menopause and it could have something to do with it. She was unable to answer outcome for this. She just wants the headache to stop. She has not been able to do anything today. She is going through menopause, which started 7 months ago. She would like to know if there is something she can take for the headache. AE Details and time of onset: Left arm hurting really bad 18:00. When she first got it, she did not feel it. As the day progressed, she could feel the pain. Headache 03:00. Dizziness and weakness 06:30. Fatigue 06:30. Chills 07:00-07:30. She layed down at that point. Body feels tender and skin feels tender to touch 09:00. NO ER or physician's office required. No prior Vaccinations (within 4 weeks). The outcome of the event dizziness was resolved, Chills was unknown, Headache was not resolved, while the outcome of the other events was resolving. Information on the lot/batch number has been requested. |

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| 995142 | 2/2/2021 | NY | 66 | F | 1/14/2021 | 1/19/2021 | Short fainting spell; This is a spontaneous report from a contactable consumer (patient). A 66-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Batch/lot number: EJ1686), intramuscularly on 14Jan2021 after 15:00 (her appointment was at 1510 but she had to wait past her appointment time before she received it) in upper right arm at single dose for Prevent Covid in hospital. No history of all previous immunization with bnt162b2 considered as suspect. No additional vaccines administered on same date of bnt162b2. Medical history included breast cancer from 9 years before 19Jan2021 (2012) and she has been Anastrozole since, she was only supposed to take Anastrozole for 5 years and when she was one month away from being done with it she had a Seizure and she was found to have a Tumor in her brain, she had had Srs surgery on her brain on 13Apr2016, she was prescribed Levetiracetam, a seizure medication, for two years and had not had any problem since. Concomitant medication included ongoing anastrozole taking for about 9 years for Post breast cancer. No prior vaccinations within 4 weeks. The patient previously took levetiracetam for seizure, she stopped taking Levetiracetam 750mg about 2 or 3 years before 19Jan2021, flu shot on 05Dec2020 for immunization at the age of 66-year-old. The patient reported that she had a short fainting spell around 8:30am on 19Jan2021 and she was not sure if it was related to the Covid vaccine. She described that she had been sitting for a while and when she got up she felt like this black curtain coming down which she has felt before in the past but she usually recovered and never lost control to where she fainted. Her husband was there to catch her. She clarified that she never passed out. She did not have any reactions in the past few days since she received the covid vaccine, she did not even have soreness at injection site. The event was not required a visit to Emergency Room nor Physician Office. Relevant Tests was none. The outcome of the event was unknown. |

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| 995146 | 2/2/2021 | | 72 | M | 1/15/2021 | 1/24/2021 | Narrative: Patient experienced cardiac arrest with PEA and a witnessed collapse upon arrival to the emergency department on 1/24/21. Patient received his first dose of the COVID vaccine on 01/15/2021 and felt poorly thereafter. He was describing shortness of breath to his wife and requiring 5L of O2 at home to maintain saturations in 80s, while he usually was on 3L to maintain saturations in the mid 90s. He had been oriented but more fatigued than normal and described bilateral shoulder pain (which was not new for him) as well as indigestion. Took Tylenol with some relief. He had decreased PO intake and less appetite. The patient's wife encouraged him to come to the hospital daily for a week prior to admission, but the patient did not want to because he felt his side effects were secondary to the vaccine. Symptoms:RespDepression, Palpitations, Syncope & cardiac arrest Treatment: EPINEPHRINE 1 MG ONCE 3 rounds given ,CALCIUM CHLORIDE 1000 MG ONCE |

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| 995223 | 2/2/2021 | | | M | 1/15/2021 | 1/17/2021 | Passed out; Low heart rate; Possible pneumonia; A spontaneous report was received from a consumer concerning an 84-year-old male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced passed out, low heart rate, and possible pneumonia. The patient's medical history was not reported. There were no concomitant medications provided. On 15 Jan 2021, the patient received the first of two planned doses of mRNA-1273 (Lot # unknown) intramuscularly, for prophylaxis of COVID-19 infection. On 17 Jan 2021, the patient was hospitalized for passed out, low heart rate, and possible pneumonia. The reporter's mom found the patient passed out on the floor. It was thought he may have passed out about 4 or 5pm. The patient was taken to the emergency room (ER) via ambulance. At that time his heart rate was 20 bpm. Physicians said he may have pneumonia. It was noted the patient still works and walks miles every day. The patient was still hospitalized at the time of this report. There was no treatment information provided. Action taken with mRNA-1273 in response to the event was not provided. The outcome for the events of passed out, low heart rate, and possible pneumonia was unknown at the time of this report.; Reporter's Comments: This case concerns a 84 year old male patient who experienced a serious unexpected events of passed out, low heart rate, and possible pneumonia. The event occurred 2 days 7 hours after first dose of the vaccine. Very limited information regarding the events has been provided at this time. Based on temporal association between the use of the product and the start date of the event/s, a causal relationship cannot be excluded. |
| 995355 | 2/2/2021 | FL | | 58 F | 1/26/2021 | 1/27/2021 | Patient had some expected side effects the day of the vaccine which included weakness, headache, body aches. At 24 hours post vaccination, patient been to feel worse and passed out. She woke up on the floor and had hit her head. She felt weak and dizzy and stayed in bed until 8 PM that night. |
| 995395 | 2/2/2021 | VA | | 82 F | 1/27/2021 | 1/27/2021 | passed out without warning around 10pm. woke up on floor. couldn't move right leg. slept on floor all night. |

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| 994732 | 2/2/2021 | TX | 68 | F | 1/6/2021 | 1/6/2021 | Reports feeling hot and faint immediately after vaccination, transported to ER where she said after lying down she started to feel better. Does report a history of "fainting spells" No admit - patient was released from ER. Upon follow up she denies any further adverse reactions. |
| 993546 | 2/2/2021 | | | F | | | head heaviness; felt like fainting; chest heaviness; This is a spontaneous report from a contactable consumer (patient). A female patient of an unspecified age (78 unit unspecified) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiry date unknown) via unspecified route of administration on unspecified date at single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient wanted to know if she can get the 2nd dose of the vaccine since she was experiencing few side effects, head heaviness, felt like fainting, chest heaviness. The patient was unsure if it was due to vaccine. The outcome of the events head heaviness, felt like fainting, chest heaviness was unknown. Follow-up activities are possible, information on the batch number has been requested. |

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| 995255 | 2/2/2021 | TX | 16 | M | 1/17/2021 | 1/1/2021 | He passed out; His blood sugar was 143; This is a spontaneous report from a contactable consumer (patient's parent). A 16-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Batch/lot number: EL3247) via an unspecified route of administration on the right arm on 17Jan2021 at single dose for COVID-19 immunisation. Medical history included hypopituitarism. Concomitant medication included somatropin (NORDITROPIN) taken for hypopituitarism. He passed out (emergency room visit needed) on 17Jan2021, his blood sugar was 143 in Jan2021. Caller stated that her son received his first dose of the Pfizer COVID vaccine on 17Jan2021, stated he passed out. Caller stated they had to drive 3 hours away to get the vaccine and wanted to know that if because he experienced this after the first dose if it would be possible to find somewhere closer to home to get the second vaccine. Caller stated she is in the trial as an adult, that she reached out to her trial coordinator and they told her that they can only administer to persons in the trial. Son feels like maybe there is a drug interaction, caller stated she was not sure about this. Stated after her son passed out, they called an ambulance, states the Medic watched him for about 45 minutes, stated they ran some tests in Jan2021, he did go home that day. His blood sugar was 143 in Jan2021. Heart Rate monitor in Jan2021 she couldn't see so is unsure of the readings. The outcome of the event passed out was recovered on 17Jan2021, of other remain event was unknown. |

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| 994612 | 2/2/2021 | WI | 31 | F | 1/28/2021 | 1/29/2021 | Approximately 2am of 01/29/2021 I became very over heated for about one hour. Around 3am I then became incredibly cold and shaking. Around 4am I got out of bed and stood for a few moments, then walked slowly around my room making my way to our bathroom. I noticed my vision was not right, almost like a fisheye affect and I felt dizzy. I made it to our master bathroom and sat down on a chair for a few moments before I completely passed out. I fell forward, face first on to the bathroom floor hitting the left side of my head. When I regained my conscious I was weak and shaking and was unable to call out to my husband. I slowly pulled myself up to the toilet trying to make some noise and my husband then came to my aide. As he talked I noticed his voice sounded much farther away than it really was. I also had a difficult time cognitively answering his questions about how I felt. I was pale, clammy, still shaking. This episode from the time I left my bed from the time my husband walked me back to the bed was about 45 minutes. My husband took my temp and I did not have a fever. The next five hours I alternated between feeling very cold and very hot. I spent the next 24 hours feeling completely depleted. I rested as much as I could and had a greater than normal appetite. |
| 994526 | 2/2/2021 | NE | 49 | F | 12/29/2020 | 12/30/2020 | Chest pain, hypotension, pre-syncope, elevated D dimer, and crp. Myalgia, headache, fever, joint pain, abdominal pain starting around 1030 am the following day. These severe symptoms lasted about 36 hours. Then continued with abdominal/pelvic pain and resulting in an interstitial cystitis symptomatology. This lasted an additional 2 weeks with increased fatigue. |
| 994507 | 2/2/2021 | IL | 41 | F | 2/1/2021 | 2/2/2021 | Severe headache during the day after vaccine given. Then around midnight , woke up with extreme chills, body aches, weakness, nausea.. Got up to go to bathroom to throw up, at this time my husband was with me and when I got to bathroom, I passed out. He was holding me, stated my eyes were open and pupils very dilated. He had to wake me out if it (maybe just under 1 min) When I woke up, I vomited a little. Then until about 4 am I continued to have extreme chills, body aches and threw up a few more times. Still currently (9:30 am) feeling very weak and have a bad headache . |

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| 994464 | 2/2/2021 | | 60 | F | 1/29/2021 | 1/30/2021 | Arm is inflamed, red, itchy. Moderate fatigue. Lightheadedness resulting in nearly fainting. Fever of 100-100.4. |
| 994323 | 2/2/2021 | KY | 32 | F | 2/1/2021 | 2/1/2021 | Systemic: Headache-Medium, Systemic: Fainting-Severe |
| 994312 | 2/2/2021 | CA | 27 | F | 1/30/2021 | 1/30/2021 | Systemic: Fainting-Mild |

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| 994134 | 2/2/2021 | NY | 42 | F | 1/26/2021 | 1/27/2021 | <p>I am going to describe all my symptoms so far in detail. Shortly after the shot in the medical observation area I experienced mild nausea that went away for the rest of the day. About an hour after the injection, I experienced nasal drainage in the back of my throat that lasted about 30 minutes. 3 hours after my shot, the arm pain at injection site began, followed by 6 hours later moderate to extreme fatigue that did not cause me to be sleepy or drowsy--simply fatigued. I had enhanced sense of taste and smell. On Wednesday, 1/27 I woke up seeming okay and tried to work at my computer from home. I experienced light-headed and dizziness, and a headache that feels like pressure, and sinus pressure at the bridge of my nose. I had to disengage from work. After lunch around 2 PM I had extreme fatigue and had to lie down in bed the rest of the afternoon and evening. I have moderate nausea that comes in goes in waves. This morning, Wednesday, 1/28 I woke up with nausea and ate breakfast with a heightened sense of smell and taste. I logged into work and the lightheadedness and dizziness began again (also sort of in waves, though the headache is more pervasive and less wave-like than the nausea), along with waves of moderate nausea and headache. The arm pain at the site of injection has significantly abated from a punch to mild pain. The "sinus" or sinus pressure on the bridge of my nose seems only a fraction improved. The headache or pressure has moved from the back of my head to the right side of my head. I had no body aches, but this morning has mild to moderate body aches this morning in my legs and hip bones. 1/29 I woke up with 20%-30% reduced symptoms of nausea and headache, but the dizziness and sinus pressure on the bridge of my nose remain the same. I still have enhanced taste and smell (a sensory plus it's not a distorted or odd enhancement, simply the same flavors and tastes enhanced). The ache that began yesterday in my lower body, my legs still ache, though it feels more like numbness than an ache. I tried doing some stretches which felt good, but my legs still feel the same after stretching. Pain at the site of injection is reduced 90%. There are some strawberries sitting next to me, and I can smell them acutely. Yesterday, 1/30, I woke up with mild nausea and fatigue. This nausea dissipated in the morning, but I felt too fatigued to do Pilates. The waves of dizziness and</p> |

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waves of nausea returned mid-day and I had a low-grade fever of 99.4 (my temp. Tends to run slightly lower than 98.6, as I take it regularly). The pain/pressure in the bridge of my nose has reduced 30%, but still remains. The ache or numbness in my thighs remains the same. This morning, 1/31, my temp is normal at 98.6, but I have mild waves of nausea and moderate waves of dizziness. The pain/pressure on my nose remains the same as yesterday. I have some mild ear pressure. My thigh weakness remains the same. I am too fatigued to attempt Pilates. Acute sense of smell and taste remains the same. The headaches or pressure also seem improved since Saturday 1/30. Monday, 02/01 - ah back to work I woke up with moderate nausea and pretty intense body fatigue and muscle aches in my lower body. I had to work, and I just wanted to crawl back into bed. I worked anyway, also the fatigue tends to worsen mid-day. The dizziness is moderate in waves, and the headache is still mild, along with that mild sinus pressure on my nose. I was in bed after dinner but could have rested all day. 02/02 I awoke with a very mild nausea! The intense fatigue (which worsened several days past my vaccine) was mild. I was ready to attempt my regular Pilates routine, and I did it! My muscle aches are mild to moderate (also, why are my muscle aches mostly confined to my thighs and hips I do have vague pain at the injection site, but its vague, and I use my whole body in Pilates) dizziness waves are back as I sit here typing and get ready to login online to my job staring at the computer screen is jarring to the dizziness waves and reminds me of the mild headache. This is the best I've felt since 1/27 through mid-day I tend to worsen and dizziness that is moderate is disturbing. The heightened sense of taste and smell also seems to have waned a bit in the past two days, back to what I was per usual? I tend to have an acute sense of smell and taste. *I would like it noted in light of new evidence that many people that have had COVID are experiencing intense reactions to the first dose that it is quite likely that I had COVID back in March when my learning center (I work with students age 4-adult, some of which are learning disabled and have autism) emergency closed because a client called to say she was positive for COVID. I had taken her sons temperature the day before. Me, and my two co-workers on my management team were also feeling sick. I had a

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| 993721 | 2/2/2021 | CT | 75 | F | 1/19/2021 | 1/19/2021 | <p>sore throat and chest pains for approx. a month, but at the time COVID testing was not widely available. Since then, My co-worker has tested positive twice for the antibodies, and her husband, who was also sick at the same time, has tested negative twice. I tested negative once for the antibodies, though given my job, my commute on the subway during rush hour my co-workers positivity, and my intense reaction to the first dose I most likely had COVID. My boyfriend's roommate recently also revealed that he is positive to the antibodies, and he was literally sneezing and coughing in the same room with us this past summer and spring. I think a 2nd dose of the same vaccine will cause fainting and vomiting, and the need for two weeks off of my work. This dizziness is alarming. I'm also thinking not having antibodies means nothing in terms of my body and immune system recognizing the vaccine and the virus, making me more ill than when and if I actually had COVID in March or last year.</p> <p>Dry mouth and nose; Dry mouth and nose; Dizziness/Feeling of fainting; This is a spontaneous report from a contactable consumer (patient). A 75-year-old female patient received first single dose of BNT162B2 (Pfizer, Solution for injection, lot number: EL9261, exp date not reported), via an unspecified route of administration (vaccine location: right arm) on 19Jan2021 09:00 for COVID-19 immunization. Medical history included atrial fibrillation. Patient was not pregnant at the time of vaccination. The patient had no known allergies. Prior to vaccination, the patient was not diagnosed with COVID-19. Patient had received other medications within 2 weeks of vaccination (not specified). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 19Jan2021 11:00, the patient experienced dry mouth and nose, and dizziness/feeling of fainting. The events were considered as non-serious by the reporter. No treatment was received for the events. Since the vaccination, the patient has not been tested for COVID-19. The patient recovered from the events on an unspecified date in Jan2021.</p> |

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| 993510 | 2/2/2021 | AZ | 76 | F | 1/13/2021 | 1/14/2021 | 24 hours after receiving the vaccine, I passed out while walking. I do not have any other new medications; This is a spontaneous report from a contactable consumer (patient). A 76-year-old female patient not pregnant received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration Arm Left on 13Jan2021 at 08:00 AM as a single dose for COVID-19 immunisation, lot number: EL3249. Medical history included bronchiectasis. Patient had no known allergies. Concomitant medications in two weeks prior to the vaccination included olodaterol hydrochloride, tiotropium bromide monohydrate (STIOLTO RESPIMAT), salbutamol (ALBUTEROL HFA) and multi vitamins. The patient did not receive any other vaccines within four weeks prior to the vaccination. On 14Jan2021 at 10:00 AM patient passed out while walking, 24 hours after receiving the vaccine, patient did not have any other new medications. Event resulted in emergency room/department or urgent care and hospitalization for one day. Treatments received included cast on hand, computerised tomogram (Ct) scans, electrocardiogram (EKG) and echocardiogram on unknown date with unknown results. Prior to the vaccination, the patient was not diagnosed with COVID-19. Since the vaccination patient had not been tested for COVID-19. Patient was recovering from the event, at the time of the report. |
| 994848 | 2/2/2021 | IL | 60 | M | 2/1/2021 | 2/2/2021 | sore arm, fatigue, fainting |
| 995401 | 2/2/2021 | IL | 57 | M | 2/2/2021 | 2/2/2021 | Near-syncope - lightheaded, generalized weakness, thigh cramps beginning around 15' post vaccination Was placed supine, BP transiently elevated Pt transported to emergency dept. where he felt better, vitals normalized, observed In ED pt denied any focal weakness |

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| 993727 | 2/2/2021 | AL | | U | | | very weak and almost passed out on Wednesday; very weak and almost passed out on Wednesday; joint pain; body aches; chills; extreme fatigue; very lethargic; pain that ran down my arm up into neck; pain that ran down my arm up into neck; This is a spontaneous report from a contactable Nurse. A patient of unspecified age and gender(Age: 59, Unit: Unspecified) received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. Patient previously received first dose of BNT162B2 and experienced fatigue sore arm. After shot 2, the patient experienced joint pain, body aches, chills, extreme fatigue and very lethargic, pain that ran down my arm up into neck. The patient got shot on Monday, symptoms were on Tuesday, the patient was very weak and almost passed out on Wednesday. The patient did not have COVID 19 before and did not take paracetamol(TYLENOL). The outcome of the events was unknown. Information on the Lot/Batch number has been requested. |
| 996279 | 2/2/2021 | TN | 74 | M | 2/2/2021 | 2/2/2021 | syncopy/fainting event with loss of consciousness, pale palor, weak pulse, shallow breathing. TX sternal rub, cold cloth patient awoke , with verbal stimuli RN loudly saying are you ok you need to wake up, then pt was alert oriented x3 prior to losing consciousness he stated to his wife "I am going out," client has a HX of syncopy/fainting not shared with staff at covid 19 vaccine drive thru prior to vaccine administration. |
| 995413 | 2/2/2021 | AR | 81 | M | 2/1/2021 | 2/2/2021 | Syncope |

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| 996529 | 2/2/2021 | TX | 68 | M | 1/27/2021 | 1/27/2021 | The patient fainted ~20 minutes post-vaccine while talking to his colleague. I immediately assessed the patient for s/sx of anaphylactic or severe reaction. He woke up within ~30 seconds of fainting. He was breathing and speaking fine. He told me he was anxious and also did not have anything to eat or drink all day and believes this is the cause of why he fainted. I had him take a few deep breaths. Injection site looked normal and no issues with breathing. Called EMS to assess him: glucose, blood pressure, & vital signs were all normal. While being assessed he passed out in chair so EMS took him to the hospital. He was discharged from the ER the same day per RN, at the facility. They did not find anything wrong with him and also believe it was due to nerves/lack of eating. No significant medical history per form patient filled out or that he verbally stated. |
| 996477 | 2/2/2021 | CA | 67 | F | 1/29/2021 | 1/29/2021 | 1) fever , and chills, sweats for 24hours (started few hours after the vaccine) 2) passed out around 3 am next day when woke up from sleep, Wanted to drink water in kitchen but she felt weak, instead got up to use the bath room to urinate, felt weak, mild dizzy, she made to urinate and when got up after urinate, she fainted. She passed out. Not remember the episode. She woke up (think after short period) looking at ceiling and thinking where she was. Next day, woke up with whole clothes wet from sweating. Denies CP, SOB, diff breath, ting, numb, weak over part of body. 3) had diarrhea for 10 days before this shot. 3 times per day, nausea +, watery, no mucus , blood. No v, Tried Immodium. No BM since 2/2. Likely syncope fr vasovagal vs hypotension fr diarrhea. |
| 996472 | 2/2/2021 | OH | 49 | F | 1/27/2021 | 1/27/2021 | At 10p after getting the vaccine at 10a I began feeling dizzy. I had severe chills. Then around 1:00a I got up to get some water and passed out. I fell flat on my back. My husband rushed to me and helped me up because I started throwing up. At that point I had memory issues. I did not know how old I was nor what month it was. My husband called 911 and I was having tachycardia. They took me to the hospital. |

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| 996468 | 2/2/2021 | NY | 76 | F | 1/20/2021 | 1/20/2021 | 76 yo female with PMHx of CAD s/p CABG 2016, abdominal aortic aneurym, HTN, HLD, Asthma, Diverticulosis, Osteopenia. Presenting to the ED after having Pre-syncope. She reported that today morning she felt nauseated with episode of vomiting, burping and abdominal discomfort after having her lunch meal, headed out to receive her vaccine, she felt well till 10 minutes after the vaccine where a nurse noticed she is pale and less responsive, BP was measured back then and was ~70 ?, the patient reported that she was sitting when that happened, she felt lightheaded, sweating, blurry vision, nauseated. But denies any chest pain, SOB, palpitation, weakness or numbness. She was out of balance and feeling weak till she came to the ED where she felt better after IV fluids. |
| 996357 | 2/2/2021 | CA | 24 | F | 1/16/2021 | 1/16/2021 | dizziness and fainting. REsolved completey. |
| 996277 | 2/2/2021 | NY | 18 | M | 2/2/2021 | 2/2/2021 | 18 y/o M with hx of anaphalaxis with green peas and white beans noted throat scratchiness with no signs of wheezing, SOB, syncope, near syncope, n/v, or angio edema. Patient alert and oriented, vital signs stable: HR 90, RR 16, BP 110/84, 99% O2 on Room air, airway patent, no rash visible. 25mg benedryl by mouth given. Symptoms resolved. Patient monitored 30 minutes in observation. Pt discharged in stable condition. |
| 996251 | 2/2/2021 | IL | 20 | F | 2/2/2021 | 2/2/2021 | Approximately 30 second after injection patient reported feeling nauseated and then passed out. Patient regained consciousness a minute later. Her vision and pulse rate was back to normal within 5 minutes. She was given juice and was able to walk to observation where she remained for at least 30 minutes. |
| 996167 | 2/2/2021 | AL | 41 | F | 1/29/2021 | 1/30/2021 | I woke up on Saturday AM, the night after receiving the vaccine, and I passed out while walking back to bed. |

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| 996134 | 2/2/2021 | OR | 23 | F | 2/2/2021 | 2/2/2021 | Vaccination administered at 5PM (4:45 appointment) Patient has history of fainting with injections. Patient asked to lie on gurney for vaccination in Medical tent B. Immediately post vaccination eyes rolled back in head. Brief tonic seizure lasting 1-1.5 minutes. Patient unresponsive @ 40 seconds then eyes open and responsive to voice. Vitals stable during episode. BP 135/77 P 103-82 R 14-16 O2 sat 94% on room air improving to 99% after 1 minute. Vital signs repeated at 17:10 and 17:25 (stable). Patient asked to remain supine on gurney for 30 minutes post injection. Patient conversing with staff 2-3 minutes post incident. Patient able to drink juice and light snack prior to DC. DC home with mother after 35 minute observation. Patient assisted to schedule next appointment. Patient asked to request to lie on medical gurney in medical tent for second injection. |
| 994711 | 2/2/2021 | MA | 37 | F | 1/26/2021 | 1/26/2021 | Symptoms started at approximately 8 hours after receiving the vaccination. Symptoms started as headache, muscle ache, fatigue and chills. Overnight I spiked a fever of 102.5 even with fever reducing medications. I also suffered from dizziness and sensation of fainting when standing for more than 15 minutes for the first 48 hours after the vaccine. Severe Muscle aches, headache, and fatigue noted for 48 hours after vaccine and symptoms were mild for day 3. |

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| 995504 | 2/2/2021 | WA | 31 | F | 1/8/2021 | 1/9/2021 | Received #2 dose of Pfizer Covid19 Vaccine on 1/08/21 at 10 AM. Approximately 12 hours later she woke up with right eye pruritus with sensitivity, maculopapular erythematous rash and itching over left cheek to temple. She was rubbing at her eyes and did develop local swelling around the right eye. She treated herself with benadryl and advil. Her swelling and eye sensitivity decreased later that day but she developed a fixed itchy maculopapular rash on btl forearms (pictures in chart). She works in the ED as a technician and was seen during her shift 36 hours post shot. Diagnosed with a possible delayed reaction to the vaccine and discharged with prednisone, allegra, hydroxyzine. Symptoms have resolved except for residual hyperpigmentation over areas on forearms where the rash was and still feels itchy, though this increased after stopping antihistamines for her visit. She reports no episodes of lightheadedness/syncope, increased nasal congestion, difficulty breathing post vaccine. She has no history of anaphylaxis or allergic reaction to prior vaccines. |
| 996409 | 2/2/2021 | GA | 71 | F | 1/16/2021 | 1/17/2021 | PATEINT FELT FINE ON THE HOME FROM PHARMACY, STARTED FILLING ILL (NOT QUITE HERSELF) BEFORE BED. SHE AWAKENED AT 5:45 AM. FELT AS IF SHE WAS GOING TO FAINT. SAT DOWN AND PASSED OUT AND HAD A SEIZURE. SLID OUT OF THE CHAIR AND URINATED ON HERSELF AND THE FLOOR. WAS TRANSPORTED BY AMBULANCE TO HOSPITAL. |
| 995419 | 2/2/2021 | TX | 37 | F | 1/26/2021 | 1/26/2021 | Shortness of breath, abnormal ECGs, lack of oxygen to the heart, numbness of legs and arms, tachycardia (130-160) for over 12 hours, difficulty breathing, bilateral pin point pain in legs, dizzy, syncopal convusions, fainting, hyperventilation, vomiting, chills, headache, heart pain, fever, kidney pain |

| <u>VAERS_ID</u> | <u>RECVDATE</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 996058 | 2/2/2021 | NY | 97 | F | 1/31/2021 | 2/1/2021 | My mother fainted on the night she was vaccinated, early in the morning. She had gone to the kitchen to get a heating pad and felt faint while standing. She didn't make it to a chair, but fell and broke her hip. While this could have been due to another health problem, my mother had never had a fall or a near-fall. it is concerning that very old adults are not warned to have someone with them after receiving the vaccine (for instance, overnight), I realize that the vaccine has not been studied specifically in geriatric populations, but it is realistic to assume that there are substantial numbers of very old people living on their own, particularly in cities where there is no need to drive, and where food and other necessities can be delivered. There should be a warning to people that they should not be alone after receiving the vaccine. |
| 995630 | 2/2/2021 | IL | 26 | M | 2/2/2021 | 2/2/2021 | 8 min after receiving the vaccination, client was sitting in waiting area. States after he sat down, he thought about being glad the shot was over. He began to get dizzy and blacked out. Fell out of chair. Unconscious for approx. 15 sec. EMS on site and attended to him. States he did not eat today. Had some snacks, but planned to eat after shot. Admits to being nervous prior to shot. Mother was present. States he has never passed out after vaccines or medical treatment. Mother believes that this was a reaction to the vaccine. Ambulance was called, however, family refused further tx. Client received ice for back of head which hit the floor when he fell out of the chair. Client left after being released from paramedics. Client was taken home by family. |
| 995662 | 2/2/2021 | CA | 44 | M | 1/1/2021 | 1/27/2021 | at 30 a.m. patient got sweaty and passed out. As a result he injured himself. Hospital said all labs were good, full work up and no foreseen reason for passing out. Said possible reaction to vaccine. |
| 995712 | 2/2/2021 | PA | 62 | F | 2/2/2021 | 2/2/2021 | Dizziness, Increase Blood Pressure, Fainting, Fatigue, |
| 995782 | 2/2/2021 | OK | 40 | F | 2/1/2021 | 2/2/2021 | Fever, passed out while driving, nausea, soreness, fatigue |

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| 995916 | 2/2/2021 | OH | 83 | M | 2/1/2021 | 2/1/2021 | Patient received vaccine at clinic, waited the 15 minutes and was released. Passenger in car, wife driving shortly after departing from clinic - wife state he passed out in the car for approximately 10 seconds, no loss of bowel, or bladder control. Had some UE jerking movements, he was quite awake and alert once he woke up and did not exhibit and post-ictal symptoms. Synocpal episode at 1300 was in Vtac per Boston Scientific Reading. |
| 996043 | 2/2/2021 | IL | 36 | F | 2/2/2021 | 2/2/2021 | Patient felt weak and nauseous after receiving vaccine dose. She states she has had vasovagal reactions in the past after giving blood and that she did not eat much today, so low blood sugar may be involved. Pharmacist took patient's blood pressure and pulse, which were both normal, and observed patient seated for 30 minutes. Patient applied ice pack to forehead and neck and drank some juice her mother bought and started to feel better. She was able to walk out on her own after sitting and never actually passed out. |
| 996054 | 2/2/2021 | OK | 40 | F | 2/1/2021 | 2/1/2021 | Fainted, legs and arms went numb and my hands froze, felt almost like a stroke. Was ok after about 30 minutes,,was just very tired rest of day |
| 1000854 | 2/2/2021 | | 73 | M | 1/20/2021 | 1/20/2021 | Narrative: Pt became unresponsive after receiving 2nd dose of covid vaccine, leading to ED visit. Pt also completed hemodialysis prior to receiving vaccine. Pt reported feeling tired, lightheaded prior to syncope. On arrival to ED, BP was 80/60 mmHg, given lactated ringers and BP improved. Pt admitted for high risk possible syncopal episode. |
| 995761 | 2/2/2021 | RI | 28 | M | 2/2/2021 | 2/2/2021 | Light headedness Diaphoresis Near syncope |

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 990356 | 2/1/2021 | FL | | F | 1/13/2021 | 1/15/2021 | <p>Passed out from cardiac arrest (her head feeling really full and really hot, and felt as if she was going to pass out, then she passed out).; Passed out; fractured her face; Head really hot; Head full; Diarrhea; heart rate dropped; platelets dropped; A spontaneous report was received from a consumer concerning a 75-years-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced head feeling really full and really hot, passed out from cardiac arrest, heart rate dropped, platelets dropped, fractured her face and diarrhea. The patient's medical history was not provided. Concomitant medication included atenolol. On 13 Jan 2021, prior to the onset of the events, the patient received her first of two planned doses of mRNA-1273 (Lot number: Unknown) in her arm for prophylaxis of COVID-19 infection. On 15 Jan 2021, the patient complained her head was feeling full and hot. Felt as she was going to pass out, then she passed out from cardiac arrest and fractured her face. After passing out she got diarrhea. On 15 Jan 2021, the patient was hospitalized. The patient's heart rate decreased to 22 beats/minute three times and to 15 beats/minutes twice, and her platelet count dropped. The second dose of mRNA-1273 was discontinued in response to the events. The outcome for the events, head feeling really full and really hot, passed out from cardiac arrest, heart rate dropped, platelets dropped, fractured her face and diarrhea, and diarrhea, was unknown.; Reporter's Comments: This spontaneous report concerning a 75-year-old, female subject who experienced unexpected events of passed out from cardiac arrest and fractured her face, head feeling really full and really hot, and felt as if she was going to pass out, then she passed out, and got diarrhea, heart rate dropped down to 22, platelets also dropped, after the first dose of the Vaccine (mRNA-1273) (Lot number: unknown, expiration date: unknown). The events developed 2 days after vaccine administration. The patient was hospitalized. Treatment and outcome are unknown.' Based on the information which includes a temporal association and the absence of any other etiology, a causal association cannot be excluded. However, there is inadequate information in that the patient's medical history is lacking and event is also confounded by patient's advanced age.</p> |

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| 991053 | 2/1/2021 | IL | 47 | F | 1/5/2021 | 1/5/2021 | After sitting for 20 minutes I went to get up and felt dizzy, light headed and almost passed out. BP was slightly elevated and slight nausea. I felt a little ?foggy? I went home and went to bed , I woke up at 3am with a severe headache and nothing helped it. It felt like a jackhammer was pounding in my head. I felt very fatigued the next day. The headache lasted about 16 hours. I woke up 1/7/21 feeling better. |
| 990992 | 2/1/2021 | IN | 47 | F | 1/30/2021 | 1/30/2021 | At approximately 9:00 p.m. on Saturday 1/30/2021, approximately 12 hours after receiving the moderna COVID 19 vaccination I passed out. I?ve ran at temperature between 99.0 - 101.8 until approximately 6 p.m. 1/31/2021 Muscle and body aches Nausea and upset stomach |
| 990957 | 2/1/2021 | FL | 65 | F | 1/27/2021 | 1/28/2021 | Nausea. Dizziness. Almost passed out. Unresponsive, out of body type of experience. Could not talk ir move for a minute or so. I knew my mouth was hanging open and couldn't shut it. My husband took my blood pressure, it was 61/50. After a few minutes I was coming to, blood pressure began to come back up. My husband had called 911 when my blood pressure dropped so low. By the time they arrived it was back up to normal. I have never had any problems with blood pressure, low or high. Or with dizziness, fainting etc. I am very sure it was from the vaccine |
| 990934 | 2/1/2021 | PA | 61 | F | 1/26/2021 | 1/26/2021 | Systemic: Fainting-Mild; symptoms lasted 1 day. |
| 990811 | 2/1/2021 | FL | 77 | F | 1/27/2021 | 1/28/2021 | My arm was a little sore and a little achy first day. Next morning, Body aches and chills all day long, had a funny taste in my mouth, no apatite as afternoon progressed developed diarrhea, nausea, was sitting on the toilet and fainted. Woke up and got up and went straight to bed and slept the entire night and got up the next morning, I was just tired and weak feeling, kind of dozing on and off. the next day Saturday i was feeling much better, and then Sunday i was perfectly fine. |
| 990696 | 2/1/2021 | FL | 34 | F | 1/25/2021 | 1/25/2021 | Myalgias, Rigors, Syncope, Hypoglycemia, Nausea, Fever |

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| 990653 | 2/1/2021 | FL | | M | 1/15/2021 | 1/16/2021 | Gas; Aches and pains; Passed out; Fell; did get hurt when he fell; Hit his head on the counter and cut open his head; Dizzy; Nausea; Weakness/He is very weak; This is a spontaneous report from a contactable consumer (caregiver). A 78-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 15Jan2021 as a single dose for COVID-19 immunisation, lot number: unknown. Medical history included Blood pressure high. Concomitant medications included some blood pressure medicine (no names reported). It was reported that patient got up in the morning the following day (on 16Jan2021), so dizzy, weak, nauseous, and he fell (did get hurt when he fell), passed out. On the way down, he hit his head on the counter and cut open his head, not a pretty sight when he got up. On unknown date patient experienced gas, aches and pains. Patient was very weak. Patient was not going to pass out, but he was very weak, and reporter thought some of it was from fall, he fell. When you pass out, you fall like a ton of bricks. He fell on a tile floor. So, he had gas, he had some aches and pains now too. Patient was going to take him to the doctor because he did get hurt when he fell. No treatment received for the events, patient had not seen a doctor yet, he will be seeing one the day of the report. Patient had not recovered from weakness, while outcome of the other reported events was unknown. Information about Batch/Lot number has been requested. |
| 990113 | 2/1/2021 | WA | 24 | F | 1/31/2021 | 1/31/2021 | 10:00 AM - fatigue, headache, joint pain 2:00 PM - fever and chills 10:10 PM - passed out, approx 5-10 seconds. No memory for 2-3 seconds prior to or 2-3 seconds after passing out. Was caught by partner and no injury from fall occurred. |

VAERS_ID RECVDATE STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

990466 2/1/2021 CA

68 F

feeling a little woozy/dizzy; My head was sideways and every time I would raise my head the room was spinning; there is not enough spit in my mouth. It's very dry; I walked very slowly; slight headache; My blood pressure now is 137/93. It was high this morning; felt lousy like I had the flu; felt like I was fainting; This is a spontaneous report from a contactable consumer. A 68-years-old female patient started to receive received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at SINGLE DOSE for COVID-19 immunisation. Medical history included transient ischaemic attack (I had a TIA prior). The patient's concomitant medications were not reported. The patient experienced "feeling a little woozy/dizzy" on an unspecified date with outcome of unknown, "my head was sideways and every time I would raise my head the room was spinning" on an unspecified date with outcome of unknown, "there is not enough spit in my mouth, it is very dry" on an unspecified date with outcome of unknown, "I walked very slowly" on an unspecified date with outcome of unknown, "slight headache" on an unspecified date with outcome of unknown, "my blood pressure now is 137/93. it was high this morning" on an unspecified date with outcome of unknown, "felt lousy like I had the flu" on an unspecified date with outcome of unknown, "felt like I was fainting" on an unspecified date with outcome of unknown. Reaction description by the reporter: "I had no pain, slight headache. My blood pressure now is 137/93. It was high this morning when I talked with the triage nurse. I had the shot/vaccine (first dose) on Friday. I feel better today than yesterday. Friday I felt fine. I got symptoms yesterday. When I woke up yesterday. I was feeling a little woozy, I always stretch slowly in bed. I slowly raised myself on the bed but before I got up my torso fell backwards. I felt like I was fainting. The room was spinning. All day yesterday I did not drive. I walked very slowly. I was holding onto the wall. I felt lousy like I had the flu. I would lay down for 20 minutes, watching tv. My head was sideways and every time I would raise my head the room was spinning. Also there is not enough spit in my mouth. It is very dry. I had a slight headache. So I did not bother but no headache today. I supposed to get my 2nd dose on 02Feb2021. The action taken was not applicable. Information on the Lot/Batch number has

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| | | | | | | | been requested. |
| 990121 | 2/1/2021 | WA | 45 | F | 1/29/2021 | 1/30/2021 | nausea, emesis, syncope, as well as extended tiredness, headache, joint pain, fever |
| 991456 | 2/1/2021 | PA | 72 | F | 1/29/2021 | 1/31/2021 | Diarrhea and vomiting beginning 1 am January 31, 2021 - passed out on way to bathroom - extreme chills - lasted approximately 2 hours. Chills continued for approximately 12 hours. |
| 991207 | 2/1/2021 | WA | 51 | F | 12/29/2020 | 12/29/2020 | 12/29 vaccination 1pm. At about 6pm experienced diarrhea, lasted till 10pm. Went to the bathroom and upon exiting, syncope and hit head. Husband call 911; could not wake me. EMT had transported to ER; dehydration, concussion. *intermittent fasting (felt good going into shot) 'barely remember the situation' |

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| 990556 | 2/1/2021 | WA | 43 | F | 1/13/2021 | 1/14/2021 | Hypoglycemic event/blood sugar dropped a bit/sweaty/clammy/hands start to shake when blood sugar is low; This is a spontaneous report from a contactable pharmacist (patient). A 43-years-old female patient receive the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on the left arm on 13Jan2021 at 12:30 at a single dose for COVID-19 immunization. Medical history included Type 2 Diabetic-diabetic for six to seven years and have had no hypoglycemic events. There were no concomitant medications. No additional vaccines administered on the same day of the second dose of BNT162B2. Prior vaccination within 4 weeks included the first dose of bnt162b2 on 23Dec2020 at 12:30 (lot number: EH9899). The patient also experienced arm soreness with prior vaccinations (did not provide product names). The patient is a healthcare worker, diabetic and on insulin only. The patient received the second dose of BNT162B2 on 13Jan2021, and in the last two mornings, she had hypoglycemic events. Nothing in her diet or routine has changed. In the morning of 14Jan2021, she was at work in the clinic and her blood sugar dropped but she doesn't know how low she dropped. She ate a chocolate chip cookie to correct her blood sugar. It was corrected to 91; she didn't have her machine with her. On 15Jan2021 at 1030, the patient was sweaty, clammy, and her hands start to shake when her blood sugar gets low. She had three 15gram fruit bars and two sips of Coke before she passed out. The nurses around her were doing blood pressure checks and a STAT blood sugar check. About five to ten minutes after that, her blood sugar was 93. Her blood sugar was checked again, and it was 198. She stated this is not surprising because she overcorrected her blood sugar. The events required a visit to the physician office that day. The patient clarified that she was diagnosed with type 2 diabetes, takes Lantus - dose changes; normal dose is between 40-45 units once a day with the Solostar pen. That morning, the patient was given a dose of 45 units. Humalog with pen for administration (dose: administered 2 units that morning). The patient uses Humalog only as needed. The patient had undergone blood tests and procedures which included blood sugar tests where blood work was drawn at the endocrinologist's office. The tests included A1C, C- |

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| 992623 | 2/1/2021 | LA | 26 | F | 1/4/2021 | 1/5/2021 | peptide, blood sugar, and to verify which kind of diabetes she has; no results to report. Following 1st COVID-19 vaccination she began having generalized fever, body aches, fatigue, and near syncope prompting her to go to the ED, 2 days after the vaccine. She also began having diffuse swelling of the LUE and L chest wall. Swelling down to elbow prior with erythema and mild rash, which I visualized in a photo. Unsure if blanched. Resolved over several days and was without symptoms when I saw her. Had IV in AC area for IVFs on impacted side but denied symptoms of infiltration. |
| 991107 | 2/1/2021 | AZ | 62 | M | 1/28/2021 | 1/28/2021 | Systemic: Fainting-Medium, Systemic: Other- Pt felt sob and went to go get help, he fainted a while after. When EMS arrived he was feeling better, and was left at the facility. Pt awaiting pacemaker, may have underlying condition. Symptoms lasted 1 day |
| 993043 | 2/1/2021 | OR | 49 | F | 1/29/2021 | 1/30/2021 | 1/30 @ 4am passed out 8n bathroom from lain and nausea. Could leave bed til 4pm that day. Due to body pain, chills and headache. 72 hours later left ear full, very dizzy and slight nausea still. |
| 992701 | 2/1/2021 | WV | 22 | F | 2/1/2021 | 2/1/2021 | SYNCOPE. PT STATED THEY WERE GOING TO PASS OUT, BUT NEVER DID. SHE LATER REPORTED THAT MY VOICE GOT SOFTER AND HAD TUNNEL VISION. DURING THE EVENT SHE STOPPED COMMUNICATING AND HAD A SLIGHT CONVULSION THAT LASTED ABOUT 20 SECONDS. PT THEN FELT HOT, CLAMMY, AND "NOT GOOD". PT FELT THIS WAY FOR ABOUT 5 MINUTES AND THEN FELT FINE. |

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| 992606 | 2/1/2021 | WI | 85 | F | 1/28/2021 | 1/30/2021 | Pfizer-BioNTech COVID-19 Vaccine EUA? Presents to the emergency department with syncope. Patient received her 1st dose of the COVID-19 1/28/21. She states she felt in her normal state of health yesterday. However, she was unable to sleep at all overnight. She took a nap between 5 a.m. and 9 a.m., Upon waking this morning, patient states she felt generally fatigued, had nausea with associated diffuse abdominal pain. Patient had 1 episode of emesis. No hematemesis. Immediately following emesis, she describes 1 to 2 episodes of syncope that occurred while she was seated in a chair. Patient did not fall or strike her head. She denies preceding chest pain, shortness of breath, back pain, numbness, tingling, weakness. Per EMS, patient was awake, somnolent but oriented, with stable vital signs including heart rate of 68, respiratory rate of 18, pulse ox of 90% on room air and blood pressure of 126 systolic. On arrival to the ED, patient appears somnolent, hemodynamically stable with normal blood pressure, afebrile. Patient feels symptomatically improved after 1 L normal saline bolus and Zofran. She was discharged home in stable condition. |
| 992570 | 2/1/2021 | NC | 38 | M | 1/18/2021 | 1/19/2021 | Developed flushing, diaphoresis, nausea, and eventually syncope about 18 hours after vaccine injection. Got up in the night to check on my kids, had been standing for about 2-3 minutes when symptoms started, and passed out in the hallway about 60 seconds after symptom onset. Recovered consciousness within a few seconds, had to lay on the floor for about 5 minutes due to nausea, then got back in bed and went back to sleep. Woke up 3 hours later and felt completely fine except a little fatigue - all other symptoms had resolved. |
| 992563 | 2/1/2021 | NM | 37 | F | 2/1/2021 | 2/1/2021 | Light headedness, ongoing (started ~1 hour ago). I don't know if it's related to vaccine; I regularly experience presyncope with various triggers. |
| 993095 | 2/1/2021 | CA | 68 | M | 1/27/2021 | 1/30/2021 | He passed out after 4th day of vaccination. According to his wife, he drank one glass of wine, but lost consciousness and had a head concussion, nose bleed, and went to ER. He is complaining massive headache right now. ER doctor prescribed him Keflex and Gabapentin. |

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| 992303 | 2/1/2021 | | 63 | F | 1/25/2021 | 1/28/2021 | Patient reported feeling dizzy and passed out at home when she was alone. She was able to call a friend when she woke up. The friend came to pick her up and drove her to the patients primary care physician. The physician found all labs and vitals to be normal and told the patient to return home and rest. |
| 992050 | 2/1/2021 | CA | 25 | F | 1/29/2021 | 1/30/2021 | Woke up in the middle of the night with severe body aches, head ache, fever, chills, fainted for 30 seconds. |
| 991954 | 2/1/2021 | | 25 | F | 1/27/2021 | 1/28/2021 | Received vaccine at 1745 on 1/27. On 1/28 had fever chills, body aches, headache. Fever lasted one day. Fatigue headache continued. Now day 5 post vaccine and still have fatigue, headache. Feeling of light headedness, has continued. Near syncope event on 1/31. I have been unable to work. |
| 991511 | 2/1/2021 | AZ | 95 | F | 1/20/2021 | 1/25/2021 | Systemic: Chills-Medium, Systemic: Generalized Body Aches -Severe, Systemic: Joint Pain-Severe, Systemic: Diarrhea-Severe, Systemic: Fainting-Severe |
| 991749 | 2/1/2021 | TX | 59 | F | 1/29/2021 | 1/29/2021 | Date of symptom onset ? 1/29/21 at 5:45 PM? Symptoms ? EE reports approximately 1 hour after vaccine she began feeling dizzy, lightheaded and pain at injection site. EE denies syncope. + nausea without emesis On Saturday, EE reports continued dizziness and lightheadedness, denies syncope. + joint pain. On Sunday, improvement in symptoms. On Monday, + lightheadedness, no syncope. EE denies fever, recent travel or exposure to COVID-19 without proper PPE. Last day of work and shift - ? 2/1/21 currently at work Home remedies? - rest Any improvement? - yes Recommendation? EE educated to increase fluid intake for hydration and to take ibuprofen as directed in the Medical for joint pain. EE educated to continue to monitor her symptoms and to contact vaccine support line for further questions or concerns. EE educated to manage her symptoms per the TCH Illness in the Workplace Policy. EE verbalized back understanding and denied further needs at this time. |

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| 992477 | 2/1/2021 | IL | 38 | F | 1/26/2021 | 1/26/2021 | 12:40 pm vaccine received 1600 chills started 1800 chills worsened, palpitations 2200 body aches, nausea, rigors 0030 severe nausea, palpitations, feeling faint, fever 100.5 0230 headache 0600 nausea stopped, palpitations stopped by Wednesday evening all but body aches and headaches resolved Thursday persistent body aches, on and off stabbing headache continued, almost passed out while walking x 1, chest vibrations in one spot - but able to work with Tylenol by Friday 100% back to normal |
| 992749 | 2/1/2021 | HI | 57 | F | 1/22/2021 | 1/29/2021 | Patient reported slight dizziness after receiving the vaccine but resolved after 30 min observation; employee denied experiencing any trouble breathing, difficulty swallowing, dizziness, fainting. On 1/29/2021 (7 days post vaccine), she started experiencing a 3-4 cm swelling in the right deltoid with an itching erythematous rash on both arms and hands without associated difficulty breathing, swallowing, or hypotension. Patient took oral diphenhydramine and applied topical tacrolimus cream and Sarna which helped control night itching. |
| 989322 | 1/31/2021 | AZ | 85 | M | 1/28/2021 | 1/30/2021 | Trouble swallowing: 30 hours after shot, continuing though current time of 70 hours Nausea, vomiting, dizzy, fainting 65 hours after shot. 2 episodes Fever - 72 hours after shot |
| 989287 | 1/31/2021 | VA | 44 | F | 1/31/2021 | 1/31/2021 | Passed out/blacked out/lost consciousness about 3 minutes after receiving the vaccine. |

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| 989275 | 1/31/2021 | KY | 36 | F | 1/14/2021 | 1/14/2021 | <p>Pfizer COVID-19 Vaccine EUA Event Description: Patient at hospital to receive her first dose of Pfizer Covid vaccine in left deltoid at ~1105. ~15 minutes after administration c/o left arm feeling hot and appearing red. Patient was observed for 45 minutes and given Benadryl 25 mg IM, Solumedrol 125 mg IM, and Pepcid 20 mg po. The redness on her arm increased and her BP and pulse continued to be elevated. She was transferred to ED for further evaluation a 1148. patient walked to ED to be evaluated for allergic reaction. Pt. reports having an 1100 vaccine appointment. Pt. received vaccine, then c/o left arm redness/swelling. HISTORY OF PRESENT ILLNESS: patient is a 36y female who presents to the ED with an allergic reaction. Pt reports she received the Pfizer COVID-19 vaccine this morning at 1100, first dose, and noted a rash along the left arm where the injection site was. Pt notes she received the first dose of the Pfizer vaccine. Pt documents a rash along the left arm which she described as "itchy and tingling." Patient initially had an area of redness following the injection site and then it extended down her entire arm to the wrist. She states that she was wearing a tighter shirt and they had her change into a loose scribed top. Patient denies any tongue swelling, throat swelling, itching, sneezing, syncope, presyncope, chest pain, shortness of breath double cough, nausea, or vomiting. No prior history of allergic/anaphylactic reactions. Patient was monitored for 1 hr and had significant improvement of symptoms. She was discharged in good condition and to return with any new, concerning, worsening symptoms. Advised to follow up with PCP in 2-3 days. Dx: acute allergic reaction to COVID-19 Vaccine Provided Rx for Benadryl and Pepcid Seen by PCP 1/22/2021 and internal reported filed, prompting VAERS report</p> |

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| 989165 | 1/31/2021 | NV | 32 | F | 1/25/2021 | 1/26/2021 | 1/26 evening I developed body aches, lower back pain, nausea, brain fog, fatigue. On Friday I started my period a week early and it was unusually heavy (this hasn't happened much since I was a teenager) on Saturday I was bleeding so heavily and had lightheadedness, near syncope, headache, nausea, weakness, fatigue and brain fog. Usually menstrual cycle is not as heavy and doesn't come early and I don't experience these types of symptoms (usually just bad cramps and back pain with less heavy bleeding). |
| 989091 | 1/31/2021 | IN | 50 | F | 1/29/2021 | 1/30/2021 | Woke up at 3 am with body aches-got up to take ibuprofen. When I was heading back to bed, my husband heard a loud thud and found me laying on the floor beside the bed, passed out. He rushed over to me and called my name several times before I became conscious. He estimates it was a span of about 30 seconds. When I awoke, I immediately began to cold sweat and dry heave several times. Then I became cold and was shivering. My husband then transported me to the hospital emergency room. I received a cardiac test, which they said was good. I also received intravenous fluids and medication to treat pain and nausea. They drew labs which they said looked normal and did an X-ray my right shoulder because I struck my head and shoulder on a night stand when I passed out. They released me about an hour later after having me stand and walk to ensure my blood pressure did not drop, causing me to feel faint again. They sent me home with a prescription for Zofran to help with any further nausea, advised me to take ibuprofen for head and shoulder pain and body aches and advised rest. They also said to return if any other incidents occur and to follow up with my family doctor if symptoms persist. |
| 989022 | 1/31/2021 | WA | 37 | F | 1/30/2021 | 1/31/2021 | Fainted while returning to bed. Patient has never fainted before. |

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| 989328 | 1/31/2021 | | 39 | F | 1/29/2021 | 1/29/2021 | In the evening of receiving the vaccine, I started to feel brief sharp pains in my chest/ back. Overnight, I was awoken by continued shooting pains all over my body, and also fine shaking. Around 2AM a headache started and progressed to be the worst headache of my life. It was received in the morning by tylenol. In the morning, I experienced extreme exhaustion and dizziness after climbing stairs I almost passed out, had to rest on the floor. Later in the day I experienced hours of chills, a temp to 103, which came down with tylenol. By the evening I was feeling well but tired. Today, 2 days after vaccination, I have neck soreness and am a little tired but well. |
| 989873 | 1/31/2021 | WA | 47 | F | 1/29/2021 | 1/30/2021 | I passed out 12 hours after vaccine received while standing in the bathroom. This followed hours of terrible chills and muscle aches that I couldn't sleep through. No medications were taken until after the episode and it didn't happen again. I did not have a working thermometer so unsure how high my temp got. I peed myself when fainted. My husband was present to pick me up off the floor and luckily I didn't hurt myself in the fall. I didn't come to until he took me back to bed. I started feeling better a few hours later and much better by 24 hours. Now just lingering body aches and fatigue at 48 hours and still taking ibuprofen/Tylenol. |
| 989051 | 1/31/2021 | NY | 25 | F | 1/11/2021 | 1/11/2021 | On Jan 11,2021 at 6:30pm I became light headed and almost passed out. My heart rate was elevated felt like it was going to beat out of my chest. My breathing was heavy and short. I got chills and extremely weak and slight pain in my chest. I ended up going to Hospital by 6:45pm. The rest of that week I was super weak, nauseous, and threw up twice. The following week I was nauseous and weak and had heavy breathing on Friday January 22nd and ended up throwing up. Then Thursday January 28th I became nauseous and light headed around 6pm. Friday January 29th around 6pm I was at work when I became extremely nauseous, light headed, and almost passed out. My heart rate was elevated and my breathing was again heavy and short and I had a pressure tingling pain in the left side of the back of my head as well as soreness in my left arm pit. I ended up going to Degraff Memorial Hospital by ambulance. |

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| 990009 | 1/31/2021 | GA | 37 | F | 1/7/2021 | 1/7/2021 | Within 1 min of getting the injection I felt my heart racing , I became dizzy, my lips and tongue started to tingle and felt weird. Then I fainted, on the floor I heard the nurse say my BP was 'dangerously low' |
| 989572 | 1/31/2021 | FL | 31 | F | 1/30/2021 | 1/31/2021 | Moderna COVID-19 Vaccine EUA. Syncope with head trauma 15 hours after receiving vaccine. |
| 989712 | 1/31/2021 | LA | 94 | M | 1/28/2021 | 1/28/2021 | Passed out and 911 was called They said blood pressure and blood sugar were low They gave patient a glass of orange juice and offered to take patient to the hospital, but patient refused. |
| 989888 | 1/31/2021 | FL | 67 | F | 1/22/2021 | 1/22/2021 | Shot administered 6:08pm. About 6:18pm I felt very tired and wanted to close my eyes. I told my husband 'I don't feel well'. Immediately my eyes rolled back and convulsions started. Then I passed out. EMTs were called over to car and started to administer oxygen. I woke up about 6:30pm cognizant of surroundings. BP was normal. No fever, no rash, no chills. I was just tired. Then 2 hours of vomiting started. Last vomit about 8:15pm in ambulance. EMT unable to administer IV. After waiting in ER waiting room for 45+ minutes, a bed was available (around 9pm). ER doctor gave me ondansetron ODT 4mg Once. Released at 10:12pm to go home. Next 3 days symptoms of lightheadedness and dull headache. |
| 989932 | 1/31/2021 | OR | 30 | F | 1/29/2021 | 1/30/2021 | I started getting fever and chills around 11pm the night following the vaccine. This progressed through the night with an eventual fainting episode at about 4am. |
| 989940 | 1/31/2021 | TN | 30 | F | 1/19/2021 | 1/19/2021 | Profuse vomiting and diarrhea, syncope, chills, seizures. ER visit received 3 bags of lactated ringers, 12 mg of IV zofran, 12.5 mg of IV phenergan, 2 CT scans. |
| 990005 | 1/31/2021 | OR | 52 | F | 1/13/2021 | 1/15/2021 | Acute onset of severe left lower quadrant pain leading to near-syncope and collapse. Severe pain lasted 15-20 min, then decreased intensity for about 12 hrs longer. Transported to ER by ambulance. |

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| 989398 | 1/31/2021 | PA | 38 | M | 1/31/2021 | 1/31/2021 | Patient expressed nerves of injections. During observation period, he went outside for fresh air and to remove mask. He passed out while walking onto concrete with a glass drink bottle in his hand. Because he was unconscious when found, epi-pen was administered. He quickly woke up and expressed he was not feeling any itching, tingling, no swelling. suspicion of post-vaccination syncope not anaphylactic reaction, however, 911/ambulance was called and took patient to the hospital for follow up. |
| 989684 | 1/31/2021 | WV | 82 | M | 1/26/2021 | 1/30/2021 | passed out |
| 988108 | 1/30/2021 | CT | 61 | F | 12/24/2020 | 12/28/2020 | alost fainted- very pale, then tachycardia, high blood pressure, diarrhea. This reoccurred i waves over the next week. Also fatigue,, muscle and joint pain. for 6 days also had sever headace, numbness in face and lips, spasm of left eyebrow. Mised wek of work, ended up in Emergency room. Had negative covid test. sent home. Was fatiques and dizzy and brain fog for next three weeks. Took a month to feel righth. |
| 988034 | 1/30/2021 | IN | 72 | M | 1/27/2021 | 1/27/2021 | covid vaccine (Moderna) at noon on wednesday, by 11:00pm got severe chills, overnight had severe uncontrollable diarrhea, very light headed. while taking shower passed out and fell, although that was just momentary (no injuries). laid up in bed two days, finally felt good enough to get out of bed friday night. symptoms indicate flu, but coincidence 10-11 hours following vaccine??? |
| 987591 | 1/30/2021 | VA | 23 | F | 1/29/2021 | 1/29/2021 | About 4 hours after, went to walk my dog. Felt dizzy and leaned in elevator, passed out and woke up to my dog licking Me. Could not see clear enough to call my roommate, could not hear, and could not walk major loss of mobility. Lasted about 3-4 minutes and then called doctor who said go to ER |

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| 987977 | 1/30/2021 | FL | 59 | M | 1/19/2021 | 1/22/2021 | <p>Approximately 60 seconds prior to emergency, patient felt a sense of panic (first time ever). Stated to me (wife) "I feel like I am having a panic attack" as we walked on to a parking garage elevator at 12:30 pm on 1.22.21. As I turned to push the button to go down, leaned against the wall of the elevator. His eyes fluttered and back, he was a little pale. When I turned around, again, he fainted and fell face down on the elevator floor. He never stopped breathing and had no convulsions. He was out for less than 30 seconds. When he came to, he got up by himself with minimal assist from me (911 was already on their way). He did not remember saying that he felt like he was having a panic attack; but he remember the fear/panic he felt just prior to. He was oriented x3. I had him smile, stick his tongue out and speak to make sure it was not a TIA or stroke and there were no symptoms of that. His bladder did release. He went by ambulance to the ER (we were on a mini vacation to celebrate his birthday). They did a CAT scan, checked his blood sugar twice, EKG twice, complete blood work panels and urinalysis. All tests were either normal or negative. They found nothing. His BP was normal for the first 30 minutes at the hospital, then increased. But has been normal ever since (he checks it daily). Absolutely no other symptoms since that episode. He met with our PCP on 1.29.21 as a follow-up and she directed us to complete this form. She has ordered a consult with a Neurologist and that is scheduled for 3.10.21. His second shot for the vaccine is due on 2.9.21.</p> |

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| 988252 | 1/30/2021 | PA | 29 | F | 1/20/2021 | 1/21/2021 | ~~Pfizer-BioNTech COVID-19 Vaccine EUA" I received my 2nd dose of the Pfizer COVID-19 vaccine on Jan. 20th, 2021. On Jan. 21st, 2021, I woke up feeling feverish. I went to use the bathroom, and after washing my hands I walked towards the bathroom door and felt light-headed and dizzy. Suddenly, I passed out and hit my head and upper neck on the tile floor. My parents heard the sound of my fall and luckily rushed to the bathroom. They found me lying unconscious on the floor with my eyes rolled up for what felt like more than a minute. I regained consciousness on my own, and I drank water with a bit of sugar and salt mixed in. I felt too weak to get up and walk, and the back of my head and upper neck were in pain. I told my parents to call 911 as I wanted to make sure that there was no serious damage to my brain or neck area. I went to the local hospital in an ambulance. I was taken to the emergency room: Vitals were done and my temperature ranged from then was 99.5-101F and my heart rate was high- it stayed around 112 bpm for some time I was given 2 L of IV Saline Fluids EKG result: no clinical abnormalities CT head/neck/spine: negative 2 different types of COVID-19 tests: results were both negative Bloodwork: CBC/BMP/D-dimer: no clinical abnormalities Chest Xray: negative 2D-doppler ultrasound: negative Holter monitor: negative for irregular heart rhythm I was discharged the same day around 4:30pm |
| 987974 | 1/30/2021 | TX | 18 | F | 1/28/2021 | 1/29/2021 | Chills, nauseous, fever, headache, body aches, joint pain & fainted |
| 987704 | 1/30/2021 | MS | 42 | M | 1/25/2021 | 1/27/2021 | Presyncope Tachycardia elevated blood pressure |
| 988684 | 1/30/2021 | TX | 82 | M | 1/27/2021 | 1/27/2021 | Patient had fall x 2 with or without syncope (conflicting documentation) with humeral fracture after receiving the vaccine. Workup demonstrated PE and DVT (appears PE was not submassive/massive, unlikely it directly precipitated fall/ syncope) |
| 987852 | 1/30/2021 | | 67 | M | 1/26/2021 | 1/26/2021 | Passed out 1/26/21 evening for 45-50 seconds similar to when he had COVID. Consulted with PMD. Reported mild pain, moderate fever 101, chills, and joint pains. Severe headache. |

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| 988378 | 1/30/2021 | WI | 66 | M | 1/30/2021 | 1/30/2021 | Patient became so dizzy he could not stand up. Said he felt rubbery, like syncope was eminent. |
| 988391 | 1/30/2021 | FL | 71 | M | 1/26/2021 | 1/26/2021 | 1. Evening of 26/27 January - Chills & low grade fever 2. Morning of 27 January, light headed, fainted, blood pressure 99over55 30 minutes after fainting 3. Lograde fever on day of 27 January 4. Sweats evening of 27/28 January 5. Rash on upper torso 29 January & 30 January 6. Itching on 30 January |
| 988528 | 1/30/2021 | CA | 70 | F | 1/27/2021 | 1/28/2021 | Acute fainting episode during the night following the day of the vaccine. Hit my head on the stone floor and was unconscious. Taken to ER in ambulance. All diagnostics were normal and after blood pressure returned to normal and getting 4 staples in my scalp I was released. Since coming home I have been very ill with weakness, vertigo, nausea, and headache. |
| 988678 | 1/30/2021 | FL | 71 | F | 1/27/2021 | 1/28/2021 | Cjills, fever, body aches, fatigue, one fainting spell |
| 988708 | 1/30/2021 | AZ | 58 | F | 1/29/2021 | 1/29/2021 | 15 seconds after injection patient felt tired and like she was going to pass out. Patient was anxious appearing. Patient taken to the Emergency Room for further evaluation. Upon presentation to the ER, patient diagnosed with vasovagal syncope, treated with fluids and zofran and discharged home. |
| 988770 | 1/30/2021 | CA | 68 | F | 1/28/2021 | 1/28/2021 | Dizziness, vomiting, felt Gross, Passed out for around 10 seconds, and was making strange noises with some difficulty breathing. Body stiffness. Applied wet towels with cold water on the nape and forehead |
| 988844 | 1/30/2021 | WA | 57 | F | 1/22/2021 | 1/23/2021 | Temp through the evening/night 99.5+, woke in the AM, went upstairs to let dogs out. Started to feel dizzy, passed out, woke approx 5-10minutes later with contusion to back of head. Went to ED, still dizzy and nauseous. X-rays/CT done. DX-Closed fx of skull w/severe concussion, laceration to scalp requiring 3 staples. |
| 988614 | 1/30/2021 | OR | 34 | F | 1/12/2021 | 1/12/2021 | 10 minutes after vaccine she became lightheaded, fainted, tingling in both legs HR:100, 40 minutes after vaccine, sore throat, neck rash itchy |

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| 988374 | 1/30/2021 | CA | 39 | F | 1/30/2021 | 1/30/2021 | <p>Pt here today for her second dose of Moderna COVID vaccine. States she did not have any issues with her first dose. Pt does endorse hx of syncope. Approximately 10 minutes after pt received vaccine, she started to feel dizzy and faint and was slouched over in her chair. Pt pale, flushed, tangibly warm and sweaty skin. Transferred pt to stretcher. Pt endorses that she did have breakfast this morning. Felt slightly nervous about getting the vaccine but not overly anxious. Vitals taken: BP 95/59, HR 75, O2 99%. Rapid response called. Rapid response nurse arrived at bedside. Repeat vitals, taken approximately 5 minutes apart: BP 109/63, HR 96, O2 99% BP 109/63, HR 97, O2 99% BP 114/77, HR 108, O2 99% BP 101/70, HR 99, O2 100% BP 106/62, HR 97, O2 100% Pt given juice with some improvement in symptoms. Started to feel her hands tingling and had sensation of cold flowing through her body. Feelings of dizziness waxed and waned. Pt transported to ED by rapid response team for further observation. ED MD notes: "MDM, ASSESSMENT AND PLAN: Overall well-appearing 39 year female experiencing lightheadedness after vaccination. She has no other signs or symptoms to suggest an acute allergic reaction. This may be vasovagal. Plan for urine pregnancy test and EKG, consider IV fluids. Patient prefers not to undergo testing unless completely necessary. We decided to obtain orthostatic vital signs and if patient is symptomatic and/or showing significant changes in blood pressure or pulse with positional change, then will proceed with limited workup for near syncope. DIAGNOSTIC STUDIES O2 sat interpretation: normal on RA Equivocal orthostats - HR incr w/ standing but so did BP. Pt states she's feeling better, tolerating po. Again denies poss pregnancy. Prefers to go home. OK to dc, close return precautions. IMPRESSION: Dizziness. Adverse medication (vaccination) reaction, not allergy.~~"</p> |
| 986169 | 1/29/2021 | RI | 27 | M | 1/29/2021 | 1/29/2021 | Vasovagal syncope |

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| 985520 | 1/29/2021 | AZ | 64 | F | 1/25/2021 | 1/25/2021 | Day of vaccine (1)-1/25/21-left arm soreness, limited ROM, could not lift arm at all, nausea, fever, chills, weakness, fatigue, fainting feeling, dizziness, body aches and headaches. Day 2-1/26/21-all same symptoms as those of day 1. Day 3-1/27/21-left side of body and left hip soreness, nausea, headaches, body aches, decreased appetite and left arm sore. Day 4-1/28/21-nothing, no symptoms. |

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| 985635 | 1/29/2021 | TX | 72 | F | 1/13/2021 | 1/13/2021 | awful burning in the chest/pain in her chest; horrible pressure and pain in her chest; nausea; felt woozy; This is a spontaneous report from a contactable consumer (patient). A 72-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number EL3246), via an unspecified route of administration in the right arm on 13Jan2021 at 17:39 at a single dose in the hospital for covid-19 immunisation. Medical history included anxiety, seizures, and high cholesterol. She passed out last summer and they put her in the hospital from 31Aug2020 and ran all kinds of tests. In the end, they said she only had a few PVCs (premature ventricular contractions) and she doesn't need to see the doctor for a year. Mentioned she also has chronic bronchitis and this is related to having low platelet count and low immunity. All of these events predate treatment with Pfizer COVID 19 vaccine. Concomitant medication included amlodipine, atorvastatin for high cholesterol, clonazepam for seizures, escitalopram for anxiety, levothyroxine sodium for thyroid, and mirtazapine for sleep; all were ongoing. Stated that she had something weird happen after her injection about four hours after the shot. She received the first dose of the Pfizer COVID 19 vaccine on 13Jan2021 at 17:39 in the right arm. About three or four hours later on 13Jan2021, she was getting ready for bed and when she sat down and leaned over she had a god awful burning in her chest and nausea. She was going to take baking soda but when she sat up she had horrible pressure and pain in her chest and felt woozy so she sat on the floor and then the pain started to radiate through her arm and into her neck. The horrible pain and pressure in her chest felt like something was sitting on her chest and the bad pain in her chest was going into her arm and a little into her neck. She laid real still on the floor, and did a lot of praying, and then 20 minutes later it totally stopped. She got up slowly and finished getting ready for bed and was fine. She was just hoping they will still let her get the second shot. The whole event only lasted 20 minutes and when it was over it was completely gone. She did tell her husband when he came home. She was alone when this happened. The patient wanted to know if she can receive second dose of vaccine. She stated it almost felt like a heart attack. She was planning to get the second dose on 03Feb2021. Wanted to know if |

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| | | | | | | | her effect will preclude her from getting the second dose of the vaccine. Outcome of the events was recovered on 13Jan2021. |
| 985737 | 1/29/2021 | TX | 37 | F | 1/23/2021 | 1/23/2021 | Patient was being elevated because she was warm. BP 115/93 at 11:44 am. Patient has Type 2 DM. She felt better denies SOB, or feeling fainting. Denies any tachycardia at 12:00 or any other complaints. Patient was released was advised to call 911 if she has SOB or chest tightness. |
| 985894 | 1/29/2021 | TX | 49 | F | 1/15/2021 | 1/15/2021 | Report of dizziness 15-20 post vaccination and continued intermittent dizziness, lightheadedness and syncope episodes. Treatment- ER - nonspecific, PCP and cardiologist. Outcome: Moderate interference with ADLS. |
| 985227 | 1/29/2021 | CO | 25 | F | 1/28/2021 | 1/29/2021 | Fainting spells with nausea and diarrhea |
| 986098 | 1/29/2021 | PA | | U | | | syncope; Dizziness; vertigo; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received both 1st and 2nd doses of BNT162B2, via an unspecified route of administration on an unspecified date at single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. It was reported that the patient had received two of the COVID vaccine and would like to report about a possible side effect. Three days after each shot the patient had an episode of dizziness with vertigo and syncope. The patient was not sure if this was related to the vaccine but since the patient had not had this before and wanted to report. Information on the Lot/batch number has been requested. |
| 984979 | 1/29/2021 | IL | 51 | F | 1/20/2021 | 1/20/2021 | Presented to ED on 1/21/21 with chest tightness and shortness of breath. Patient reports chest pain with deep inspiration. Shortness of breath started shortly after receiving vaccine on 1/20/21 and persisted into 1/21/21. Patient reports no cough, positive lightheadedness with no syncope, positive nausea with no vomiting. Per exam no fever, no rash, no tongue/mouth swelling. Emergency Department MD states does not meet threshold for anaphylaxis thus no epinephrine administered. Patient received Benadryl 50mg IV, Pepcid 20mg IVPB, Solu-Medrol 125mg IV, and 0.9% NaCl 1L IV bolus. |

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| 986016 | 1/29/2021 | | 52 | M | 1/14/2021 | 1/15/2021 | trouble breathing; severe body aches; fevers and chills; extreme fatigue; headaches; passed out/ when trying to return to bed, passed out a second time; This is a spontaneous report from a non-contactable physician. A 52-years-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 14Jan2021 07:30 at a single dose for COVID-19 immunization at the workplace clinic. The patient's medical history was not reported. Patient has no known allergies. Concomitant medication included venlafaxine hydrochloride (EFFEXOR). Patient previously had the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on an unknown date. On 15Jan2021 04:00, patient had severe body aches, followed very quickly by fevers and chills. At 4:45am started to have trouble breathing. Patient was concerned about respiratory symptoms, and woke his spouse, then stood up to try and breathe better, took a couple steps, and passed out. When the patient woke, when trying to return to bed, passed out a second time. Over the next few hours respiratory symptoms improved. Remainder of day characterized by extreme fatigue, body aches and headaches. Patient had an unspecified over the counter anti-inflammatory medication. The patient has a negative COVID 19 test via a nasal swab on an unknown date. Patient was recovering from the events. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported passed out and the administration of the COVID 19 vaccine, BNT162B2, based on the reasonable temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate. |
| 985201 | 1/29/2021 | MA | 59 | F | 1/28/2021 | 1/28/2021 | Patient fainted after receiving the vaccine. BP 95/75HR 100, O2Sat100%. PATient was transferred to stretcher BP 106/65, HR 79, O2Sat 100% CAT team was called Patient was transferred to ED |

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| 985193 | 1/29/2021 | MI | 38 | F | 1/27/2021 | 1/27/2021 | employee received the COVID vaccine, after 15 minutes she felt her pulse racing, she sat down for a few more minutes before quickly standing and passed out |
| 986185 | 1/29/2021 | TX | 74 | F | 1/29/2021 | 1/29/2021 | DIZZINESS, SYNCOPE |
| 985040 | 1/29/2021 | NY | 41 | F | 1/13/2021 | 1/13/2021 | Pt. Was seen for covid-19 vaccination on 1/13/21. She presented to observation at 12:29pm for her 15 minute observation. Between 12:34-12:38pm pt. Endorsed sudden onset of dizziness and chills. I called for RN assistance who obtained VS and I began clinical assessment. Pt. Denied CP, SOB, DOE, difficulty swallowing was reported. She was able to speak in full sentences, no audible wheezing, facial swelling, one sided weakness or difficulty with speech production. On exam: breath sounds clear, pt. diaphoretic, cool to touch, visible pallor. She denies prior allergic rxn to vaccinations, denies daily medication. Reports medical hx including Sjögren's syndrome and psoriasis. She reports eating breakfast (meal&juice) prior to vaccine administration. Denies allergies to food or medications. 12:40pm: BP 60/49, pulse 81, O2 sat 100%, RR 16. Repeat BP 60/33, rapid response (code blue) was called. Pt assisted transferred to clinical reclining chair, placed in supine reclining position, fluids started (500 bolus NS), FS glucose 93, and EMS called. Patient remained a&o x3, no syncope. 12:46-12:50pm: reported onset of stiffening of hands and l/e. below the knee. AROM remained intact in extremities. Approximately 12:56pm EMS arrived, EKG WNL (per EMS), patient able to ambulate with assistance from reclining chair to EMS transport chair. Approximately 12:58pm BP 93/47. Pt. was stabilized in DTMO following 500 mL NS, BP 92/54 prior to departure to ED at 1:05pm. RN contacted pt. Emergency contact (as documented in RN note) with EMS arrival and prior to ED departure. Pt. Belongings were collected, including cellular phone, and placed in patient belonging bag and given to patient prior to her departure. RN will follow up with patient tomorrow and schedule in office follow up. PCP notified per rapid response report. |

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| 985857 | 1/29/2021 | AZ | 38 | F | 1/22/2021 | 1/23/2021 | Fever, body aches, chills, nausea for 1.5 days after vaccine. Fainting episode 1 day after receiving vaccine. Severe pain and redness on injection site and swelling x 3 days. Took Tylenol and Ibuprofen for fever and pain. |
| 984853 | 1/29/2021 | | 29 | F | 1/29/2021 | 1/29/2021 | Syncope versus seizure with urinary incontinence and shaking. Transported to ED via EMS. |
| 984827 | 1/29/2021 | IL | 40 | F | 1/27/2021 | 1/28/2021 | 210 am woke up hot. Walked downstairs had ringing in my ear and saw stars, held the wall almost passed out. Began profusely sweating drenching my clothes. Nausea began. Went back upstairs sat on my bathroom floor due to nausea/ dry heave. All of a sudden SEVERE abdominal pain began 10/10. Cried for my husband. Dripping sweat gave me a cold rag and foam large diarrhea began. Still 10/10 pain in abdomen. Felt like my lower abdomen was getting ripped out. About 45 minutes or so later still 10/10 wanted to go to ER. I could not stand. If I stood my legs and body felt like I wanted to curl in a ball on the floor. He called an ambulance. I was pale as a ghost, no fever, normal vital signs. Went into full reynauds flare from body stress. Ambulance was unable to get oxygen sat and glucose at the time due to flare. Arrived at the ER labs drawn. WBC 10.9 and Glucose 194. I am not or never have been diabetic. Vaccine related. Like a lightswitch all symptoms stopped except sweating hot and cold spells, sore arm and drowsiness. Discharged at 6am |
| 984803 | 1/29/2021 | AL | 39 | M | 1/27/2021 | 1/27/2021 | Dizziness, lethargy, weakness, near syncope within 15 min of dose. Given 1liter of ns and discharged 1300 1/27. Full body aches continuing. Significantly worse am of 1/29/21, fever 101, fatigue, body aches, nausea, loss of taste. |
| 984730 | 1/29/2021 | TX | 21 | M | 1/28/2021 | 1/28/2021 | Patient received the COVID-19 vaccine and fainted during the 15 min wait in the observation room. |

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| 984390 | 1/29/2021 | GA | 32 | M | 12/28/2020 | 12/28/2020 | <p>Felt like might pass out; Proceeded to become limp, pale and sweaty; Proceeded to become limp, pale and sweaty; Hands rhythmically twitched back and forth; A spontaneous report was received from a nurse concerning a 32-year-old, male, patient who received Moderna's COVID-19 vaccine (mRNA-1273) and felt like he might pass out, became limp, pale, and sweaty, and hands rhythmically twitched back and forth. The patient's medical history included allergy to penicillin. No relevant concomitant product use was reported. On 28 Dec 2020, approximately three minutes prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: 011J20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 28 Dec 2020, the patient began to feel like he was going to pass out minutes after receiving the vaccine. He became more limp, pale, and sweaty and his hands rhythmically twitched back and forth. His eyes closed and he leaned back in his chair, but he remained upright. The nurse elevated his feet, fanned his face and upper body, and applied wet paper towels to the back of his neck. After approximately two minutes, the patient's level of consciousness returned to baseline and he felt better after five minutes. He remained seated and sipped water for 30 minutes. Action taken with mRNA-1273 in response to the events was not provided. The outcome of the events, felt like he might pass out, became limp, pale, and sweaty, and hands rhythmically twitched back and forth, was considered resolved on 28 Dec 2020.;</p> <p>Reporter's Comments: This case concerns a 32-year-old, male, patient, who experienced a serious unexpected event of presyncope and non-serious unexpected event of pallor, hyperhidrosis This case concerns a 32-year-old, male, patient, who experienced a serious unexpected event of presyncope and non-serious unexpected event of pallor, hyperhidrosis and muscle twitching. The event occurred 15 min after first dose of mRNA-1273, lot # 011J20A. Treatment included no medications, but feet elevation and wet towel on the back of his neck. Based on the current available information and temporal association between the use of the product and onset of the events a causal relationship cannot be excluded.</p> |

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| 985053 | 1/29/2021 | NY | 49 | F | 1/28/2021 | 1/28/2021 | Patient became dizzy and light headed, passed out into chair (briefly), employee felt tightness in chest, SOB, taken to emergency room at this point, increased heart rate, blood pressure and SOB. Patient given Neb treatment, Solu-Medrol, Toradol (for migraine). Patient discharged from emergency room with improved breathing. Patient reports she is still SOB at times, has muscle aches, fatigue and soreness at injection site. |
| 987296 | 1/29/2021 | KY | 40 | F | 1/8/2021 | 1/8/2021 | patient felt lightheaded within 30 minutes after vaccine, then about 6 hours later she passed out and had to go to the hospital; she was treated with IV fluids, meclizine, and ativan |
| 985679 | 1/29/2021 | | 61 | M | 1/28/2021 | 1/28/2021 | Fever, shaking chills, headache, body aches, nausea. Episode of dizziness/syncope once overnight. |
| 986330 | 1/29/2021 | MI | 46 | F | 1/25/2021 | 1/25/2021 | Syncope. Breathing but unresponsive. Dizziness and weakness prior to syncope event. |
| 988605 | 1/29/2021 | MI | 79 | M | 1/27/2021 | 1/28/2021 | Patient received COVID-19 vaccine on 1/27/21 and had episode requiring ED visit on 1/28/21. He had nausea, chills, SOB, hypoxia on exertion and syncope with collapse. He went to ED and they found no reason for these issues. He has COPD at baseline but his lungs sound fine and he did not have issues at the ED. ED did not provide any treatment, we provided 4mg Zofran. Vitals are at baseline 1/29/2021 and he reports he feels excellent, no further nausea, chills, lightheaded ness or SOB. |
| 988544 | 1/29/2021 | OH | 26 | F | 1/6/2021 | 1/6/2021 | Employee, a police officer had hit her head during struggle with an aggressive pt.. Vaccine at 1705. Left after her 15 minutes observation and left to see a friend. Friend noted she was flushed. Employee felt her heart race and began to drive back to the hospital. She passed out and ran off of the road into a field; awoke and called for a medic; passing out while talking to the dispatcher. Upon arrival of the medic was awake and while walking in the field to medic she passed out again. In the medic woke up experiencing chills, shakes, nausea, vomiting and muscle soreness to her left side, left arm, her ribs, and shoulder blade. Medic blood sugar 350IU, non diabetic. In ER normal. |

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| 987577 | 1/29/2021 | AR | 66 | M | 1/12/2021 | 1/12/2021 | Excessive thirst after both vaccines, just after second vaccine, face becoming bright red and blood pressure low, two days after second vaccine, unable to sleep, passed out when standing up X 1, nausea, fatigue |
| 987347 | 1/29/2021 | TX | 40 | F | 1/28/2021 | 1/29/2021 | 12 hours after vaccine, near syncope episode, severe muscle aches and chills, severe vomiting low grade fever 100.2, unable to sit up for 12 hours without almost fainting or having to vomit |
| 987229 | 1/29/2021 | PA | 43 | M | 1/29/2021 | 1/29/2021 | Patient (DOB 09/20/77) had a reaction to the Moderna Covid-19 vaccine given on 1/29/2021. On the screening form, patient indicated she had allergies. She verbally said she had multiple allergies and had an anaphylactic reaction previously to allergy shots received in a doctor's office. She said she does carry an EpiPen. RPh counseled on the cases of anaphylaxis with the Pfizer vaccine and recommended a 30 minute monitoring period following the vaccine in accordance with CDC guidelines. Patient agreed and received the vaccine at approximately 11:30am with instructions to check back in with RPh at 12:00pm. A few minutes later (at least 5 minutes), a friend of Patient alerted RPh that patient had fainted. The friend was able to catch patient before she fell off the chair and lower her to the ground. Patient was awake and answering questions but appeared to be having trouble maintaining consciousness. She denied shortness of breath, itching, swelling, and no rash or wheezing was evident. An EpiPen was available and present but not administered due to lack of respiratory symptoms. 911 was called at 11:39am with the patient's permission. Her symptoms remained the same until EMS arrived and she left in the ambulance at 11:57am. |
| 987100 | 1/29/2021 | IN | 22 | F | 1/29/2021 | 1/29/2021 | Patient felt dizzy and passed out. |

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| 987033 | 1/29/2021 | CA | 45 | F | 1/22/2021 | 1/22/2021 | <p>12 hours after my second dose I felt paresthesias in my extremities - particularly in my hands and feet - as well as my face. I also had chills and rigors. I felt lightheaded and nearly fainted. Day 1 post vaccine: I had chills and rigors and the hand/feet paresthesias were persisting. I also felt heavy and weak. Day 2 post vaccine: the chills had resolved but the hand/feet paresthesias were persisting as well and the generalized weakness got worse. I went to the ER and was sent home with instructions to follow up with neurology. That evening my hands became swollen and tight. Day 3 post vaccine: the weakness improved but the paresthesias were persisting. I went to work and on my drive home a I felt electric jolts throughout my body but especially my extremities - which caused me to shake. The rigors came back and I also had abdominal pain. Day 4 post vaccine: I still felt similar symptoms but milder than the night before. I got evaluated and tested for covid which was negative. Labwork and U/A were also negative. The symptoms resolved that evening but the paresthesias were persisting and started to become more painful. I had an MRI of my brain and spine which were negative. Day 5 post vaccine: The paresthesias had become more painful. I was started on Lyrica by my neurologist. Day 6 post vaccine: I felt chest pressure and a globus sensation in my chest, weakness, and jolts in my extremities. The dysthesias in my extremities were persisting. I was evaluated by my neurologist had an EMG which was normal and was diagnosed with small fiber neuropathy. I was told to continue Lyrica and titrate the dose up until the symptoms resolve. Day 7 post vaccine: I have been having heaviness, jolts in my extremities and face, and dysthesias in my hands and feet for most of the day. Lyrica helps a little. Throughout the entire time I have also had intermittent paresthesias in my face and jolts of pain in my face at times. I also had paresthesias in my face and intermittent dysthesias in my extremities 7-10 days after my first Moderna dose. Symptoms got a lot worse after the second one. Given the timing I am concerned that these symptoms are vaccine-related.</p> |

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| 986663 | 1/29/2021 | MI | 62 | F | 1/21/2021 | 1/21/2021 | Patients daughter reported that the patient had a swollen tongue, swollen throat, swelling in her face and fainted. This was after treatment at home - unknown how much time had passed after vaccination. Patient received a dose of their own Epipen. Patient had consented to the vaccination and had received the VIS |
| 986412 | 1/29/2021 | TX | 54 | F | 1/28/2021 | 1/29/2021 | Syncope episode, fever, arm pain, neck pain, nausea, vomiting Still not feeling well |
| 987386 | 1/29/2021 | | 70 | F | 1/29/2021 | 1/29/2021 | pt was vaccinated with no reported issues. pt waited required 15 minutes in pharmacy area with no reported issues. when pt sat up from chair and began walking to care they experienced the following: tremors, flushing, sweating, near fainting like symptoms, muscle weakness. symptoms lasted approximately 5-10 minutes and were resolved completely after given cold water and after sitting for an extra 15 minutes. |
| 986468 | 1/29/2021 | WI | 24 | F | 1/26/2021 | 1/27/2021 | Fever of 101.6 F, body aches, chills, headache, nausea and vomiting, and fainting. |
| 986919 | 1/29/2021 | MT | 51 | F | 1/28/2021 | 1/28/2021 | patient had a vagal response and partial syncope episode minutes after vaccine was administered. Patient did not recover so 911 was called and ems arrived to take to the emergency room |
| 986674 | 1/29/2021 | WI | 22 | F | 1/26/2021 | 1/27/2021 | Vasovagal syncope response shortly after waking in the morning, only passed out for less than 30 seconds, required suturing for chin laceration |
| 986682 | 1/29/2021 | VA | 87 | F | 1/27/2021 | 1/27/2021 | Near syncope, headache X 2 d |
| 986739 | 1/29/2021 | NE | 30 | F | 1/26/2021 | 1/27/2021 | Pt woke up on 1/27 at approximately 0300 , stood up and fainted. Husband states she was unresponsive for about 5 minutes. EMS was called, arrived & evaluated the patient. Patient did not go to the hospital. Patient's also noticed shaking & chills for about 1 hour after the incident. She state she slept for a couple hours and the next day she didn't have any energy. Pt reports that on 1/28 she felt better with a minor headache and neck pain. Pt did not seek out her PCP after the incident. |

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| 986845 | 1/29/2021 | NH | 32 | M | 1/29/2021 | 1/29/2021 | VR passed out several minutes after injection. He had brief seizure like activity and quickly regained consciousness within approximately a minute. His BP , HR, RR and O2 saturation were within normal limits afterward. He notes that he stayed up all night working the night shift as a police officer and then had caffeine this morning. He had an identical episode years ago after being sleep deprived and receiving a dental injection. EMS was summoned, but he declined transport to the hospital and elected to go home. He was driven home by his wife. |
| 986865 | 1/29/2021 | | 50 | F | 1/29/2021 | 1/29/2021 | SOB with chest tightness and syncope episode with loss of consciousness. c/o elephant sitting on the chest. O2 92%, BP 160/ 90, AED no shock advised. EMS arrived and transported to ED |
| 986911 | 1/29/2021 | IL | 57 | F | 1/25/2021 | 1/25/2021 | ~~Moderna COVID-19 Vaccine EUA". I started with dizziness around 2pm. 9pm started extreme chills, teeth chattering. 1am nausea, sweating profusely, headache. 4:30 am worse headache, light headed, passed out on kitchen floor. Woke up around 1pm on Tuesday and temp was 37.8. Took Ibuprofen for h/a and fever once my stomach felt better. Headache remained until Weds am. I felt great today (Friday). |
| 981744 | 1/28/2021 | AL | 91 | F | 1/25/2021 | 1/25/2021 | Systemic: Fainting-Mild |
| 982435 | 1/28/2021 | FL | 65 | F | 1/25/2021 | 1/25/2021 | Immediately following vaccination, the patient became dizzy, weak, and suffered a syncopal episode. Blood pressure was noted as hypotensive at 70/60. IV fluids were administered by EMS and patient was transported to the Hospital emergency department for evaluation. After lying flat and receiving IV fluids, Patient's BP improved to 136/79 per triage note. Patient was discharged from the ED with vasovagal syncope and instructed to submit VAERS report. |
| 982381 | 1/28/2021 | NJ | 27 | F | 1/26/2021 | 1/26/2021 | nauseous, hx of vasovagal syncope. Resolved with rest and cold pack. VS- BP 110/80 |

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| 982360 | 1/28/2021 | OH | 44 | F | 1/25/2021 | 1/25/2021 | Within an hour I had a headache. By 4 hours my arm was very sore. At 8-13 hours I felt like I had the flu with body aches, chills, and sweating. Between hours 14-44 my experience was intense with fever >102 (that was not responsive to Tylenol or Motrin), uncontrollable shaking with an episode of urinary incontinence, fainting, rash on chest/neck, right facial twitching, right arm twitching, nausea, vomiting, diarrhea, chills, profuse sweating, flashing lights in both eyes (open and closed), intense body aches, the sensation that my skin was burning, muscle spasms (back), joint pain (knees/hips), dizziness, agitation, and insomnia. After 44 hours the intense symptoms resolved and I had fatigue, right facial twitching, right arm pain/itching/redness. I went to see my doctor on 1/28/2021 to document my experience. |
| 982237 | 1/28/2021 | SD | 72 | F | 1/21/2021 | 1/28/2021 | 3 or more instances of syncope/lightheadedness |
| 982026 | 1/28/2021 | | 39 | M | 1/28/2021 | 1/28/2021 | Patient passed out in chair in waiting area. Was treated in the room for sinus brady and nausea. 18 g IV established 1 mg atropine and 4mg Zofran administered. Pt. started to "Feel Better". Not sinus rhythm and nausea subsided. Pt. transported to the hospital via Ambulance for further treatment if needed and monitoring. |
| 981974 | 1/28/2021 | CA | 40 | F | 1/25/2021 | 1/27/2021 | 1. Abdominal pain, Left side towards the back, leading to 2. vasovagal reaction, near fainting episode. 2-3 hours. 3. Rash covering entire left upper arm at site of injection site and surrounding it |
| 981937 | 1/28/2021 | FL | 59 | F | 1/26/2021 | 1/26/2021 | Syncope, nausea, headache |
| 981759 | 1/28/2021 | WI | 30 | F | 1/18/2021 | 1/18/2021 | Chills and fever starting around 7:00 PM, lightheadedness, near-syncope around 2:00 AM |

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| 982396 | 1/28/2021 | TX | 44 | F | 1/25/2021 | 1/26/2021 | Headache, nausea, body aches, chills and fever (highest 101.1) began around 1am 1/26/21 and continued throughout the day, fever finally breaking around 7pm that night. I woke the following morning 1/27/21 at 7:20a feeling better, only slightly tired. I was awake about 30mins when my husband reported I stated I felt very dizzy while standing in our kitchen, he states I started walking over to our living room when I fainted and fell face first into the side of our sofa. He stated I came too about 20-30 seconds later. After awaking my hearing was muffled and my arms were very tingly for about 3 mins. I felt completely exhausted and slept for a few hours, remaining very fatigued the rest of the day. Today, 1/28/21, I woke up feeling tired but tightness to base of my head and neck, no other symptoms. |
| 981659 | 1/28/2021 | NY | 54 | F | 1/8/2021 | 1/8/2021 | Client states "I feel warm" approximately 2 minutes post vaccination. Client became nauseous, dizzy and fainted. Paramedics and Physician assisted and client recovered. |
| 981624 | 1/28/2021 | FL | 70 | F | 1/7/2021 | 1/8/2021 | 28 hours post vaccine : fever of 101.2, headache,chills,fainting,nausea, arm sore,red. Systemic symptoms lasted 40 hours and resolved. Arm continued to swell and a hard, hot red lump developed. Redness expanded to cover entire upper arm. A hive like rash developed day 2-3 and lasted for 3 days. Day 7 I contacted my physician and was told he doesn't deal with COVID and vaccine issues. Day 15-16 swelling and redness mostly resolved. Day 21 arm is still sore. |

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| 981582 | 1/28/2021 | NH | 63 | F | 1/21/2021 | 1/23/2021 | Patient received her vaccine on Thursday, 1/21/21. From then until Saturday afternoon she had been experiencing extreme fatigue. On Sat. around 5:00 PM she was standing at her flat-top stove cooking dinner. A wave of very extreme fatigue came over her, so she leaned over to turn off the burner. When she did this, she passed out leaning forward with her hand on the burner and touching the frying pan. When she came to, she went to the couch and laid down - not realizing for 10 minutes that her hand and right breast were burned. The resulting injuries lead to her having to see her PCP on Monday, and then a General Surgeon on Weds 1/27/21. Injuries sustained include a second degree burn on her right breast, On the right arm, laterally above the wrist is a small superficial partially healed burn. On the dorsal aspect of the right fifth finger there is a longitudinal burn that goes from the MCP joint to almost the tip of the finger. She has limited range of motion due to discomfort and swelling. The blister encompasses the entire dorsal lateral aspect of the finger. The fourth right finger has a less extensive blistered area on the PIP joint. The burn on the fifth finger is deep second degree. |
| 981577 | 1/28/2021 | MA | 37 | F | 1/27/2021 | 1/27/2021 | I receive the injection at 7:30 in the morning. At 10:30 in the evening I awoke to having severe Rigors . Shaking uncontrollably. I then became very nauseous. I walked to my bathroom but then felt very dizzy so I had ole my husband up and got myself to the floor . I then passed out and lost consciousness. My husband almost called 911 as he said I was convulsing and he thought I was having a seizure. When I came to I started vomiting . Today I have a headache , body aches , body chills and exhaustion . |

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| 981451 | 1/28/2021 | AR | 36 | F | 1/14/2021 | 1/14/2021 | 1/14/21: 7:30PM = arm pain & extreme fatigue (hit by truck) and went to bed 1/15/21 0300am = woke up with 10/10 left arm pain - crushing, dizzy, nauseous, continuous night sweats - went to stand slowly and almost fainted immediately. took ibuprofen 800mg and applied anicar cream to left arm when I could get up - helped pain 6/10. am - left nostril congested, headache. ibuprofen 800mg 1/17: sore throat 1/18: worse sore throat and drainage - like a sinus infections, fatigue, headache (ibuprofen 800mg) 1/19: same as on 1/18 and now coughing up thick clear sputum also. Got COVID tested today, nausea COVID neg. took Cepacol lozenger, drank tea w/honey, soup 1/20: weds - headache, nausea, sore throat/drainage - improving - ibuprofen 800mg 1/21: same as on 1/20 but significantly better 1/22 - minor sore throat, on/off headache 1/23 all better 1/25 - returned to work. was off from 1/15-1/24 due to my reaction and pending COVID test result im still fatigued and getting headaches on/off. My headache history was fixed until receiving the vaccine on 1/14. |
| 981277 | 1/28/2021 | OH | 62 | F | 1/25/2021 | 1/25/2021 | About 9PM after the receiving the vaccine I started had riggers which lasted for about an hour. I couldn't reach for my phone or call for help. I either passed out or fell asleep. Around 1AM I woke up and checked my temperature 102.7. Some point after I took some Tylenol but don't remember when. I finally had to call for help from my family in the morning because I was not able to pee or drink. Tuesday was my fever was still 102.7 with taking Tylenol and Advil it would just go back up. Tuesday I had Riggers again about 5:30 it only lasted 3-5 minutes. Wednesday my fever went down to 101.4-101.5. Have had difficulty swallowing when the fever is high, did not feel as if I had a allergic reaction or that my throat was sore it was just hard to swallow. I have a weird bruise on my arm I have clue where I got it. I didn't urinate for 9 hours. Headache. Pulse OX was at 93-94 for Monday and Tuesday but then it came it up 95-98 yesterday. As of today I still pretty weak no fever when I woke up. |
| 981227 | 1/28/2021 | GA | 81 | F | 1/27/2021 | 1/27/2021 | night of injection chills lasted about an hr. this morning when i woke up i felt very weak and went to the bathroom and tried to sit down and i passed out. |

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| 981210 | 1/28/2021 | NC | 45 | F | 1/6/2021 | 1/6/2021 | Patient with a PMH significant for allergic rhinitis and cyclic neutropenia, as well a pre-syncope with previous blood donations received COVID-19 vaccine at 0645 and approximately 1 hour later developed a generalized feeling of warmth, followed by lightheadedness/dizziness. She denies frank LOC. She also reports palpitations and a rapid heart rate. She denied any rash, pruritis, dyspnea or chest pain, or N/V/D. Patient works in hospital and was transported to ED and upon arrival vitals were stable with HR of 79, BP 151/84, SaO2 of 100% on RA. Additional information for Item 18: Patient treated with IVF and released. Patient discharged to home and by 1:00pm that day was no longer symptomatic. She does endorse pre-syncope with previous blood draws. |

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| 980617 | 1/28/2021 | TN | 75 | F | 1/8/2021 | 1/10/2021 | Dizziness; history included compromised immune status; history included compromised immune status; getting really tired/fatigue; Gets real sweaty; chills; almost passed out at doctor's office; Nausea; Felt cold; Blood in urine; Feeling unwell; Feeling bad; This is a spontaneous report from a contactable consumer (patient). A 75-year-old female received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number EJ1686), intramuscular in the left upper arm on 08Jan2021 at 15:45 at 0.3 mL, single for COVID-19 immunization. Medical history included Leighton Plantar Alopecia (hair follicle is an enemy), skin infection (infection in body most of the time, at least on skin), diagnosed allergies, compromised immune status, respiratory illness, genetic/chromosomal abnormalities, endocrine abnormalities, obesity, autoimmune disorder (diagnosed 8 months ago). She has lost some height, prior to taking the vaccine and she said it was related to age. There were no concomitant medications. The patient experienced feeling unwell on 10Jan2021; blood in urine on 10Jan2021 at 17:00; nausea at 10:00, chills at 11:00, almost passed out at doctor's office at 10:00, felt cold - all on 11Jan2021; getting really tired/fatigue on 14Jan2021 at 09:30; gets really sweaty on 13Jan2021 at 10:00; and dizziness on unknown date. The patient had the first shot on Friday (08Jan2021). On Sunday (10Jan2021), she started feeling bad. She was feeling good about getting it and had no reaction. She has an autoimmune disorder that made her a little afraid to take, but with all the indications, they said it would be much better for her to take it than to get the COVID virus. Sunday (10Jan2021), she does not feel good. So, she started having blood in urine. She thought she had a UTI and had not had one in 20 years. It felt like that is what she had and with the blood in urine. She just took Tylenol and waited until Monday morning because she does not like sitting in doctor's office. They gave her a cup to give sample and said she didn't need to see provider. They will have it checked and in the meantime call in a prescription. It kept getting worse and worse. She was about to passed out in the doctor's office on 11Jan2021, she got nauseous and almost threw up. She got in the car with her husband and he was trying to get her home. She got chills and got so cold and could not warm her body up. Her husband gave her Phenergan and it kind of knocked |

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her out for a while to ease her nausea. She was thinking of going later today (14Jan2021), when she gets enough energy, to get a COVID test. She does not know if it will give false positive or not. She had chills and now she gets sweaty since 13Jan2021. She took her temperature and she did not have one. She just now got up. It is 10:00. She got up this morning (14Jan2021) and was really tired. She was not sweating this morning. Tiredness is kind of new, and when she talked to the nurse, she sort of felt like maybe it was a reaction to the COVID vaccine, but then she talked to her daughter and she said the symptoms she was having are usually symptoms that occur with second dose of the vaccine. It is not uncommon for people to have symptoms she was having. She wanted to know if she should have a COVID test. If she has had just one shot, would the test give a false positive coming from the COVID. They were asking if patient should take the second dose, and should she continue her UTI medication. Doctor's visit to give urine sample on 11Jan2021 (results: negative for UTI). She did not see a doctor though. They sent sample and prescribed a sulfa based medication for a UTI. She did start feeling a little better and stopped having blood in her urine. She plans to continue it because she does not like to stop taking an antibiotic. She did not have any clue that it was not a UTI until the nurse from her provider's office called to tell her results of urine sample was negative. Outcome of event getting really tired/fatigue was not recovered; events almost passed out at doctor's office, blood in urine, chills, and gets really sweaty was recovering; and unknown for other events.

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| 980361 | 1/28/2021 | NY | 40 | F | 1/12/2021 | 1/12/2021 | Fainted to the floor; Dizzy; Too dizzy, hot and sweaty; Nausea; A little vomit; sweaty; A spontaneous report was received from a non-health professional who was a 40-years-old, female patient who received Moderna's COVID-19 vaccine and fainted, was dizzy, felt hot, had nausea and vomiting, and sweaty. The patient's medical history included a propensity for fainting and low blood pressure. Concomitant product use was not provided by the reporter. On 12 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: 039K20A) intramuscularly in the right arm for prophylaxis of COVID-19 infection. On 12 Jan 2021, after receiving the vaccine, the patient got dizzy, had nausea, a little vomit, and fainted to the floor. She reported feeling dizzy, hot and sweaty. Patient did not take medication to treat her symptoms. Action taken with the second dose of mRNA-1273 in response to the event was not reported. The outcome for the events, fainted, dizziness, felt hot, nausea and vomiting, and sweaty were unknown.; Reporter's Comments: This case concerns a 40-year-old female patient with medical history of propensity for fainting and low blood pressure who received their first of two planned doses of mRNA-1273 (Lot unknown), and who experienced the unlisted event of Syncope which was considered medically significant. Additionally, the patient experienced the non-serious listed events of Nausea and Vomiting, and the non-serious unlisted events of Feeling Hot, Dizziness and Hyperhidrosis. Based on the current available information and temporal association between the use of the product and the onset of events on the day of vaccination, a causal relationship cannot be excluded and the events are considered possibly related to the vaccine. We would note that the patient's history of propensity for fainting and low blood pressure could be also contributory. |

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| 980362 | 1/28/2021 | PA | 51 | F | 1/13/2021 | 1/13/2021 | Fainted; unconscious for 1-2 minutes; Felt dizzy; sweating; shaking; brain feels foggy; didn't sleep well; left arm started hurting from shoulder to elbow; A spontaneous report was received from a consumer who was an 51-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced the events of left arm started hurting from shoulder to elbow, didn't sleep well, felt dizzy, fainted, unconscious for 1-2 minutes, sweating, shaking, and brain feels foggy. The patient's medical history included asthma, hypoglycemia allergy to penicillin and tuberculin (TB) test. No concomitant medications were reported. On 13 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: 012L20A) intramuscularly in the left deltoid for prophylaxis of COVID-19 infection. On the same day, the patient experienced left arm started hurting from shoulder to elbow. On 14 Jan 2021, the patient reported that she didn't sleep well, felt dizzy, and fainted. The patient was unconscious for 1-2 minutes before the ambulance arrived. It was noted that the patient's vitals were normal, so she declined to go to the hospital. The patient also experienced sweating, shaking, and brain feels foggy like she has a hangover. The patient stated that the Moderna vaccine gave her the same reaction except with penicillin and TB test she went unconscious immediately. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not provided. The events, fainted and unconscious for 1-2 minutes, was considered resolved on 14 Jan 2021. The outcome for the events, felt dizzy and brain feels foggy, was not resolved. The outcome for the events, left arm started hurting from shoulder to elbow, sweating, shaking and didn't sleep well, was unknown.; Reporter's Comments: This spontaneous report refers to a 51-year-old female patient with medical history of asthma who experienced unexpected serious events of fainted and loss of consciousness (1-2 minutes), and non-serious events of dizziness, sweating, shaking, brain feels foggy, didn't sleep well and left arm started hurting from shoulder to elbow) the next day after administration of the first dose of mRNA-1273, lot # : 012L20A, Exp date-unknown. Based on temporal information provided and with no other etiological factors, a causal association cannot be excluded. The event of |

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| | | | | | | | left arm started hurting from shoulder to elbow is consistent with the known safety profile of the study medication. |
| 983928 | 1/28/2021 | DE | 23 | F | 1/16/2021 | 1/17/2021 | Vaccine around 3:30pm. Went to bed that same night with slight arm pain. Throughout the night arm pain got progressively worse and could not sleep due to extreme pain and inability to move through range of motion, in addition to night sweats. (did not have a fever). Woke up the next morning with a severe headache and nausea. Fainted around 10am (18 hours post vaccination). Headache and minor dizziness continued throughout the rest of the day. By 24 hours post vaccine, no symptoms besides very minimal arm soreness. |
| 985111 | 1/28/2021 | | 40 | F | | | Patient is a healthcare worker who received the first dose of the COVID-19 vaccine. Later that day, patient had excessive fatigue and some site injection pain. The next morning patient has loss of consciousness witnessed by husband. At the same time patient was drooling, not speaking clearly, and then eyes rolled back in her head, and passed out for a few minutes. |
| 983914 | 1/28/2021 | OR | 29 | F | 1/27/2021 | 1/28/2021 | Around 12:45pm today (1/28/21) I fainted after getting up from using the restroom. My partner was with me and said that after I got up I began shaking and he helped me to the ground where I continued to "shiver", as he called it, for another few seconds before going limp. Once I came to (a few seconds later) I felt very confused at where I was and had a pounding headache and my ears were ringing loudly. It was all I could focus on. After that my partner helped me to bed where he continued to check on me and I slept for 5 hours. |
| 983832 | 1/28/2021 | TX | 43 | F | 1/28/2021 | 1/28/2021 | Received vaccine at 14:30H at work. Was monitored for 15 minutes. Felt fine. Went back to work as a nurse on the same hospital where vaccine was administered. At 15:50H felt light headed, dizzy, palpitations, near syncope. Blood pressure 150/101, Hr 103. Was taken to the emergency room. Observed for 1 hr. Then discharged home. |

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| 983757 | 1/28/2021 | CA | 53 | M | 1/28/2021 | 1/28/2021 | He tolerated the injection and went to the waiting room for sit. About 13 minutes after the injection, the patient walked back to the nurse's station, stating that he did not feel good. He was pale and clammy and started to fall. He was sat in the chair, and he started to lose consciousness. Pulse was faint and the blood pressure was initially 61, pulse about 60. He has no skin rash, stridor, respiratory distress. Respiration was regular and unlabored. Within 10 minutes, he opens his eyes and started responding, his blood pressure improved to 110-120's, pulses 60's, O2 sat 98%, unlabored breathing. He was transferred to a wheelchair and laid down on the exam table. He was observed for another 30 minutes. His vital signs remained stable. He is able to drink water and able to walk around in his own power without difficulty. The patient stated that he does not like needles, and he has not had any vaccination for a long time. Impression: Vasovagal syncope Adverse reaction to the SARS-CoV-2 vaccine, not anaphylactic reaction. |
| 983664 | 1/28/2021 | | 43 | M | 1/27/2021 | 1/27/2021 | Abdominal pain, diarrhea, syncope, bradycardia, fever |
| 983487 | 1/28/2021 | CA | 71 | F | 1/28/2021 | 1/28/2021 | Patient received first dose of covid vaccine on 1/28/21. Reported dizziness, fainting, and mild shortness of breath. |
| 983467 | 1/28/2021 | TX | 30 | F | 1/27/2021 | 1/28/2021 | Tachycardia (active) Had expected chills, headache, fever (101.5-101.9, oral)... around 6am on 1/28/21, I took a warm shower and had near vasovagal syncope episode after feeling lightheaded and dizzy. As a result, I had mild nausea. If went away after 20 minutes. As the expected chills, headache, and fever continued, I started to develop tachycardia at rest (107-172bpm) with heart palpitations around 9:30am. The palpitations went away approximately 2 hours later. I still continue to have tachycardia with minor shortness of breath sensation. My heart rate is currently 115bpm at rest. My typical resting heart rate is 65-70bpm. |

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| 983369 | 1/28/2021 | IL | 49 | F | 1/21/2021 | 1/21/2021 | 1/21/21 Vaccine given at 4:30pm CST. By 11:30pm, felt feverish, started chills and headache. 1/22/21-3:30am- body and joint aches started and chills worsened, headache continued 6:30amCST- chills continued, body and joint pain worse. Took 2 Excedrin to help. 10:30am- fever of 100.3 noted. Continued with chills. Arm visibly red and sore. Swelling started in arm at injection site. 12:00pm- dizziness started. Tunnel vision, and almost passed out. 1:30pm- dizziness worsened, and weakness started in legs. 2:30pm unable to stand without assistance. Left work because unable to continue working and called the doctor. Went home, and started to drink electrolyte supplements. 5:30pm- fever went up to 102.5. Unable to stand without assistance and experienced extreme dizziness. Frequent urination at that time. Arm developed a very large swelling about the size of an egg at the injection site, and was very red. Glands under the arm started swelling, and experienced pain if I tried to lower my arm to my side. Chills continued, joint/muscle/bone pain continued. Became nauseated from the dizziness. Took 2 additional Excedrin for fever and pain. Could not sleep due to the pain in my joints and bones, and pain under arm from glands. 1/23/21 3:30am- Frequent urination during the night. Finally regained ability to stand on my legs, and dizziness started to lessen. 8am Remained on the couch all day except to use bathroom. Fever reduced to 100.1. Continued to use Excedrin as needed for joint/muscle/bone pain. Arm too sore to touch, and swelling protruding from muscle size of a large egg. Very red, hot and itchy as well as pain. 1/24/21- A.M.- most of the dizziness subsided, with just occasional issues. Temperature went back to normal. Still severe pain at injection site with swelling, redness, and itching. Some joint/muscle pain still. 1/25/21- Mostly Arm/injection site issues. Still red/painful, swollen, and itching. very mild joint/muscle pain. 1/26/21- Arm/injection site issues more mild. Swelling reducing, pain & itching reducing. Glands under arm reduced, and pain reducing. 1/27/21- Slight redness at injection site. Swelling down to size of a grape. Slight pain & Itching. Glandular swelling & Pain completely gone. 1/28/21- A.M- No symptoms at all. By 9am, started having twitching/muscle spasms on Left side of scalp above ear. Progressed and worsened through day. By 4pm, spasms and twitching lasts bursts |

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| | | | | | | | of 2-3 minutes. then stop for 15-20 seconds. Consulted with physician, and concerned about vaccine related issues. Muscle relaxer prescribed. **This is when I submitted the report- symptoms are continuing with the scalp spasms. |
| 983288 | 1/28/2021 | WA | | U | 1/11/2021 | 1/11/2021 | Late entry: Vaccine reaction on 1/11/21. Reaction for 1st does , syncope at work and vomited. 2nd vaccine- Dizziness and lightheadedness. No other symptoms. Vital Signs stable. monitored, discharged - with ride to pick up. |
| 983274 | 1/28/2021 | IL | 52 | F | 1/26/2021 | 1/26/2021 | Chills, rigors, extreme weakness, severe headache, syncope x 1 episode with brief loss of consciousness, nausea more from the pain |
| 982617 | 1/28/2021 | | 56 | F | 1/23/2021 | 1/25/2021 | presents today for sharp stabbing headache x2 days. Patient states that the headache is constant and has not gotten better. Patient states that she has never had a headache or migraine in the past, patient states that pain is located on the right temporal side and is sharp and throbbing with a 10 out of 10 pain. She did have the vaccine for COVID-19 on Saturday and is unsure if that is what is causing her headache. Patient has been taking Tylenol for the headache which has not provided any relief. Patient states that she was going to go to the ER but did not want to go and wait so came to the immediate care. The pain does not radiate to any other area besides her head. Patient denies any nausea, vomiting, syncope, palpitations, fever, change/loss of vision. Patient denies any history of migraines. Patient was driven here today by her son. |
| 983109 | 1/28/2021 | MS | 53 | F | 12/23/2020 | 1/2/2021 | 12/23 Vaccination 1/2/2021 Woke up at 1am, stepped outside. Feeling extremely dizzy, passed out faced down on the ground. Nose was bleeding. Referred to PCP |

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| 983103 | 1/28/2021 | MI | 36 | M | 1/27/2021 | 1/28/2021 | roughly 10 hours after receiving the vaccine I woke up not feeling well, I can only describe it as shock/septic shock signs and symptoms symptoms! my fever must have been through the roof because I was so cold I couldn't even move to get and take some Tylenol! probably about an hour or two after waking up I was able to crawl and take some Tylenol and instantly went back to bed or passed out I woke up a hour later with nausea and vomiting probably once my fever started to come down when making my way to the bathroom I was having trouble standing up from the fever or blood pressure I can't be certain because I wasn't able to take my blood pressure. after my vomiting had subsided I took a 1000 mg of Tylenol and didn't wake up until the next day where signs and symptoms are evident but not severe as the previous night |
| 982933 | 1/28/2021 | OH | 76 | F | 1/28/2021 | 1/28/2021 | Case was observed for standard 15 minutes. Was released, then fainting heading out to her car to leave. |
| 982897 | 1/28/2021 | TX | 32 | F | 1/27/2021 | 1/27/2021 | Around 9:15am She began complaining of epigastric/midsternal chest pain, non-radiating. She was not short of breath or diaphoretic. She denied nausea but did heave and spit up clear fluid. She had elevated HR 131-86 during a 45minute time period and elevated blood pressure 165-135/90-103 during the same time period. She had what appeared to be a brief fainting spell and experienced some confusion. She was transported to ER/EMS at 10:47am. She was sent home from the ER later in the day. |
| 982840 | 1/28/2021 | TX | 33 | M | 1/28/2021 | 1/28/2021 | Patient passed out. Witness (girlfriend) reports patient's eyes rolled to the back of his head and his foot hit the gas when waiting in observation area. Symptoms started about 5 minutes after vaccination. Patient reports mild lightheadedness and has history of passing out with needles (panic attack). Patient was observed by EMS and was cleared after 20 minutes. |
| 982770 | 1/28/2021 | IN | 62 | F | 1/25/2021 | 1/25/2021 | Itching at injection site Flushing Tachycardia Syncope Unable to control BUE?s. Felt very heavy |
| 982769 | 1/28/2021 | MN | 35 | F | 1/21/2021 | 1/21/2021 | I started having presyncope each time I stood up that night. Then again the next morning at about 7:40am |

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| 982722 | 1/28/2021 | FL | 31 | F | 1/13/2021 | 1/13/2021 | Within 15-minutes of vaccination, patient reported headache, nausea, and dizziness. Stated " room was spinning". No syncope reported. ALS administered 4mg PO Ondansetron prior to EMS arrival. No orthostatic blood pressures. Patient refused EMS transport for further evaluation. |
| 982445 | 1/28/2021 | RI | 24 | F | 1/28/2021 | 1/28/2021 | Near syncope. sweating. Blurred and blacked out vision. Drop in BP. Nausea. Slight chest pain when resolving. |
| 983273 | 1/28/2021 | IL | 43 | F | 1/27/2021 | 1/28/2021 | Patient passed out, lost consciousness for an unknown period of time and hit their head. |
| 977543 | 1/27/2021 | CA | 22 | F | 1/26/2021 | 1/26/2021 | 3:00pm arm soreness 5:00 pm total body soreness 6:00pm fever and chill through the night, unable to sleep 8:00pm lack of blood flow to toes, became cold white, then purple 11:00 pm fainting spells whenever I try to get out of bed 5:00am headache with aura |
| 977719 | 1/27/2021 | WI | 36 | F | 1/26/2021 | 1/27/2021 | The morning after 2nd dose of COVID 19 Moderna vaccination I felt nauseous and fainted. I passed out for about 2 minutes. In addition I had arm pain at site of injection and general fatigue. |
| 977813 | 1/27/2021 | NY | 24 | F | 1/12/2021 | 1/13/2021 | (Vaccine at 5pm 1/12/21) That night, 2am on 1/13/21, a fever of 101 developed. At 7am that morning (still 1/13) fever of 101, chills, rash on injection site, vomiting, diarrhea, and 2 syncope episodes (unconscious 1-2 minutes each time). Symptoms were gone by late evening (1/13), and completely gone by the next day (1/14). Tylenol and flu & cold medication given throughout the time of the fever. |
| 977829 | 1/27/2021 | CA | 47 | F | 1/25/2021 | 1/25/2021 | 1st night 01.25.20, Fever 101. now .low grade all day. Dizzy, Body Aches. Feeling of ?stabbing? Pins and needles in fingers and toes, felt like fainting, blacking out during this time. Loss of taste today, 01.27.21. |

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| 978123 | 1/27/2021 | CO | 76 | F | 1/26/2021 | 1/27/2021 | Pt states she got her second Moderna COVID19 vaccine in her LUE yesterday 1/26/21. She developed a low grade fever and nausea last night. Today, 1/27/21, around 0800, pt states that she fainted, fell on her left side and injured her L elbow. She states that her husband found her and said it appeared as if she was having a "mini seizure". Husband states pts fainting/seizure episode lasted for 15-20 seconds. Pt states that her L elbow pain was 7/10, but is currently 2/10 and she is now experiencing some tingling in her L third and fourth fingers. Pt denies any hx of a seizure and is currently able to get up and walk around. Pt speaking in full and coherent sentences while on call. Pt advised by triage RN and PCP to go to ER for an evaluation |

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| 978313 | 1/27/2021 | FL | 66 | F | 1/6/2021 | 1/6/2021 | Tiredness; A sore arm/Arm was a little sore; Dizziness; Passed out; Chills; Tremor in fingers; A headache; This is a spontaneous report from a contactable Nurse (patient). A 66-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; Batch/lot number: EH9899, expiry date: unknown), via an unspecified route of administration on 06Jan2021 10:30 at single dose (Right upper arm) for COVID-19 immunization. Medical history included Blood pressure (takes blood pressure medication). The patient's concomitant medications included blood pressure medication. The patient experienced a sore arm, chills, tremor in fingers and a headache when she came home from being vaccinated. The morning after, she experienced dizziness, tiredness and passed out. She then checked her blood pressure and it was fine and then she went to bed and slept all day. She got up around 7 pm and was fine. It was further reports that the patient received first COVID Vaccine on 06Jan2021. She came home and was fine. Arm was a little sore. During night had chills and noticed fingers had tremors. Had a bad headache. Woke up in morning and went to do usual things. Was dizzy and passed out. Woke up on floor. Husband helped her back into bed and she slept the whole day. After that she was absolutely fine. They were curious, but a little bit concerned about taking the second dose. Advised patient to follow up with primary care physician. She went to primary care physician yesterday. Primary care physician advised her to take the second dose of COVID Vaccine stating he didn't see why she couldn't take it. HCP Details: Address and email address are unknown Received first dose of COVID Vaccine on 06Jan2021 around 10:30. Chills: began at 23:00 Fingers had tremors: began 23:00 Bad headache: did not provide time of onset Dizzy and passed out: 08:00 Woke up absolutely fine on 07Jan2021 around 19:00 Indication: 66 years old and it was available to her Causality: Yes, because she was fine before then History and Investigations: Takes blood pressure medication, but blood pressure has been normal. Product name not provided by caller. Vaccination facility type was at a skilled nursing facility. The outcome of the events was unknown. Chills, Tremor in fingers, headache, Dizziness, and Passed out were reported as Medically significant events. Reaction assessed for Chills, Fingers had |

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tremors, Had a bad headache, Dizzy, and Passed out. Source of assessment: Primary Source Reporter, Method of assessment: Global Introspection, Drug result: Related.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported events including chills, tremor in fingers, headache, dizziness, and passed out, and the administration of COVID 19 vaccine, BNT162B2, based on the reasonable temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.

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| 977516 | 1/27/2021 | MO | 52 | F | 1/20/2021 | 1/21/2021 | this is a report of my personal experience I received the 2nd dose of the Moderna Covid Vaccine Wednesday January 20th at approximately 4:30pm Cox North. The injection was painful, the person administering the injection inserted the needle VERY slowly, and then pressed the plunger VERY slowly. However, other than injection site pain, I had no symptoms at that time. I then went home and went to bed for the evening at approximately 6:30pm. The following morning, Thursday January 21st, I woke up at 5am (normal time). Before getting up, my stomach felt "funny" mild nausea. When I stood up, I experienced weakness, mild lightheadedness, and nausea; and sat back down IMMEDIATELY. I then stood up to walk to the restroom with the intention to take Tums to settle my stomach. I walked approximately 12 feet, put one tums in my mouth and immediately passed out. (my partner reported that I was unconscious for approximately 2 full minutes). When I regained consciousness I was very disoriented. (did not know where I was, what day it was) I could not stand, and could not use my arms. My partner picked me up and physically put me back in bed. I was unable to roll over on my own. (he then called my supervisor to report the event. My supervisor called him back after speaking with the Nurse who advised "bed rest and hydration") I slept on and off for the next 5 hours. at which time I attempted to sit up. I was unable to remain upright, but could sit in a recliner at that time. I was unable to hold a bottle of water on my own until approximately 2pm. I had no headache, no fever, no nausea (after the initial 5am experience) but DID experience extreme muscle weakness until approximately 2pm Thursday January 21, 2021. (too weak to chew food) Friday January 22nd, I felt "fine", but still mild tiredness. (I was told by our office manager that I should fill out an RL to report my experience) |
| 978621 | 1/27/2021 | MO | 38 | F | 1/20/2021 | 1/20/2021 | Shot recieved Wednesday. By Wednesday night, I had a headache (forehead and back of neck) and fatigue. Friday I became dizzy, and had 2 near fainting spells (this included dizziness, weak muscles, and slight loss of sight). I became achy (back and shoulders) and my headache continued. These dizzy spells and headaches have continued for 6 days. The dizziness is starting to subside, however the headache and fatigue remains. |

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| 977181 | 1/27/2021 | NC | 43 | F | 1/20/2021 | 1/21/2021 | SYNCOPE EPISODE (FAINTED AND FELL TO FLOOR, CAUSING LIP LACERATION AND FRACTURED TEETH), RIGORS, CHILLS, TACHYCARDIA |
| 978535 | 1/27/2021 | WA | 34 | F | 12/30/2020 | 1/1/2021 | Trachycardia, syncope, dizziness, facial swelling, full body numbness, rash over arms |
| 977421 | 1/27/2021 | VA | 29 | F | 1/26/2021 | 1/27/2021 | Severe fatigue, paresthesias, and pre-syncope if tries to leave a supine position. |
| 977412 | 1/27/2021 | | 37 | M | 1/8/2021 | 1/8/2021 | Chills, headache, dehydration, syncope - 12 hours post-dose |
| 977380 | 1/27/2021 | MA | 34 | F | 12/24/2020 | 12/24/2020 | info from incident rpt-approximately 5 minutes after receiving Moderna Vaccine at the employee clinic, pt c/o nausea, and dizziness. Pt began dry heaving and hyperventilating, became very weak and ? LOC for a few second. Symptoms resolved in about 45 minutes without medicine. No hives or angioedema noted, no difficulty breathing once she stopped hyperventilating; telephone call with employee: states got vaccine on 12/24- within 15 minutes felt dizzy, face "felt big", passed out, was put on stretcher, woke and vomited, was still feeling nausea so went home; had fever the next day, lost appetite, feeling fatigued, nausea, yesterday (12/29/20) felt weak -states was covid + in March 2020, had another test recently which was negative, |
| 977363 | 1/27/2021 | MA | 34 | F | 12/26/2020 | 12/26/2020 | info from incident rpt-approximately 5 minutes after receiving Moderna Vaccine at the employee clinic, pt c/o nausea, and dizziness. Pt began dry heaving and hyperventilating, became very weak and ? LOC for a few second. Symptoms resolved in about 45 minutes without medicine. No hives or angioedema noted, no difficulty breathing once she stopped hyperventilating; telephone call with employee: states got vaccine on 12/24- within 15 minutes felt dizzy, face "felt big", passed out, was put on stretcher, woke and vomited, was still feeling nausea so went home; had fever the next day, lost appetite, feeling fatigued, nausea, yesterday (12/29/20) felt weak -states was covid + in March 2020, had another test recently which was negative, ? whether can get the second vaccine. consult allergy - ok for vaccine 30 min watch ; |

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| 977201 | 1/27/2021 | AL | 45 | F | 1/25/2021 | 1/25/2021 | Systemic: Exhaustion-Medium, Systemic: Fainting-Medium |
| 977163 | 1/27/2021 | NC | 54 | F | 1/25/2021 | 1/25/2021 | Systemic: Nausea-Medium, Systemic: Fainting-Severe, Systemic: Other- After 2nd dose of covid-19, Patient reported tingling, blood pressure was 198/102, high pulse, tingling in the arm and hand, chest pain, dizziness |
| 976812 | 1/27/2021 | PA | 26 | F | 1/12/2021 | 1/12/2021 | syncope; Fever; Joint pain; Weakness; Dizziness; Tachycardia; Fatigue; This is a spontaneous report from a contactable nurse (patient). A 26-year-old female patient (not pregnant) received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot number EL3302 via an unspecified route of administration in left arm, on 12Jan2021 17:00 at single dose for covid-19 immunisation. Previously the patient received the first dose of BNT162B2 on 22Dec2020 at 17:00, lot number EJ1685, in left arm, for covid-19 immunisation. The vaccine was administered at Hospital Facility. No other vaccine was administered in four weeks. No COVID prior vaccination. COVID was not tested post vaccination. No known allergies. Medical history included asthma and postural orthostatic tachycardia syndrome, from an unknown date and unknown if ongoing. The patient's concomitant medications were not reported. On 12Jan2021 the patient experienced syncope, fever, joint pain, weakness, dizziness, tachycardia, fatigue. The events required Physician Office visit. The patient was not treated for the events. The outcome of the events was resolving.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported syncope cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate. |
| 978630 | 1/27/2021 | CA | 63 | F | 1/26/2021 | 1/26/2021 | The patient experienced syncope after the first vaccine dose. Has been on thyroid medications for hypothyroidism and on a long-acting beta blocker. |

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| 977139 | 1/27/2021 | MI | 34 | F | 1/26/2021 | 1/26/2021 | Approximately 7 minutes after vaccination I became lightheaded and dizzy. Felt like fainting. Heart rate jumped up to 179 BPM using a pulse oximeter to read and was breathing heavily. Was assisted to a wheelchair and spent a few minutes breathing in through my nose and out through my mouth and after a few minutes of this, my heart rate went back down and the symptoms subsided. As of today (1/27/2021) I am very exhausted. |
| 977309 | 1/27/2021 | IL | 48 | F | 1/27/2021 | 1/27/2021 | Pt fainted after 5 minutes in receiving the vaccine. |
| 981007 | 1/27/2021 | CA | 41 | F | 1/20/2021 | 1/21/2021 | I had one episode of syncope in the morning on 1/22/2021 after waking up in the morning, two days after the 2nd shot but within 48 hrs. Other than that, I just had a moderate left arm pain (starting on 1/21/2021). Also generalized low energy level (starting on 1/21/2021) and very mild muscle soreness especially with both legs (starting on 1/22/2021). |

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| 976544 | 1/27/2021 | TX | | F | 1/8/2021 | 1/11/2021 | Fainted; A spontaneous report was received from a consumer concerning a 79-year-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and fainted. The patient's medical history included diabetes, cholesterol, hypertension, and osteoporosis. Concomitant product use reported included unspecified medications for diabetes, cholesterol, high blood pressure, and osteoporosis. On 08 Jan 2021, approximately three days prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: VW7392) intramuscularly in the arm for prophylaxis of COVID-19 infection. On 11 Jan 2021, the patient fainted at 3:00 am and again at 7:00 pm. No treatment information was provided. Action taken with mRNA-1273 in response to the event was not reported. The outcome for the event, fainting, was not reported.; Reporter's Comments: This case concerns a 79 year old female subject, with medical history of diabetes, cholesterol and hypertension, who experienced a serious unlisted event of syncope. The event occurred 3 days after the first dose of mRNA-1273. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. However a definitive assessment is confounded by the patient's history of diabetes and hypertension. |
| 978920 | 1/27/2021 | AZ | 76 | M | 1/24/2021 | 1/25/2021 | 1. OK day of inoculation 2. Next day 1/25/21, 7:30 am, Blood Pressure (BP) was 141/76. Temp 98.1, pulse 88. (note my normal temp is 95.5-96.5) 8:30 am BP dropped to 66/46, cold sweat, dizziness. Woozy, passed out, but woke when I hit the deck. 9:26 am, BP up to 85/50, 80 bps, 96.2 degrees. 10:08 am, BP 98/55, 82 pps, temp 96.1. 1:23 pm, BP 88/54, temp 96.1. 6:30 pm, BP 103/60, 82 bps. 8:19 pm, BP 156/72, 80 bps. Temp up to 100.4 degrees. 11:28 pm, BP 125/65, 68 bps, temp 98.4 degrees 1/26/2021: 5:15 am, BP 123/70, 71 bps, temp 99.7 degrees 8:14 am, BP 110/60, 64 bps, temp 97.4 8:02 pm, BP 124/70, 72 bps, temp 97.6 1/27/21: 1:06 am, BP 132/75, 62 bps, temp 97.6. 7:35 am, BP 123/75, 63 bps, temp 95.3 (back to normal range) 1/27/21 |

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| 980111 | 1/27/2021 | | 40 | F | 1/26/2021 | 1/26/2021 | Constant Fever despite taking Tylenol around the clock, 103.1. Chills, syncope, seizure, extreme fatigue, nausea, headache, loss of appetite. |
| 980054 | 1/27/2021 | | 26 | F | 1/27/2021 | 1/27/2021 | PATIENT FAINTED A COUPLE OF MINUTES AFTER THE SHOT AND WAS BACK TO HER CONSICOUESNESS AFTER 2-3 SECONDS. |
| 980037 | 1/27/2021 | | 31 | F | 1/26/2021 | 1/26/2021 | Pt developed heart pain, tinging in the arms and legs, increased blood pressue. Her blood pressure was taken multiple times ranging from 145/80 to 155/95. After approximately 40 minutes after the vaccine, the patient stood up and fainted. We kept the patient on the floor as she was light headed and not very responsive. At that time, 911 was called. She was taken tp the ER and discardged the same evening. |
| 980027 | 1/27/2021 | | 49 | F | 1/25/2021 | 1/26/2021 | Patient woke up to use restroom overnight, and nearly fainted. Blood pressure taken a few minutes later 85/61. Took about 10-15 minutes for lightheadedness/dizziness to subside. |
| 980007 | 1/27/2021 | CA | 33 | F | 1/16/2021 | 1/25/2021 | Redness , itching and swelling started 2 days ago. It has continued to increased. Today dizziness and nausea. Feel very weak like fainting is possible |
| 979739 | 1/27/2021 | CO | 42 | F | 1/21/2021 | 1/21/2021 | Severe chills, severe muscle and joint pain, extreme lethargy, fainting |
| 979727 | 1/27/2021 | CA | 34 | F | 1/27/2021 | 1/27/2021 | Near Syncope episode, Sweaty, Heart rate (pulse) slowed down to 50. 10:14 got Vaccination and abt 10:25 woke up in ER . Reported by Nurse who gave Vaccination Injection. |
| 979594 | 1/27/2021 | | 80 | F | 1/27/2021 | 1/27/2021 | Patient observed slumping over in chair. When assessed she stated she felt lightheaded and was diaphoretic. Blood pressure obtained at 1400, BP 63/34, HR 84. EMS contacted and dispatched. Patient experienced syncope. 1405 EPI administered per protocol. 1414 vital signs as follows: BP, 168/135; HR 60. |

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| 979162 | 1/27/2021 | FL | 65 | F | 1/25/2021 | 1/25/2021 | When I signed up for the vaccine, the website said that i was at high risk for the vaccine and would need to wait 15-30 minutes after the injection. I checked with doctor re: this warning and she felt the vaccine was still beneficial but to do my research and make a decision. I received the vaccine at the Center. I sat down as instructed. 5 minutes later, something felt off and I removed my protective visor. A paramedic came over about a minute later and asked if i was ok. I said that i didn't feel well. He said that he was going to get a chair with wheels for me and at that time i must have passed out. The next thing that i remember was waking up laying on the floor. My husband said that there were 4 paramedics in attendance. The primary paramedic was telling me that my BP was 72/60. An ekg was being run, an iv inserted and run full force. they checked my blood sugar which was fine. The primary paramedic kept talking to me to check my level of consciousness. I was there for quite a while. Not sure who the paramedics checked with, but they decided that i needed to go via ambulance to the hospital. The paramedics were very concerned that the ambulance go to the back door to pick me up so others getting the vaccine would not be frightened. I was transported to Medical Center for further evaluation. I was there for a few hours and my labwork was normal. EKG and chest xray were completed as well as cardiac monitoring. I called doctor's office the next morning to notify her of the event. It was very scary!!! |
| 979563 | 1/27/2021 | TX | 97 | F | 1/13/2021 | 1/13/2021 | Systemic: Cardiac Disorder (diagnosed by MD), Systemic: Nausea-Severe, Systemic: Vomiting-Severe, Systemic: Fainting-Severe, Systemic: hypothyroidism vitmain d deficiency; symptoms lasted 1 day |
| 978942 | 1/27/2021 | | 85 | F | 1/18/2021 | 1/18/2021 | When sitting in chair during observation patient passed out. Syncopal episode. EMS was activated and patient taken to hospital for further evaluation. |

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| 979077 | 1/27/2021 | KS | 40 | F | 1/27/2021 | 1/27/2021 | Around 10 minutes after injection, she developed symptoms that included nausea, dizziness, and syncope. Symptoms progressed over time until she seemed almost catatonic at times including delayed responses, staring straight ahead (later she closed her eyes), slurred speech. She kept repeating, "I feel like jelly" and that she was very tired. Pharmacist gave her 25 mg diphenhydramine at 10:55 am. Around 11:10 the facilities administer called 911 at the request of (PharmD). |
| 979227 | 1/27/2021 | ME | 57 | M | 1/24/2021 | 1/24/2021 | Systemic: Exhaustion, Systemic: described by the EMT as a vasovagal reaction. patient passed out and had seizure like reactions. was unresponsive and given epi pen. after EMT arrived, patient was monitored and allowed to leave; symptoms lasted 1 day |
| 979228 | 1/27/2021 | CA | 21 | F | 1/27/2021 | 1/27/2021 | Per witness, patient "fainted", falling out of chair shortly after arriving to recovery area. Upon writer arrival patient was diaphoretic, A&Ox4, V/S WNL (121/80, HR 99, O2 100%, Resp. 18), patient reports hx of anxiety and untreated syncopal episodes. EMS activated. Upon EMS arrival, VS 117/62, HR 116, Resp. 18, O2 100%, finger stick blood sugar 96. Patient transported to ED by EMS at own request. |
| 979235 | 1/27/2021 | MT | 66 | F | 1/22/2021 | 1/22/2021 | Pfizer-BioNTech COVID-19 Vaccine EUA Vagal Near-Syncope |
| 979260 | 1/27/2021 | FL | 33 | F | 1/26/2021 | 1/26/2021 | Around 11pm approximately 15 hours or so after the injection, I began with severe arm pain at the sight of injection (could not raise arm), body aches, fatigue, fever, and I ended up fainting. I fainted after trying to sit up, for maybe a few seconds, before coming to. Then proceeded with shaking and cold sweats through the night. Next day is better, but still body aches, fatigue and very small fever of 99.5 |

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| 979301 | 1/27/2021 | ID | 51 | F | 1/18/2021 | 1/18/2021 | Client states that on 01/18/2021 after receiving the Covid vaccine client started having cramping in Her R-foot. Finalt was able to sleep. Went to work that morning having some body aches. around 9:00 am states she passed out. Her boss called for the EMT's and they called an ambulance and client was transported to the hospital. Stayed in the hospital ER all day and returned home around 4:00pm that same day. She stated that the medical provider said they could find nothing that could have caused the reaction other than she had received the Covid vaccine the day before. |
| 979465 | 1/27/2021 | NY | 73 | F | 1/25/2021 | 1/25/2021 | Injection site pain, Nausea, light headed same day (1/25//2021) after injection. That evening, Nausea, fever and chills. Took Tylenol. Next day (1/26/2021) Nausea, fever and chills continued. On 1/27/2021 in the morning became faint and weak and fell or fainted. Due to fall hit her head. Daughter living in same house treated her with Ice Pack and brought her to Hospital ER for evaluation. Hospital identified fever and began antibiotic treatment and fluids. |
| 979552 | 1/27/2021 | MA | 23 | M | 1/26/2021 | 1/26/2021 | Systemic: Fainting-Severe; symptoms lasted 1 day |
| 973822 | 1/26/2021 | PA | 80 | F | 1/23/2021 | 1/24/2021 | Passed out the morning after receiving the vaccine without any dizziness or prior warning |
| 974468 | 1/26/2021 | CA | 81 | M | 1/18/2021 | 1/18/2021 | Syncope. Patient presented to ED due to syncope in the shower. Patient received 2nd dose of Covid vaccination this afternoon. Patient also received dialysis today. EKG sinus rhythm with 1st degree AV block. BP WNL, BG 132. Admitted. It is possible that patient had mild hypovolemia following dialysis or vasovagal event, and less likely by Covid vaccine thus got discharged. Patient had a ground level fall on next day at ALF. No acute findings noted |

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| 974589 | 1/26/2021 | KY | | F | 1/8/2021 | 1/8/2021 | 5 - 6 bowel movements; A little achy; Passed out; Dizziness; Arm tingling; Shaking; Chest burn; Triggered acid reflux; Stomach rolling around; Vision was blurry; Eyes bloodshot; Weakness; Funny feeling; Felt like a heart attack from the bad heart burn; Headache; Sore arm; Nausea; A spontaneous report was received from a consumer concerning a 55-years-old, female patient who received Moderna's COVID-19 Vaccine, and who experienced passed out, headache, sore arm, dizziness, arm tingling, shaking, chest burn, triggered acid reflux, stomach rolling around, 5 - 6 bowel movements, vision was blurry, eyes bloodshot, a funny feeling, nausea, weakness, achy and felt like a heart attack from bad heartburn. The patient's medical history included acid reflux. Concomitant medication included lansoprazole. On 08 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number 012L20A) at 13:07 intramuscularly in the deltoid muscle of her left arm for prophylaxis of COVID-19 infection. On 08 Jan 2021, right after the first vaccination, the patient reported that she got a headache and sore arm but over all felt okay. As the day went on, she got dizzy and lightheaded. She went to bed around 22:30 but had to get up to use the bathroom. As she was getting up, she felt bad to the point where her husband asked her if she was okay, which she told him that her head felt funny and dizzy, and a couple of seconds later she couldn't see him anymore as if her vision was going blurry. Her husband took her to the couch, and she blacked out or passed out for a few seconds according to her husband. Shortly after she had aroused, her husband noticed that her eyes were bloodshot, and she said she felt weak, she was shaking, and her arm was tingly. At that time, her husband took her to the emergency room (this was about 12 hours after she got the Moderna COVID-19 shot). On arrival to the emergency room she felt confused and shaky. Shortly after arrival to the emergency room she was better and the worst of it was subsiding. The emergency room (ER) nurse said she could take paracetamol. The patient stated that she felt like she was physically there, but she was not mentally there. That day, the patient was discharged from the emergency room. Once home she had 5-6 bowel movements throughout the night (but not diarrhea), her stomach was rolling around almost as if she had a |

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stomach virus, nausea, bad acid reflux to the point where her chest really burned. She felt like she was having a heart attack from the bad heart burn. She ended up taking lansoprazole to help. On 09 Jan 2021, her head was still hurting while eating breakfast, so she took paracetamol, and it helped. She was a little achy but not a whole lot; it wasn't bad. On 10 Jan 2021, she felt a little better but did still feel weak and shaky; however, her headache was gone. On 11 Jan 2021, she had a funny feeling and dizziness. Action taken with mRNA-1273 in response to the events was unknown. The events of passed out and vision was blurry were considered resolved on 08 Jan 2021. The event of arm tingling was considered resolved on 09 Jan 2021. The event of headache was considered resolved on 10 Jan 2021. The event of shaking was considered resolved on 11 Jan 2021. The outcome of the events sore arm, dizziness, chest burn, triggered acid reflux, stomach rolling around, 5 - 6 bowel movements, eyes bloodshot, and funny feeling were unknown.; Reporter's Comments: This case concerns a 55-year-old female patient with medical history acid reflux who experienced a serious event of passed out and non-serious events of dizziness, felt weak, shaking and her arm was tingly, confused, 5-6 bowel movements through the night, nauseous, triggered her acid reflux, felt like she was having a heart attack from the bad heart burn, chest burn, vision blurry, eyes bloodshot, funny feeling, headache, sore arm, little achy and weak, within one day of the administration of the first and only dose of the mRNA-1273 (Lot number 012L20A, Exp. date: unknown). Based on temporal association between the use of the product and the start date of the reported events and the absence of any other etiology factors, a causal association cannot be excluded. The events of headache and sore arm are consistent with the known safety profile of the vaccine.

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| 974583 | 1/26/2021 | AZ | 82 | F | 1/7/2021 | 1/7/2021 | Fainted; A spontaneous report was received from a consumer, who was an 82-year old, female, patient who received Moderna's COVID-19 vaccine (mRNA-1273) and fainted. The patient's medical history was not provided. No relevant concomitant medications were reported. On 07 Jan 2021, approximately 6 hours prior to the onset of the event, the patient received their first of two planned doses of mRNA-1273 (Lot number: 025L20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 07 Jan 2021 at 19:30, the patient fainted. No treatment information was provided. Action taken with mRNA-1273 in response to the event was not reported. The outcome of the event, fainted, was unknown.; Reporter's Comments: This case concerns a 82 year old female patient who experienced a serious unexpected event of Syncope. The event occurred 6 hours after first dose of mRNA-1273. Very limited information regarding this event has been provided at this time. Based on temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. |
| 974552 | 1/26/2021 | MD | 49 | F | 1/25/2021 | 1/26/2021 | At about 3 -4 am on the morning after the vaccine I went to the Bathroom to Urinate, upon rising I slumped to the floor and passed out. I also had sweating and profound weakness. I crawled back to the bedroom and was placed in bed with assistance. I also experience feverish ness, sweating, chills, insomnia, muscle aches, and nausea throughout the night. The next morning I am able to stand, eat, and walk. I still have a headache, muscle aches, and fatigue. It is now 1pm on 1/26. |
| 974502 | 1/26/2021 | NM | 60 | F | 1/23/2021 | 1/23/2021 | Moderna COVID-19 Vaccine EUA 1/23/21: in the night, experied: fever; chills; fatigue; ;muscle pain; body aches; diarrhea; dizziness; headache, and passed out twice. 1/24/21: chills, muscle pain, weak, fatigue, light headed 1/25/21: unable to go to work (teacher): ongoing fatigue, feeling wrung from intensity of reaction; 11:00 pm - heart racing; chills 1/26/21: back to work; stablizing; arm still very sore |

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| 974498 | 1/26/2021 | CA | 28 | F | 1/19/2021 | 1/19/2021 | Vertigo. Patient presented with lightheadedness and dizziness with associated body tremors. Symptoms started 5-10 minutes after patient received her 2nd Pfizer vaccine dose. Patient has h/o vertigo and reported vertigo, headache, nausea, and emesis following the first vaccine dose. Unsure if syncope 2/2 vaccine vs vaccine administration anxiety vs h/o vertigo. NS bolus, Benadryl, Ativan, Tylenol, and Motrin were given. Normal EKG. Symptoms improved and patient discharged from the ED. |
| 975011 | 1/26/2021 | NY | 43 | F | 1/25/2021 | 1/26/2021 | vomiting, dizzy, severe headache, ?passed out?, currently remains tired with headache she has taken ibuprofen |
| 974130 | 1/26/2021 | AZ | 48 | F | 1/25/2021 | 1/26/2021 | Sudden onset of nausea, vomiting, diarrhea, shortness of breath, uncontrolled shaking and vasovagal response with near syncope episode. Gave Diphenhydramine approximately 25 minutes after onset. |
| 974128 | 1/26/2021 | AL | 63 | F | 12/29/2020 | 12/29/2020 | Patient age 63 presented for her second dose of moderna vaccine. She reports after 1st dose several hours after injection she had fatigue and some swelling in her throat with a palpable lump and difficulty swallowing. The morning after woke up with dizziness and abdominal pain and passed out. She reported itching about 3-4 days after dose |
| 974053 | 1/26/2021 | NY | 45 | F | 1/26/2021 | 1/26/2021 | Immediately after 2nd injection, mouth tingling, felt cold like she might pass out. Never passed out. Felt better minutes later. Reports rash to body 2 weeks after 1st injection. |
| 974034 | 1/26/2021 | OK | 48 | F | 12/31/2020 | 1/1/2021 | Within 3 hours of the event, started having expected side effects of headache, bodyaches. That night had difficulty sleeping and new onset neck pain as well. Finally took tylenol at 3AM. Woke up at 9:15 and walked from bedroom to kitchen at which time had severe orthostatic hypotension with near sycope that did not progress to full syncope due to lying down quickly. Continued with tachycardia for several days and mild shortness of breath for two days. That evening, had new onset RUQ abdominal pain for 2-3 hours that resolved. |

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| 973189 | 1/26/2021 | WI | | F | 12/17/2020 | | extreme episode of over heating (at night); almost passed out; This is a spontaneous report from a contactable nurse. A 35-year-old non-pregnant female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: Ej1685), via an unspecified route of administration, on her left arm on 17Dec2020 at a single dose for COVID-19 immunisation. Medical history included asthma, hypothyroidism, attention deficit hyperactivity disorder (ADD) and known seasonal allergies; all from an unknown date and unknown if ongoing. The patient previously took erythromycin and experienced allergies. On day 5 after both shots (unspecified date), patient had an extreme episode of overheating (at night) the first time, got up and almost passed out. There was no treatment received for the events. The outcome of the events was recovering. |
| 973833 | 1/26/2021 | KY | 38 | F | 12/30/2020 | 12/30/2020 | Within minutes had shortness of breath, elevated heart rate, dizziness, flushed feeling and almost passed out. Had fuzzy head, fatigue, elevated heart rate, very sore injection site, and headache feeling for 24-48 hours. 24 hours after had chills and flushed feelings, body aches and soreness, dizziness. 3-5 days after still have elevated heart rate and had swollen lymph nodes under arm of injection and swollen lymph nodes in face with extreme soreness. Was instructed by MD to not take second dose. |

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| 973554 | 1/26/2021 | WI | 35 | F | 1/6/2021 | 1/10/2021 | <p>day 5 of the second shot I woke up extremely hot, felt like my skin And everything around me was burning/overheating; I also had mild hot flashes after the second vaccine and headaches; I also had mild hot flashes after the second vaccine and headaches; This is a spontaneous report from a contactable nurse (patient). A 35-year-old female patient (pregnant: No) received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: Ej1685) intramuscular at left arm on 06Jan2021 10:30 at single dose for COVID-19 immunization. Medical history included Asthma, hypothyroidism, ADD. Concomitant medications were not reported. Patient had known allergies to erythromycin and seasonal allergies. it was unknown if covid prior vaccination. There were other medications in two weeks. Patient used took first dose of BNT162B2 (lot number: Ej1685) on 17Dec2020 at left arm at single dose for COVID-19 immunization and experienced extreme episode of overheating (at night) the first time, got up and almost passed out. It was reported day 5 after both shots patient had an extreme episode of overheating (at night) the first time she got up and almost passed out. day 5 of the second shot she woke up extremely hot, felt like her skin and everything around her was burning, it was inescapable, she had to open a window and wait it out, lasted about 30 minutes. she also had mild hot flashes after the second vaccine and headaches. adverse event start date was 10Jan2021. No covid tested post vaccination. no treatment received for the events. Patient was recovering from the events.</p> |

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| 973515 | 1/26/2021 | RI | 32 | F | 1/12/2021 | 1/12/2021 | <p>Arm swelling with itchiness; Arm swelling with itchiness; warm to touch at site of injection; severe chills with shaking; severe chills with shaking; 103 fever/ approx 20hrs after injection, fever of 100 or greater for 24hrs with minimal relief with Tylenol; body aches; pains in left flank; the first dose on 20Dec2020/second dose on 12Jan2021; This is a spontaneous report from a contactable Other Healthcare Professional (patient). A 32-year-old female patient (not pregnant) received the second dose of bnt162b2 via an unspecified route of administration on 12Jan2021 10:30 AM at single dose in Left arm for COVID-19 immunisation. Medical history included cardiogenic syncope, no COVID prior vaccination. Concomitant medications included birth control drugs, no other vaccine in four weeks. The patient previously received the first dose of bnt162b2 on 20Dec2020 03:00PM on Left arm for COVID-19 immunization, topiramate (TOPAMAX) and experienced drug allergy, morphine and experienced drug allergy (hives). The patient experienced arm swelling with itchiness and warm to touch at site of injection, severe chills with shaking, 103 fever, approx. 20 hours after injection, fever of 100 or greater for 24 hours with minimal relief with Tylenol, body aches and pains in left flank. The adverse events started from 12Jan2021, 06:00 PM. Therapeutic measures taken for fever included Tylenol, no treatment was received for other events. The outcome of the events was recovering. The patient didn't test COVID post vaccination. Information on the lot/batch number has been requested.</p> |
| 975185 | 1/26/2021 | MO | 54 | F | 12/23/2020 | 12/23/2020 | <p>Employee experienced dizziness, weakness, almost fainted very soon after receiving the vaccine. Employee felt fine the next day.</p> |

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| 973964 | 1/26/2021 | OK | 46 | F | 1/9/2021 | 1/10/2021 | <p>Saturday, 01/09/21 1300-received 2nd vaccine Sunday, 01/10/21 0500 -severe left arm pain, began at injection site, radiated: up and across L shoulder blade area, up neck and into head, down to L fingertips 0600 -all above continued, R knee joint pain (sharp/stabbing) 1400 -all above continued except R knee joint pain; spinal pain and intercostal pain began 1900 -all above continued; TMJ, jaw, and 'tooth' pain began Monday, 1/11/21 TMJ, jaw, and 'tooth' pain, nausea, fatigue, night sweat Tuesday, 1/12/21 TMJ, jaw, and 'tooth' pain, nausea, fatigue, night sweat Went to dentist (scheduled appointment on Monday) for cleaning and thorough exam...exam was normal Wednesday, 1/13/21 continuation of symptoms from 1/12/21, but pain worse, ear pain Thursday, 1/14/21 0630 had eaten a full can of chicken noodle soup. Was sitting and working on CEs for work, had taken medications for the day, but added in hydrocodone, half of a 7.5/325mg tablet and ibuprofen 200mg. Felt a severe wave of nausea. Laid my head down on my arms on the table. Do not remember getting up, but remember walking through the kitchen in front of the refrigerator, reaching up to feel my pulse, felt two beats which were too far apart and thought to myself, "I'm going to faint". Apparently I was able to walk about 6 feet further, but I don't remember it. I don't know what time I fainted, but I think I must have fallen. I woke up sometime after 7, disoriented and my head hurt, lying on the kitchen floor. My husband came to my side after I called out to him about 5 times. I was drenched in sweat and very weak. When firefighters arrived they said my heart rate was 'all over the place', from 46 to I don't know what (did not hear). Ambulance arrived around 0730. Glucose was normal. Was taken for evaluation. Was given IV NS (I think 1000mls). Labwork was drawn. CXR, CT, and EKG. ER Dr recommended I follow up with my cardiologist, as she noted mitral valve regurgitation and thought a Holter monitor would be advisable. CXR and CT normal. EKG normal sinus rhythm, but showed anteroseptal infarct of unknown age, confirmed by cardiologist who read the EKG. Also seen by my PCP at 1430, he checked my ears, as they had been hurting as well, said they were clear. Advised alternating tylenol and ibuprofen Q4-6H. Friday and Sunday 1/15 and 1/16 night sweat, TMJ pain, nauseated, headache, neckache, fatigue, shoulders sore, eyes sore, inner ear pain Sunday, 1/17 0500 woke up,</p> |

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| 976059 | 1/26/2021 | GA | 80 | F | 1/19/2021 | 1/20/2021 | lying in bed, dizzy, clammy palms, chest pain (mid-clavicular, just below left breast, stabbing), night sweat, TMJ pain, nauseated, headache, neckache, fatigue, L & R flank pain, BP 115/70, HR 54 Monday 1/18, Tuesday, 1/19, Wednesday 1/20, Thursday 1/21, Friday 1/22, and Saturday 1/23 varying degrees of: fatigue, nausea, dizziness, TMJ, jaw, and 'tooth' pain, palpitations, and ear pain. TMJ and jaw pain worsens with activity. |
| 974880 | 1/26/2021 | MD | 66 | F | 1/25/2021 | 1/26/2021 | The patient received the Moderna Covid 19 vaccine on 1/19/21 and reported to the pharmacy that during the night on 1/20/21, she passed out. She reported having a mild headache all day but no other problems. She was putting drops in her husband's eyes around 11pm and told him she needed to sit down that she was going to "pass out." Her husband said she did pass out and he called 911. He said she was unconscious maybe 3 or 4 minutes. She woke up alert and knew what had happened. The EMT's checked her out--said she had no temperature, blood pressure was ok, and blood sugar was 280. They told the couple they thought it was probably from the vaccine. They wanted to transport her to the ER to be "checked out" but the patient refused to go. She has not had any problems since the incident except some fatigue |
| 975230 | 1/26/2021 | OH | 68 | F | 1/15/2021 | 1/15/2021 | 12 hours post vaccination - Rigors 22 hours post vaccination - Nausea, syncope, loss of consciousness for ~ 1 minute Treatment - Tylenol Observed by husband (physician) |
| 977050 | 1/26/2021 | LA | 77 | F | 1/20/2021 | 1/21/2021 | Patient self-reported through the hospital. In her own words, "After 2nd dose of Pfizer COVID-19 Vaccine 1/15/21 @ 0630, at 2030 developed generalized aching, chills, weakness and sleepiness. Woke up at 0300, went to bathroom and passed out returning to bed. Awakened soaked in perspiration. Had dry heaves and 1 loose stool. Felt weak and sleepy until 0700, then felt mostly normal. Symptoms relieved by 1000. No other symptoms after that". |
| | | | | | | | admitted to hospital on 21 Jan 21 with Acute cystitis without hematuria; Cardiovascular disease; Diarrhea; ST segment depression; Syncope, unspecified syncope type Discharged on 26 Jan 21 |

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| 976114 | 1/26/2021 | TX | 72 | M | 1/21/2021 | 1/22/2021 | Moderna COVID-19 Vaccine EUA At 9:00 AM on January 22, itching, breaking out in hives on more than 50 % of the body. dizziness, and passed out.. 911 was called and I was taken by ambulance to hospital. Given fluids, and the following medications, Sodium Chloride 0.9% 1000ml by IV. methylprednisolone 125 mg by IVP, famotidine 20mg by IVP, These were started at about 11:00 AM and by 3:pm I was release to go home feeling much better |
| 976033 | 1/26/2021 | GA | 80 | F | 1/19/2021 | 1/20/2021 | The patient received the Moderna Covid 19 vaccine on 1/19/21 and reported to the pharmacy that during the night on 1/20/21, she passed out. She reported having a mild headache all day but no other problems. She was putting drops in her husband's eyes around 11pm and told him she needed to sit down that she was going to "pass out." Her husband said she did pass out and he called 911. He said she was unconscious maybe 3 or 4 minutes. She woke up alert and knew what had happened. The EMT's checked her out--said she had no temperature, blood pressure was ok, and blood sugar was 280. They told the couple they thought it was probably from the vaccine. They wanted to transport her to the ER to be "checked out" but the patient refused to go. She has not had any problems since the incident except some fatigue |
| 976007 | 1/26/2021 | CT | 45 | F | 1/20/2021 | 1/26/2021 | I woke up at 1 am to go to bathroom , I fainted in hallway , waking up husband. I then came to , didn?t feel good and vomited 4 times with no energy. The following day facial swelling at 1 am . Could be from fall . Very bad migraine until Saturday afternoon. |
| 976001 | 1/26/2021 | MI | 56 | F | 1/25/2021 | 1/25/2021 | Moderate headache immediately after vaccination, sore arm; Excedrin taken 1400 hrs. 12 Hours P vaccination: chills; light headedness w/subsequent syncope; ostensible "sneezing" during syncope (reported by family member); emesis; errythema over face, arms, chest (vasculitis-like appearance); severe headache, multiple joint pain. Vasovagal response continued 11 hrs later. Treatment: hydration as tolerated, sleep, Excedrin at 24 hrs P vaccination, and 4 hrs later. General fatigue and feeling of pre-syncope persisted between 24 hr mark and 32 hr mark P vaccination. Symptoms resolved by 36 hrs P vaccination. |

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| 975887 | 1/26/2021 | MS | 38 | F | 1/26/2021 | 1/26/2021 | About 25-30 minutes after I left the site I had chills and started feeling weird. I had to pull over because I started to black out. Was seeing stars, ears ringing, sweating, and feeling heavy. Almost passed out completely. Slurring words while talking to 911. Went to ER. Have felt heavy, arm sore, heart rate high, and tired after this event today. |
| 975407 | 1/26/2021 | WA | 31 | F | 1/25/2021 | 1/26/2021 | Was fine immediately post vaccine. Drove home and proceeded with a normal rest of the day at home. Went to sleep around 10 pm. Woke up at 4 am with my arm very sore. Got up to take meds for my arm pain and once I got to the bathroom felt pale, sweaty, nauseous and had chills, very weak - an overwhelming sense of not feeling right and strong fatigue. I sat on the toilet and went to the bathroom (urination and defecation) but did not have the energy to wipe properly. I stood up and turned on the sink faucet, took my meds with a few sips of water and next thing I remember is me laying on the bathroom floor confused and with my ears ringing. I figured I had laid down but then I realized the toilet was running and the sink faucet water was still running and I looked in the mirror and had a cut bleeding on my chin that I had no idea was there. Then I realized that I must have passed out while standing at the sink. I put a bandaid on the cut and went back to bed. In the morning when I was able to assess my self better, I realized during my fall/ fainting episode I had bitten my lip, cut my chin, had abrasions on my right thigh and left shoulder and bruised my right knee and some poop in my underwear I hadn't wiped properly at the time, that's how out of it I was. I have never fainted or passed out ever before in my 31 years of life. I live alone and it was a very scary incident for me. Luckily my injuries were minor and I have recovered but I felt like I might die during the episode. My body had a very strong adverse reaction 12 hours post vaccine. |

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| 975817 | 1/26/2021 | AR | 66 | F | 1/19/2021 | 1/19/2021 | Patient states worst of side effects started about 11:20pm that night. Patient went to bed after getting home about 8pm. Patient had pain that started in arm where she got shot, then hurt in right leg, and then left leg and arm. Patient passed out at one point, causing her to fall and hit head on bathroom floor. She did not seek any medical attention at that time and has not since her vaccine. She had extreme thirst from 8pm until 3am. She could not sleep due to pain. Patient was foggy after that for several days, but she is back at work today and feels much better. Patient doesn't think she had fever. She did have a lot of hot/cold flashes. Patient states she is entering information into the VAERS online system herself since she knows all her symptoms. Patient is wanting to speak to someone that knows about Mold toxicity and if it correlates to the covid Vaccine. She states she had the same symptoms when she had mold toxicity before. States she had a mold toxin dump at that time when she lived in Dallas and was given an IV which caused symptoms to stop. Patient states she will look up someone if she needs to and does not want the provider to do any leg work. She has several books and has ordered more. When this occurred before, she had hyperbaric oxygen therapy and believes this pushed toxins out of her cells into her body |
| 975800 | 1/26/2021 | MA | 40 | F | 1/21/2021 | 1/21/2021 | Roughly 25 minutes after getting vaccine I passed out and when I came to my throat felt like it was closing and I was very itchy on my neck and chest . Had hives |
| 975746 | 1/26/2021 | NY | 60 | F | 1/25/2021 | 1/25/2021 | The patient experienced syncope within 30 minutes after receiving the covid-19 vaccine. At 2:30pm, she felt dizziness, her head was spinning, weakness of the arms, and slurred speech. Her FS was at 108 (Normal), BP 195/105 (Extremely high), Pulse 91, O2 saturation was at 100%. At 2:48PM, her BP lowered to 167/92. At this time, she can smile, she can put her hands up, she can kick her feet and she can opened/closed her eyes. Due to her high BP, Doctor requested that the should go to the ER via the ambulance. |
| 975650 | 1/26/2021 | CA | 95 | F | 1/26/2021 | 1/26/2021 | Patient fainted on the toilet. EpiPen brought her back to consciousness. |

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| 975630 | 1/26/2021 | NY | 60 | F | 1/25/2021 | 1/25/2021 | Syncope,dizziness, head spinning,weakness of arms slurred speech BP 195/105 PULSE 91 Repeat BP 167/92 |
| 975436 | 1/26/2021 | NJ | 83 | F | 1/22/2021 | 1/22/2021 | Patient was observed for 15 minutes after the injection time. Patient left with her daughter to the car and while she was in the car she had a vasovagal syncope. This last for couple seconds. Vital signs were stable except for her pulse Ox at RA was 80%. The ambulance was called and the EMT kept patient on the ambulance monitoring her vital signs. |
| 975830 | 1/26/2021 | AR | 66 | F | 1/19/2021 | 1/19/2021 | Patient states worst of side effects started about 11:20pm that night. Patient went to bed after getting home about 8pm. Patient had pain that started in arm where she got shot, then hurt in right leg, and then left leg and arm. Patient passed out at one point, causing her to fall and hit head on bathroom floor. She did not seek any medical attention at that time and has not since her vaccine. She had extreme thirst from 8pm until 3am. She could not sleep due to pain. Patient was foggy after that for several days, but she is back at work today and feels much better. Patient doesn't think she had fever. She did have a lot of hot/cold flashes. Patient states she is entering information into the VAERS online system herself since she knows all her symptoms. Patient is wanting to speak to someone that knows about Mold toxicity and if it correlates to the covid Vaccine. She states she had the same symptoms when she had mold toxicity before. States she had a mold toxin dump at that time when she lived in Dallas and was given an IV which caused symptoms to stop. Patient states she will look up someone if she needs to and does not want the provider to do any leg work. She has several books and has ordered more. When this occurred before, she had hyperbaric oxygen therapy and believes this pushed toxins out of her cells into her body |

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| 976123 | 1/26/2021 | NJ | 58 | F | 1/21/2021 | 1/21/2021 | Having Ehlers Danlos and Mast Cell Degranulation as well as Dysautonomia... Anaphylaxis is often referred to as slow roll and without the typical face swelling and rash. It is more subtle and can be harder to detect. And that was my experience: as follows: I became faint and briefly passed out within 2 minutes of injection. I stabilized quickly within a 30 minute hold although developed increasing nausea, I and med tech was satisfied that it might just be my dysautonomia. I spent the evening with severe headache vomiting as passed out again. I experienced throat tightening but not full closure. The next day I had flue like symptoms that I assume were normal and vaccine related. When this passed in the evening I again suffered nausea and dizziness, vomiting and throat tightening when I tried to eat. These symptoms were not similar to the flush feelings earlier in the day. The symptoms ebbed and waned for 2 days with increased frequency as I took chromalyn , Benadryl with some effect at first and ate with great care as not to introduce more allergens. I had increased chest pain, sweating, fainting, throat tightening became severe Benadryl was not effective. I was having trouble swallowing. I was forced to use an epi pen and call 911. This is a typical anaphylactic response for EDS< Mast Cell patients. It became clear that I could not get past this on my own and the symptoms were increasing. I started to shake with chills and feared shock as my chest pains increased. The epi pen injection and hospital visit via ambulance occurred Monday 1/25-1/26. I became very faint during the Ems intake with the techs having to hold me up to check vitals etc.. My HR dropped despite the Epi. At the ER I was given IV steroids, IV Benedryl and Potassium, tablets and fluids throughout the night, admitted for evaluation. |
| 975272 | 1/26/2021 | NC | 54 | F | 1/25/2021 | 1/25/2021 | Systemic: Nausea-Medium, Systemic: Fainting-Severe, Systemic: Other- After 2nd dose of covid-19, Patient reported tingling, blood pressure was 198/102, high pulse, tingling in the arm and hand, chest pain, dizziness |

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| 971177 | 1/25/2021 | | 22 | F | 1/24/2021 | 1/25/2021 | Patient experienced syncope on the night of 1/24, hours after receiving the second dose of the Pfizer COVID vaccination. Patient reported feeling "hot and clammy", claimed her blood pressure dropped, and she fainted. She presented to the ER and was released the same night. Upon follow-up on 1/25 patient reports she has recovered from her fainting episode but feels tired, achy, and generally unwell; these side effects are to be expected following the 2nd dose of the Pfizer COVID vaccine. |
| 971183 | 1/25/2021 | NC | 40 | F | 1/22/2021 | 1/22/2021 | Sudden onset dizziness, near syncope, tachycardia, shortness of breath, facial numbness, shaking/rigors |
| 971199 | 1/25/2021 | FL | 31 | F | 1/25/2021 | 1/25/2021 | While being observed in waiting area, patient reported that she felt as if she was going to pass out. Patient was then lowered to the ground by 2 medics in which patient briefly passed out. Patient was taken to medic area where she informed that she often has syncopal episodes. |

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| 971272 | 1/25/2021 | NY | 25 | F | 1/12/2021 | 1/12/2021 | Nausea; diarrhea; vomiting/Throwing up; Hot and sweaty from head to toe; Hot and sweaty from head to toe; Fainted in the bathroom; Chills and could not stay warm; could not stay warm; This is a spontaneous report from a contactable consumer (patient). A 25-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in the left arm on 12Jan2021 (reported as yesterday) around 11 AM as a single dose for COVID-19 immunization, lot number: EL0140 3-4. Medical history and concomitant medications were reported as none. First vaccine dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) was administered on unknown date via an unspecified route of administration for COVID-19 immunization lot number: EL0140. Patient stated that she experienced side effects such as vomiting, diarrhea, fainting while going to the bathroom 14 hours after receiving her second shot of the Covid vaccine. She wanted to know if these were normal side effects and if she should seek medical attention. Patient reported the side effects that she had from the second dose of the Pfizer COVID Vaccine. She has gotten no answers regarding the side effects and she wanted to speak with someone about it. She got the second dose on 12Jan2021 (reported as yesterday) around 11 AM. She felt pretty normal. By 5 PM she got chills and could not stay warm. She thought it was normal. Then over night she got really nauseous, had diarrhea and was throwing up. She was hot and sweaty from head to toe. She tried to get up afterwards and fainted in the bathroom. She was reading what the pharmacy gave her for mild to moderate side effects, and none of what she experienced are listed on there. She also stated that nausea started around 1 AM this morning. It has persisted and is intermittent. Diarrhea occurred a little after 1 AM she got up to pee. Then went back to bed. Then about 10 minutes later had to go to the bathroom, and it started then. It is still occurring this morning. It last happened around 9 AM. She has not eaten anything new. Throwing up Lasted for about 15 minutes and fainted occurred one time. Patient recovered from chills and could not stay warm on 12Jan2021, she recovered from throwing up, hot and sweaty from head to toe and fainted in the bathroom on 13Jan2021, she had not recovered from nausea, diarrhea. |

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| 971989 | 1/25/2021 | TX | 70 | M | 1/15/2021 | 1/16/2021 | <p>Following are my symptoms and severe side effects and events after receiving the COVID-19 Vaccine. 1- Receive COVID 19 vaccine at 4.00 PM on 01/15/21. 2- Stay about 20 minutes after Vaccination and observe no reactions and symptoms. Dive back home. take dinner and sleep well whole night. 3- Next day morning when I wake up feel till bit of Nausea/Vomiting. 4- Take breakfast at about 10.00 AM and after that feeling of Nausea got increased and i also start feeling weakness. These symptoms remains all day. 5- At about 5.15 PM I went to take Shower. After about 2 minutes during shower, i feel shortness of Breath,pressure on chest and Dizziness 6- These Symptoms was for about 4 to 5 second and goes off. 7- After about one minute I feel second time shortness of Breath, pressure on chest and Dizziness. It was bit intensive and for a longer period for about 10 second. 8- At this point I realized that this is something serious happening to me. 9- I came out from the Vertical Shower and called my wife that I am not feeling well. She was at this time at first floor. 10- I think it is about 1 minute after when I came from shower, I feel third time shortness of Breath, pressure on chest and Dizziness. I was very severe and within a second or so I passed out and fell down into the Jacuzzi which is beside the Vertical Shower. 11- Within a minute, my wife and my son came to the scene. At this time my wife finds me unconscious with my eyes open. 12- She shouted my name and then I came into my senses and told them to get me out of Jacuzzi. 12- My wife and my son get me out and carried over to the bedroom. I was feeling no shortness of Breath and Dizziness but mild pressure on chest, shivering and chill. 13- Thanks GOD I did not get any body injury except little bit of hit at my Neck and back of the Head. 14- My wife immediately called to my Primary Care Nurse and then I talk to her explain the whole situation and then asking for advise. 15- She advise me to go to any near Hospital Emergency for any urgent Medical care. 16-A about 6.00 PM I went to Emergency. At this time I was feeling Nausea and Shortness of breath. 17- The Nurse immediately check my blood pressure, temperature, oxygen and pulse. These all was normal. Nurse also provide me IV medicine for Nausea. 18- During my stay at Emergency, I again feeling mild tightness/pressure in chest beside shortness of breath and shivering, therefore Emergency</p> |

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Doctor advise me that will admit to the hospital and do the complete check of any stroke and heart attack. 19- I was in the Hospital for 2 nights. During this stay I was under care of: -Attending Physicist: -Cardiology Physician 20- They have carried out Multiple Blood and Radiology Test as stated below. As per Doctors, all of my Test results are Normal, and they did not find any sign of Stoke and Heart Attack. -Multiple Blood Lab test. -XR CHEST 1 V -CT C-SPINE WO CONT. -CT HEAD-BRAIN WO CONT. -CT ANGIO HEAD W&WO CONT. -CT ANGIO NECK W&WO CONT. -CTA CHEST FOR PE -MRI BRAIN WO CONTRAST . -STRESS TEST. 21- I was discharge from the Hospital on 01/18/21 at 17.34.

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| 971532 | 1/25/2021 | | 33 | F | 1/13/2021 | 1/13/2021 | <p>passed out briefly; a fruity taste in her mouth; turned "Beet red" on her neck/face; have an episode of hypertension; feeling hot; was "swaying"; had menstrual like cramps that radiated from her abdomen to her entire body; had menstrual like cramps that radiated from her abdomen to her entire body; This is a spontaneous report from a contactable pharmacist. A 33-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) , via an unspecified route of administration on 13Jan2021 at the first single dose for covid-19 immunisation . The patient medical history was not reported. The patient's concomitant medications were not reported. Within in minutes of receiving the vaccine on 13Jan2021, the patient reported a fruity taste in her mouth, turned "Beet red" on her neck/face, and passed out briefly. When she regained consciousness, she was given Benadryl, and also was reported to have an episode of hypertension. She reported feeling hot and was "swaying" and had menstrual like cramps that radiated from her abdomen to her entire body. The outcome of events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the compatible temporal association, the vaccination with BNT162B2 might play a contributory role in triggering the onset of the event "passed out briefly". The impacts of this report on the benefit/risk profile of the product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021027150 same reporter/drug, similar event, different patient</p> |

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| 969615 | 1/25/2021 | OR | | F | 1/4/2021 | 1/4/2020 | High Troponin Levels; Felt dizzy; Chest felt tight; Mitral valve filling defect; Difficulty breathing; Concern of anaphylaxis; Passed out unconscious; A spontaneous report was received from a physician concerning an approximately 28-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced the events, felt dizzy, chest felt tight, difficulty breathing, passed out unconscious, concern of anaphylaxis, non-ST segment elevation myocardial infraction, high troponin levels, and mitral valve filling defect. The patient's medical history as provided by the reporter included a history of anxiety. Concomitant medication use included sertraline, buspirone, acyclovir, propranolol, hydroxyzine and lorazepam for unknown indications. On 04 Jan 2020, prior to the onset of the events, the patient received her first of two planned doses of mRNA-1273 (Lot number: 011L20A, Exp. date: 03 Jul 2021) intramuscularly, in her left deltoid, for prophylaxis of COVID-19 infection. On 04 Jan 2020, a couple of minutes after receiving the vaccine, the patient experienced dizziness, chest felt tight, difficulty breathing, and she passed out unconscious. Due to concern of anaphylaxis, while the patient was still unconscious, she was treated with epinephrine followed by intramuscular injection of cetirizine hydrochloride. In addition, ammonia salt was used. The patient woke up briefly and passed back out. Emergency medical services (EMS) arrived and almost had to intubate the patient. The patient stayed overnight in the hospital due to lab values indicating non-ST segment elevation myocardial infraction, high troponin levels, and a mitral valve filling defect. It was noted that the patient has never had an allergy to anything, including the excipients in the Moderna vaccine. In addition, the patient had no history of loss of consciousness or anaphylaxis. Relevant laboratory tests conducted included an echocardiogram which found no issues with cardiac function and noted a mitral valve filling defect. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events, felt dizzy, chest felt tight, difficulty breathing, passed out unconscious, concern of anaphylaxis, non-ST segment elevation myocardial infraction, high troponin levels, and mitral valve filling defect was unknown.; Reporter's Comments: This case concerns a 28 year old female patient with medical |

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history anxiety who experienced Concern of anaphylaxis , high troponin levels, dizziness, chest discomfort, difficulty breathing, loss of consciousness and Mitral valve filling defect same day after administration of the first and only dose of the mRNA-1273 (Lot number: 011L20A, Exp. date: 03 Jul 2021). Based on temporal association between the use of the product and the start date of the reported events and the absence of any other etiology factors, a causal association cannot be excluded.

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| 971550 | 1/25/2021 | SC | 43 | F | 1/9/2021 | 1/11/2021 | COVID-19 immunization on 22Dec2020/ COVID-19 immunization on 09Jan2021; Syncopal episode; loss of consciousness; This is a spontaneous report from a contactable nurse (patient). A 43-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: Ek9231) via unspecified route on right arm single dose for COVID-19 immunization on 09Jan2021, 11:00 AM, at 43-year-old. Medical history included: allergies: Cephalosporins; sulfa; clarithromycin (BIAXIN); metronidazole benzoate (FLAGYL). The patient did not have COVID prior vaccination. Concomitant medications in two weeks included: ibuprofen; loratadine, pseudoephedrine sulfate (CLARITIN-D); fluticasone propionate (FLONASE). The patient did not have other vaccine in four weeks. The patient previously received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on right arm for COVID-19 immunization on 22Dec2020, 12:00 PM, at 43-year-old. On 11Jan2021, 12:15AM, the patient had syncopal episode, loss of consciousness for approximate 10 minutes, more than two hours to fully recover. This resulted in emergency room/department or urgent care. Treatment received included: IVFs, sutures. The patient was not tested for COVID post vaccination. Action taken for BNT162B2 was not applicable. Outcome of the events syncope and loss of consciousness was resolved on 11Jan2021, of else event was unknown.; Sender's Comments: Based on the time association, the possible contribution of suspect BNT162B2 to the events syncope and loss of consciousness cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate. |
| 971143 | 1/25/2021 | FL | 31 | F | 1/25/2021 | 1/25/2021 | While being observed in waiting area, patient reported that she felt as if she was going to pass out. Patient was then lowered to the ground by 2 medics as patient briefly passed out. Patient was taken to medic area where she informed that she often has syncopal episodes. |

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| 969653 | 1/25/2021 | TX | | M | 1/8/2021 | 1/8/2021 | <p>Passed out; Feeling funny, that his insides were cold; Heart rate low; A spontaneous report was received from a 32-years-old male patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and reported felt funny, his insides were cold, low heart rate, and passed out. The patient's medical history was not provided. Concomitant medications were not reported. The patient received their first of two planned doses of mRNA-1273 on an undisclosed date. On 08 Jan 2021, prior to the onset of events, the patient received their second dose of mRNA-1273 (Batch number: unknown) intramuscularly in his left arm for prophylaxis of COVID-19 infection. Afterwards, he felt funny, his insides were cold, and he passed out. His smartwatch reported that his heart rate was low. He said now he was feeling better. No treatment information was provided. The patient received both scheduled doses of mRNA-1273 prior to the events; therefore, action taken with the drug in response to the events is not applicable. The outcome of the events, felt funny, his insides were cold, low heart rate, and passed out, were recovered on 08 Jan 2021.; Reporter's Comments: This case concerns a 32 year old male patient who experienced serious events of Loss of consciousness and Chills and a non-serious event of Heart rate decreased following their second dose of mRNA-1273 (Batch number: unknown). Very limited information regarding the events has been provided at this time. Based on temporal association between the use of the product and the onset of the events, a causal relationship cannot be excluded.</p> |

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| 971537 | 1/25/2021 | FL | 36 | F | 1/11/2021 | 1/12/2021 | Vasovagal syncope with asystole; Vasovagal syncope with asystole; This is a spontaneous report from a contactable pharmacist (patient). A 36-year-old female patient received the second dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: EJ1686), via an unspecified route of administration in the right arm on 11Jan2021 at 14:45 at 36-years-old at a single dose for COVID-19 immunization in a hospital. Medical history included Wilms tumor from an unknown date and unknown if ongoing, Kidney resection and chemo from 1986 to an unknown date, sulfonamide allergy from an unknown date and unknown if ongoing, premature ventricular contractions (PVCs) from an unknown date and unknown if ongoing. The patient's concomitant medications were not reported. The patient previously received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: EH9899) for COVID-19 immunization on 21Dec2020. On 12Jan2021 at 04:00, the patient experienced vasovagal syncope with asystole (hospitalization, medically significant). The patient was hospitalized for vasovagal syncope with asystole on unknown dates for 4 days (at the time of the report). It was reported that the patient did not receive any treatment due to the events. The clinical course was reported as follows: The patient experienced what was believed to be a vasovagal syncope with asystole; approximately 12 hours after receiving the second dose. The patient had been admitted to the hospital since all cardiac diagnosis tests were negative for structural or functional abnormalities. The patient remained in-patient at this time for initiation of therapy for frequent PVCs, which were diagnosis about one year ago; but chose not to treat at that time, as the symptoms were not affecting her lifestyle. The patient underwent lab tests and procedures which included cardiac diagnosis tests: negative for structural or functional abnormalities on an unknown date. The clinical outcome of the events was recovering. The patient did not have COVID prior to vaccination; and was not tested for COVID post vaccination.; Sender's Comments: Based on the information currently available, a possible contributory role of the suspect BNT162B2 in the development of the vasovagal syncope with asystole cannot be excluded. The event is confounded by the patient's underlying |

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| 971007 | 1/25/2021 | KS | 32 | F | 1/22/2021 | 1/22/2021 | <p>premature ventricular contractions. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p> <p>FRIDAY 1/22/21- 2:30pm headache started, 3pm started feeling really tired, by 6pm started feeling achy - arm was super warm to touch and hurt a lot, went to be early due to extreme exhaustion and malaise around 9pm Saturday - woke at 4am to extreme body aches - had to move to couch to stay sitting up to be able to sleep; all day felt horrible body aches, fever, chills (was super hot but also freezing at the same time), skin felt hot to touch-almost painful, extreme fatigue, joint pain - worst in knees and shoulders, hurt to walk, had a little cough, migraine (I'd rate pain around a 10/10) Saturday night into Sunday morning - woke several times drenched in sweat, got up to use bathroom, would be freezing to the point of shaking, then 30 mins later sweating under the covers but still so cold. Continued though out night. Sunday - same symptoms but less painful (rate it around a 9/10) - went to store to get groceries with husband around 8:30pm and almost passed out, super weak and felt like puking - not sure if it was just the mask making it hard to breathe. Monday - woke drenched in sweat but not as bad as over the weekend, still achy but not as bad, headache, arm is still super sore and enlarged, hot to touch, fatigue, malaise - but able to go to work (pain down to 6/10, so definitely better than before)</p> |
| 970964 | 1/25/2021 | | 61 | F | 1/23/2021 | 1/23/2021 | Chills. Fever. Nausea. Vomiting. Fainted |

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| 970919 | 1/25/2021 | IL | 56 | F | 1/22/2021 | 1/22/2021 | 2 hrs after vaccine began to feel chills, did not have good appetite and didn't eat lunch. Started feeling lightheaded 3 hrs post vaccine. Able to stay at work until 4pm, went home, felt lightheaded, ate a meal and felt somewhat better. Got up around 9:30pm, was on feet for a couple of minutes, went to kitchen and reached for a plate on top of the refrigerator. Had presyncopal aura, then fainted. Apparently fell on buttocks, which are sore. No other symptoms. Constitutional symptoms have resolved. Evaluated in ED today. |
| 970710 | 1/25/2021 | GA | 52 | M | 1/22/2021 | 1/24/2021 | 6 episodes of syncope two days after vaccination resulting in hospital admission for what may be an autonomic dysfunction |
| 970493 | 1/25/2021 | NC | 50 | F | 1/11/2021 | 1/11/2021 | 1st vaccine - hypertension, tachycardia, full body tingling, lightheaded - resolved after 60 minutes of observation 2nd vaccine - within 2 minutes, similar symptoms started but gradually intensified. Additionally, had chest pressure, throat dryness, sensation of needing to breath faster (but not shortness of breath), presyncope, full body shaking (rigors) and hand numbness. Code medic called and wheeled down to ER. Symptoms (all of them) came in waves and intensified further in ER. Given IV solumedrol, benadryl and famotidine. Within a minute of IV meds, all symptoms resolved and felt fine for 15 minutes. The symptoms then returned in similar waves but with less intensity and further apart. |
| 970423 | 1/25/2021 | TX | 32 | F | 1/12/2021 | 1/23/2021 | Fainting, blacking out, less than 15 seconds at a time. Has occurred twice now. Once on Saturday night 1/23/2021, and once this morning 1/25/2021 at 8:40am. |

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| 970304 | 1/25/2021 | VT | 65 | F | 1/23/2021 | 1/23/2021 | Grade 3 systemic reactions, much worse than the first time. Injection site (right arm) pain, swelling. Overall body pain, skin, muscle joint, Fever up to 101.6 for 36 hours, now running 99.5 on day 2 post injection, nausea, diarrhea, gas, bloating, dizziness, weakness, fainting, fatigue. Unable to function or to work. Symptoms are again substantially worse than 10 other individuals vaccinated at the same time for dose 2. I suspect my reactions may be dose to weight dependent. I am a very small adult, 4'9", 123 pounds. There may be cause to consider smaller doses for smaller people. That would also allow more doses to be available for the population. I am a healthcare professional. Many lay people would probably not have been willing to take a second dose at this level of reaction. |
| 970237 | 1/25/2021 | WV | 67 | F | 1/21/2021 | 1/21/2021 | 1-21-2021 vaccinated #2 light headed dizzy - must has passed out during night getting up to bathroom work up in am with bloody sheets and pillow - went to ED for staples for laceration on head. |

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| 970029 | 1/25/2021 | WI | 51 | F | 1/3/2021 | 1/3/2021 | short of breath; lightheaded, dizzy, like pre-syncope as I felt like I could pass out but did not do so; lightheaded, dizzy, like pre-syncope as I felt like I could pass out but did not do so; This is a spontaneous report from a contactable nurse (patient herself). A 51-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EL1284; expiry date: unknown) via an unspecified route of administration in the left arm, on 03Jan2021 at 10:00, at a single dose, for covid-19 immunization. Medical history included known allergies (unspecified). The patient is not pregnant at the time of vaccination. The patient was not diagnosed with COVID prior vaccination. The patient did not receive other vaccines within four weeks prior to COVID vaccination. The vaccine was administered in a doctor's office/urgent care. The patient experienced 3 "waves" or what her many coworkers were describing as "whooshes". The first two occurred minutes apart approximately 4-5 minutes post vaccine-last less than one minute each. The 3rd wave occurred after lunch approximately 3 hours later-lasting approximately 2 hours but not as intense as the first times. The patient further described the symptoms as "felt like a rush" (unspecified) experienced when receiving epinephrine. She was short of breath, lightheaded, dizzy, like pre-syncope as she felt like she could pass out but did not do so. The events occurred on 03Jan2021. The patient did not receive treatment for the events. The patient recovered from the events on an unspecified date. The patient has not been tested for COVID-19 since vaccination. |

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| 969621 | 1/25/2021 | NC | 79 | F | 1/5/2021 | 1/5/2021 | <p>Passed out; Felt weak; Sweaty; Could not walk; Arm still sore at the left arm injection site; A spontaneous report was received from a consumer, who was an 80-year-old patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and passed out, felt weak, sweaty, couldn't walk, and arm still sore at the left arm injection site. The patient's medical history was not provided. Concomitant product use was not reported. On 05 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 05 Jan 2021, the patient woke up real sweaty at 3 am. She got up and went to the bathroom and passed out. The patient reported that she fell on the commode then got to the floor because she felt weak and could not walk. Once she regained her strength, she returned to bed. On 07 Jan 2021, the patient reported that her arm was still sore at the injection site and continued to feel weak. Treatment information was not provided. Action taken with mRNA-1273 in response to the events was not provided. The events, passed out, sweaty, and couldn't walk were considered resolved on 06 Jan 2021. The outcome of the events, felt weak and arm still sore at the left arm injection site, were considered not resolved.;</p> <p>Reporter's Comments: This case concerns an 80-year-old female patient with unknown medical history, who received their first of two planned doses of mRNA-1273 (Lot unknown), and who experienced the serious unlisted event of Loss of consciousness, the non-serious listed event of Injection site pain, and the non-serious unlisted events of Asthenia, Hyperhidrosis, and Gait disturbance. Based on the current available information and temporal association between the use of the product and the onset of the events on the day after vaccination, a causal relationship cannot be excluded and the events are considered possibly related to the vaccine.</p> |

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| 971552 | 1/25/2021 | PA | 30 | F | 1/11/2021 | 1/11/2021 | Passed out; Chest tightness; Dizziness; Trouble breathing; Itching throat; This is a spontaneous report from a non-contactable consumer (patient). A 30-year-old female patient (no pregnancy) received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL0140), via an unspecified route of administration at site of left arm at 17:15 on 11Jan2021 at single dose for COVID-19 immunization. Medical history included migraine and seizure. Concomitant medication included lamotrigine (LAMICTAL) and zonisamide (ZONEGRAN). Both received within two weeks of vaccination. The patient experienced passed out, chest tightness, dizziness, trouble breathing, and itching throat, all at 17:30 on 11Jan2021. No other vaccines received in four weeks. Facility type vaccine was in hospital. Adverse events resulted in doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care. The patient received salbutamol (ALBUTEROL), steroids, diphenhydramine hydrochloride (BENADRYL), lansoprazole (PREVACID) and IV fluids for treatment. No covid prior vaccination. No covid tested post vaccination. No known allergies. The outcome of events was recovering. No follow-up attempts are possible. No further information is expected. |
| 970205 | 1/25/2021 | OK | 61 | F | 1/6/2021 | 1/6/2021 | Malaise, High Blood pressure, fainting, tachycardia, thready pulse, facial drooping, chest discomfort, disoriented, feeling a sense of impending doom. |
| 973013 | 1/25/2021 | TX | 42 | F | 1/22/2021 | 1/23/2021 | Almost passed out in bathroom, had to get help to get back to bed. Foot cramps. Had been to the bathroom 3 times that night w/ pale clear urine. Had a small dinner the evening before. Drank Gatorade the following morning. |

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| 971555 | 1/25/2021 | NC | 85 | M | 1/11/2021 | 1/12/2021 | Passed out; massive diarrhea; fell and hit his face; fell and hit his face; This is a spontaneous report from a contactable consumer. An 85-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 11Jan2021 at single dose for covid-19 immunisation. Medical history included epilepsy from an unknown date and unknown if ongoing (Caller says her father in law hasn't had seizure in years, it was diagnosed when he was a kid, 60-70 years ago). There were no concomitant medications. The reporter is calling on behalf of her father in law. She said he had his first dose of the COVID vaccine recently, she pulled this number off of the paperwork today. She says that she believes he had a side effect for it, and also he was rescheduled for his second dose. She says his second dose was supposed to be in 21 days but they rescheduled him for it at 18 days instead. She says he got the first dose on 11Jan, and they rescheduled his next for the 29th. She says she wanted to know if this was correct or ok. The reporter says that the following day he ended up having massive diarrhea, that it caused him while he was on the commode to pass out and he fell and hit his face, the best she can tell he was alone at the time. She says he did not go to the hospital for that, he got up and cleaned himself off and took a nap, and the nurse next door checked on him later on. The outcome of the events was unknown. Information on the lot/batch number has been requested. |
| 973034 | 1/25/2021 | | 28 | F | 1/20/2021 | 1/21/2021 | Approximately 12 hours after receiving my 2nd dose of COVID vaccination, I fainted. This type of event is not normal and hasn't occurred in more than 10 years. |

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| 972909 | 1/25/2021 | NV | 39 | F | 1/14/2021 | 1/14/2021 | I got the first dose of the Moderna COVID-19 vaccine last Thursday (1/14/21) at clinic and had a pretty severe reaction within a few minutes of the receiving the vaccine. I didn't alert anyone because I wasn't sure if it was related to the vaccine or not. I felt hot suddenly, then very dizzy/faint, then experienced very bad tinnitus and couldn't hear any of the words being spoken around me, just muffled sounds. I felt slightly nauseous, was seeing spots, and felt very close to fainting. My pulse was racing. I did deep breathing until it subsided (which was about 10 minutes later). For the next 5 days after the vaccine, I experience extreme soreness and weakness in the left arm where the injection was given. I also had redness and itching and it was hot to the touch and slightly swollen. I had extreme fatigue and a headache and a loss of appetite. After 5 days, those subsided. 1 week after the vaccine (01/21/21), I experienced intense itching at the injection site and redness and it was hot to the touch. I also experienced intense itching on my chin and skin numbness in that area of my chin. The chin area resolved after about 4 hours. The arm itching did not resolved. i woke up on 01/22/21 with the entire left shoulder area swollen, red, hot to the touch, and extremely itchy. it lasted all day. I woke up on 01/23/21 and the swelling had gone down, but the redness spread to a larger area on the upper left arm and the itching persisted all day. I woke up on 01/24/21 and the redness and swelling was almost gone but the itching was still there and the area that had swollen up felt very bruised, but no visible bruising. Today (01/25/21) there is no more itching or redness but the bruised sensation continues. |
| 972894 | 1/25/2021 | | 55 | F | 1/11/2021 | 1/12/2021 | Intense throbbing and pain at injection site, severe nausea, got up to vomit in bathroom, fainted and hit my head, was unconscious a couple of minutes. |

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| 972803 | 1/25/2021 | IN | 36 | M | 1/25/2021 | 1/25/2021 | Patient received vaccine without incident. As patient was walking to the observation area, he felt a little dizzy. He ambulated to the observation room without difficulty. As he was sitting in the chair in observation he passed out in the chair with observer present who caught him and then the patient was placed in a wheelchair to take him to private observation area. By the time he was wheeled to the private area he was semi-alert. Vital signs were taken, EMS was called. Patient became fully alert within 5 minutes. He was diaphretic. VS were within normal limits. Patient did state he had a very light lunch. He had something to eat in the ambulance and felt better. EMS returned him to the clinic after about 30 minutes and patient stated he felt fine. |

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| 972638 | 1/25/2021 | CA | 38 | F | 1/21/2021 | 1/22/2021 | <p>The day following the 2nd vaccination dose, I had zero symptoms other than a slightly sore injection site. Around hour 30 following the vaccination I began to feel warm, and I got up to brush my teeth and cool off in the bathroom. As I was brushing my teeth, I started experiencing an increasing ringing noise in both my ears that I thought was strange and somewhat alarming, but I didn't feel any signs of dizziness or dysphoria. The next thing I remember is waking up the bathroom floor with my husband standing over me. Apparently I experienced a complete lose of consciousness and fell to the floor, hitting my chin on the bathroom vanity as I fell and splitting my chin open, which I have zero recollection of. My husband states that when he found me, that my eyes were open, but I was staring blankly at him with a glazed over look and my whole body was limp and diaphoretic. I came too in about 30 seconds after he found me, but I was very confused, not making a lot of sense, and felt very disoriented and weak. It took about 20 mins for my fever to break, and to have the strength and power to get up and walk to bed. We changed all my clothes because I had soaked through them, and he got me into bed after cleaning/bandaging up my chin. I then slept solidly until noon the next day, which is very unlike me, but since then I have felt relatively fine with no other experiences of fever/chills/disorientation, just some continued mild fatigue off and on. After discussing with my nursing colleagues, they all had similar experiences around hour 24-30 post 2nd vaccine with fevers, chills, restless sleep, or just general malaise, but no one experienced a complete lose of consciousness, so I reached out to my PCP yesterday, and she confirmed today that I should report this to VAERS. I have never experienced any form of loss of consciousness/fainting/black-out/syncope prior to this, which is another reason I thought it was important for me to report this.</p> |

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| 972546 | 1/25/2021 | MD | 44 | F | 1/25/2021 | 1/25/2021 | After patient received vaccine she C/O tingling face was given Benadryl @1341 , 15 minutes later patient was C/O tight throat, Solumedrol 60mg IM administered to Rt buttocks by this nurse. Pt then escorted to ER for further evaluation. On 1/25/21 at 1359: Patient reported tingling of lips and throat felt tight. SPO2 via finger with a result of 99%. Emergency room provider's note: 44-year-old female patient presents ED after allergic reaction. Patient received her first COVID-19 vaccination and during the 15-minute observation period began to feel as if she had some tightness in her throat and difficulty swallowing. She has a scratchy sensation to her posterior pharynx. She denies specifically shortness of breath, nausea vomiting, dizziness or near syncope. She was medicated with 50 mg of Benadryl p.o. as well as 60 mg of Solu-Medrol IM prior to arrival. She states she has never previously had allergic reactions to vaccinations in the past |
| 972490 | 1/25/2021 | GA | 67 | F | 1/25/2021 | 1/25/2021 | The patient fainted about 15 minutes post-vaccination. Elevate Hr 115 BP 95/65 RR: 20 unlabored. Took 5-7 minute for symptoms to subside. Vital signs were taken again HR 90 BP 98/64 RR 18 and the stable patient stated that she felt fine and was going home. He spouse was driving her home. |
| 972424 | 1/25/2021 | TX | 78 | M | 1/22/2021 | 1/22/2021 | Pfizer-BioNTech COVID- 19 Vaccine EUA:Patient with significant PMHx of alcoholism, AFIB, CHF, COPD, DM, GERD, MI, HTN, pacemaker placement stroke, and hyperlipidemia who presents to the ED with CC of dizziness. Pt states that two days prior he slipped and fell and hit his head, and was unable to ambulate after the fall. Pt denies any LOC, but states he is currently on Xarelto. Pt currently c/o back pain. Pt went for his first COVID-19 immunization 1/22/2021 when he became suddenly dizzy. Patient denies chest pain, shortness of breath, nausea, vomiting, diarrhea, abdominal pain, fever, chills, or any other acute complaints. Progress Note: "Dizziness, near-syncope: Onset following injection of COVID-19 vaccination. |
| 972421 | 1/25/2021 | | 44 | F | 1/8/2021 | 1/18/2021 | Lower extremity weakness, dysarthria, presyncope |

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| 972257 | 1/25/2021 | NJ | 23 | F | 1/21/2021 | 1/22/2021 | Pt stated she was feeling very anxious prior to vaccine. She has a hx of fainting with medical procedures. Last even was 2 years ago, 4 days post wisdom tooth extraction. She did not alert nurse of this history prior to vaccination. After receiving vaccine she stood up and appeared to have vasovagal syncope as she stepped out of the vaccination booth. Nurse had her sit immediately. O2 sat was retrieved and applied mask at 4 liters. Transported to medical booth via wheelchair. Placed supine on cot with legs elevated. Color returned quickly, and pt was talking, alert and oriented. Initial O2 sat- 86 but quickly increased to 98 on O2. O2 sat on room air fluctuated 95-97 but increased when her mask was pulled away and deep breath taken. EMS assessed. Pt and mom declined transport and will f/u with physician. |
| 972209 | 1/25/2021 | IN | 58 | F | 1/22/2021 | 1/22/2021 | Patient began feeling lightheaded and passed out a few minutes after receiving her first dose of Moderna. She quickly recovered, was placed in a Trendelenburg chair and vitals were normal upon being checked. EMS was onsite to evaluate the patient. No further treatment was necessary. |
| 972180 | 1/25/2021 | MI | 49 | F | 1/22/2021 | 1/22/2021 | Systemic: Anaphylaxis-Medium, Systemic: Fainting-Medium |

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| 972165 | 1/25/2021 | | 40 | F | 1/25/2021 | 1/25/2021 | 1340 - As patient left shot table, she became faint and eased to floor by assist of staff at shot table. Patient panicked stating she needs air. Patient instructed to remove mask and deep breath. Assisted x 2 into w/c and taken to private observation area. EMT on site in attendance. 1349 - c/o inability to catch breath, opened back doors and sat partially outside. Mask off, on room air. BP 135/103; HR 85. Offered water, patient declined. 1356 - BP 129/95; HR 73 1405 - BP 135/111; Recheck of BP with another cuff and is 144/96; O2 sat 98% on r/a. HR 79 then 71. Denies SOB, or difficulty breathing. Talking and explaining medical history. States she feels a lot better. Patient denies injuries from being assisted to the floor. EMT does not indicate need for ambulance for further eval or for transport. Patient declines EMS for further eval. 1417 BP 118/89; HR 72 Patient states she feels fine. States she has had this vagal reaction before but not with an injection. Discussed with patient to attempt to obtain dose #2 in a private setting, however to notify wherever second dose is taken to notify staff so she can be placed in a w/c from beginning through observation. Pt. laughed, stating she will be fine. Re-stressed the need to avoid fainting and should either recline or be in a w/c for dose #2. Patient agreed. Patient stood and re-assessed. No dizziness noted. Patient ambulated to parking lot independently, accompanied by nurse. Gait steady. No SOB noted. |
| 972117 | 1/25/2021 | TX | 44 | M | 12/28/2020 | 12/31/2020 | Syncope, hospitalization for GI bleed for 4 days. probable diagnosis diverticulosis bleed |

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| 972077 | 1/25/2021 | GA | 34 | F | 1/20/2021 | 1/21/2021 | After I received the vaccine I felt fine. Later that night I had a slight headache and the injection site was sore. I took my medicine and went to bed. I woke in the middle of the night in serve pain at the injection site and still had a headache. I went back to sleep. I woke at 8am feeling nauseous and I started trying to walk to the bathroom and tried to throw up. I passed out my husband caught me. He sat me up and put water on face. He called the 911. EMS came out and checked my blood pressure was really low 80/60 range. The night before I checked my blood pressure before taking my blood pressure pill and it was 121/80. Refused to go to the hospital and I stayed at home and just rested for a couple of hours. I went to work later that night. Every since then I have been feeling weak, dizzy, and moving slow. I feel like it I turn to fast I will fall. I have not been feeling myself. Just got new insurance and has been trying to find a new doctor and she has been unsuccessful. She is going to urgent care tomorrow. |
| 971985 | 1/25/2021 | TN | 75 | M | 1/21/2021 | 1/21/2021 | Patient was in observation area after having the 1st dose of the Pfizer COVID Vaccine. He became short of breath, complained of chest tightness, and nearly passed out.911 called at 0945AM and responded to the Center. Patient moved to wheelchair without incident due to fall concerns. Patient transported to ER via ambulance to follow up due to reaction. Treatment Rendered: Patient was assessed by EMS and placed onto stretcher. He was then transported via ambulance to local ER. |
| 971701 | 1/25/2021 | SD | 65 | M | 1/12/2021 | 1/12/2021 | Patient describes feeling light headed and fainting a few hours after vaccination. |
| 971891 | 1/25/2021 | FL | 66 | F | 1/15/2021 | 1/15/2021 | 1350 - Vagal reaction to injection. Vitals taken 160/80 P63. 1400- Vitals 125/80 P57 O2 98% 1411 - Repeat vagal reaction. - EMS called to site. Pt was bradycardic - alert and never lost consciousness. History of syncope in past. Pt has been sating at 97%. O2 applied at 6L and pt is now sating at 100%. 1415- EMS arrived on scene, is present and evaluating patient. Pt continues to sat at 100%. 1420 Pt is refusing transport and signed AMA. Pt given instructions. |

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| 972323 | 1/25/2021 | LA | 66 | F | 1/20/2021 | 1/23/2021 | Vaccinated 1/20 at her PCP. Pt was seen by NP via telemedicine urgent care complaining of severe persistent headache and all-over body pain since 1/23, reportedly in too much pain to even move out of bed all day on day 4 after COVID vaccination (1/24). Still in pain today, primarily in arms and shoulders, but is able to ambulate and conduct ADLs. Headache persists with some dizziness. Encouraged to rest, hydrate, and take Tylenol PRN. Strict ED precautions for any CP, SOB, syncope, or evidence of allergic reaction. |
| 971894 | 1/25/2021 | GA | 75 | M | 1/20/2021 | 1/21/2021 | During night after receiving the shot I woke up at about 2)) AM to go to the bathroom. When I got into the bathroom I suddenly had very strong chills and immediately passed out. While passed out I uninated . I woke up and have not had any problems since. |
| 968781 | 1/24/2021 | IN | 77 | M | 1/22/2021 | 1/23/2021 | On 1/23/2021, one day after receiving the mentioned vaccination, I was working as a volunteer and at about 11:30 am I became very dizzy and nearly passed out. a passerby helped me to a seat, a coworker brought me water, and called security for assistance, An EMT came and checked my vitals, gave me a small package of raw honey, and checked my blood sugar. Everything checked out ok, except my blood sugar was slightly low. I quickly soon felt better, and resumed my volunteer shift. I don't know if the vaccine was related to this incident, but felt it best to report it to you. |
| 968531 | 1/24/2021 | NJ | 58 | F | 1/23/2021 | 1/24/2021 | Syncope upon rising this am, rested on cold bathroom floor, sweating profusely, nausea, vomiting |
| 968540 | 1/24/2021 | NJ | 58 | F | 1/23/2021 | 1/24/2021 | Syncope upon rising, sweating profusely, nausea, vomiting |
| 968734 | 1/24/2021 | MI | 42 | M | 1/19/2021 | 1/19/2021 | States about an hour after the shot went back to work- was sitting there-felt warm & fuzzy-the next thing he woke up-was on the floor-staff called 911-was taken to ER-states had coughing & couldn't catch his breath & apparently passed out. |
| 968773 | 1/24/2021 | NC | 24 | F | 1/23/2021 | 1/23/2021 | Nausea, vomiting, fainting, chest pains, arm/hand turned blue. Transported via ambulance to er for being unconscious |

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| 969189 | 1/24/2021 | WI | 76 | F | 1/10/2021 | 1/13/2021 | On 1/13/21 throat suddenly seized, had to work hard to expell or inhale air Turned slightly got dizzy then almost passed out but held on to handle of cart and then it passed and was able to breathe freely whole episode took about 20 seconds on the following night (1//14/21) about the same time was overwhelmed with nausea and strong abdominal cramps . Thought I was coming down with the stomach flu. Reaction disappeared after about an hour. |
| 969381 | 1/24/2021 | MO | 34 | F | 1/21/2021 | 1/21/2021 | COVID-19 vaccination - 2/2 in series. Reportedly, patient fainted following first dose. Approximately 5-6 minutes after patient received second dose, she become lethargic, progressing to non-responsive. A rapid response was called and patient was transferred to the emergency department. She was protecting her airway. En route to the ED, patient's eyes rolled backwards and she began having generalized tonic-clonic movement indicative of a seizure. Patient was turned onto her side until seizure activity subsided. Post-ictal state lasted approximately 5-10 minutes after seizure activity ceased and patient became alert and oriented and able to answer all questions. All lab tests and imaging were normal. |
| 968737 | 1/24/2021 | AZ | 21 | F | 1/22/2021 | 1/22/2021 | Passed out twice. Once at 6:20am was going to the bathroom and ended up on the floor going in and out of consciousness for roughly 30 minutes (boyfriend is witness) Around 9am was standing at bathroom sink fell forward with my head rested on the mirror, drooled, then passed out backwards, boyfriend was able to catch me. I was out for 10-15 seconds non responsive. When conscious again, both arms were tingling and my hands were spasmed with my thumbs stuck reaching toward my middle fingers for 5-10 minutes. |
| 967482 | 1/23/2021 | MA | 73 | F | 1/22/2021 | 1/23/2021 | 8pm tried to get up out of the bathtub, called husband he helped me to the toilet and i passed out. He helped me up and I vomited twice. Very crazy experience, I never had something happen to me like that. I only received one regular flu shot in my life no other shots. |
| 967900 | 1/23/2021 | WA | 56 | F | 1/22/2021 | 1/22/2021 | Sore arm, extreme fatigue, followed by fainting for a few seconds later that night around 2am |

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| 967278 | 1/23/2021 | CO | 81 | M | 1/22/2021 | 1/22/2021 | PATIENT FAINTED WITHIN 15 MIN OF RECIEVING VACCINATIONS - PT WAS ASSESSED ON SCENE BY ON SCENE MEDICS, THEN WERE CALLED TO SCENE FOR FURTHER ASSESSMENT/TREATMENT. PT WAS TRANSPORTED TO ER FOR ASSESSMENT BY ER PER PT. REQUEST |
| 967334 | 1/23/2021 | WI | 71 | F | 1/20/2021 | 1/20/2021 | I spoke to my sister on the phone an hour or two after she got the vaccine and she was slurring her words. The next day around 5:38 someone called me to say she was found on the floor in the bathroom between the toilet and the wall. I believe she passed out because she has no recollection of what happened at that time. She was also reported as having a very dry mouth and sweating by the staff. She was taken to ER after they found her in the bathroom. She is currently having trouble getting around, has pain and is very tired. She seems to be improving though. |
| 967356 | 1/23/2021 | PA | 55 | M | 1/19/2021 | 1/19/2021 | 12 hours after injection: 12 hours after injection and then resolved the next day: drenching night sweats severe joint pain especially in hips and knees - even ribs hurt passed out and disoriented significant contracture of bilateral upper extremities from elbow to hands when I could not open them for over an hour rt ear tinnitus numbness in hands and feet tiredness |
| 967382 | 1/23/2021 | OH | 53 | F | 1/22/2021 | 1/22/2021 | Dizziness, sweating, light headedness (45 minutes after vaccine); fainting (1 hour after vaccine); low grade fever, body aches (12 hours after vaccine) |
| 967396 | 1/23/2021 | MN | 34 | F | 1/21/2021 | 1/22/2021 | After mild vaccine reaction symptoms (myalgia, chills) I passed out and was unresponsive for 2 minutes. |
| 967419 | 1/23/2021 | MD | 36 | F | 12/29/2020 | 12/30/2020 | At aprox 36hrs post vaccine I developed a rapid onset of left arm and left sided body weakness. continuing near syncope episodes. diagnosed as a complex mोगraine which lasted 5-6hrs. and lingering headache for about 8days |
| 967467 | 1/23/2021 | NY | 35 | F | 1/23/2021 | 1/23/2021 | Vasovagal syncope with panic attack, tingling at onset of vaccine |

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| 967477 | 1/23/2021 | TN | 42 | F | 1/20/2021 | 1/20/2021 | Day 1. Fatigue. Sleepiness. Loss of appetite Day 2. Muscle aches. Headache. Chills. Loss of appetite. Episode of severe abdominal pain, chest pain, right shoulder pain, shortness of breath, syncope, diaphoresis, vomiting Day 3. Fatigue. Headache. Chest pain. |
| 968283 | 1/23/2021 | WA | 37 | F | 12/31/2020 | 12/31/2020 | About 15 min after vaccine, going back to work station and felt ringing in my ear (tinnitus) vertigo; headache - went downstairs and drank a lot of water and took my legs up to prevent fainting and i didn't get better. 30 min later - 103/115 BP (Higher than normal -- 96/58or 60); after 12 Pm started having chills, shaking and chest hurt and difficulty breathing. Went ER at 12:55 pm and they did an EKG - not a regular heartbeat; blood work and x-ray. My BP was high - 143/122; I had low potassium; white blood cells higher than normal -10.9 (in mid Nov - only 7.5); They gave me potassium to take. December 30, when I got home at 6:30 - nausea started and I was throwing up two-three days in a row more than 5 or 6 times a day; weird metallic taste; fever at night; arm pain and swollen under my armpits. (Stayed off work three days.) Went to dr on Jan. 7 - did a follow up appt. and did all the blood work again and everything was back to normal. |
| 967547 | 1/23/2021 | MI | 65 | F | 1/20/2021 | 1/22/2021 | Severe nausea, syncope, headache |
| 967553 | 1/23/2021 | TX | 30 | F | 1/19/2021 | 1/19/2021 | The patient was due for their dose on 1/25/21 and received it early on 1/19/21. Around 10 minutes after receiving the second dose, the patient experienced some syncope which subsided about 10 minutes later and did not leave the vaccination site until she was feeling better. The other side effect that the patient experienced was redness/swelling/irritation at the injection site for about 24 hours after the injection. |
| 967836 | 1/23/2021 | MA | 32 | F | 1/21/2021 | 1/21/2021 | I passed out/minor seizure? Was transported to the ER and given fluids. All test results came back OK and I was released. Nothing like this has ever happened in my life. |
| 967651 | 1/23/2021 | WA | 51 | F | 12/28/2020 | 12/30/2020 | I had a syncope on Wednesday night with a nose bleed. I also had bleeding from the back up from my throat. My family called 911 and at home the paramedics checked blood sugar, blood pressure and said everything looked ok. |

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| 968098 | 1/23/2021 | UT | 31 | M | 1/23/2021 | 1/23/2021 | Syncope after injection only. Recovered. Pt has hx of syncope with fear of needles |
| 968165 | 1/23/2021 | CA | 87 | M | 1/21/2021 | 1/21/2021 | - vomiting multiple times 2-3 hours after the vaccine - severe headache 2-3 hours after the vaccine- given tylenol - severe dizziness 2-3 hours after the vaccine - fainting 2-3 hours after the vaccine - extremely tired |
| 968278 | 1/23/2021 | AK | 47 | F | 1/23/2021 | 1/23/2021 | Anaphylaxis with shortness of breath, throat tightness, dizziness and wheezing with near syncope. |
| 968363 | 1/23/2021 | MN | 33 | F | 1/20/2021 | 1/20/2021 | At 11pm had unbearable abdominal pain with chills. Passing gas, having a bowel movement and walking did not help relieve the pain. The pain lasted 4 hours. Every hour made me consider going to the ER because it hurt so bad. I finally passed out from not sleeping. When I woke up 2 hours later for work I was fine. |
| 967535 | 1/23/2021 | | 30 | F | 1/20/2021 | 1/20/2021 | Dizziness (I passed out several hours after getting the shot); nausea; muscle aches; fatigue |
| 965033 | 1/22/2021 | OH | 74 | F | 1/21/2021 | 1/21/2021 | All information in this description are according to a narrative report submitted by Emergency Management in post vaccine observation area of Covid Vaccine event. Patient reported experiencing chest heaviness post vaccination approx. 10:10am. patient relayed she had a history of syncope arrythmia and other cardiovascular problems. was relocated to a private room an placed in Semi Fowler's position and attended to by a task force Registered Nurse. Registered Nurse took BP and Pulse and reported values of BP 181/64 and pulse rate of 49. Patient declined EMS transport for further evaluation and said her "chest discomfort was lifting." Narrative submitted by Emergency Management Observant notes no nasal flaring or rash/urticaria. Patient did relate that it was slightly difficult to catch her breath. RN from strike team and EMS personnel continued attending to the patient. Narrative states she refused transport and "after a short wait was ready to leave." Narrative further states "Patient further related she was feeling better and was encouraged to seek out medical attention by her cardiologist. Patient ambulated out of County Health Department without assistance.~~ |

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| 965047 | 1/22/2021 | NE | 57 | F | 12/28/2020 | 12/29/2020 | At 12:00pm I experienced chills, shakiness at work and kept working throughout the day. I asked my supervisor if I could leave work bit earlier because I did not feel well. I went to the break room, sat down when I started feeling lightheaded and passed out in a chair. I had a syncope. Under my right and left arm, my lymph nodes felt inflamed and the ER doctor said they were not inflamed but upon palpation were tender. I was put on oxygen, my BP was extremely low. My BP resumed to come back up within a few minutes. At this time I am still having trouble with my lungs, I am on an albuterol inhaler as needed. I had a followup with my PCP on 01-13-21, she extended treatment for Azithromax and continue with Albuterol inhaler. |
| 965067 | 1/22/2021 | OH | 24 | F | 1/20/2021 | 1/20/2021 | 1/20 1:30pm: 2nd dose Moderna vaccine received 1/20 9:00pm: fatigue, malaise, chills, headache, body aches 1/20 10:00pm: brief 5 second hallucination upon waking up from sleep 1/21 3:30am: recommended dosage of Dayquil taken (this was the only time medication was taken) 1/21 5:30am: fainted and blacked out for 5-10 seconds after standing for 5-10 minutes (face flushed and started twitching, felt nauseous, managed to sit down on the ground first before blacking out.) 1/21 5:35am: stood back up, fainted and blacked out again for 5-10 seconds (was able to sit down again before blacking out. After regaining vision: started sweating, lips and hands were tingling, and vision was blurry.) 1/21 3:00pm: symptoms subsided and no additional fainting or blacking out occurred Patient has never experienced adverse side effects to vaccines (including common vaccines as well as travel vaccines such as yellow fever, typhoid, first dose of COVID-19 vaccine, etc.) - only chills for 1 hour after an influenza vaccine one time. Patient has no medical history of blacking out or fainting, even when taking Dayquil in the past. |

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| 965153 | 1/22/2021 | NY | 44 | M | 1/6/2021 | 1/6/2021 | 10 min after vaccine-twitch in left calf, quad twitching, bicep, glute--only twitching on left side for first 30 min following vaccination Then after 30 minutes it switched to right side twitching (twitching not painful) Employee also had trouble breathing at that moment and was diaphoretic--Rapid Response Called VSS--employee returned to work Two hours later employee experienced diaphoresis, presyncope--went to Emergency Dept at this time--all labs and tests came back WNL 1/7: Fever 100, twitching continues (superficial) 1/7-14-superficial twitching throughout body 1/14-1/15?twitching seems to go deeper--in intestine, deep in LRQ 1/22 still having these twitches (not painful, just disturbing/odd)--Employee estimates these twitches happen 20x an hour |
| 965201 | 1/22/2021 | CA | 24 | F | 12/28/2020 | 12/28/2020 | STOOD UP TO CLOSE OFFICE DOOR AND STARTED LOOSING VISION AND FEELING LIGHT HEADED AND THEN BROKE OUT WITH COLD SWEAT. HEARING WAS FADING AND SAT BACK DOWN, BODY TINGLING AND LOOSING FEELING IN ARMS AND LEGS, FELT LIKE FAINTING. ELEVATED LEGS AND DRANK WATER. FEELING BETTER AFTER 10MIN OR SO. THE FOLLOWING DAY C/O PAIN IN INJECTION SITE ONLY. |
| 964999 | 1/22/2021 | | 24 | F | 1/22/2021 | 1/22/2021 | Approximately 9 minutes after patient's vaccination she had a vasovagal episode and passed out for approximately 10-15 seconds. Patient hit her head when she fell to the floor. Patient placed on gurney and vitals were taken. Denied any respiratory issues. Complaining of nausea. Patient had worked her first night shift and came after her shift to receive her injection. Patient had stated she was very tired and was closing her eyes while she was waiting after her injection. Patient had no recollection of passing out. Complaining of head and neck pain. BP 98/55, HR 55, 100% O2 sat on room air. Patient transported to Emergency Department talking to staff. |

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| 965556 | 1/22/2021 | VA | | F | 1/12/2021 | 1/12/2021 | 3 near syncopal episodes; Arm soreness at injection site; Chills; muscle aches; This is Spontaneous report from a contactable Other Healthcare Professional reported for herself. A 49-years-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), Lot number=EL1283 via intramuscularly on 12Jan2021 10:30 at single dose Vaccine location: Right arm for covid-19 immunisation ,facility type vaccine: hospital. Medical history included hypertension and the first dose of BNT162B2 Lot number=EK5730 in Dec2020 10:00 Intramuscular, Vaccine location Right arm Facility type vaccine Hospital. Concomitant medication included hydrochlorothiazide (HYDROCHLOROTHIAZIDE) and multi-vitamin. On 12Jan2021 22:00 the patient experienced 3 near syncopal episodes, arm soreness at injection site, chills and muscle aches. No treatment received. The event outcome was recovered and action taken is not applicable.; Sender's Comments: Based on the time association, the possible contribution of suspect BNT162B2 to the event near syncope cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate. |
| 965577 | 1/22/2021 | CT | 41 | F | 1/21/2021 | 1/21/2021 | Pt received vaccine and was cleared for discharge after 15 minute evaluation. Pt left clinic site and saw a friend and sat down to speak to this person for a few minutes. During this interaction, the pt began to feel unwell and apparently fainted. The nurse gave oxygen and alerted EMS. Vital signs were assessed and were stable; the pt regained alertness rapidly prior to her disposition by ambulance for emergency evaluation. |
| 965635 | 1/22/2021 | IA | 38 | F | 1/20/2021 | 1/20/2021 | All over red skin and burning sensation, tachycardia to 165 bpm and near syncope. Next day fever, body aches, chills and headache. |

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| 965551 | 1/22/2021 | MN | 22 | F | 1/11/2021 | 1/12/2021 | dizziness then syncope; dizziness then syncope; This is a spontaneous report from a contactable Other HCP. A 22-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular on 11Jan2021 14:00 at single dose for COVID-19 immunisation. Medical history included situational anxiety, known allergies_penicillin. Concomitant medication included colecalciferol (VITAMIN D [COLECALCIFEROL]). The patient previously took amoxicillin;clavulanic acid (AUGMENTIN) and moxifloxacin and experienced allergies. The patient experienced dizziness then syncope on 12Jan2021 05:45. The patient underwent lab tests and procedures which included electrocardiogram: unknown results, laboratory test: unknown results. Therapeutic measures were taken as a result of dizziness then syncope. The outcome of the events was resolving. Information on batch/lot number was requested.; Sender's Comments: Based on the time association, the event syncope is possibly related to suspect BNT162B2 administration. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate. |
| 964947 | 1/22/2021 | WY | 41 | F | 1/19/2021 | 1/19/2021 | Near Syncope, lymphadenopathy, decreased urine output, elevated D-Dimer |

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| 964750 | 1/22/2021 | CA | 76 | F | 1/21/2021 | 1/22/2021 | <p>Pt well until approximately 2:55am when she passed out in bathroom according to her husband. Pt was diaphoretic. Denied dyspnea, chest pain, fever, redness, or difficulty breathing. Patient: Age: 76 Years</p> <p>Additional information for Item 18: Date/Time: 01/22/21 03:19 Time of my initial contact with patient: 0319</p> <p>Mode of Arrival: Ambulance Private Medical Doctor: Triage Narrative: Pt. bib medics from home after near syncopal event in bathroom, lowered herself on the ground, no LOC/trauma. BP on medic arrival was 86/50 HR in 50s, improved to 100/68 w/ lying down and 250ml bolus. Received 1st covid vax today, has felt weak w/ diarrhea since then. Denies pain, skin pale/w/d, AxOx3, resp e/u. Chief Complaint: Syncope/Near syncope</p> <p>History of Present Illness: This is a 76-year-old female with history of CAD status post remote PCI, previous CVA on Plavix, hysterectomy, migraines who presents ER today for a syncopal event. Patient was given her first dose of Covid vaccine earlier today, per patient's primary doctor found in prior to arrival she had been very hesitant because she was concerned for triggering migraines, this was clear with her neurologist that she was pretreated with Benadryl, she states that she initially felt fine after vaccine administration, she states however later in the evening she developed 4 episodes of loose watery bowel movements and crampy abdominal pain, she states she was feeling tired and so she laid down to go to bed, she states that she woke up feeling as if she had to have another diarrheal episode, she reports that when she stood up and went to the bathroom she was not feeling well, she reports feeling very lightheaded while on the toilet and trying to have a bowel movement, she attempted to stand up however felt acutely lightheaded, she states that she sat back down on the toilet and slumped down and woke up on the ground. She denies any pain other than her abdominal pain and a sensation that she has had further bowel movements.</p> <p>Per EMS patient was noted to be hypotensive on arrival 86/50 with heart rate in the 50s, this improved with laying flat on the gurney and given a 250 cc bolus. Patient has been seen in the past for syncopal events with postural changing. She denies any new medication changes, she states that she had been drinking water throughout the day but has had a poor appetite no dysuria frequency urgency no headache head injury neck pain back pain</p> |

new numbness tingling or weakness in arms or legs no difficulty with speech Problem List & Past Medical/Surgical History: CAD (coronary artery disease) Dysuria Hysterectomy Migraine Potential stroke Stent Family History: No related illness Social History: The patient does not smoke tobacco or abuse alcohol. Allergies: Imitrex morphine (Nausea) shellfish traMADol Medications: Available Med List Reviewed Review of Systems: All other systems reviewed and are negative except per HPI Physical Exam: Vital Signs BP: 151/93 mmHg Temp (Oral): 36.4 DegC (97.5 DegF) HR: 73 bpm Resp: 18 br/min SpO2: 97 % GENERAL: Patient appears well developed, well nourished. HEENT: Normocephalic and atraumatic. EOMI. No scleral icterus. Airway is patent NECK: Supple Trachea is midline. No midline tenderness full range of motion without pain or discomfort RESP: Lungs are clear to auscultation bilaterally. No wheezing, rhonchi, rales CARDIOVASCULAR: Regular rate and rhythm 2+ radial and DP pulses symmetric bilaterally GASTROINTESTINAL: Abdomen is soft, mild diffuse tenderness and nondistended. No rebound, no guarding. No pulsatile mass appreciated. BACK: No CVA or spinal midline tenderness to palpation MUSCULOSKELETAL: No clubbing, cyanosis, or edema. No calf tenderness to palpation. SKIN: Warm and dry. No external evidence of trauma NEURO: The patient is alert and oriented x3, not confused. Speech not slurred. Normal facial symmetry. No subjective facial numbness. No vision changes. EOMI. Upper and lower extremities with 5/5 strength globally. Normal sensation noted over all extremities. No subjective dizziness. Finger-to-nose testing normal. Normal gait. PSYCHIATRIC: Alert and appropriate. Test Results: Labs Results 01/22/21 03:38 134 L 102 9 109 4.2 23 0.6 01/22/21 03:38 12.9 9.6 355 37.8 01/22/21 05:20 Cardiac Studies Troponin-HS <2.0 01/22/21 03:38 Hematology WBC 9.6 HGB 12.9 HCT 37.8 PLT 355 MCV 94 RBC 4.03 MCH 32 MCHC 34.2

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RDW 13.1 MPV 6.1 L Neutrophils 55
 Lymphocytes 34 Monocytes 8 Eosinophils 2
 Basophils 1 Neut Absolute 5.2 Lymph Absolute
 3.3 Mono Absolute 0.8 Eos Absolute 0.2
 Baso Absolute 0.1 Cardiac Studies Troponin-
 HS <2.0 Chemistry Calcium Lvl 8.1 L Anion
 Gap 9 Sodium Lvl 134 L Potassium Lvl 4.2
 Chloride 102 CO2 23 Glucose Lvl 109 BUN
 9 Creatinine 0.6 Alk Phos 75 ALT 13
 AST 15 Bili Total 0.4 Total Protein 5.8 L
 Albumin Lvl 3.5 LAB >60 LAB >60 01/22/21
 03:17 Chemistry Gluc POC 106 Gluc POC
 106 (01/22/21 03:17) Diagnostic Results
 Preliminary CT head reveals no acute intracranial
 abnormality Preliminary CT abdomen pelvis revealed no
 acute intracranial abnormality other than hiatal hernia
 Chest x-ray is negative for acute pulmonary pathology
 EKG Results EKG obtained at 0323 interpreted by me
 reveals normal sinus rhythm, patient has diffuse T wave
 flattening which appears similar to previous no STEMI,
 no ectopy no heart block no WPW Brugada prolonged
 QTC Emergency Department Course and Procedures:
 Medications, IV's and Blood Products Ordered Sodium
 Chloride 0.9% (Sodium Chloride 0.9% Bolus) 1,000 mL
 once IV Bolus, Reason for Infusion = Abnormal fluid
 losses Other Orders Nursing to Initiate Saline lock
 Insertion Careset (Stat) Oxygen Therapy (Titrate for
 SaO2 > 95%) Reexamination/Reevaluation: Critical
 Care Note The high probability of sudden, clinically
 significant deterioration in the patient's condition required
 the highest level of my preparedness to intervene
 urgently. Critical care was necessary to treat or prevent
 imminent or life-threatening deterioration of the following
 conditions: cardiac failure, circulatory failure, CNS failure
 or compromise, dehydration, hepatic failure, endocrine
 crisis, metabolic crisis, renal failure, sepsis, respiratory
 failure, shock, toxidrome and trauma. I provided critical
 care services requiring my management in the following
 manner: chart data review, documentation time,
 medication orders and management, re-evaluations, vital
 signs assessments and reviewing monitor data, and
 ordering and reviewing lab tests. Aggregate Critical care
 time was 30 minutes. My time did not include minutes
 spent treating any other patient simultaneously or on
 activities that did not directly contribute to the patient's

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treatment. It did not include time spent performing other reported procedures. Medical Decision Making: This is a 76-year-old female who presented ER today for evaluation of syncope. Patient was reportedly mildly hypotensive which improved with IV fluids. I suspect that patient had dehydration given 4 episodes of large watery stools. Patient had no recent antibiotic use and has no C. difficile risk factors, suspect this may be related to her Covid vaccine, she had no evidence to suggest anaphylactic shock, patient felt better after IV fluid bolus was able to ambulate around the emergency department without lightheadedness or near syncope. She had troponins x2 which were negative, her EKG was nonischemic and there was no evidence of ectopy or arrhythmia. Patient did have syncope and fell onto her side, she denies discrete head injury although patient is anticoagulated, CT head was obtained to rule out intracranial hemorrhage given the syncopal event. Patient CT abd/pelvis was negative for obvious cause of patient's abdominal tenderness may be related to her diarrheal illness patient will be prescribed Bentyl. She will call her primary care doctor in the morning to arrange close follow-up. She understands need for aggressive oral hydration at home. She will have low threshold to return should she develop lightheadedness syncope chest pain shortness of breath palpitations worsening abdominal pain bloody or dark stools any new or concerning symptoms. The patient presented to the emergency department with potentially life or limb-threatening symptoms. After my history, examination, and workup have decided that the patient is stable. My impression is that they are safe to go home at this time. I have reviewed ED return precautions with the patient. They understand to return if they are concerned for any reason. They will follow-up with their PCP in 1-2 days. Impression: Syncope, hypotension-improved, dehydration Plan: Discharge Follow Up Within: 1-2 days Comments: Please call your doctor in the morning to arrange follow-up with your primary care doctor in the next 24 hours. Please stay well-hydrated and eat regular meals. Please take Bentyl as needed for abdominal cramping with diarrhea. Please return to the ER if you develop worsening abdominal pain, feelings of lightheadedness passing out any new or concerning symptoms. Patient Education Syncope, Easy-to-Read

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| 963802 | 1/22/2021 | FL | 68 | F | 1/4/2021 | 1/4/2021 | Diarrhea, Adult Discharge Meds dicyclomine 10 mg 1 cap, PO, QID, 20 cap Referral for suspected pre-hypertension or hypertension was given. Please note: Unless specifically stated, all procedures mentioned, tests done and medications given were performed/interpreted by the emergency physician, or were under the direct supervision of the emergency physician. This ED Note was completed using voice-recognition transcription and may contain inadvertent errors. Additional information for Item 9: Fainted; Did not feel well; Hit head; A little pain in arm; A spontaneous report was received from a 68-year-old female patient, who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced the events, fainted, hit head, did not feel well, and a little pain in arm. The patient's medical history was not provided. Relevant concomitant medications reported included ezetimibe, atorvastatin, and atenolol. On 04 Jan 2021 at 9:00 am, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 in the left arm for prophylaxis of COVID-19 infection. On 06 Jan 2021, the patient reported that she took the vaccine on 04 Jan 2021 and she did not feel anything after but a little pain in her arm. On 05 Jan 2021 around 7:00 pm, the patient went to her fridge for a drink and told her husband she did not feel very well, and then fainted. The patient reported that she hit her head and has never fainted before. No treatment information was reported. Action taken with mRNA-1273 in response to the events was not reported. The outcome for the events, fainted, hit head, did not feel well, and a little pain in arm, were unknown.; Reporter's Comments: This case concerns a 68-year-old female patient with unknown medical history, who received their first of two planned doses of mRNA-1273 (Lot unknown), and who experienced the serious unlisted event of Syncope, the non-serious listed event of Pain in extremity, and the non-serious unlisted events of Head injury and Malaise. Based on the current available information and temporal association between the use of the product and the onset of the events on the day after vaccination, a causal relationship cannot be excluded and the events are considered possibly related to the vaccine. |

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| 964678 | 1/22/2021 | NY | 73 | F | 1/21/2021 | 1/21/2021 | Pt had Moderna Vaccine. Pt verbalized lip tingling sensation, followed by throat swelling and fainting and grunting with inspiration. Was not able to obtain BP at the time. Epinephrine 0.1 mcg x 2 was given 3-5 minutes apart. Pt responded well. Was alert, and verbally responsive. Pt also received Benadryl 50 mg IM, Famotidine 20 mg, and Solumedrol 40 mg. Pt was taken by Paramedics to Emergency department for continued management. Pt was advised to not take second dose of Moderna Vaccine. |
| 964528 | 1/22/2021 | AR | 41 | F | 1/20/2021 | 1/21/2021 | Congestion, out of body experience (like a fog where you cannot think), headache, syncope |
| 964177 | 1/22/2021 | CT | 92 | F | 1/15/2021 | 1/18/2021 | Vasal vagal syncope |
| 964128 | 1/22/2021 | NY | 27 | F | 1/15/2021 | 1/16/2021 | Syncope |
| 964125 | 1/22/2021 | OH | 44 | F | 1/19/2021 | 1/20/2021 | Woke up the next morning after receiving the vaccine, and felt horrible. Fever 101, aches, chills. Was only out of bed for a couple of minutes, knew that something was not right, and then I passed out on the floor for at least 15 minutes. |

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| 963815 | 1/22/2021 | FL | 68 | F | 1/4/2021 | 1/4/2021 | fainted; a little pain in arm; A spontaneous report was received from a consumer concerning a 68-years-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced fainting and pain in her arm. The patient's medical history was not provided. Concomitant product use was not provided by the reporter. On 04 Jan 2021, at approximately 09:00am, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: 011J20A) intramuscularly in the left deltoid prophylaxis of COVID-19 infection. On 04 Jan 2021, after receiving the vaccine, the patient felt a little pain in her arm. On 05 Jan 2021, at approximately 19:00 the patient fainted after standing up. She hit her head on the floor and had a small bump on her head. No treatment information was provided. Action taken with the second dose of mRNA-1273 in response to the event was not reported. The outcome of the events, fainting and pain in her arm, were considered unknown.; Reporter's Comments: This case concerns a 68-year-old female subject with who experienced a serious, unexpected event of fainting and pain her arm. Her medical history and con meds were not provided. The fainting event occurred 1 day after the first dose of the mRNA-1273 study medication administration, after patient stood up, fainted, and hit her head on the floor and sustained a small bump on her head. Treatment for this event was not provided. Very limited information regarding the fainting event has been provided at this time. Based on temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. |
| 967026 | 1/22/2021 | LA | 35 | F | 1/19/2021 | 1/20/2021 | Body aches leading into flushing and nausea. Then vasovagal event. Unconscious for an unknown period of time. Symptoms occurred at approximately 02:30am, no treatment sought at time of event. Dizziness and weakness continued for about another hour. No further episodes of fainting. Body aches and fatigue continued into the next day for approximately 24 hours in total, pain managed with Motrin. All symptoms then resolved. |

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| 965835 | 1/22/2021 | FL | 42 | F | 1/4/2021 | 1/5/2021 | Vaccine 1/4 Left arm, ED visit 1/5 due to dizziness, light headed, chills, HA, fever went up to 102.0, almost passed out; oxygen given, HR rate went up to 230, started to have convulsions, o2 sats down, RR 70, given ativan for convulsions; Follow up with Care Spot 1/; MMI 1/13 |
| 964690 | 1/22/2021 | TX | 25 | F | 1/16/2021 | 1/16/2021 | 1855 BP 125/86 HR-86 O2 Sat 99% on room air. Patient reported numbness in left arm to wrist and on left side of mouth. Numbness remained localized throughout 30 minute extended monitoring. Lungs CTA, Cap refill <3 sec, AOx4, 0/10 pain, no tingling sensation. No loss of taste/smell. Pt reports similar numbness as a first sign of migraines. Patient has fainted during blood draw 1 year ago. 1920 No improvement in numbness, provided snacks and water during monitoring. No swelling, denies dizziness, no weakness in arm or generalized weakness reported. No redness, no inflammation at injection site on inspection. Airway clear, no difficulty breathing. Skin pink, arm to touch WNL. Patient responsive to pin prick sensation and deep pressure in left arm. Motor functions WNL on assessment. No edema. 1934 Patient stable, will end extended monitoring. Patient will visit urgent care if symptoms do not improve or worsen. All s/s will be reported in v-safe app. |
| 967020 | 1/22/2021 | | 44 | F | 1/20/2021 | 1/20/2021 | Fever almost fainted feels BP dropped. left work |
| 966876 | 1/22/2021 | NY | 43 | F | 1/18/2021 | 1/18/2021 | Immediately felt sore in arm then felt hot and sweaty in post vaccine waiting room dizzy blurred and blacked out vision... Vasovagal syncope episode Emt and nurses came right over gave me oxygen and water....felt better after approximately 25 minutes of treatment....drank 3 bottles of water was able to walk and leave without going to hospital around 12:15pm Arm severely sore for 48 hours. |
| 965876 | 1/22/2021 | MI | 22 | M | 1/22/2021 | 1/22/2021 | Within 1 minute of receiving vaccination, patient fainted - slumped in chair, clammy, and pale. Unresponsive to verbal stimuli. Eyes rolled back with some jerkiness in extremities. Resolved in about 1 minute. No respiratory distress. Became responsive to verbal stimuli and was alert and oriented. Drank one bottle of orange juice, and after 10 minutes of sitting, able to walk back to monitor area without issue. Observed another 20 minutes. |

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| 967174 | 1/22/2021 | CA | 35 | F | 1/9/2021 | 1/9/2021 | PT C/O L ARM PAIN STARTING @ INJECTION SITE, WITH TINGLING TO L HAND. PT FAINTED. 911 INITIATED, PT REFUSED TO GO W/ PARAMEDICS . PT STAYED FOR AN HOUR LONGER @ POST VAX. VITALS WNL. PT LEFT W/ NO FURTHER INCIDENT. |
| 967119 | 1/22/2021 | AR | 87 | F | 1/22/2021 | 1/22/2021 | 89 y/o female w/ history of syncope presented to RX for 1st dose COVID-19 vaccination. Patient buckled in wheel-chair, unable to walk, assisted. Requested vaccine be administered without moving patient from wheelchair. After administration, patient remained in waiting area for recommended 15 minute observation time, then patient's wheelchair was moved nearby, but still waiting area. Approximately 20 minutes after vaccination, granddaughter called me over to help. Patient was unconscious and appeared not to be breathing, but pulse was palpable. Called for code white. Pharmacist asked granddaughter to hold patient's head up. Pulse remained palpable, pharmacist administered 1 dose of 0.3mg epinephrine via epi-pen into patient's left thigh. Patient quickly regained consciousness, spoke to family, said she didn't feel well. EMS arrived. Patient began to vomit, was placed on stretcher by EMS and left with EMS. A few hours later the granddaughter reported to us that the patient had a UTI and physical exam by ER attributed her experience to untreated infection. |
| 967083 | 1/22/2021 | AK | 57 | F | 1/22/2021 | 1/22/2021 | Patient felt faint after 10 minutes. Fainted x 3 in lobby with Involuntary movements of right upper extremity. EMS called. Patient transferred to ER. |
| 967062 | 1/22/2021 | OH | 85 | F | 1/22/2021 | 1/22/2021 | After 15 minutes of observation and no adverse reactions, patient went to the restroom, and went shopping. 30 minutes after administration, patient was extremely fatigued, unresponsive, unable to be aroused. Called 911. Blood pressure was 60/Error or blood pressure machine was not working properly. Began to gasp and vomit. Epinephrine was administered at that time. 45 minutes after administration, EMS arrived. Patient was discharged from hospital around 3pm and her diagnosis was syncope. |

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| 967220 | 1/22/2021 | CA | 35 | M | 1/22/2021 | 1/22/2021 | 15:32 35 Y/O white male post Moderna vaccination presented with near syncope episode accompanied with lightheadness, diaphoresis, and mild blurry vision. Patient has no past/surgical history. Med reconciliation without dosage includes daily multivitamins, oil of oregano, men?s probiotic, biotin, osteobiflex, clobetasole, and po cranberry. Pt reports a feeling of dizziness, lightheadness, and blurry vision 7 mins after administration of Modern vaccination. Patient states that he doesn?t have a PCP and is usually healthy. Interventions included hydration of fluids (32oz with 45 min rest). Evaluated and D/C from post vaccination area @ 16:17 accompanied with spouse with instructions to report to the ED if experiencing similar symptoms, SOB, chest tightness, or syncopial sensation. Vitals: 15:42 BP 110/60, HR 72, O2 98% 15:53 BP 98/56, HR 90, O2 98% D/C Vitals 16:00 BP 108/82, HR 64, O2 99% |
| 966822 | 1/22/2021 | IL | 52 | F | 1/20/2021 | 1/21/2021 | Once I received the shot and went to my car I noticed I had a rash on my face so I immediately took benadryl. When I woke up the next morning I was extremely dizzy and fell in the shower. It was more than just being dizzy it was like I couldn't see and it was hard to pick myself up. I may have fainted because I didn't recall falling just noticed I was on the shower floor. I thought I had gotten up but then again I was still on the floor. I made it back to bed and slept for a few hours. After that I seemed fine. |
| 966768 | 1/22/2021 | NY | 39 | M | 1/21/2021 | 1/22/2021 | Woke up at 6:00am, felt hot, had to use the bathroom. Got up, went to the bathroom felt dizzy, I was able to get to the floor before passing out/fainted. Felt chills when I finally went back, but could have been from how long I was laying on the floor. |
| 966574 | 1/22/2021 | SC | 60 | F | 1/15/2021 | 1/20/2021 | Extreme fatigue day of and following week of vaccine. On 1/20/21 had episode of brain fog or complete lapse in memory of event I talked to a person just the day before. (Never happened before) Today, 1/22/21 I was sitting at my desk talking to another person and fainted for no reason. (Never happened before). I came to and after short while felt better.. Left work to rest at home. Have not seen a doctor yet but worried about 2nd vaccine dose. The syncope episode concerns me. |

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| 966036 | 1/22/2021 | FL | 69 | M | 1/22/2021 | 1/22/2021 | Patient received his covid-19 vaccine and during observation period experienced syncope and unconsciousness |
| 967072 | 1/22/2021 | CO | 37 | F | 1/14/2021 | 1/15/2021 | Flu like symptoms and fainting started 12 hours after receiving the vaccine and continued for about 36 hours. |
| 965942 | 1/22/2021 | PA | 31 | F | 1/8/2021 | 1/8/2021 | I received the vaccine at approximately 10:45a, I then went next door to be monitored for 15 minutes. Within a few minutes, I began to feel dizzy and lightheaded. I waited out the 15 minutes and went back to my office. When I got into my office I still felt lightheaded and I informed my supervisor. I explained to him that I was going to try and eat something and drink some water and I would feel better. I went into my office and continued to work for the next hour. After that hour, I began to feel very dizzy and "out of it" as I almost didn't know where I was at. I went to speak to my supervisor and I sat down in his office where I almost fainted. He took me back to my office where I sat with another co-worker. Duri time, I continued to feel light headed, although it came in waves. My husband drove me home, I showered, ate something and was feeling better. Around 6:00p, I began to feel lightheaded again and began to experience body aches, hot and cold flashes that would come in waves. Saturday morning, I woke up feeling better, but around 10:00a I began to experience the same symptoms. I laid down for a few hours that would get up and attempt tasks around the house, then I would ended up back in bed at 6:00p with the same symptoms again. I did meet virtually with a doctor and she explained to me to wait it out. On Monday, I met with my pcp and she informed me of the same, that these symptoms would eventually go away. Sunday, Monday, Tuesday, Wednesday, the only symptom that remained was the dizziness. At times, I still will feel dizzy for instance Saturday morning I woke up and felt pretty dizzy throughout the day. |
| 966426 | 1/22/2021 | SD | 80 | M | 1/21/2021 | 1/21/2021 | Pt got home at 3pm. Pt passed out and fell down. Pt did not hit head, but did bite his tongue. Pt reported to feeling nauseated and tired the rest of the evening. |

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| 966046 | 1/22/2021 | CT | 45 | M | 12/22/2020 | 12/22/2020 | right shoulder soreness for the first dose for 1-2 days. left shoulder soreness after second dose, then approximately 8-10 hours later, I developed headache, neck ache, and by the morning, had skin sensitivity especially noticeable in touching my hair and genitals in the shower which was approximately 15 hours later. By 18 hours later my headache had worsened and i began to get light-headed. i drank tons of water and had no urination. I got hot and almost fainted. I had extreme uncontrollable shivering by 20 hours after injection. i nearly passed out at work. I also had nausea and burping. By the next day(more than 24 hours after injection), I was completely fine. |
| 966056 | 1/22/2021 | KY | 44 | F | 1/21/2021 | 1/21/2021 | Lightheadedness, faintness, fatigue the night of receiving 2nd dose. Morning following second dose patient passed out while taking a shower and injured her arm. Contusion and bruising was prominent |
| 966057 | 1/22/2021 | NY | 80 | F | 1/19/2021 | 1/19/2021 | Extreme cramping in both legs, fainting |
| 966106 | 1/22/2021 | CO | 77 | M | 1/21/2021 | 1/21/2021 | Passed out cold around 8 a.m. when heading to bathroom. He doesn't remember anything; woke up at some point half in and half out of his closet; injured elbow. Other symptoms beginning during the night were dizziness, weakness, headache, nausea, fever of 101, chills, extreme fatigue. |
| 966108 | 1/22/2021 | TX | 43 | F | 1/4/2021 | 1/4/2021 | Had rash, felt like she was having hot flashes and passed out on her dialysis unit and was taken to the ED. |

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| 966131 | 1/22/2021 | NC | 34 | F | 12/16/2020 | 12/17/2020 | The Patient is a 34 year old female. The patient is a 34 yo female with a history of hypothyroidism who received Pfizer Covid vaccine on 16 DEC (lot #EK5730) after work. She experienced no immediate adverse effects other than about 5 minutes after vaccine receipt she experienced a sensation of ' blood rushed to my ears.' No dizziness or syncope occurred. She had no oral/face/throat/tongue swelling, no urticaria, pruritis, SOB, Wheezing, dyspnea, cough, CP, n/v/d. The following morning she awoke with pruritus to eyes, face, and urticaria to arms, thighs, chest, face and head. She was treated with 8 mgs of decadron and a dose pack. The symptoms abated. The following morning she experienced recurrence which improved with next steroid dose. She took benadryl that night. Symptoms have continued to recur as steroid wanes. |
| 966312 | 1/22/2021 | NY | 26 | F | 1/22/2021 | 1/22/2021 | Within five minutes I felt very faint and dizzy along with nausea. Then came the shortness of breath and the feeling of pins and needles which also brought itching and some minor hives with it. The dizziness, nausea, and feeling of fainting went away after about 10 minutes and I had to go to the Emergency Department to take care of the shortness of breath and hive like reaction. I was given some medications and they diagnosed it as a moderate allergic reaction to the vaccine. I was completely fine with the first one. |
| 961639 | 1/21/2021 | OH | 23 | F | 12/29/2020 | 12/30/2020 | On 12/30/2020, I experienced extreme abdominal pain and cramping, diarrhea that resulted in syncope, severe fatigue, injection site pain and swelling, nausea, dizziness, lethargy, apathy. These symptoms lasted for over a week. The only syncope episode was the morning after the vaccine. |

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| 962330 | 1/21/2021 | NY | 32 | F | 1/18/2021 | 1/18/2021 | She had a history of hives and fainting when she received the pertussis vaccine. This was her first dose of the COVID-19 vaccine and she had no known allergy to components of the COVID-19 vaccine. She said she had spoken with her doctor prior to her appointment. Staff at the vaccination facility set up a precaution in case she fainted including 1:1 observation immediately following injection. She had no fainting, and proceeded to the post vaccination area after about 15 minutes, when she said she felt fine. At about 30 minutes after receiving the vaccine, she reported a rash across her chest, visible hives and hot to the touch, and she had a few areas of rash on her arms. She did not express any difficulty breathing. EMS was onsite and were immediately notified. In the course of her evaluation by EMS, she drank water, used an ice pack on rash, and took her own Benadryl and reported that she was beginning to feel better after approximately 30 more minutes. EMS confirmed that she was stable and okay to leave. On-site DOHMH medical greeter informed her about v-safe, told her to talk with her PCP, and inform people at the time of her next vaccination. At approximately 6pm, this reporter (non-medical professional) followed up with patient to check on her symptoms. She expressed that she was feeling better, the rash subsided but that her hands were swollen. This reporter reiterated the importance of following up with her regular medical provider. |
| 961725 | 1/21/2021 | MD | 21 | M | 1/20/2021 | 1/21/2021 | Headache and pain in arm that injection was given in then passed out |
| 961711 | 1/21/2021 | CT | 75 | F | 1/19/2021 | 1/19/2021 | dry mouth Dry nose dizzy feeling of fainting |
| 961709 | 1/21/2021 | WA | 72 | F | 1/21/2021 | 1/21/2021 | Patient passed out a few minutes after her vaccine. "Patient hard to wake with verbal and mild shaking. Provider applied ice packs to chest and face. Patient came became more verbal and was able to speak and drink water. Patient was observed longer by provider. During this time the patient reported her tongue was swelling and throat felt funny. Provider ordered we administered Diphenhydramine 25 mg IM. EMS was called and patient was transported to area hospital. |

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| 960569 | 1/21/2021 | KS | 38 | M | 1/12/2021 | 1/12/2021 | About one hour after shot, I fainted while going up stairs to go to work. I woke up on stairs. No head injury. This was around 1200pm on 12 JAN. I began to feel ill. Arm hurt, headache, weight on chest. Body hurt. I went to bed early. I woke up on 13 JAN and felt worse. I stayed in bed until around 1300. I got up and went and sat in my office to work. At around 1700, I went to go get my children from a neighbors yard to bring them for supper. I made it to my back yard before feeling to tired to continue. I went inside and laid down. At around 1900 or 1930, I was putting my kids to bed. I then fainted once more. I don't know how long I was out each time. I don't think I hit anything with my head. I got up and went to my bed and texted a Doc. |
| 961656 | 1/21/2021 | OH | 56 | F | 1/19/2021 | 1/19/2021 | Site: Redness at Injection Site-Mild, Systemic: Generalized Body Aches -Mild, Systemic: Fainting-Mild, Systemic: Patient felt faint then had an overall body flushing sensation, quickly went away shortly after vaccination-Mild |
| 962871 | 1/21/2021 | AL | 23 | F | 1/21/2021 | 1/21/2021 | Patient fainted for less than 1 minute after becoming dizzy and nauseous within 5 minutes of receiving the vaccine. |
| 962331 | 1/21/2021 | VA | 34 | F | 1/13/2021 | 1/13/2021 | From 15-30 hours post vaccination, experienced chills, 2 degree rise in temperature, extreme headache, nausea, and 1 episode of near-syncope. At the onset of symptoms, I took Tylenol q4-6 hours and sipped on Gatorade. From hours 30-40, I changed over to ibuprofen and experienced headache only while up doing activities. |

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| 961479 | 1/21/2021 | FL | 55 | F | 1/7/2021 | 1/8/2021 | several fainting spells because of everything going on; elevated HR in the 130's; Uncontrollable chills; fever of 102.8; pain all over my body; intractable vomiting; This is a spontaneous report from a contactable nurse (patient). A 55-year-old female patient (not pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot EL0140, via an unspecified route of administration in left arm on 07Jan2021 10:45 at single dose for covid-19 immunisation. Medical history included covid-19 on an unknown date prior vaccination. There were not known allergies. Covid was not tested post vaccination. Concomitant medication included vitamin D; vitamin E. On 08Jan2021 at 02:00 the patient experienced several fainting spells because of everything going on, uncontrollable chills, fever of 102.8, pain all over the body, elevated heart rate in the 130's, and intractable vomiting. The patient was not treated for the events. The outcome of the events was resolved in Jan2021.; Sender's Comments: Based on the time association, all events are reasonably related to suspect BNT162B2 administration. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate. |
| 961397 | 1/21/2021 | NC | 50 | F | 12/16/2020 | 12/16/2020 | She report receipt of vaccine and 30-45 minutes later experienced severe headache, nausea, scratchy throat and loss of voice and breathing was 'heavy'. She reports pallor, increased heart rate and near syncope. She denies pruritis, urticaria, flushing, watery eyes, face/tongue or lip swelling, CP, cough. She was seen in ER and treated with zofran, pepcid, solumedrol, monitored and then released. ER records note tachycardia at 107 but otherwise normal VS and exam. . |

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| 961324 | 1/21/2021 | VA | 80 | F | 1/18/2021 | 1/18/2021 | At 7 pm arm began hurting, by 11 pm was vomiting then passed out, vomited 4 more times during the night and passed out each time very briefly, for a total of 5 times. Stopped by 6 a.m. Did not vomit or pass out any more after 6 a.m. Next day (1/19/21) stayed in bed and slept most of day, started eating again normally 1/20/21. Feels much more normal 1/21/20 other than sore arm. |

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| 961281 | 1/21/2021 | MI | 44 | F | 12/19/2020 | 12/19/2020 | near syncope; Sinus Tachycardia; Hypothyroidism; tested positive for Covid 19; tested positive for Covid 19; lost weight; No sense of taste or smell; No sense of taste or smell; losing hair; heart rate started increasing; high blood pressure; Increased cough; Sleepy; tired; Headache; This is a spontaneous report from a contactable other healthcare professional (patient) through the Medical Information Team and Pfizer-sponsored program Pfizer First Connect. A 44-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EL0140), intramuscularly on the arm on 19Dec2020 11:15 at a single dose for COVID-19 immunization. Medical history included tachycardia and stroke from 2019 and diabetes mellitus diagnosed in summer of 2020 and ongoing. Family medical history included father had type 2 diabetes. Concomitant medication included metformin hydrochloride, sitagliptin (JANUMET) for diabetes. The patient previously took regular flu shot and had body aches; it did not happen at the year of report but in years past she did have it. The patient took the COVID vaccine for precaution as she was a healthcare worker/paramedic and stated there was no prescriber. She received the vaccination at a health department facility, not a military facility. She had no previous immunizations and no additional vaccines were administered on the same date as COVID-19 vaccine. The patient received her first dose of COVID-19 vaccine on 19Dec2020 and after nine days, she tested positive for COVID-19 on 30Dec2020 and had an inpatient hospital stay. She mentioned she was so happy that she did not have any symptoms for those days. She stated that she got the shot on the 19th and later that evening was when she started having symptoms. She tried to sleep and it woke her up, she felt sleepy, tired and experienced headache on 19Dec2020 20:00 to 21:00. On 28Dec2020 23:00, she had an increased cough. She initially had increased cough from wearing mask and was having post nasal drip, then she got wet cough and that was when she decided to get tested. She went back and forth on dates; stated she was confused with the dates because of being in the hospital, it had been a while and the dates were all meshing in together. Her specimen was collected and they did the test on 29Dec2020 then found out that she tested positive for COVID virus with a COVID test nasal swab |

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on 30Dec2020 17:30. She mentioned she lost weight after she got COVID, had no sense of taste or smell on unspecified dates. She did not know if it was related to her thyroid but she started losing hair and her heart rate started increasing on Monday, so they took her off all her meds and said the COVID was doing crazy things to the body. She had to go on Carvedilol for the sinus tachycardia and had high blood pressure now. This was all new after she tested positive. She has had bouts of tachycardia before and did have a heart monitor as she had a stroke last year. So those have never been persistent or symptomatic. If she did have a high heart rate, it always went down. This one was symptomatic. She did fine the whole week after the shot, just had that little bit of sleepiness, was tired, and had a headache. The patient reported near syncope with sinus tachycardia due to COVID-19 and hypothyroidism on 08Jan2021 14:30 to 15:00, which required hospitalization from 08Jan2021 to 10Jan2021 (2 days). ER or physician's office was required. She never went to the ER for the vaccination, it was just for the near syncope with sinus tachycardia due to COVID-19 and hypothyroidism that she went and was then admitted to hospital. She just got out of the hospital the day before report (10Jan2021), was there for two days and was still recovering. She was supposed to receive her second vaccination on the day of report however her doctor did not know if she should get the second dose due to double antibodies. She did not ask if she still had the virus or it went away. She has not been to work in two weeks. Outcome of the events tested positive for COVID virus was not recovered; near syncope with sinus tachycardia due to COVID-19 and hypothyroidism was recovered with sequel; sleepy, tired and headache was recovering; while the remaining events was unknown.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

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| 961215 | 1/21/2021 | NC | 77 | M | 1/17/2021 | 1/17/2021 | The patient reported a history of syncope episodes with injections in the past. He reported that he vomited and passed out with his last four vaccines- flu and pneumonia. This time he was given his vaccine at 9:45 am and was sent to "high risk" observation and was monitored for 30 minutes. He experienced hypotension and tachycardia but did not faint. He was evaluated by the EMS at 10:10 and transported to the ED at 10:39 am. Upon arrival, his systolic BP was 90 mmHg with normal heart rate. He was monitored and discharged home with the final diagnosis of vasovagal syncopal response. |
| 961122 | 1/21/2021 | IN | 30 | F | 1/19/2021 | 1/19/2021 | I had mild to intense sensitivity to light within 5 hours of the vaccine. Around 9pm the night of my second and final dose, I could not settle. I tried to sleep under my usual schedule and routine. I kept waking up for no apparent reason. I felt like my body would rest but my brain never actually fell into sleep. I was not able to achieve REM sleep until around 7am. I woke up late around 11am feeling like I passed out from sleep deprivation. I woke feeling like I had a strange "hang over". I felt dizzy and light headed. I had a general feeling of being unwell. I had a pressure in my head above my temples that circled my head to the back of my crown area. |
| 961079 | 1/21/2021 | CA | 85 | F | 1/13/2021 | 1/20/2021 | 1 week after receiving vaccine. 85 year old patient experienced fainting and very low blood pressure. |
| 960944 | 1/21/2021 | NC | 41 | M | 1/19/2021 | 1/20/2021 | Started with flu like symptoms, chills, aches, etc. For about 12 hours. Then I rapidly spiked a 102.7 fever and became so physically weak I felt paralyzed. Oxygen saturation dropped into the low 90s and I began to have labored breathing. I made an attempt to stand up and urinate, then passed out and collapsed. Ems came to the house and checked me out. I declined their offer to go to the hospital because I broke the fever, was breathing better, and had no concussion signs from the fall. |

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| 960900 | 1/21/2021 | PA | 57 | F | 1/21/2021 | 1/21/2021 | Numbness and tingling to mainly L face as well as L arm and foot. Feeling as if I am going to pass out at any time. Have not passed out, just very "Fuzzy". Started approximately 15 minutes after injection and slightly worsened for the next two hours. After one night sleep, L face and L hand remain mildly numb and tingly as well as the foggy feeling mentally. |
| 962363 | 1/21/2021 | CA | 44 | F | 1/13/2021 | 1/14/2021 | Jan 14th - fatigue. Jan 15th - fatigue worsened, had to leave work. Arm sore but manageable. PM - chills, severe fatigue. Mild arm soreness. Almost fainted on my commute home while driving. Jan 16th. Fever 102, chills, fatigue, nausea, vomiting, diarrhea, massive headache, dizziness. Jan 17th Nausea, diarrhea, fatigue, headache, chills and fever 100 with Tylenol and Advil every 4-6 hours. Jan 18th - chills, fever, headache, nausea, diarrhea. Could not go to work. Jan 19th - nausea, fatigue, dizzy, diarrhea, had to leave work early. Jan 20th - fatigue, nausea. Jan 21st woke up with huge reaction at injection site. Swelling, itching, and very hot to the touch. Roughly 4" wide, and hard. Mild pain, but manageable. Nausea and fatigue still present. At work, but was sent home early. |
| 960874 | 1/21/2021 | OH | 24 | M | 1/20/2021 | 1/20/2021 | Patient became nauseated at 11pm 1/20/21 and fever of 101, passed out in bathroom dry heaving and woke up at 4am, Heartrate 182, short of breath, continuous vomiting, called EMS, was given zofran on route to ER, upon arrival to ER heartrate reduced to 130's, patient reports being given toradol and IV Fluids, and was released. Patient reports fever range of 101-103. |
| 963617 | 1/21/2021 | PA | 18 | F | 1/21/2021 | 1/21/2021 | Vasovagal episode. pt briefly passed out after reported blurred vision, dizziness and tingling arms. Staff supported patient by moving pt to ground and elevated pt feet. pt did not lose consciousness and reported feeling better after laying down for a few minutes. We moved her to a sitting position on the ground, then to the chair. continued to monitor and pt reported feeling fine. Patient recovered within 10 minutes of episode. |

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| 962407 | 1/21/2021 | AZ | 56 | M | 1/21/2021 | 1/21/2021 | Patient was sitting in chair and fainted, would not respond to sternal rub or name. Called rapid response and was taken to ED. Patient was not responding for 2 minutes, proceeded to take vitals and gave him some orange juice in case low sugar. Took vitals and patient had low BP, felt cold, all other vitals were WNL. Taken to ED after about 15 minutes where they ran tests and made sure patient was okay. |
| 962785 | 1/21/2021 | VA | 35 | M | 1/21/2021 | 1/21/2021 | Patient received vaccine and walked over to the monitoring room to have a seat. After about 15 minutes, he felt lightheaded and passed out. Patient woke up and was still lightheaded. 911 was called and patient was sent to the ER. Patient is now doing well. |
| 963633 | 1/21/2021 | CA | 23 | M | 1/21/2021 | 1/21/2021 | PT RECEIVED VACCINE, 30 MINUTES LATER EXPERIENCED LIGHT HEADEDNESS AND FAINTED AT CHECKSTAND. DID NOT HIT HEAD |
| 963533 | 1/21/2021 | TN | 25 | F | 1/20/2021 | 1/20/2021 | Fever, fatigue, passed out, vomiting, headache, nausea, abdominal pain, joint pain, dizziness, pain, dehydration |
| 963414 | 1/21/2021 | WI | 31 | F | 1/19/2021 | 1/19/2021 | Low Blood pressure , passed out , cold sweats, lightheadedness , loose stool |
| 963336 | 1/21/2021 | WA | 68 | M | 1/20/2021 | 1/21/2021 | PER PATIENT REPORT IN ABOUT THE 12TH HOUR MARK AFTER RECEIVING THE VACCINE PT WAS CONFUSED, LOOKED PALE, WAS NON VERBAL, UNRESPONSIVE, FAINTED AND PASSED OUT FOR ABOUT 10 MINUTES. HIS WIFE USED TO BE A REGISTERED NURSE AND SHE MENTIONED SHE HEARD HIS LUNGS AND THEY HAD FLUID WHICH RESOLVED LATER ON. |
| 963253 | 1/21/2021 | NC | 24 | F | 1/19/2021 | 1/19/2021 | Syncope approximately 5-7 minutes after receiving vaccination. Patient spontaneously recovered approximately 20-30 seconds later. She had recurrent vomiting over the next hour. She was observed. At no time did she have recurrent syncope or develop rash or respiratory or upper airway symptoms. No medications were administered. Due to her persistent vomiting she was transported to the ER for further evaluation. |

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| 963248 | 1/21/2021 | WV | 41 | F | 1/1/2021 | 1/14/2021 | <p>Within first 15 min my throat started to feel like it was closing up. My tongue also felt like it going towards the back of my throat and I was dizzy/lightheaded. It lasted. About 5/7 min. It felt like was easing up so the school nurse told me wait an additional 15 min to be sure I was ok. She also took my blood pressure and said was normal. Dr. a pharmacist brought me orange juice a d said maybe was just low blood sugar. I said it felt similar to when my epidural during last delivery was up too high and my throat closed up and I couldn?t breathe. About ten min later it began again. I tried to get up and walk around some and I felt a little better at first but then started to get significantly worse. I felt like I was struggling to breathe and tongue was swollen feeling and stuck to back of mouth as if it was paralyzed. I say back down and my blood pressure was high (just told bottom number was 106). I was moved to another room to lie down and pharmacist mentioned using epi pen or benedryl shot. I had to sit up and almost passed out. I was having difficulty breathing. Not because of my lungs but my throat and tongue seemed frozen. He decided to give me a 25 mg Benadryl shot but had me drink it. It had a horrible bitter taste and made my throat and tongue numb. At this point it was about 12:30. My administrator called a coworker to drive me home. I decided to leave about 29 min after I had the benedryl. I could still feel that my throat was somewhat tight but it had improved enough that I didn?t think I was in danger of not being to breathe again. I went home (15 min drive) and by then my throat felt a lot tighter. I took 25 mg more of benedryl and it felt better. About four hours later it became tight again and I took 50 mg of benedryl. Through out all this I had severe pain at site of injection in my left arm, dizziness, nausea, and headache.</p> |

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| 962617 | 1/21/2021 | CA | 48 | F | 1/12/2021 | 1/13/2021 | Patient received #2 COVID-19 vaccine 1/12/21 and slept through the night. When she was standing at the kitchen sink making breakfast at 10:00 am on 1/13/21 she fainted and woke up on the floor. Her child stated that she had fallen to the floor. She did not hit her head. Patient had an appointment to see her PCP the following day concerning something else. She did relay this information to her PCP who is asking that she follow up with a cardiologist. The PCP had no opinion if the vaccine may have caused her syncope. She currently has a appointment with a cardiologist. |
| 964020 | 1/21/2021 | CA | 38 | F | 1/5/2021 | 1/5/2021 | Was completely fine about 13-15 I got dizzy and blacked out. I was not able to talk. I don't think I completely passed out but everything went black. Spent a couple hours on a gurney being monitored. My blood pressure (normally low/normal) went up to 170/101. And my heart rate was in the 140s. My oxygen saturation at one point was 82% but I was not having any trouble breathing and was breathing normally. I had a terrible headache and was shaking uncontrollably for about 20 min. Eventually I felt well enough to go to work. About five hours after my shot, I passed out again. I was taken to emergency room. My blood pressure was high and my heart rate was still elevated. They ruled out anything being wrong and eventually sent me home. I had a migraine and fatigue for two days. I felt tired for two weeks. And everything that usually hurts, hurt extra bad. |
| 963006 | 1/21/2021 | AL | 85 | M | 1/13/2021 | 1/18/2021 | bilateral neck pain, low back pain, Left arm pain. Pt reports he "passed out" at ER. Pt states he went to the ER at 6:00 due to symptoms- Pt reported all testing in ER came back normal |
| 962613 | 1/21/2021 | CA | 48 | F | 1/12/2021 | 1/13/2021 | Employee received #2 COVID-19 vaccine 1/12/21 and slept through the night. When she was standing at the kitchen sink making breakfast at 10:00 am on 1/13/21 she fainted and woke up on the floor. Her child stated that she had fallen to the floor. She did not hit her head. This employee had an appointment to see her PCP the following day concerning something else. She did relay this information to her PCP who is asking that she follow up with a cardiologist. The PCP had no opinion if the vaccine may have caused her syncope. She currently has a appointment with a cardiologist. |

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| 962603 | 1/21/2021 | CA | 48 | F | 1/12/2021 | 1/13/2021 | Patient received #2 COVID-19 vaccine 1/12/21 and slept through the night. When she was standing at the kitchen sink making breakfast at 10:00 am on 1/13/21 she fainted and woke up on the floor. Her child stated that she had fallen to the floor. She did not hit her head. Patient had an appointment to see her PCP the following day concerning something else. She did relay this information to her PCP who is asking that she follow up with a cardiologist. The PCP had no opinion if the vaccine may have caused her syncope. She currently has a appointment with a cardiologist. |
| 962624 | 1/21/2021 | CA | 48 | F | 1/12/2021 | 1/13/2021 | Employee received #2 COVID-19 vaccine 1/12/21 and slept through the night. When she was standing at the kitchen sink making breakfast at 10:00 am on 1/13/21 she fainted and woke up on the floor. Her child stated that she had fallen to the floor. She did not hit her head. This employee had an appointment to see her PCP the following day concerning something else. She did relay this information to her PCP who is asking that she follow up with a cardiologist. The PCP had no opinion if the vaccine may have caused her syncope. She currently has a appointment with a cardiologist. |
| 962778 | 1/21/2021 | MN | 36 | F | 1/20/2021 | 1/21/2021 | AT 6:00am when getting ready for work had onset of a bloody nose, very lightheaded while in the shower, she saw stars, she sat down then when going to get out she fainted. When she was able she attempted to get up and started passing out. Went back to bed, sever bone aches, and feeling very cold, unable to warm up. Now she has had a onset of a headache remains at home in bed. |
| 962851 | 1/21/2021 | | 91 | F | 1/15/2021 | 1/15/2021 | presented to the ED 1/5/21 with syncope 1 hour after receiving COVID vaccine found to have acute hypoxic resp failure at rest. Per family patient's pulse ox low with exertion at baseline for the past couple of months, but she always recovers to above 90%. She was discharged home with home health with oxygen 1/19/21 |

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| 962900 | 1/21/2021 | CO | 64 | F | 1/20/2021 | 1/20/2021 | Vaccine recipient c/o near syncope to RN monitor in the vaccination clinic. Cool, pale, dry skin. She placed her head on the table and asked for help. RN monitor requested assistance. Patient had strong pulse, no respiratory difficulties, no hives noted but was unable to stand. ED Charge nurse notified and ED RN transported patient to the ED via gurney without incident. |
| 962939 | 1/21/2021 | CT | 29 | M | 1/21/2021 | 1/21/2021 | Vaccine administered @ 11:00a.m. @ 11:01 patient vomited x1. Reported feeling hot, skin pale in color. Systolic BP in 80's. HR 60 RR 16 O2 sat 92% rm air. Patient responsive, increasingly, "feeling hot" Assisted to floor in supine position. 11:15a.m. 130/79 HR 76 RR 16 Symptoms improving. 11:20a.m. Patient able to stand and walk to observation area where he sat until 11:45a.m. Declined EMS transport to hospital. Denied further complaints. Ambulated out of clinic. VS on d/c 148/72 HR 88 RR 18 O2 sat 98% rm air. A&O x3. Reported hx. of syncope during past blood draws. |
| 958649 | 1/20/2021 | TX | 64 | F | 1/20/2021 | 1/20/2021 | Pt passed out & shaking (possible seizure) shortly after injection. 911 called. Pt conscious after 1-2 minutes. Declined transport to ER. Monitored by RN and pharmacist for 45 min. Pt's husband drove her home when status returned to normal |
| 958369 | 1/20/2021 | NJ | 45 | F | 1/20/2021 | 1/20/2021 | Pt received vaccine. She was being observed for 15 min after injection. About 5 minutes into her observation time, she alerted the nurse that she was not feeling well. Nurse went over to talk to her and pt started to seem wobbly in seat. Pt then fainted and once on the ground, she started having a seizure. Epipen 0.3mg was administered and 911 was called. Pt stopped seizing upon receiving epinephrine. Paramedics and ambulance arrived and pt was taken to the ED. |
| 958516 | 1/20/2021 | | 74 | F | 1/19/2021 | 1/20/2021 | Syncope x2 |
| 958509 | 1/20/2021 | CA | 46 | F | 1/19/2021 | 1/19/2021 | Fainting, dizziness and weakness, trembling, BP 168/129. HR 145 |

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| 958381 | 1/20/2021 | NY | 29 | F | 12/30/2020 | 12/30/2020 | P29 y/o f with no pmh, on OCP's, citrus allergy (contact dermatitis), non smoker, sent to ED with palpitations, SOB approximately 5 mins after receiving COVID vaccine. Patient describes palpitations as heart beating fast also with tingling in her tongue. She was given epinephrine and symptoms improved, however restarted shortly after. She denies chest pain, rash, oral swelling, difficulty swallowing, coughing, nausea, vomiting, syncope. Treated with benadryl, dexamethasone, famotidine |
| 958647 | 1/20/2021 | MA | 37 | F | 12/23/2020 | 12/23/2020 | Felt flushed. Passed out after a minute. |
| 958348 | 1/20/2021 | FL | 22 | F | 1/19/2021 | 1/19/2021 | Systemic: Nausea-Mild, Systemic: Vomiting-Mild, Systemic: Fainting-Mild, Systemic: Visual disturbance ("blue spots," "dark visual waves") |
| 958313 | 1/20/2021 | | 46 | F | 1/20/2021 | 1/20/2021 | Patient felt dizzy and weak approximately 20 minutes after vaccination and passed out when walking out of the clinic. Patient given one round of Epi and offered supplemental oxygen. Patient was monitored after resolution of symptoms and released to home care. |
| 958042 | 1/20/2021 | VA | 43 | F | 1/6/2021 | 1/20/2021 | near syncope w/in 30 min. of vaccine- taken to ER immediately monitored, EKG, and kept for observation increased heart rate, light headed, orthostatic after vaccine continued w/ rapid heart rate, light headed and orthostatic for 3 days day 2 severe body aches, chills, fatigue and headache,, arm pain only at injection site, swollen lymph nodes- Tylenol taken but barely touched pain day 3 still joint aches and headache, fatigue and chills, slight arm pain only at injection site, swollen lymph nodes- Tylenol and rest day 4 felt better, rash began on torso and spread to arms, groin, neck, swollen lymph nodes day 4 rash which began to itch lasting day 4,5,6,7,8- took Benadryl so I could sleep, swollen lymph nodes Continue w/ intermittent chills, body aches, headache and light headed for days 4,5,6,7,8 Continue w/ swollen lymph nodes under left and right arm and today is day 14 |

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| 957831 | 1/20/2021 | | 37 | F | 1/16/2021 | | 37y female with history of anxiety disorder who presents to ED with chief complaint of feeling shaky, hot, and racing heart after receiving 1st dose of Moderna COVID-19 vaccine. Patient reports receiving injection, subsequently walking to the check out line and suddenly feeling hot, tremulous, and tachy. She endorses tingling and numbness in bilateral upper extremities, diaphoresis, heart palpitations, and blurry vision. She denies HA, n/v chest pain, SOB, hemoptysis, syncope, loss of consciousness, bowel incontinence, and bladder incontinence, HR improved, patient left ED with no concerns |
| 958743 | 1/20/2021 | NC | 69 | F | 1/20/2021 | 1/20/2021 | Patient is a 69 y.o. female with history of multiple medical problems as indicated below including rheumatoid arthritis. She is a non-smoker. She tells me she has "a heart condition" and is followed by a cardiologist. She tells me she was in her usual state of health and took her COVID-19 first vaccine today. Approximately 30 seconds later she noted chest tightness/burning that has been constant. It is rated 9/10 at maximum and improved to 5/10 after about 10 to 15 minutes. She also states, "my eyes feel funny. I feel cold. I am dizzy." She endorses palpitations and dyspnea. She denies any abdominal pain, nausea, vomiting, fevers, diaphoresis, headache, cough, rash, or syncope. She does have a history of seafood allergies and had similar reactions after eating seafood. She tells me 3 years ago after a flu shot she fainted. She tells me the past 2 years after her flu shot she had nausea or vomiting. She tells me she fell yesterday and hurt her hip but she did not hit her head. No LOC. She tells me she takes baby aspirin nightly. Family history: Mom and dad both died at age 82 from lung cancer. They both had heart disease. She was sent back from the vaccination area to urgent care to be evaluated after her reaction to the COVID-19 vaccine. |
| 957972 | 1/20/2021 | IN | 33 | F | 1/18/2021 | 1/18/2021 | Onset 10-12 hours after dose on 1/18/21 Body aches, chills awakening from sleep. Fever 100.5 after acetaminophen. Weakness, dizziness, mild Pre-syncope, nausea. Persisted through the night and early morning and gradually improving the next day. 24 hours after symptom onset, temp was still 99.5. Much improved with residual generalize muscle soreness upon awakening on 1/20/21 |

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| 957973 | 1/20/2021 | MI | 81 | U | 1/11/2021 | 1/15/2021 | Syncope with trembling |
| 959824 | 1/20/2021 | ID | 49 | F | 1/1/2021 | 1/1/2021 | Profound fatigue lingering, sleep disturbances, Diarrhea, nausea, fainting feeling, intermittent high heart rate. I?ve had post viral postural orthostatic tachycardia syndrome and you thousand 15 to 2016. And this feels like the same thing. I have not had a flare until I received the vaccine |

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| 958841 | 1/20/2021 | PA | 65 | F | 1/7/2021 | 1/9/2021 | <p>passed out; dizzy; hit the ground; nausea; pain at injection site; fever; chills; tired; severe headache; vomiting x 2; cold; experienced orthostatic hypotension; This is a spontaneous report from a contactable other HCP. A 65-years-old female patient started to receive bnt162b2 (BNT162B2; Lot # EK9231) vaccine , intramuscular in the left arm on 07Jan2021 11:00 at single dose for Covid-19 immunisation . Medical history included rubber sensitivity (Latex). The patient's concomitant medications were not reported. On 09Jan2021 12:00 the patient experienced orthostatic hypotension , passed out with outcome of recovered , dizzy with outcome of recovered , hit the ground with outcome of recovered. These events were considered serious because medically significant. On 09Jan2021 12:00 the patient also experienced the following non serious events: nausea with outcome of recovered , pain at injection site with outcome of recovered , fever with outcome of recovered , chills with outcome of recovered , tired with outcome of recovered , severe headache on with outcome of recovered , vomiting twice with outcome of recovered , cold with outcome of recovered. The reporter stated the patient attempted to get out of bed and she passed and hit the floor. Caller states she think she may have experienced orthostatic hypotension. Caller stated if she had stayed in bed she probably would not have fallen. Her husband found her laying in vomit The patient underwent lab tests and procedures which included body temperature: 99.6 fahrenheit on unknown date.; Sender's Comments: Based on a chronological temporal association a causal relationship between events orthostatic hypotension , passed out dizzy and falling down and BNT162B2 vaccine cannot be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p> |

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| 957700 | 1/20/2021 | | 26 | F | 1/13/2021 | 1/13/2021 | I had been lying down for 1-2 hours. When I got up, I suddenly became lightheaded and nauseous. I had to sit on the floor to steady myself. I became extremely sweaty with chills and my entire left arm (side of injection) became numb and tingly. The episode lasted approximately 20 minutes, and I was symptom-free within an hour. I never fainted or vomited. |
| 959929 | 1/20/2021 | | 70 | M | 1/17/2021 | 1/18/2021 | Narrative: Patient seen in ED 1-17-21 with c/c of "bloating with epigastric pain". Patient with complicated medical history including stage 1B pancreatic cancer (was currently on chemotherapy mFOLFIRINOX), and a leadless permanent pacemaker implantation on 1-11-21 for long episodes of SR with complete heart block following symptoms of syncope (other cardiac history: CAD s/p CABG 2009, PAF, and HTN). Regarding ER visit for epigastric pain, nothing notable was found on workup and patient was to discharge home to rest. There were available doses of COVID-19 Vaccine following a vaccine clinic that same day, and patient was offered and agreed to a dose of vaccine. Patient was monitored for 15 minutes post vaccine with no notable issues. The following day, Monday 1-18-21, patient's caregiver called facility at 22:30 to report he had a fever of 102.8 degrees and that he had been "feeling kind of bad all day". Patient was advise to seek urgent medical care and reported back to ED on 1-19-21 at 00:55. Patient was admitted for SIRS (tachycardia and febrile) -- patient also reported diffuse myalgia. WBC WNL, CXR unremarkable for infection, UA neg for bacteria, LFTs WNL, blood cultures negative. Procalcitonin elevated at 17.8 -- suggesting inflammatory response. Patient initially reported feeling better on the morning of 1-19-21, but around 13:00 began rapidly declining (confusion, unable to walk) and started experiencing EKG changes (9 beats of SVT). Patient then coded and resuscitation was attempted for approximately 30 minutes. Patient did not survive the code. Coroner has been notified and family is considering autopsy at time of this report. |

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| 959928 | 1/20/2021 | | 50 | F | 1/20/2021 | | Agitation, BlurredVision, Confusion, Anaphylaxis, UrticariaPruritus, Syncope, Pt experienced reaction three days PRIOR to first vaccine - event documentation only. Narrative: Pt has history of likely environmental allergies resulting in 4-5 mild reactions annually. Has seen allergist-immunologist in the community and has epi-pens, ranitidine and diphenhydramine. Had reaction three days PRIOR to first covid vaccine dose. She did NOT experience any untoward reaction to either dose of vaccine. |
| 959771 | 1/20/2021 | CT | 76 | F | 1/18/2021 | 1/18/2021 | Lowered body temperature 30 min after dose, left hand began to itch approx. 45 minutes, both hands itching & swelling, then feet within hour. Total lose of vision within 90 min followed by fainting approx 10 minutes later. Fainted at check-in desk of emergency room |
| 959635 | 1/20/2021 | CO | 37 | F | 1/14/2021 | 1/14/2021 | extreme immune? reaction, starting around 11 pm the same day of reaction, including high subjective fever, delirium, repeated episodes of syncope, extreme weakness lasting 2-3 hours. overall - flu like symptoms that lasted 36 hours post injection. |
| 959489 | 1/20/2021 | NH | 24 | F | 1/20/2021 | 1/20/2021 | VR described a brief syncopal episode several minutes after injection. VR feels almost entirely back to normal after event. She has a history of syncope with injections. She improved without any treatment. |
| 959449 | 1/20/2021 | KY | 41 | F | 1/13/2021 | 1/14/2021 | Moderna COVID-19 vaccine EUA 1-14-21 migraine lasting 4 hours (patient has no Hx of migraines) 1-14-21 and daily through and including date of reporting 1-20-21 Intermittent Dizziness mild to severe/near fainting, unable to recreate with canal repositioning techniques. Tested for OHTN with no significant statistical alteration in BP readings. Dizziness presents similar to stepping off of a boat. Comes and goes in waves. Has happened daily usually beginning around 1-2pm and lasting through bedtime. |

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| 959435 | 1/20/2021 | OH | 80 | F | 1/20/2021 | 1/20/2021 | Patient was still within the 15 minute observation period. Patient starting saying she was hot. Bottle of water given to patient. Patient then passed out, attempted to talk to patient and performed sternal rub. Patient was lowered to floor with assistance to flat surface, rolled to side. Patient become alert. Rapid Response was called and patient was then taken to the Emergency Department. |
| 959019 | 1/20/2021 | PA | 30 | F | 1/20/2021 | 1/20/2021 | Patient was in Observation area. Witnessed by RN fainting and sliding to floor. Other RNS and Paramedic immediately at her side. Initially groggy but came alert and oriented quickly. Initially Bradycardic and hypotensive. IV started and immediate improvement. History of vasovagal episode with blood draws. Denied injuries or discomfort. Sent by ambulance |
| 958911 | 1/20/2021 | IN | 43 | F | 1/9/2021 | 1/9/2021 | 8 mins after receiving first dose, I became very dizzy, my heart rate increased and I started sweating. I never passed out and remained sitting. The episode lasted 1-2 minutes. I did not need assistance. Then 2 -3 hours later I had the exact same episode and reported it to the downtown clinic and they only urged me to self monitor or report to ER if needed. Those were the only 2 episodes. My blood pressure was elevated that afternoon but was very low for 3 days and I did not take my atenolol for those days. |

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| 958843 | 1/20/2021 | WA | 58 | F | 1/9/2021 | 1/10/2021 | <p>I began to pass out and yelled for my husband, he said when he came in I was sitting on the toilet with my head back, eyes rolling back not responsive.; I had my 2nd vaccine at work early Sat the 9th and felt increasingly worse all day; I woke up at midnight and felt extreme malaise; I was covered in sweat; vomited; I checked my temp and it was 99.7°F; sore; I think I had either a seizure or a vasovagal response.; This is a spontaneous report from a contactable nurse (patient). This 58-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot EJ1685 or FJ1685), intramuscular at single dose in the left arm on 09Jan2021 06:00 for Covid-19 immunisation. Medical history included atrial fibrillation on unknown date (1 episode), allergic to Keflex. There were no concomitant medications. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot EJ1685 or FJ1685), intramuscular in the left arm on 22Dec2020 for Covid-19 immunisation. On 10Jan2021 01:00 AM, the patient experienced: I began to pass out and yelled for my husband, he said when he came in i was sitting on the toilet with my head back, eyes rolling back not responsive (loss of consciousness) (medically significant), I had my 2nd vaccine at work early sat the 9th and felt increasingly worse all day (feeling abnormal), I woke up at midnight and felt extreme malaise (malaise), I was covered in sweat (hyperhidrosis), vomited (vomiting), I checked my temp and it was 99.7°F (pyrexia), sore (pain), I think I had either a seizure or a vasovagal response (seizure). No treatment required. The outcome of the events was recovered. The events were described as follows: I am healthy RN with no active medical problems. I had my 2nd vaccine at work early Sat the 9th and felt increasingly worse all day, I expected this so was not alarmed and went to bed around 10pm. I woke up at midnight and felt extreme malaise and went to the bathroom in case I might vomit, etc. and I tried to have a BM. I began to pass out and yelled for my husband, he said when he came in I was sitting on the toilet with my head back, eyes rolling back not responsive. He yelled at me for about 10 seconds and I came to, I was covered in sweat. I asked him to walk me back to the bedroom where I again passed out, fell to the floor and hit the bed, then was unresponsive</p> |

VAERS_ID RECVD STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 960034 | 1/20/2021 | CA | 55 | F | 1/13/2021 | 1/20/2021 | again for about 10 seconds then came to again and vomited. After this I felt completely relieved of my malaise. I checked my temp and it was 99.7°F. After this I was sore but otherwise completely okay, the next day I had a temp of 99.5°F. Today I am back to normal. I think I had either a seizure or a vasovagal response. The vaccine was administered at Hospital Facility. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination. The patient had not been tested for COVID-19 since the vaccination. The patient was not pregnant at the time of vaccination.; Sender's Comments: Based on the close temporal relationship, the association between the event "began to pass out" with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate. |
| 960034 | 1/20/2021 | CA | 55 | F | 1/13/2021 | 1/20/2021 | Red, raised bump where injection was administered, the circumference is about 1/4 inch. Directly below the injection site there are approximately 8 distinct scattered red raised dots(bumps) surrounded by cloud-like formation of swollen, also raised dark pinkish skin (surrounding the red bumps), although no distinct borders between the swollen , raised pinkish skin. The size of this swollen area is about 2 inches in diameter, right below the injection site. The said area is very warm to touch, but no pain, however it is very itchy. The bumps do not appear to contain fluid. No break in the skin or bleeding is evident. No nausea, no fainting, no dizziness experienced. However, slight headache experienced. Registered nurse on call recommended washing the area with warm water, applying cold compress and placing steroid cream |
| 954699 | 1/19/2021 | OR | 35 | F | 1/15/2021 | 1/15/2021 | After 5-8 minutes I suddenly became hot/sweaty, pale, dizzy, nauseous, sudden drop in blood pressure, syncope. I was given epinephrine and a rapid response team was called and I was taken to the ED |

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| 955649 | 1/19/2021 | NC | 37 | M | 1/18/2021 | 1/18/2021 | Pt. had a Syncope episode within 20 min. of getting immunization. BP dropped to 80's - Systolic. , and HR dropped to the 40's. Pt. placed on Ground-Legs elevated. Provided PO H2O, Rest, Cool packs and recovered well within 30 min. Left Hospital without incident. |
| 955942 | 1/19/2021 | MN | 77 | M | 1/18/2021 | 1/18/2021 | Systemic: Fainting-Mild |
| 955933 | 1/19/2021 | UT | 53 | F | 1/11/2021 | 1/12/2021 | I experienced chills, body aches, back pain, dizziness, nausea, dry heaves and passed out. When I passed out, I bit my lower lip and it bled quite a bit. I had brain fog, and couldn't come up with the correct words. Also, I could not sleep that night, at all without taking a few sleeping pills. It has been a week since this happened and I still can't sleep on my own. I used to be able to go right to sleep without any sleeping pills within about 5 min after laying down at night. |
| 955926 | 1/19/2021 | KS | 25 | F | 1/13/2021 | 1/18/2021 | Syncope Woke up from a nap, stood up about 1 minute later I started seeing black and woke up on the floor. Went to ER and all tests and labs were normal. |
| 955899 | 1/19/2021 | CA | 28 | F | 1/15/2021 | 1/15/2021 | blood pressure drop, cold body, sweaty/clamy, dizziness, loss of hearing, shortness of breathe and unconsciousness/fainting. This happened 4 hours after vaccine was administered with a duration of 5 minutes. |
| 955313 | 1/19/2021 | MD | 36 | F | 1/14/2021 | 1/14/2021 | Day of vaccine, headache, feeling of fainting, weakness, feeling of being nauseous. Felt better after eating. Next day, felt very weak, had headache in forehead and eye area, bit of dizziness. Throughout day arm got feeling bad and extremely painful with long sleeve on. Could not move arm due to pain. Got a bruise in the puncture area, 2 finger underneath got very hard and slightly red, not rash but raised and hard. Throughout the next day, was going away, and through the night able to raise arm normally, but still had bump and redness until Sunday. Still slightly red, but has lessened and almost gone, but still has bruise which is not unusual for her. Also had itching and was painful to scratch, could only lightly touch. All has resolved. |
| 955214 | 1/19/2021 | OH | 22 | F | 12/28/2020 | 12/28/2020 | Right after I felt fine.. I felt nauseas . Later that night , I was really dizzy, Fainted, nauseas, I felt feverish |

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| 955179 | 1/19/2021 | TN | 79 | F | 1/2/2021 | 1/4/2021 | Two days after her shot, she was sitting down working on her computer paying bills. She became nauseas and dizzy and then fainted. She hit the tile floor. |
| 955138 | 1/19/2021 | | 21 | M | 1/19/2021 | 1/19/2021 | Near syncope 2 minutes after vaccine. Patient caught by personnel prior to falling. |
| 955070 | 1/19/2021 | WV | 31 | F | 12/23/2020 | 12/28/2020 | She began to have full body urticaria, facial and lip swelling, fever, diarrhea, nausea, and vomiting 5 days after receiving dose 1 of Moderna COVID vaccine. She reports at that time she was experiencing dizziness, but denies syncope. She was given Solu-Medrol 125mg IM and this helped. |
| 954979 | 1/19/2021 | IN | 33 | F | 1/16/2021 | 1/17/2021 | Syncope Fatigue Malaise Chills Weakness when walking Dizziness Lethargic |
| 956019 | 1/19/2021 | MN | 32 | F | 1/15/2021 | 1/15/2021 | Employee received the Covid 19 vaccine around 4pm on 1/15/21. Employee waited 15 minutes then returned to the floor her shift. Around 5:15 employee felt dizzy and has slight headache and stomachache. Employee passed out and hit head on floor and was not breathing. RN Charge at time called code blue and started compressions and gave employee O2. 911 was called, paramedics arrived and transferred via ambulance . |
| 955000 | 1/19/2021 | FL | 42 | F | 1/8/2021 | 1/8/2021 | Patient was administered 2nd vaccine on 1-8-21 by a nursing student. During 15 observation period, arm began to feel cold at injection site area. At that point the patient realized the vaccine was given toward the back of upper left arm near the fatty tissue instead of toward the middle of the arm. Approximately 20 min after vaccine administration, patient became short of breath, dizzy, light headed, and throat felt a little swollen and almost passed out. A rapid response was called and the patient was seen by Occupational Health. The patient's BP and heart rate were elevated but normalized during observation in Occupational Health. At this time, the patient did not feel they needed to be seen in the emergency department. The patient was discharged home at this time. 12 hours after the shot, the patient began experiencing normal side effects from the vaccine. The nursing student was informed of administration at the incorrect site. |

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| 957185 | 1/19/2021 | OH | 48 | F | 1/15/2021 | 1/16/2021 | I went to bed Friday night around 10:00PM. I woke around 12:30AM with a throbbing headache, sore throat, post-nasal drainage, body aches, chills, fever, sweating, weakness and nausea. I went down to use the bathroom and then back to bed but could not sleep due to the throbbing headache and chills. I got back up around 2:30AM and soaked in a warm bath. I went back to bed around 4:30AM. I was able to go to sleep. I slept until around 8:30AM. At that time, I drank some water and went back to sleep. I slept until approximately 10:30AM and started drinking Powerade Zero. The Powerade was taken to bed and sipped on when I would stir and change positions. I slept until approximately 2:30PM, when I got up to use the bathroom. I urinated, washed my hands and went to walk out of the bathroom when everything went black. I remember yelling for my husband but then nothing else until I heard him yell my name several times and I was lying on the floor in the doorway of the bathroom. I passed out. I was sat up in the recliner and monitored. Above symptoms continued. Tylenol and Motrin were alternated every 4 hours for the fever. |
| 956010 | 1/19/2021 | ME | 29 | F | 1/18/2021 | 1/18/2021 | Symptoms within 15 minutes of vaccination. Staggering, flushed and dizzy. Low pulse. Passed out while sitting in the chair while waiting to go to ED. Regained conscious within 1 minute, disorientated, complaining of chest pain. Taken to ED - thought to be a vasovagal episode. |

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| 954426 | 1/19/2021 | IL | 43 | F | 12/29/2020 | 12/31/2020 | <p>Hospitalized for stroke on 31Dec two days after vaccine.; sudden loss of hearing to right ear; dizzy and lightheaded/severe dizziness/felt like fainting; difficulty breathing; vomiting; This is a spontaneous report from a contactable nurse (patient). This 43-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), (Lot number: EL1285) via intramuscular route on 29Dec2020 14:30 at single dose on the left arm for COVID-19 immunization. Medical history included anxiety. No known allergies. Concomitant medications were not reported. Patient was not pregnant. Facility type vaccine was Nursing Home/Senior Living Facility. No other vaccine received in four weeks. Patient hospitalized for stroke on 31Dec2020 two days after vaccine (Days of hospitalization: 4). Day of vaccine-6 hours after patient had dizzy and lightheaded for about 45 min then went away. On 31Dec2020 at 19:15 had sudden loss of hearing to right ear and severe dizziness, difficulty breathing, vomiting, and felt like fainting. Paramedics were called-sent to ER, had CTA which showed partial blockage and received TPA. Treatment included TPA, fluids, medications, hospital stay, outpatient follow ups, physical therapy. Patient was not diagnosed with COVID prior to vaccination. Patient has been tested for COVID post vaccination. The patient underwent lab tests and procedures which included Nasal Swab: Negative and Pixel: Negative on 08Jan2021. Outcome of the events was recovering.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported events including stroke, dizzy/lightheaded/felt like fainting, difficulty breathing, vomiting, and sudden loss of hearing to right, and the administration of the COVID-19 vaccine, BNT162B2. More information regarding the patient's underlying medical conditions, relevant lab tests would be helpful for the Company to make a more meaningful causality assessment.</p> |

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| 956013 | 1/19/2021 | MA | 23 | F | 1/15/2021 | 1/18/2021 | Per email received on 1/18-So I had my first dose of Pfizer?s covid vaccine last Friday (3pm). I experienced several side effects that day: lightheadedness, dizziness, fainting, nausea, throat constriction leading to shortness of breath and difficulty in swallowing, hives, flushed face, and fatigue. The throat constriction honestly frightened me and I almost went to the ER, but it eventually went away. For Saturday and Sunday, I developed fever, muscle ache, and extreme fatigue. Today, I thought it would get better but I still have fever and the extreme fatigue has not gone away. And unfortunately, as I am typing this, I think my tongue is getting quite swollen and is making it uncomfortable to breathe and swallow |
| 956999 | 1/19/2021 | WA | 28 | F | 12/29/2020 | 12/29/2020 | Syncope episode. Fainted and was unconscious for 3-5 minutes. |
| 956821 | 1/19/2021 | CA | 29 | F | 1/19/2021 | 1/19/2021 | FEELING LIGHTHEADED AND FOGGY. ETA 10AM FEELING NAUSEA , SHAKY AND SWEATY. DISCOLORATION IN FACE STARTED HAPPENING AND HEART WAS FEELING FAST. PER EMPLOYEE FEELING LIKE FAINTING. ICE PACK WAS APPLIED TO FACE/HEAD, DRANK COLD WATER, JUICE AND HAD A PIECE OF CANDY. 15MIN AFTER, PER EMPLOYEE FELT BETTER. |
| 956756 | 1/19/2021 | | 53 | F | 1/5/2021 | 1/7/2021 | I have been feeling dizzy; at times felt fainting; fell on the ground on 1/7/2021 evening between 8-9pm after feeling fainting. |
| 956713 | 1/19/2021 | MI | 46 | F | 1/1/2021 | 1/18/2021 | Fainted, chills sweating bodyaches and extremely bad headache |
| 956623 | 1/19/2021 | | 51 | F | 1/18/2021 | 1/18/2021 | vasovagal syncope followed by panic attack |

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| 956477 | 1/19/2021 | MO | 34 | F | 12/24/2020 | 12/24/2020 | Her fir was on 12/24 and she reports 7 hours later she had blurry vision and passed out. She continued to have nausea and couldn?t eat missed several days of work and lost 5 kg due to nausea. She received the second on 1/24 and she reports that 3 ½ hours later her heart rate was high, blurry vision and soa. She reports she does not remember much other than resting and her husband picking her up. She stated that she couldn?t remember much after that and was difficult to wake up by her family. Was off work a few days and is now back but feeling weak. |
| 956471 | 1/19/2021 | MO | 34 | F | 12/24/2020 | 12/24/2020 | Her fir was on 12/24 and she reports 7 hours later she had blurry vision and passed out. She continued to have nausea and couldn?t eat missed several days of work and lost 5 kg due to nausea. She received the second on 1/24 and she reports that 3 ½ hours later her heart rate was high, blurry vision and soa. She reports she does not remember much other than resting and her husband picking her up. She stated that she couldn?t remember much after that and was difficult to wake up by her family. Was off work a few days and is now back but feeling weak. |
| 956410 | 1/19/2021 | NH | 38 | F | 12/23/2020 | 12/23/2020 | Started with dull headache. Progressed to severe arm pain, radiating into neck and cramping in palm of hand. Unable to abduct arm. Symptoms lasted approx 36 hours. About 24 hours after administration, started with weakness, near syncope, and nausea with dry heaving. This lasted an additional 24 hours. There is persistent weakness in left arm compared to right when moving arm overhead. This weakness has persisted more than 3 weeks after injection. |
| 956406 | 1/19/2021 | | 43 | F | 1/19/2021 | 1/19/2021 | Reports red rashes to bilateral upper extremities within developing 3 minutes post vaccination. Felt lump to throat developing, dizziness, warm flashes, felt like fainting, and shortness of breath. She was taken immediately to ED and was provided medications in the ED- IV benadryl and sodium medrol. Lump to throat relieved after medication IV administration. Was prescribed diphenhydramine and prednisone on discharge. |

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| 956118 | 1/19/2021 | OK | 63 | F | 1/15/2021 | 1/15/2021 | 1/15/2021: That night after vaccine, feeling very cold, unsure of having fever and very tired. Reports arms and legs were burning that night. Nauseous that night also. Employee took Ibuprofen. At 4:00 am, feeling better. Saturday night, 1/16, feeling the same; nauseous, burning feeling in legs and arms, and chills. Reported into work on Sunday, 1/17. Talking to coworker in breakroom and said not feeling right and passed out. Employee has no memory of event after passing out. Staff reporting employee went unresponsive, gurgling like going to aspirate. Staff tipped employee to side to prevent aspiration and took employee to emergency room to be evaluated by physician. Vitals were stable, labwork unremarkable except potassium of 3.3. Chest xray was normal. No signs of infection. Doctors determined reaction to vaccination on Friday, 1/15 |
| 956078 | 1/19/2021 | MD | 29 | F | 1/19/2021 | 1/19/2021 | Syncope minutes after vaccination |
| 956697 | 1/19/2021 | MO | 48 | F | 1/2/2021 | 1/3/2021 | fever chills nausea no vomiting fainting x 1 body aches arm swelling |

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| 951972 | 1/18/2021 | KY | 69 | F | 1/8/2021 | 1/9/2021 | I felt quite sick, like I had the flu; became very lightheaded and dizzy; passed out; felt quite sick; This is a spontaneous report from a contactable consumer (patient). A 69-year-old non-pregnant female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 08Jan2021 at 12:30 at single dose in left arm for covid-19 immunization. Medical history included R.A.D., osteopenia, migraine with aura, the patient had previously suffered episodes of vasal vagal syncope when she got the flu or other severe illnesses, and the patient was diagnosed with COVID-19 prior to vaccination. Concomitant medication included atenolol, atorvastatin, azelastine, and fluticasone. The patient previously took gramicidin, neomycin sulfate, polymyxin b sulfate (NEOSPORIN) and experienced allergies. The morning after receiving the vaccine, she felt quite sick, like she had the flu. When she got up from bed and went to the bathroom to urinate, she became very lightheaded and dizzy. She attempted to return to bed, but passed out on the bedroom floor before she could get to the bed, and seized while she was unconscious. Once she came to, she was helped to bed and, after about 90 minutes, felt much better, and got up, and ate food and had coffee. All events occurred at 07:30 AM on 09Jan2021. All events were reported as non-serious by reporter. The patient did not receive treatment for the events. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient has not been tested for COVID-19 since the vaccination. The outcome of the events was resolved in Jan2021. Information on the lot/batch number has been requested. |
| 953085 | 1/18/2021 | MN | 24 | F | 1/15/2021 | 1/16/2021 | Dizzy, nauseous, fainted, emesis, severe sweating from 6am-8:30am |

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| 953072 | 1/18/2021 | RI | 29 | F | 1/8/2021 | 1/9/2021 | <p>Syncopal event; Nausea; Vomiting; This is a spontaneous report from a contactable nurse. A 29-year-old female received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number:EL1284), via an unspecified route of administration on the right arm on 08Jan2021 12:15 at single dose for COVID-19 immunisation. The patient medical history was not reported. Concomitant medication included influenza vaccine (INFLUENZA VACCINE) on 13Dec2020. The patient previously took first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899) on 18Dec2021 12:15. The patient experienced syncopal event, nausea and vomiting on 09Jan2021 05:00. The patient received no treatment. The outcome of the events was recovering. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Based on the compatible time association, the event syncope is possibly related to suspect drug BNT162B2 administration. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p> |
| 952835 | 1/18/2021 | CT | 52 | F | 1/8/2021 | 1/12/2021 | <p>Typical muscle soreness lasted a couple days. Lingering headache off and on. Feeling of tiredness for a couple days. Tuesday started with brain fog. Thursday was more noticeable at work trying to perform normal tasks. Friday felt lightheaded and dizzy. Couldn't focus and waves of anxiety with headache. Coworker mentioned my complexion was yellow and eyes were red. Feels faint and fell over but didn't lose consciousness. Saturday felt lightheaded and still went to work and passed out at work. Today is Monday 10 days after vaccine. I can't work or drive due to weakness, lightheaded and faint. I'm slow with speech and get confused very easily. Didn't recognize my own kitchen at one point. Wasn't sure where my bathroom was earlier. No appetite. Sharp pains randomly in my head.</p> |

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| 952720 | 1/18/2021 | AZ | 26 | F | 1/14/2021 | 1/15/2021 | Received second dose of vaccination at approximately 4:50 PM. Awoke at 2:30 AM with mild fever, body aches, chills, and nausea. Got out of bed for to drink fluids; after walking around for approximately 10 to 15 minutes I experienced a blood pressure drop resulting in me passing out on my bathroom floor. Prior to passing out attempts to regulate breathing and placing head between my legs failed to keep me conscious. Unknown duration of time spent passed out on floor; eventually was able to walk back to bed upon waking and lying on floor for additional 5 minutes (conscious). Awoke again at 8 AM with mild fever, chills, and body aches, while experiencing mild drops in blood pressure (no nausea). Symptoms ceased the following day of 1/16/2020. |
| 952472 | 1/18/2021 | OR | 46 | F | 1/15/2021 | 1/17/2021 | presents to clinic today for evaluation of adverse reaction to COVID-19 vaccination. She received the first dose of the Moderna vaccine two days ago on 1/15/21. She reports fatigue, chills, and body aches started later that day. Reports around 2 am that night she woke up feeling nauseous, at that time she went to the bathroom, was sitting on the toilet concerned she may have vomiting and/or diarrhea, she had what sounds like a vasovagal response, she became lightheaded and sweaty and fainted, she woke up sitting on the toilet but leaning over. She has been taking Ibuprofen for her body aches. Yesterday morning 1/16/21 she noticed a rash started around her umbilicus. Her body aches and other symptoms were starting to improve. She reports since then the rash has spread and is present all over her trunk, armpits, beginning to spread down legs. She denies itching, burning, or any discomfort associated with the rash. She also reports feeling shaky, weak, and mildly SOB with exertion today. She denies any throat swelling. She has a history of PFO and takes Plavix |
| 952409 | 1/18/2021 | | 64 | F | 1/5/2021 | 1/6/2021 | 1/6/21 HA, severe leg cramps, N/V, fatigue, syncope |
| 952178 | 1/18/2021 | PR | 65 | F | 12/30/2020 | 12/31/2020 | Fainting episode . I was standing by a friend ,I fainted and hit my head on the floor . Regained consciousness right away and had no other subsequent events. |

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| 952101 | 1/18/2021 | | 19 | F | 1/14/2021 | 1/14/2021 | The day of vaccination, the patient presented to the emergency room with a complaint of dizziness and syncope. Reported that she became dizzy, presyncopal feelings, and had a witnessed syncopal event. The patient stated she does have vasovagal syncopal events after blood draws in the past. The patient was assigned an overnight admission for a potential post-vaccination adverse event, new onset atrial fibrillation, dehydration, and syncope. Patient was discharged the following day. |
| 953100 | 1/18/2021 | CA | 51 | F | 1/15/2021 | 1/15/2021 | Severe abdominal cramps, syncope feeling, sweating, nausea, migraine, vision impairment, loose bowel movement, chills, muscle cramps |

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| 951973 | 1/18/2021 | VA | 30 | F | 1/8/2021 | 1/1/2021 | <p>Blacked out; Fainted; Felt very unwell; Nauseous; Chills; Fell; Knocked out, hit her nose, started to bleed; Humongous scar on her nose; In her hand there's a rash with different dots/red; She has petechiae/rash on the forearm; hit her face; knocked out, hit her nose; This is a spontaneous report from a contactable physician. This physician reported that a 30-year-old female patient (daughter) received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 08Jan2021 at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced blacked out, fainted, felt very unwell, nauseous, chills, fell, knocked out, hit her nose, started to bleed, humongous scar on her nose, in her hand there's a rash with different dots/red, she has petechiae/rash on the forearm, all on an unspecified date in Jan2021. The Caller wanted information on side effects specifically looking at platelet or clotting or bleeding issues. Her daughter, (female, age 29 date of birth) received the 2nd dose of Pfizer vaccine, received it at the (State name), last night. She felt very unwell, nauseous, chills, and then blacked out, fell, knocked out, hit her nose, started to bleed; fainted and hit her face, didn't stop bleeding for 2 hours. There's a humongous scar on her nose. It took 2 hours to stop bleeding. She's going to urgent care today. Her daughter was healthy, yesterday was 2nd dose. In her hand, there's a rash with different dots/red. She has petechiae/rash on the forearm. Thankfully it (bleeding) did stop. The outcome of events for 'knocked out, hit her nose, started to bleed' was resolved on an unspecified date, for other events was unknown. The case was reported as non-serious. Information on the Batch/Lot number has been requested.; Sender's Comments: Based solely on a chronological association a causal relationship between events blacked out and fainted and BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), cannot be completely excluded. The case will be reevaluated should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly</p> |

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| 951811 | 1/18/2021 | | 22 | F | 1/10/2021 | 1/11/2021 | notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate. episode of syncope ~15 hours after vaccine administration (next morning). sudden onset of lightheadedness which persisted for few minutes then lost consciousness. have never fainted before. tests in ER suggest low blood pressure but nothing else abnormal. |

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| 951979 | 1/18/2021 | IN | 30 | F | 1/7/2021 | 1/1/2021 | fist dose on 21Dec2020, second dose on 07Jan2021; pain and stiffness radiating from injection site all the way down arm,into breast, and middle of back; pain and stiffness radiating from injection site all the way down arm,into breast, and middle of back; pain and stiffness radiating from injection site all the way down arm,into breast, and middle of back; Started having chills; Severe headache; collapsed on the way back to bathroom and was unable to get up for about 20 minutes; tachycardia; extremely fatigued entire day; This is a spontaneous report from a contactable Pharmacist who reported for herself. A 30-year-old female patient received her second dose of BNT162B2 (Pfizer/ BioNTech Covid-19 vaccine, lot number Ej1685) at a single dose at 09:45 AM 07Jan2021 at left arm for Covid-19 immunization in a hospital. The patient had her first dose of Pfizer Covid-19 vaccine on 21Dec2020 at 12:00 PM at left arm, and experienced very mild reactions which included mild pain at injection site and runny nose/sneezing day after vaccine. The patient had a medical history of rash to penicillin as a child. Concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks prior to her first dose of Pfizer COVID vaccine. In the evening of second vaccine (around 17:00), pain and stiffness radiated from injection site all the way down arm, into breast, and middle of back. She started having chills. Around 10 hours after dose chills became somewhat violent despite being under 4 blankets. Severe headache also started. In the middle of the night to go to bathroom, she collapsed on the way back and was unable to get up for about 20 minutes. She also suffered from tachycardia overnight. her baseline heart rate runs in 60s- 70s, but was in 110s-120s (based on Apple Watch monitoring). Day after vaccine, she was extremely fatigue entire day and spent all but a few hours in bed. Arm pain mostly gone. Headache was very strong and persistent through the day. On second night chills not as bad but still occurred overnight. HR still elevated in 80s overnight. Morning of day 2 still had headache and fatigue. The patient did not receive any treatment for the events. The outcome of collapse and unable to get up for 20minutes, pain and stiffness radiating from injection site all the way down arm,into breast, and middle of back was resolved, chills and tachycardia was resolving, headache, fatigue was not resolved. Prior to vaccination, |

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| | | | | | | | the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The reporter considered that the events was non-serious.; Sender's Comments: Based on a chronological temporal association and known BNT162B2 vaccine safety profile, causality between events fainting, violent chills and severe headache and BNT162B2 ((Pfizer/ BioNTech Covid-19 vaccine) cannot be completely excluded. The case will be reevaluated should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate. |
| 954041 | 1/18/2021 | IL | 51 | F | 1/7/2021 | 1/8/2021 | On 1/8 I passed out at home, losing consciousness for a few seconds. |
| 953123 | 1/18/2021 | CA | 34 | F | 1/11/2021 | 1/12/2021 | At 1:00 - 3:00 in morning - 100.3 temperature and chills and headache. Headache became severe - 7:00 in morning. Really severe joint pain and headache - not quite a migraine - no aura but very severe headache. Had to medicate with 1000 mg Tylenol and 600 of Advil. Headache for days. Pain at injection site and that has been with every vaccine I've ever had. Headache went away within three or four days. Joint pain was there for about two days. Only medicated the headache the first couple of days then it slowly got better. Didn't get vertigo and didn't get flushed after the vaccine. Didn't have the fainting feeling. |
| 954101 | 1/18/2021 | OH | 61 | M | 1/13/2021 | 1/13/2021 | heavy sweating, then passed out twice ,hitting the floor 5 hours after getting shot . went to summa ed the next day , cat scan,bloodwork and ekg came back ok. on jan 16th i went to a dentist for a abscessed tooth.after i passed out i had a headache for 2 days and felt out of sorts. |

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| 954073 | 1/18/2021 | TX | 32 | F | 12/30/2020 | 12/30/2020 | Immediately felt dizziness, shortness of breathe and left body numbness. Fainted in and out and left body tightness/pain for 2 hours post injection. fever, fatigue, headache, shortness of breathe, muscle fatigue, chest ache for several days after. 01/08/2021 all symptoms become worse and severe. Left body muscle tightness and fatigue, heart palpations, vomiting, chest pain, dizziness, syncope, difficult breathing, unable to walk. ER Visit 01/08/21, 01/09/21, 01/09/21, and 01/11/21 PCP visit 01/12/21 Cardiologist visit 01/15/21 |
| 953929 | 1/18/2021 | WI | 64 | F | 1/13/2021 | 1/14/2021 | On 01/14/2021 patient experienced severe chills and shaking upon awakening. She subsequently vomited three times following the episode of chills and shaking. Later in the day the client experienced two episodes either extreme fatigue or fainting - she is unsure of the nature of the events since she does not recall falling asleep, and both events occurred in her vehicle while parked. |
| 953794 | 1/18/2021 | NE | 23 | F | 12/30/2020 | 1/5/2021 | Individual felt fine except a sore arm until 1/5/2021 legs became weak and dizziness and light headed and did t" feel well" and passed out. had general muscle weakness and went to ER. She was given fluid for possible dehydration and went home and weakness increase and went back to ER and was admitted to hospital for testing. |
| 953681 | 1/18/2021 | CA | 59 | F | 1/18/2021 | 1/18/2021 | 20-30 min post injection, patient experienced tachycardia, palpitations, shortness of breath, syncope, loss of consciousness. 911 contacted by nursing home staff. Patient was placed in nursing home bed, 1 EpiPen dose administered by clinic nurse (RN. Nursing home staff began supportive care, supplemental oxygen given. patient experienced petit mal seizure and was non-responsive for a few minutes. Eventually came to but was still unstable. Paramedics took over at this point and patient was evaluated and transferred to hospital. |
| 953628 | 1/18/2021 | CA | 73 | F | 1/14/2021 | 1/15/2021 | 24 hours after vaccine: tiredness weakness, chills, fever, nausea, vomiting, fainted, unconscious few seconds. No medical treatment, resting at home, |

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| 953598 | 1/18/2021 | FL | 29 | F | 1/8/2021 | 1/8/2021 | <p>Started to have symptoms and fainted; Hit her nose and has a scar now; She blacked out; hit her nose, got the scar in the nose, ...she was bleeding from that scar; hit her nose, got the scar in the nose, ...she was bleeding from that scar; She started to feel unwell; Chills; Nausea; Rash in her arm; She had little red in her bumps; This is a spontaneous report from a contactable physician. A 29-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE Solution for injection, batch/lot no. and expiry date: unknown), via an unspecified route of administration on arm on unspecified date at a single dose (2nd dose) for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. Physician stated, "she had no medical conditions, she was in very good you know very like standing with herself." Patient had her 1st dose of Covid vaccine on unspecified date for COVID-19 immunization. Physician (reporter) stated, "I am the parent of someone who got the COVID dose, the second dose yesterday. I am very concerned because my daughter yesterday (08Jan2021) started to have symptoms and fainted at 4:00 in the morning and hit her nose and has a scar now. She had her second dose yesterday (pending clarification), after the second dose last night she started to feel unwell, getting chills, nausea and when she got up to go to the bathroom, she fainted, she blacked out. She lives alone, she is an adult, she hit her nose, got the scar in the nose, and the bleeding wouldn't stop, she was bleeding from that scar. She told me it took two hours for bleeding to stop from that scar." When asked when the events started, Physician stated, "Last night (08Jan2021), at 4:00 am she took the shot during the day while she was at work. She said, she started to getting chills and then she was nauseated." When asked if patient was still experiencing the event, the parent reported no as patient was just resting. Also stated, "She didn't take any treatment but she said she took Tylenol." Physician further added, "I am concerned, we are going to be taking her to the urgent care now but I am concerned about what is going on with platelets and all of that because of what had happened, last night the bleeding wouldn't stop for two hours and she was alone at the night and weekends. She said, she had to lay down and then her dad is there now because he is closer, he is going to be taking care of the urgent care</p> |

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| 953449 | 1/18/2021 | PA | 38 | F | 1/17/2021 | 1/18/2021 | but I want Pfizer to know what my daughter has gone through last night after she took this second dose." Physician further added, "she is having a rash in her arm, she had little red in her bumps as well. I want her to go get checked up as soon as possible in urgent care." Patient was taking some Ibuprofen (later clarified that patient took Tylenol as treatment). She was not taking any other medication. Outcome of the events was unknown. Information Requested on Lot/ Batch number.; Sender's Comments: The reported faint was most likely due to an accident, and less likely causally related to the use of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE). The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate. |
| 953215 | 1/18/2021 | CA | 69 | F | 1/14/2021 | 1/17/2021 | Fainted approximately 19 hours after vaccination for an unknown amount of time. Horrendous arm pain. Have been using Tylenol for pain. Could not move arm and could not touch injection site area without severe pain. Pain has lessened with use of Tylenol. |
| | | | | | | | 3 days later had an episode of faintness, as if I stood up quickly. Vision darkened but I never passed out. I was sitting and reading after eating about an hour after exercise. No further episodes. |

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| 953126 | 1/18/2021 | OH | 53 | F | 1/16/2021 | 1/17/2021 | Moderna COVID-19 Vaccine EUA received on Saturday. Sunday morning in the middle of my sleep, I woke feeling hot and sweaty, slightly nauseated, and like I had to defecate. I stood up, felt like low blood pressure but wanted to get to the bathroom. I walked towards the door, opened the door and fainted, falling backwards. My spouse states I was pale, staring at the ceiling and kind of stiff in my arms and legs for about 3 minutes. He spoke to me, checked my pulse, covered me, poked my feet. As I came back to awareness I tried to speak and was unintelligible but then became more conscious. He tested me with questions to make sure I was ok. I defecated after that but did not vomit. I was tired the rest of the day and napped for several hours. I don't seem to have hurt anything in the fall. I am instructed to be off work Monday by my supervisor. |
| 954100 | 1/18/2021 | TX | 58 | F | 1/15/2021 | 1/16/2021 | Unable to make out the Lot number due to illegible. The pain in my right arm and around the back of my head and neck increased all day on Saturday, latter that night the pain woke me out of my sleep, and as I attempted to go to the restroom, I passed out. I woke up on the floor where I had passed out face down, with a busted bloody lip and bruises and broken skin on both knees. Very frightening, Thank God that I woke up because I live alone. Thank you. |
| 951647 | 1/17/2021 | DE | 27 | M | 1/16/2021 | 1/16/2021 | Approximately 6 hours after injection, fainted 4-5 times. Struggled with consciousness for about 10 minutes. Had low blood pressure and required emergency medical attention. |
| 951436 | 1/17/2021 | GA | 38 | M | 1/16/2021 | 1/17/2021 | I had a headache and fatigue starting about 5 to 6 hours after shot. After going to sleep at 10 am, I woke up not feeling well at 2am...after going to the bathroom and walking towards my bed I passed out. My wife found me on the floor a few seconds later confused and covered in sweat..my headache was much worse.. I went back to sleep and in the morning still had a headache as well as muscle aches and pains. \ |

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| 951123 | 1/17/2021 | TX | 53 | F | 12/18/2020 | 1/1/2021 | On 01/01/21, I experienced a vaso vagal syncope episode and actually passed out and injured my upper back and right side of rib cage. I am a nurse and was looking up the required reporting and saw this as a reportable event, and even though it indicates within 7 days, I thought it might be worth reporting. I have never passed out like that before. |
| 951169 | 1/17/2021 | MS | 20 | F | 1/16/2021 | 1/16/2021 | Patient became pale and experienced a vasovagal syncope episode. She never lost consciousness and once she vomitted she felt better. An IV was started and normal saline was given at a KVO rate and patient's status improved back to baseline within minutes. She was transferred to the local ER to be evaluated out of caution. |
| 951182 | 1/17/2021 | FL | 30 | F | 1/15/2021 | 1/16/2021 | Woke up at 3 am with severe chills, went to the bathroom to check temperature. Got incredibly nauseous and light headed. Passed out on the bathroom floor and hit my chin. Had to get stitches, fluid, and CT. |
| 951211 | 1/17/2021 | NY | 30 | M | 1/16/2021 | 1/17/2021 | Around 11:15 am, Jan 17, 2021, while standing at the toilet, my son either lost his balance or fainted and fell to the floor. He was able to cushion his fall so that he did not have any broken bones, bleeding etc. He said he felt weak and tired. I had to help him up from the floor. He was able to assist me but it was like lifting a dead weight (he weighs about 150). He was able to walk to his bed with his arms around my neck holding him upright. He is very tired/lethargic and not himself. Temperature is 99.7F by mouth. He has rested since the incident. Giving him apple juice to keep him hydrated. I need to help him up to a sitting position before he can drink. |

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| 951271 | 1/17/2021 | OR | 46 | F | 1/15/2021 | 1/15/2021 | Nine hours after the vaccine was administered I began to have symptoms. It started with severe chills. I bundled up and went to bed. I woke at about 2am with severe nausea. Went to the bathroom still suffering from chills, and in severe pain from joints and muscles attempted to use the toilet and passed out. Revived and climbed back into bed. The next day 01/16/21 continued to have chills, nausea, and joint and muscle pain. At 2pm on 01/16/21 started to have a rash in my stomach. By 8pm the rash was on my stomach, and back. Sunday 01/17/21 still having mild chills and aches, the rash is now wide spread over my torso and back. |
| 951555 | 1/17/2021 | MI | 30 | F | 1/15/2021 | 1/15/2021 | 2:30PM Chest pains, weakness, dizziness, feeling shaky. 6:20pm Tachycardia, hypertension, fever, fainted, whole body went limp and unable to keep head up. 8:30 able to use arms again and feel them 10:30pm able to use legs and walk again |
| 951637 | 1/17/2021 | NV | 54 | F | 1/7/2021 | 1/7/2021 | Sudden onset of extreme vertigo with associated near syncope (felt like vagal). No vomiting and no real nausea. Vertigo still present but now minimal. That same night I had a mild fever, but I am not concerned by this. Had some mild vertigo after the first vaccination (lot EH9899) but it only lasted 48 hrs. |
| 951656 | 1/17/2021 | WI | 49 | F | 1/13/2021 | 1/15/2021 | Sig stomach and gut cramps to the point of near syncope. Missed half day work. Nausea, lack of appetite. Lasted over 4 hs severe, 12 hs moderate |
| 951684 | 1/17/2021 | MA | 56 | F | 1/15/2021 | 1/16/2021 | I got the vaccine at 5:45 Friday night was having symptoms of arm pain headache dizziness lightheadedness and nausea upon awakening Saturday morning. Saturday night was having increased nausea and lightheadedness. Got up to use the bathroom at 1 AM Sunday morning was very dizzy and nauseous and passed out on my hallway floor. I woke choking on vomit, crawled to the bathroom, continued to vomit. Sustained bruised lump to forehead, bruised nose, split lips. Went back to bed. Later Sunday felt better. |

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| 951705 | 1/17/2021 | FL | 42 | F | 1/13/2021 | 1/14/2021 | Severe pain/swelling on R upper arm, R lateral breast/axilla and R side of the neck starting the morning of 1/14/21. Pain got steadily worse to the point of full body myalgias, severe fatigue/weakness and severe nausea. Almost passed out at work and ended up being bedridden for the rest of the day on 1/14 and all day 1/15 and 1/16. Also had hematuria that developed on 1/15. Went to urgent care clinic on 1/16 and received one bag of IV fluids and zofran for the nausea. CBC, CK, CMP all normal but 1+ hematuria on U/A. Symptoms finally improved on 1/17 |
| 951614 | 1/17/2021 | GA | 65 | F | 1/16/2021 | 1/16/2021 | Severe chills began at 10:30 pm; then fever spiked; slept fitfully and finally got up around 2 am to get a thermometer -while in bathroom the room started spinning and I fainted or passed out. I came to on the bathroom floor and managed to crawl back to the bed. There was confusion and the inability to understand what was going on. I remained in bed until the next morning when all symptoms abated except for some fatigue. |
| 950339 | 1/16/2021 | | 45 | F | 1/16/2021 | 1/16/2021 | Felt dizzy and lightheaded 8 minutes after vaccine. Felt like she was fainting. Monitored vitals . |
| 950618 | 1/16/2021 | NJ | 62 | F | 1/15/2021 | 1/16/2021 | Sore Arm at site of injection onset couple of hours after shot Fever of 100.2 onset approximately 14 hours after the shot Chills and slight headache onset 14 hours after shot Fainting onset about 14 hours after the shot Aches and Pains onset about 14 hours post injection Fatigue |

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| 949903 | 1/16/2021 | WI | 35 | F | 1/15/2021 | 1/15/2021 | That morning I had taken amlodipine for the 2nd time in my life to help Raynaud's. Both times I have taken amlodipine now I have felt lightheaded and less cognitively sharp than normal basically the entire day. I received the above Pfizer COVID-19 vaccine around 12:45 PM, within about 3-5 minutes of receiving the vaccine and standing in line to check out I suddenly felt I was going to loss consciousness/collapse so started lowering myself to the ground and then became unconscious and fell. Healthcare staff informed me I was unconscious for about 20-30 seconds. I woke up and initially felt confused, but quickly realized what had happened. Then I felt nauseated, had some stomach cramps and thought I was going to have diarrhea. They considered giving me Epi for possible anaphylaxis, but I requested they observe further for any skin reaction/hives, airway symptoms, etc given I was skeptical the syncope may have been fully or partially related to the amlodipine I took that morning. Symptoms slowly improved over 20-30 minutes, but the lightheaded feeling and nauseated lasted hours. No Epi, medications, or interventions were needed. |
| 949942 | 1/16/2021 | VA | 37 | F | 1/14/2021 | 1/14/2021 | About 10-20 seconds after receiving vaccine I felt faint and the darkness started to close in and I almost passed out. The back of my tongue became very dry. I felt better after 10 minutes and never passed out. They took my vital signs and everything was normal. I have never been bothered by needles before at all so it was strange. However I do have a long history of anxiety so it?s possible it was just that. |
| 949992 | 1/16/2021 | TX | 79 | M | 1/9/2021 | 1/9/2021 | Vasovagal syncope several minutes after administration Patient transferred to the ER for cardiac evaluation and left against medical advice |

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| 950096 | 1/16/2021 | OH | 23 | F | 1/11/2021 | 1/12/2021 | Moderna COVID-19 Vaccine EUA Night of shot arm began to hurt. It became very painful by the time I went to bed. 10x worse than a flu shot Next morning at 8am, got up and almost passed out. Went back to bed. Got up at 10. Arm was painful to move. Began fever at 12 noon. Highest was 102. Terrible chills and aches and pains throughout entire body... lasted through bedtime. Tylenol did not manage the symptoms. Day 3 I was much better. I did experience fatigue, but arm pain was wearing off quickly. |
| 950238 | 1/16/2021 | IA | 43 | F | 1/16/2021 | 1/16/2021 | Right arm cold feeling progressed to neck and legs. Tried to return to facility after 25 minute interval after the vaccination. Then felt faint and called 911 who responded reported passed out while on 911 dispatch. |
| 949824 | 1/16/2021 | CA | 32 | F | 1/15/2021 | 1/15/2021 | Patient had her first Moderna COVID vaccination at 4:00 PM today and 5 min later felt dizziness, worsening, associated with headache, nausea, sore throat, hot flashes, and dizziness is from side to side when she looks at her phone, no dizziness when she does not look at it. Patient primary complaint is headache on bilateral temples. All other symptoms resolved, and no dizziness if not looking at phone. Patient has history of headaches, similar in quality, but this is more intense (6/10 intensity, less than her scoliosis pains, but more than usual headache pain), but otherwise the same, pounding sensation, and she can feel throbbing. Headache is about the same currently. Started simultaneously as dizziness, immediately, unchanged. No changes in vision. Peak intensity of headache around 30 min after onset, peak at 4:30 or so. Patient notified the vaccine clinic staff and was instructed to be observed in another area, and did not improve. Patient remembered that her initial blood pressure was low and it fluctuated. Patient was then sent to the ED. Upon initial assessment in the Emergency Department 2 hours after her initial injection, the assessment is likely vasovagal near syncope with tension headache, rather than true allergic reaction. Given metoclopramide, diphenhydramine, normal saline, and obtained labs. |

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| 950617 | 1/16/2021 | AR | 47 | F | 1/13/2021 | 1/13/2021 | 1st dose only side effect was sore injection site - 2nd dose- 14 minutes after injection near syncope episode with severe dizziness, nausea, tachycardia, high blood pressure. Benadryl 50 mg was administered. 45 minutes after Benadryl administration driven home and severe dizziness was present until next morning. 17 hrs post injection had severe flu like symptoms (chills, severe headache, muscle/body aches/no fever). Took Advil 800mg. At 48hrs no symptoms remain. At 69 hrs post injection had severe dizziness that is still present at 72.5 hrs post injection. |
| 950624 | 1/16/2021 | NY | 65 | F | 1/16/2021 | 1/16/2021 | Patient started to feel dizzy after approximately 10 minutes. She was taken into counseling room and laid flat on the floor with her feet up as syncope treatment. She stated her tongue was swelling and her throat was scratchy and EMS 911 was called. She stated she was having trouble breathing and was administered 1 epinephrine 0.3mg auto-injector. After approximately 5 minutes symptoms continued to progress and she stated her entire body was tingling. She stated she was still having trouble breathing and a second epinephrine 0.3mg auto-injector was administered. |
| 950683 | 1/16/2021 | NY | 35 | M | 12/30/2020 | 12/30/2020 | About 45 seconds after injection. A warm cloudy feeling spread over my body from the injection site. Became dizzy, when I sat down I passed out. They estimated about 15-20 minutes. When I came to my body was limp, sweaty, shivering, I had motor functions but could not feel my body. Fingers and toes had a painful pulsating feeling. EMS was called I was placed on oxygen why they took my vitals |
| 950697 | 1/16/2021 | PA | 27 | M | 1/15/2021 | 1/16/2021 | About 8 hours after vaccine administration on 1/15/21 - woke up in the middle of the night with chills, headache, pain in joints and injection site, nausea. Sat up on the side of the bed - passed out and woke up on the floor. Tried to readjust slowly, passed out again. Place ice pack on stomach and behind neck to treatment with legs up. 1/16/21 continued to experience chills, headache despite cool compress and Tylenol 1000mg TID and Motrin 600mg x 1 dose at 1900. Fatigue and body aches throughout the day - very limited on any daily activities. Sweats and joint pain and pain around L arm injection site. |

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| 950701 | 1/16/2021 | VA | 58 | F | 1/13/2021 | 1/14/2021 | Chills,fever,almost fainting,numbness in hands ,arms,shins,hyperventilating. Symptoms started the night of the vaccine. Went by ambulance to ED |
| 950603 | 1/16/2021 | DE | 31 | M | 1/16/2021 | 1/16/2021 | Patient became faint and passed out twice within minutes of receiving vaccine. Patient came to both times relatively quickly. EMT at the scene evaluated patient and his vital signs were all normal. Patient then stated "this happens sometimes~~ |
| 950397 | 1/16/2021 | PR | 36 | F | 1/7/2021 | 1/7/2021 | Dizziness, nausea, and weakness. Later, around 3pm, I fainted (syncope) and I totally lost consciousness. I hit my head hard and many parts of the body. |
| 947198 | 1/15/2021 | FL | | F | 1/15/2021 | 1/15/2021 | immediately after vax patient fainted. Monitored her for 30 min. She was able to communicate with us and everything was well |

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| 946593 | 1/15/2021 | KS | 47 | F | 1/14/2021 | 1/14/2021 | <p>Notes 1/14/2021</p> <p>Subjective 47 y.o. female who was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. She denied any history of previous adverse reactions to vaccines. She was given the Moderna vaccination in the left deltoid muscle. During her 15 minute waiting period after the injection, the patient began to experience lightheadedness and syncope. She denied rash, hives, welts, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, lightheadedness, dizziness, facial swelling, lip swelling and tongue swelling. This provider was notified of patient reaction and she was then assessed in the emergency bay area. Monitored patient for severe reaction symptoms, including but not limited to abdominal pain, blood pressure abnormality, chest pain, collapse, drooling, hypotension, increased swelling, rapid progression of symptoms, respiratory distress with dyspnea, skin changes, tongue swelling and vomiting. ALLERGY REVIEW OF SYSTEMS Previous Reactions: Patient states that she has a hx of vaso-vagal symptoms with blood draws. Objective Vitals Vitals: 01/14/21 1128 01/14/21 1141 01/14/21 1204 01/14/21 1229 BP: 118/65 123/71 130/72 121/77 Pulse: 71 66 65 92 SpO2: 97% 98% 99% 100% Orthostatic Vitals at 1147a Sitting B/P: 127/71 Sitting Pulse: 70 Standing B/P: 113/62 Standing Pulse: 83 Blood Sugar 103 collected at 1119 Physical Exam Vitals signs reviewed. Constitutional: Appearance: Normal appearance. Comments: Alert but drowsy HENT: Head: Normocephalic and atraumatic. Nose: Nose normal. Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Pulses: Normal pulses. Heart sounds: Normal heart sounds. Pulmonary: Effort: Pulmonary effort is normal. Breath sounds: Normal breath sounds. Abdominal: Palpations: Abdomen is soft. Musculoskeletal: Normal range of motion. Skin: General: Skin is warm. Capillary Refill: Capillary refill takes less than 2 seconds. Psychiatric: Mood and Affect: Mood normal. Behavior: Behavior normal. Thought Content: Thought content normal. Judgment: Judgment normal. Assessment/Plan Treatment included: water, cold packs, granoloa bar.</p> |

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| 946749 | 1/15/2021 | FL | 91 | F | 1/9/2021 | 1/9/2021 | Follow up response to treatment: good. Fully alert Patient discharge: Stable to go home and follow up with PCP. 1/14/2021 12:31 PM |
| 946794 | 1/15/2021 | MI | 31 | F | 1/15/2021 | 1/15/2021 | 7:00PM fatigued, burning up fever 100., ibuprofen/tylenol dose; Sunday afternoon nausea, loss control of body, anxious, feeling of fainting, unable to move-paralyzed, pressed button for medical help, ambulance arrived, pt transported to ER -- 102. temp ambulance, RN at hosp temp 98., pt was shaky, 8:30PM erratic heartbeat per admitting doctor - pt admitted. Pt PCP/Cardiologist contacted, kept on heart monitor, pt discharged Monday afternoon. 1/14/21 chest pain, nausea, 102. fever. symptoms |
| 946804 | 1/15/2021 | VA | 30 | F | 1/14/2021 | 1/15/2021 | approx. 17 min after receiving vaccine, pt returned to desk to get the vaccine card that she had forgotten to take with her, She was handed the card, went to sit in the chair near her, asked if she was feeling ok, slumped to a sitting position, then passed out. Immediately regained consciousness, denied shortness of breath, no evidence of hitting head on ground during this episode |
| | | | | | | | 20 hours after first dose of COVID19 vaccine arm was very sore (normal). Around 2:30am felt pressure and warmth (coming in waves) up towards my chest, lasting 1-2 seconds and occurring about every 5 minutes . Was able to withstand feeling until it became difficult to breath. Lips and face turned white and blue, fainted. Felt extremely nausea when awake. Called 911. Vitals were normal apart from BP was very high 130/100's. EKG was NSR. Blood sugar taken was normal around 113. After 1 hour of event, I took a shower and drank water. I felt the wave one more time before trying to fall asleep. Then stopped. Woke up fine. |

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| 946549 | 1/15/2021 | MA | 59 | F | 1/8/2021 | 1/8/2021 | On 1/8 she took her 2nd dose of Pfizer vaccine around 3 PM. She went home in the evening and started sweating. She passed out. Her daughter was at home and she took her to the nearest hospital. Her BP was 60/34 and she had a temp of 100.3F on 1/8 during hospital admission. Her K was low. She received lot of fluids. She called our office on 1/10 and during the f/u she was still in the hospital. On 1/10 she has a temp of 98.4F and BP of 109/61. But she still has dizziness, nausea, anorexia and mild cough (Former smoker). COVID-19 test was done on 1/9, its negative. Dx was dehydration. Discharged from the hospital on 1/11, feels better but is tired. Will follow up with PCP on 1/16/21. |
| 947130 | 1/15/2021 | TX | 39 | F | 1/5/2021 | 1/5/2021 | Pt received vaccine at 9:30am on 1/5/2021 At 7pm she reports generalized body aches At 5:30am on 1/6/21 she reported "slight headache", sudden dizziness, "seeing black spots", then fainting for unknown period of time. Upon regaining consciousness, she c/o head and back pain, globus sensation in throat, runny nose, "vomiting phlegm", cough, trouble breathing and wheezing. Family called 911, she was transferred to ED via ambulance (told +tachycardia on EKG in ambulance). Once in ED tx w/ IV fluids, promethazine and Toradol and discharged w/ dx of syncope, dehydration. Pt reports intermittent HA and dizziness since event, worse during the first 48hr hrs (1/6 - 1/8) and progressively improving. *Pt was positive for Covid-19 in July 2020 and had headache, loss of taste, smell, sinus congestion and post-nasal drip x 2 weeks. |
| 946256 | 1/15/2021 | OH | 40 | F | 1/13/2021 | 1/14/2021 | Awoke at 3 am with severe chills, diaphoresis, nausea, vomiting, diarrhea and headache. Syncope episode within that hour. Worsening full body joint and muscular pain which became severe by 8am lasting until around 7pm. Able at this time to tolerate 400 mg ibuprofen without vomiting and gain control of pain level. Continued, more mild headache, body ache, fatigue, presyncope and diaphoresis lasting until following day. |

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| 947480 | 1/15/2021 | NC | 22 | F | 1/7/2021 | 1/7/2021 | fainting spell; almost passed out; dizzy spells; weak; This is a spontaneous report from a contactable consumer (patient herself). A 22-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot: EL3246), via an unspecified route of administration on 07Jan2021 in right upper arm shoulder area at single dose for prevent covid. Medical history included ongoing acne. Concomitant medication included doxycycline from 2020 (taking it 6 months ago) and ongoing for acne. Patient stated that she got the Covid vaccine yesterday 07Jan2021 and almost passed out in her kitchen after a couple hours. Patient stated got in shower had dizzy spells and was weak 07Jan2021, she felt better now. Patient stated that she was a small girl of 105 pounds and the dose could have made her sick. She wanted to make sure she did not need to go and be seen. Patient had another spell in shower this morning and stated that the fainting spell and feeling weak started at 9:00 yesterday evening on 07Jan2021. Outcome of dizzy spells was recovering, and outcome of other events were unknown. |

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| 947506 | 1/15/2021 | PA | 44 | F | 1/5/2021 | 1/1/2021 | Dizzy; headaches; flu feeling; side effects she had were like the COVID symptoms she had, like the chills and everything; lethargic feeling; weak; Nausea; the whole left side of her body went numb including even her vagina; left side of her body was so numb and weird and tingly feeling/left leg went numb; whole left side of face swelled up; left eye turned red; pressure in head; felt like someone squeezing her eyeball out; eye went black/left eye looked bruised/blackness around the eyes; whole face went numb/left side of face slightly numb; bells palsy; allergic reaction; This is a spontaneous report from a contactable consumer (patient). A 44-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in arm left on 05Jan2021 at single dose for COVID-19 immunization. Medical history included cutaneous t-cell lymphoma from 2017 and ongoing, ongoing cholesterol, ongoing thyroid, covid-19 from Nov2020 to an unknown date not ongoing (lasted about 1-1.5 months; she did not have any breathing problems) and blood cancer. Concomitant medication included bexarotene ongoing for cutaneous T-cell lymphoma, rosuvastatin ongoing for cholesterol, levothyroxine ongoing for thyroid. The patient underwent lab tests and procedures which included COVID 19: positive in Nov2020, found out tested positive around holiday. Clinical course: onset about 26 hours after administered the first dose; onset as soon as she got back to work next day: 06Jan2021. The side effects were at their worst for at least 24-48 hours. Further described as all side effects occurred only on left side of her body: whole left side of face swelled up on 06Jan2021; left eye turned red on 06Jan2021; whole face went numb/left side of face slightly numb on 05Jan2021; eye went black/left eye looked bruised on 05Jan2021; pressure in head on 06Jan2021; felt like someone squeezing her eyeball out on 06Jan2021, within the first 24-48 hours, her 'left leg went numb'. She called to talk to physician and nurse who advised her to take Benadryl; which she did take and the Benadryl stopped the side effects; but she could not take a lot of Benadryl or anything because she was at work. She stayed at work because at least there were healthcare professionals, adults in case she passed out; at home she has 7 young children and is also raising her grandchild. The side effects did not completely go away. |

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| | | | | | | <p>The arm thing was normal; The next day she was at work and had the swelling on left side of face; blackness around the eyes; arriving home she had headaches on 07Jan2021 and then her leg went numb for like 20 mins; the whole left side of her body went numb including even her vagina; left side of her body was so numb and weird and tingly feeling that she started panicking because she was driving on 06Jan2021. She calmed herself down thinking it's only the left side; you can drive with your right side to get home and be fine. It was more like left side of her body was asleep, tingling, she has never had that happen before. Everything else like the headache, flu feeling was about 48 hours later (on 07Jan2021). She had COVID already back in Nov2020 for about 1-1.5 months; the next side effects she had were like the COVID symptoms she had, like the chills and everything on 06Jan2021. She had the lethargic feeling again, her head was hurting, she felt extremely weak on 06Jan2021. Patient also felt nausea on 06Jan2021, Dizzy on 08Jan2021. Another doctor said it sounded like the side effects she experienced with the vaccine sounded like allergic reaction or Bell's palsy. Patient was asking the doctor if she could get like an Epi-pen or prescription Benadryl or something because she is afraid to get the second dose of Pfizer COVID-19 Vaccine and not have something to respond to side effects with. The outcome of event whole face went numb/left side of face slightly numb was recovered on 07Jan2021, for headaches was recovering, chills and nausea was recovered on 08Jan2021. Outcome of other events was unknown. Information about lot/batch number has been requested.</p> | |
| 946930 | 1/15/2021 | IN | 37 | F | 1/14/2021 | 1/14/2021 | Systemic: Fainting-Mild |
| 946532 | 1/15/2021 | PR | 26 | F | 1/7/2021 | 1/7/2021 | Symptoms starts 9am with headache. For 3 times panadol q 4 hours 500mg. At 8pm start fever (40.2 C), nauseas, dizzines, shaking chills and lost smell. Vomiting starts at 9:25 pm end 2:00 am. 01/08/2021 at 2:26 am visit Emergency Room, in clinic fainted and present high blood pressure 155/99. In hospital medication administred: Zofran, pepcid, .45 NSS and Phenergan IM at 01-08-2021. |

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| 946446 | 1/15/2021 | NY | 41 | F | 1/9/2021 | 1/9/2021 | Injection given IM in patient's L deltoid. EUA distributed to patient per CDC regulations. Lot # 011J20A Manufactured by Moderna Patient filled out COVID 19 Immunization Screening and Consent Form. Pt presented to clinic 1/9/2021 for first dose of Moderna COVID-19 vaccine. 10-12 mins post vaccine pt began to feel warm/dizzy. Pt experienced a brief episode of syncope, shortly after pt regained consciousness , and then experienced 1 episode of emesis Pt was alert, reported hx of vasovagal type sx's, She was given juice, took Midodrine, and given IV Sodium Chloride 0.9% VSS Pt then reported feeling fast heart rate, EKG done w/ NSR Pt began to experience body tremors, HR 109, BP WNL EpiPen administered at 10:58 a.m. per provider's order Pt reports subjective tongue swelling , Second dose of Epi given 11:08a.m. Pt transported to Hospital via ambulance |
| 946362 | 1/15/2021 | NY | 35 | F | 1/14/2021 | 1/14/2021 | Presyncope. |
| 946232 | 1/15/2021 | PA | 24 | F | 1/14/2021 | 1/15/2021 | When I woke up the next morning, my blood sugar had dropped. I did not have a glucometer to measure my blood sugar, by I almost had an episode of syncope at approximately 7:00 am. |
| 946179 | 1/15/2021 | PA | 42 | F | 1/6/2021 | 1/7/2021 | I felt very heavy (especially my limbs) and had a slight headache on Thursday (the day after receiving the vaccine). This feeling continued into Friday morning when I nearly passed out (blacked out and collapsed for a split second) as I was crouched position for approximately 10 minutes at work. I felt dizzy and slow moving for the next several hours. My blood pressure was rated as normal, blood oxygen normal, and pulse slightly low by a nurse on staff who took my vitals after the episode. My temperature, which had been 97.8 prior to the event that morning (typical for me) was elevated during this time to 100.2 and returned to normal after approximately 4 hours without medication. I was fatigued, so I slept for approximately 4-5 hours that afternoon and began feeling better the following day (Saturday). |

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| 946175 | 1/15/2021 | MD | 62 | F | 12/23/2020 | 12/23/2020 | As per Emergency Dept note of 23 Dec 2020: "Syncope, related to getting the vaccine. Normal ECG, no evidence of arrhythmia, normal H/H, no evidence of ACS, CHF clinically. Normal nonfocal exam. Symptoms resolved. Home with reassurance." As per follow-up note of 04 Jan 2021: "62yo female s/p first dose of Pfizer-BioNTech vaccine on 12/23/2020 who experienced syncope, hypertension (200/100) within minutes after receiving the vaccine. She was then transported to the ED where she was given IV fluids, anti-emetic and discharged a few hours later. She reports the onset of fever, chills, anorexia, malaise, and emesis 4 hours after receiving the vaccine. The malaise, chills and anorexia persisted for 4 days at which point she started feeling better. COVID test was reportedly negative. She wants to decline 2nd dose of vaccine.~~ |

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| 945905 | 1/15/2021 | MT | 29 | F | 12/31/2020 | 1/1/2021 | <p>Achy neck; Stiff neck; Monocyte was high; Diarrhea; Passed out; Very dizzy; Chills; Headache; Fatigue; Walking across a room takes breath out; Lightheaded; A spontaneous report was received from a consumer, who was a 29-year-old female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced the events, passed out, very dizzy, lightheaded, fatigue, walking across a room takes breath out, headache, chills, diarrhea, monocyte was high, and stiff and achy neck. The patient's medical history was not provided. Concomitant product use included acetylsalicylic acid. On 31 Dec 2020, approximately one day prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 intramuscularly in the right arm for prophylaxis of COVID-19 infection. During the morning hours of 01 Jan 2021, the patient passed out, felt dizzy, lightheaded, fatigued, had a headache, and chills. The patient reported that walking across a room took the breath out of her. On 02 Jan 2021 the patient experienced diarrhea in the evening. On 03 Jan 2021 the patient presented to the emergency room but was not admitted. Her monocyte count was high, but other lab results were normal. Her headache was treated with anti-migraine medication intravenously. She stated she was still experiencing dizziness and her neck was still achy and stiff. No additional treatment information was provided. Action taken with mRNA-1273 in response to the events was not provided. The outcome of the events, passed out, lightheaded, fatigue, walking across a room takes breath out, headache, chills, diarrhea, and monocyte was high, was unknown. The events, dizziness and stiff and achy neck, were considered not resolved.; Reporter's Comments: This case concerns a 29-year-old female patient with unknown medical history, who received their first of two planned doses of mRNA-1273 (Lot 0371C20A), and who experienced the serious unlisted event of Syncope, the non-serious listed events of diarrhea, chills, headache, and fatigue, and the non-serious unlisted events of Dizziness, Monocyte count increased, Musculoskeletal stiffness, Dizziness (lightheadedness), Neck pain, and Dyspnoea. Based on the current available information and temporal association between the use of the product and the onset of the events on the day after vaccination, a causal</p> |

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| 945770 | 1/15/2021 NV | 22 F | 12/31/2020 | 12/31/2020 | <p>relationship cannot be excluded and the events are considered possibly related to the vaccine. The events may be explained by an undiagnosed viral illness based on the constellation of symptoms and elevated monocyte count.</p> <p>Fainting; Dizziness; Body ache; Joint pain; A spontaneous report was received from a 22-year-old female consumer, who received Moderna's COVID-19 vaccine and experienced dizziness, fainting, joint pain, and body aches. The patient's medical history was not provided. No relevant concomitant medications were reported. On 31 Dec 2020 at 13:30, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 31 Dec 2020, after vaccine administration, the patient experienced dizziness, fainting, joint pain, and body aches. No treatment information was provided. Action taken with mRNA-1273 in response to the event was not reported. The outcome for the events, dizziness, fainting, joint pain, and body aches, was not reported.; Reporter's Comments: This case concerns a 22 year-old, female patient, who experienced events of dizziness, fainting, joint pain, and body aches. The events occurred on the same day after the first dose of mRNA-1273 vaccine administration. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded and the events are assessed as possibly related.</p> |
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| 949735 | 1/15/2021 | NE | 21 | F | 1/14/2021 | 1/15/2021 | I got up to use the bathroom at 4:30 this morning. I was extremely shaky but made it. I was using the bathroom and had the feeling that I was going to vomit. Next thing I know I was seeing stars and I fainted and fell off the toilet face forward and hit my head on my tile floor. I don't remember getting to the couch, but my dad was awake to let out the dogs and I couldn't really speak but he heard me and came downstairs and got me water and a cool rag. I was sweating but shivering. I am nauseous and have slept a total of 13 hours since 4:30am. I am pretty sure I have a concussion. I have a headache, on and off chills, muscle spasms beginning at 9:00PM on 1/14/21. I also have ringing in my ears. My resting heart rate is typically between 75-85 and I checked it at 7pm and it was 100. I have not sought out medical attention and have been debating it all day. |

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| 947518 | 1/15/2021 | OR | 34 | F | 1/5/2021 | 1/5/2021 | tunnel vision; experienced a sudden onset of vertigo; presyncope; My hands became cold and numb; My hands became cold and numb; fatigue; sore arm, leg/thigh aching; sniffles; sore throat; brief dry cough; slight headache; neck ache; This is a spontaneous report from a contactable Nurse (patient). A 34-year-old non-pregnant female patient received the first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular on 05Jan2021 at 12:30 at single dose in left arm for covid-19 immunization. Medical history included Mild ADHD/ADD. The patient's concomitant medications were not reported. Approximately 5 minutes after receiving vaccination, she was standing in the observation room (where they had all of them stay for at least 15 minutes to ensure no severe reactions) and experienced a sudden onset of vertigo, tunnel vision and pre-syncope. Her hands became cold and numb and she was trying to talk to another staff member who was arranging/scheduling her second vaccination dose at the same time when this event occurred, but it subsided quickly and she started to feel normal again. All these events occurred at 12:45 on 05Jan2021. She reported this event right away and they had her stay in the room longer. She was stable at that point but experienced these symptoms again but very mildly twice more while she walked back to her car to go home. Other side effects on 05Jan2021 that started in the evening and for the following 2-3 days included fatigue, sore arm, leg/thigh aching, sniffles/sore throat, brief dry cough and slight headache/neck ache. Very mild and tolerable symptoms. All events were reported as non-serious by reporter. The patient did not receive treatment for the events. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination, and the patient has not been tested for COVID-19 since the vaccination. The outcome of all events was resolved in Jan2021. Information on the lot/batch number has been requested.; Sender's Comments: Based on temporal association, a possible contributory role of BNT162B2 cannot be excluded for reported events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern |

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| | | | | | | identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate. | |
| 946423 | 1/15/2021 | TX | 34 | F | 1/12/2021 | 1/12/2021 | Tachycardia, Tachypnea, achy joints, feeling febrile but no fever, near syncope, anxiety, redness and hard at injection site 2 days late |
| 949440 | 1/15/2021 | NY | 53 | F | 1/15/2021 | 1/15/2021 | Patient reported feeling like she was going to "pass out". Patient reports syncope following her allergy shot once. |
| 947528 | 1/15/2021 | MA | | F | 1/8/2021 | 1/9/2021 | Experienced vasovagal syncope after standing, resulting in fall; Experienced vasovagal syncope after standing, resulting in fall; Awoke with severe chills; nausea; body/muscle aches; body/muscle aches; left arm pain; extreme thirst; fatigue; This is a spontaneous report from a contactable consumer. A 44-year-old female patient (non-pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot: EK9231), via an unspecified route of administration on 08Jan2021 14:30 in left arm at single dose for covid-19 immunization. There was no medical history and concomitant medications. Allergies to medications, food, or other products was no. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The most recent COVID-19 vaccine was administered was in hospital. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. On 09Jan2021 01:30 am, patient woke with severe chills, nausea, body/muscle aches, left arm pain, nausea, extreme thirst. Patient experienced vasovagal syncope after standing, resulting in fall. Worst symptoms were lasted about 30 minutes, muscle aches and fatigue continue about 16 hours later. All events were reported as non-serious. No treatment was received for these events. Outcome of all events were recovering. |
| 949578 | 1/15/2021 | OH | 32 | F | 1/8/2021 | 1/8/2021 | Immediate slight dizziness, continued for 1.5 hours, slight headache. Then 1.5 hours post vaccination syncope, fall to floor. ER workup was clear immediately following event, no abnormal testing, labs and ekg all normal. 1 week post vaccine, no other symptoms aside from sore arm. |

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| 949620 | 1/15/2021 | WA | 61 | F | 12/21/2020 | 12/21/2020 | As stated I fainted about 3 hours after injection. I thought it was because I had worked all night. I fell forward and sustained bruising to my right cheek and temple. I will be reporting another report regarding the second dose with adverse reaction that is the same but required EMS and Emergency Room visit. Approximately 3 hours after injection I was getting ready for bed (as I work nights). I was talking with my daughter and I stood up and remember waking up on the floor. Bruising to the right cheek and temple. I did not seek medical attention and went to bed. I had no further episode but remained dizzy for several days. |
| 949761 | 1/15/2021 | NC | 49 | F | 1/15/2021 | 1/15/2021 | Patient information was reviewed. Patient was asked if they ever had any form of severe reaction to anything they had had in the past. Patient did not state yes to anything other than having a reaction that was managed at home to shellfish as a child. They stated their throat had swollen as a child during the event. Patient was told that it was an anaphylactic reaction and shouldn't have been managed at home as a child by nurse and should have been taken to the hospital. Patient was told they would be monitored for 30 minutes after receiving the vaccine. Within 2-3 minutes after receiving the vaccine the patient reported tingling or burning around the site of injections. Within 5 minutes they stated to be feeling tired and that their arm had felt numb. After this the patient began starring into the distance and was unresponsive. Called for help and advice by turning around as patient had syncope. Got nurses and other team members attention and had an epi-pen ready just in case it was needed. Patient began having notable distress with respiration and administered an epi-pen. Advised for a nurse to call EMS for patient and crash cart/oxygen was also obtained by the facility. Oxygen was required. Patient was not responsive after the first dose and was given a second as they remained un-alert with notable distress. The patient became alert a while after receiving the second shot and not long after that the EMS arrived to the event. |
| 949442 | 1/15/2021 | MI | 62 | U | 1/15/2021 | 1/15/2021 | She passed out. Developed a rash on both arms with itching, and nauseous. Gave patient EPI PEN IM into right thigh. started IV and transferred to the ER. Patient was discharged. |

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| 949744 | 1/15/2021 | WA | 63 | F | 1/9/2021 | 1/10/2021 | extremely dizzy, passed out, took blood pressure 3 times over 45 minutes, 56/34, 62/43, 81/56 |
| 949400 | 1/15/2021 | RI | 32 | F | 1/15/2021 | 1/15/2021 | Shortly after receiving Dose 1 of Pfizer-BioNTech COVID-19 vaccine, patient reported feeling dizzy and nauseous. Patient was given water and apple juice. Patient educated on techniques to reduce symptoms/prevent fainting. Patient was then escorted to a room in the facility to lay down and elevate feet. Patient vomited a few times. Patient closely monitored for over 30 minutes by pharmacist and facility staff. Patient symptoms improved and did not require EMS. |
| 948484 | 1/15/2021 | VA | 22 | F | 1/14/2021 | 1/15/2021 | Fever and chills, headache, syncope (experienced around 6:30 am following the morning after vaccination was received) |
| 948458 | 1/15/2021 | CT | 32 | F | 1/13/2021 | 1/14/2021 | Severe arm pain at injection site night of. At 5:15 AM the following morning (1/14/21) I experienced lightheadedness and fainted off the toilet hitting my face on the wall/radiator in front of me. My husband (who witnessed the fainting episode) stated I began convulsing and my eyes were rolled to the back of my head for 5-10 seconds. Upon regaining consciousness I was covered in sweat. After being assisted back to bed, I had nausea and headache with continued severe pain at injection site. I went to the ER around 6:45 AM since my severe headache, dizziness and nausea continued and to examine if I broke my nose in the fall. While in triage at the ER I experienced severe nausea and a second episode of fainting. |

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| 948410 | 1/15/2021 | NC | 40 | F | 1/14/2021 | 1/14/2021 | This facility staff member received her first dose of the MODERNA COVID-19 vaccine (Lot037K20A/EXP 6/22/21) at clinic at approximately 9:15AM on 1/14/21. She initially answered "no" to any allergies on the VAR but revealed to the pharmacist reviewing the VAR that she had experienced an allergy to food and contrast dye that required an epi-pen and hospital attention. She did not offer additional details and explained that she had tolerated other shots (including the 2020 flu shot) without incident. I advised patient to remain for a 30 minute monitoring period post-vaccination due to history of allergic reaction. Patient presented with some anxiety before the shot and immediately started to complain of feeling "sick" and said she was having trouble breathing due to chest pressure. We advised patient to remove her mask and provided her with water and a trash can though no vomiting occurred. After 15-20 minutes, patient still complained of chest pressure and difficulty breathing. When asked if she was experiencing any itchiness or throat swelling, patient said she did feel some throat swelling so she was given 25MG of Benadryl. After an additional 15 minutes, patient's condition seemed unchanged (not worsening, not improving) so the facility's nursing team was called to evaluate patient. Patient said she was still experiencing difficulty breathing and throat swelling so nursing advised use of EPI-PEN and patient consented. I administered a dose of 0.3MG (LOT0FM4066/EXP 02/2022) to the right lateral thigh and nurse called for EMS. Immediately after injection, patient's eyes fluttered and she seemed to be on the verge of fainting. Nursing checked her oxygen saturation which was 100%. Patient reported no improvement after 5 minutes so another EPI-PEN 0.3MG was administered to the left lateral thigh. Nursing also gave the patient 81MG chewable aspirin due to the patient experiencing a stroke last month. EMS arrived a few minutes after the second EPI-PEN dose and patient was transported to the hospital for evaluation. Facility reported that patient went home that afternoon but did not provide details. Based on my assessment of patient's symptoms and behavior, I feel it is likely that she experienced either an acute panic attack or anaphylaxis due to vaccine administration. I called the patient today (the day after the incident) and she confirms that she received treatment for an anaphylactic reaction to the Moderna COVID shot and is |

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| | | | | | | | doing well without any lasting adverse effects. |
| 948380 | 1/15/2021 | | | F | 1/4/2021 | 1/5/2021 | 1/5/2021 0718 Pt received 2nd COVID vaccine 1/4/21. Oral temp 100.6, near syncope, muscle aches and head aches. Per EMS NSR, denies SOB, and chest pain. 500 ml bolus received in route. In ED, Pt c/o nausea. Pt anxious, sweating and uncomfortable. 0855 Pt resting comfortably, reports decrease in pain/body aches 4/10. 1043 Discharge disposition: home. Accompanied By: self. Mode: walk. --Hospital |
| 948143 | 1/15/2021 | FL | 68 | F | 1/15/2021 | 1/15/2021 | Patient was given Covid vaccine and then was instructed to sit for about 15 minutes. About 5 minutes later after receiving vaccine she passed out and fell onto floor. I went over to provide aid and rolled her over to have her lying face up while another staff member was calling 911. She was still awake and responsive when I proceeded to ask her questions and she informed me she felt "hot all over and dizzy." 911 informed us to keep her lying down on the floor as comfortable for her as possible until EMS arrives on scene. While waiting for EMS to arrive her pulse was low (~40 bpm), but shortly before EMS arrived on scene her pulse rose to a normal heart rate (~80 bpm). EMS then took her to the hospital for further evaluation. |
| 948095 | 1/15/2021 | NM | 54 | F | 1/8/2021 | 1/8/2021 | Syncope. Rested and recovered. Fainted about 5 minutes after receiving the vaccine- walked quickly from the vaccination station to the observation station, and was seen wobbling, caught her and laid her until she recovered. She was embarrassed, indicated she has fainted with shots before. |
| 948075 | 1/15/2021 | CA | 24 | M | 1/14/2021 | 1/14/2021 | Vasovagal Syncope |

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| 948073 | 1/15/2021 | NJ | 65 | F | 1/14/2021 | 1/14/2021 | Immediate sensation of slight mental status change which resolved but within 2 minutes started to feel slightly woozy and pre-syncope, as if anaphylaxis starting. Informed staff. Put on stretcher. Vital signs obtained. O2Sat upper 90s. BP elevated with diastolic in low 100s with sensation of pre-syncope and very slight confusion. Resolved slowly over 30 minutes to about 90% of prior mental status. Continued to feel somewhat dizzy for several hours. Went to bed early. Had very intense disturbing dreams. Very sore vaccine site. Resolved by morning. Arm soreness about 50% of day prior. |
| 948046 | 1/15/2021 | NM | 69 | F | 1/8/2021 | 1/8/2021 | Nauseated and lightheaded, near syncope. Lasted about 20 minutes, took vitals, rested, and recovered. |
| 948416 | 1/15/2021 | TX | 31 | F | 1/13/2021 | 1/14/2021 | Just over 24 hours after I received the COVID-19 vaccine I had a syncope episode while standing talking to others at work. I began feeling hot, started feeling like I was sweating, started seeing black and white lines, and then fainted. The symptoms came on very quickly. I did not remember falling and we believe I hit my head on the corner of a table when I fell, and I had to get 3 staples in my head. I have no other medical concerns at this time, and all of the test run at the ER showed no concerns. At the ER they ran labs, took a CT scan, and did an EKG. I was released from the ER after about 4 hours. I have had a 3 other episode previously when I felt like I was going to pass out, most recent March 2020, but they were linked to the flu and strep. This event has not been linked to either of those conditions at this time, and my doctor encouraged me to report it. |
| 949453 | 1/15/2021 | CO | 37 | F | 1/13/2021 | 1/14/2021 | Employee received second dose of Pfizer COVID vaccine on 1/13/2021 at 1400. Employee had a syncope episode on 1/14/2021 around 1300. Employee called the nurse on 1/15/2021 at 0840 to report syncope. Employee denies any current dizziness, nausea or vomiting. |

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| 948008 | 1/15/2021 | FL | 68 | F | 1/15/2021 | 1/15/2021 | Patient received vaccine at 1:48 pm then approximately 5 minutes afterwards fainted and fell to the floor while sitting in a chair. I went over and rolled patient over having her lay face up and then proceeded to ask her questions. We had a staff member called 911 while I was helping her. I asked her how she felt and she responded and said she felt "hot all over and dizzy." Her pulse was low (~40 bpm). 911 informed us to lie her down on the floor until EMS arrived which we already had been doing at the time. After getting off the phone with 911, she started feeling better and her pulse returned to a normal rate (~80 bpm). EMS still took her to the hospital for further evaluation. |
| 947904 | 1/15/2021 | SC | 40 | F | 1/13/2021 | 1/14/2021 | Patient had regular soreness, redness of injection site. Fever, chills, fatigue hours after vaccine. Patient experienced syncope the morning after vaccination for about 15 minutes. Having bruised head and left eye. |
| 944094 | 1/14/2021 | KY | 60 | F | 1/11/2021 | 1/11/2021 | Systemic: Fainting-Medium; symptoms lasted 0 days |

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| 943636 | 1/14/2021 | CO | 25 | F | 1/13/2021 | 1/13/2021 | Vasovagal syncope (loss of consciousness) Tonic seizure (tensing and twitching of arms) Irregular heartbeat (per EKG) Extremely low blood pressure I received the vaccine at a public health pop-up, drive through clinic for first responders - I accessed the vaccine through my employer as a first responder. The vaccine was administered to my left arm without complication at approximately 1:00pm (my scheduled appointment). I proceeded to the area designated for patients to be observed after receiving the vaccine and was asked to wait 15 minutes. I recall getting to the observation area then telling my spouse I felt unwell - after the event he notified me that I told him I was about to pass out and asked him to get medical help. I lost consciousness approximately 5-10 minutes following the vaccine. My husband reported that after losing consciousness I seemed to have a minor seizure, as evidenced by my head jerking and my arms and fingers "tensing and curling up". I was sitting in the passenger seat of my car at this time, so I suffered no fall or fall related injury. Public health officials and EMT responded. They indicated to my spouse that I had experienced a vasovagal syncope episode and that I had "gone tonic"/ had a "tonic seizure". They took my blood pressure, which was very low (I don't recall exactly but it was 80 over something). They also took my blood sugar among other things that I do not recall. I was given oxygen and put into an ambulance. I was shaking, so they wrapped me in blankets. I believe they may have done an EKG and placed a blood pressure cuff while I was in the ambulance, but I do not recall any specifics about this. The EMT also drew my blood, placed an IV, and administered IV fluids while I was in the ambulance. I was taken by ambulance to the emergency department |

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| 943724 | 1/14/2021 | OH | 41 | F | 1/5/2021 | 1/6/2021 | A day after the shot I was in the shower and started experiencing exhaustion and shortness of breath. I also had tachycardia. I proceeded not to feel well they're very next day. Then on Friday I was dizzy and a coworker said that I was flushed and I wasn't feeling well. I proceeded to go see patients and while examining a patient I became very dizzy and lightheaded while bent over and almost passed out when I came up. at that time I decided to leave work and go to my PCP. Orthostatic's were positive and EKG showed normal sinus rhythm and an echo is ordered. Echo was normal. Throughout the week I continued to have tachycardia and shortness of breath with any type of exertion. I left work this morning and was tested for Covid because of my symptoms. |
| 943775 | 1/14/2021 | VA | 52 | F | 1/5/2021 | 1/5/2021 | Systemic: Anaphylaxis-Severe, Systemic: Nausea-Medium, Systemic: Fainting-Medium |
| 943807 | 1/14/2021 | NM | 36 | F | 1/10/2021 | 1/10/2021 | Systemic: Chills-Mild, Systemic: Fainting-Medium, Systemic: clammy, dizzy, tingling in ears, O2 sat ok,temp ok; symptoms lasted 0 days |
| 943945 | 1/14/2021 | NC | 43 | F | 1/12/2021 | 1/13/2021 | I was fine the day of the vaccination. I started feeling bad overnight - got a headache and arm got sore. When I woke up in the morning to get ready for work I felt very weak. I walked into my bathroom and lost consciousness. I woke up on the floor and had hit my forehead on the tile floor. I was confused when I got up, and proceeded to get into the shower. I then passed out again in the shower and hit the back of my head against the shower wall. My husband found me as I woke up on the shower floor. He called my doctor and took me to the emergency department on doctors advice. |
| 943996 | 1/14/2021 | OK | 39 | F | 1/14/2021 | 1/14/2021 | pt was given vaccine at an off site location but had reaction of high bp, fast heart rate, dizziness, presyncope, and throat numbness that occurred about an hour after the vaccine. the other reactions occurred 20 min after vaccine. |
| 943472 | 1/14/2021 | NC | 73 | M | 1/6/2021 | 1/7/2021 | Syncope due to orthostatic hypotension-antihypertensive discontinued and oral fluids pushed for 24 hours with resolution in symptoms within 48 hours. |

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| 943992 | 1/14/2021 | NC | 28 | F | 1/11/2021 | 1/11/2021 | Systemic: Fainting-Medium, Systemic: Seizure-Medium; symptoms lasted 0 days |
| 943426 | 1/14/2021 | WI | 34 | F | 1/13/2021 | 1/14/2021 | Hypotension 91/71 with orthostatic hypotension <80 SBP (my BP cuff doesn?t read lower than that). Near syncope at 0615. Loss of vision, tinnitus, lowered to the ground and followed by nausea and sweating. Resolved in minutes. Continue to be dizzy today with clammy and dizzy upon standing |
| 943364 | 1/14/2021 | AL | 61 | F | 1/4/2021 | 1/4/2021 | Systemic: Anaphylaxis-Severe, Systemic: Fainting, Systemic: Pharmacist submitting: unable to determine if anaphalaxis or panic attack, patient experienced facial weakness, chest tightening, tremmors, inability to breathe, and fainting within 10 min of administ |
| 943275 | 1/14/2021 | IN | 57 | F | 1/12/2021 | 1/12/2021 | Chills, fever (101), muscle aches, fatigue, headache x36 hours. Passed out x1, without warning- lost consciousness >1min. Hit head, went to ED. |
| 943262 | 1/14/2021 | MA | 64 | F | 1/4/2021 | 1/4/2021 | Systemic: Fainting-Mild |

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| 943194 | 1/14/2021 | TX | 38 | F | 1/13/2021 | 1/13/2021 | Symptoms - EE reports after vaccine she waited the 30 minute observation period and felt fine. At approximately 7:00 pm EE reports she went to store and when she went to get out of her car she felt really dizzy. EE reports she hadn't eaten much that day so tried to eat some chocolate covered pretzels and coke. EE denied syncope. EE reports she started feeling ?chest tightness? and starting panicking. EE denies airway issues and SOB. EE said she got nervous and went to hospital across the street for assessment. EE reports at triage her SPO2 was 100% but slightly tachycardiac. EE reports after her triage assessment she called her daughter to come pick her up and did not seek further medical care. EE reports when she got home she started with generalized itchiness, denies rash. EE reports she took 50 mg Benadryl, 25 mg Atarax, and 40 mg Pepcid at 8:45 PM. EE reports not change in itchiness and took 2nd dose of 50 mg Benadryl around 01:30 (1/14). EE reports she woke up around 06:45 (1/14) with bilateral arm bruising from scratching overnight per EE and feeling chilled. Last day of work and shift - ? scheduled to work tonight (1/14) Home remedies? ? see symptoms for home remedies Any improvement? ? mild improvement Recommendation? EE encouraged to continue to monitor symptoms and to contact EH vaccine support line with further questions or concerns. EE encouraged to take Claritin and Benadryl as outline by the Medical Directive at hospital. EE educated to only take Benadryl if she will be at home today and that is she unable to take Benadryl when at work, EE verbalized back understanding. EE educated if she is still feeling unwell for her shift tonight, to notify her manager and to manage per hospital Illness in the Workplace Policy. EE denied further questions at this time. |
| 942975 | 1/14/2021 | PA | 52 | F | 12/22/2020 | 12/23/2020 | Patient returned for 2nd Covid vaccine and reported that after previous vaccine she fainted 3 times, had a swollen arm, severe leg pain and nausea and vomiting. At that time, we decided that she should receive guidance from her PCP prior to receiving the 2nd dose in the series. |

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| 944279 | 1/14/2021 | NH | 27 | F | 1/8/2021 | 1/1/2021 | fever and chills; fever and chills; blood pressure was low, about 90/50; did not feel well; syncope episode; unconscious; This is a spontaneous report from a contactable other health professional. A 27-year-old non-pregnant female patient received the first dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: EH9899), via an unspecified route of administration in the left arm on 08Jan2021 at 12:00 at a single dose for COVID-19 immunization; received at a nursing home/senior living facility. The patient did not receive any other vaccines within four weeks prior to the COVID vaccine. Medical history included COVID-19 from an unknown date and unknown if ongoing. No known allergies. Concomitant medications included unspecified birth control taken for an unspecified indication from an unknown date to an unknown date; within two weeks of vaccination. The patient experienced the following events and outcomes: syncope episode in Jan2021 with outcome of unknown, unconscious in Jan2021 with outcome of unknown, fever and chills on 09Jan2021 with outcome of unknown, blood pressure was low, about 90/50 on 09Jan2021 with outcome of unknown, did not feel well in Jan2021 with outcome of unknown; all of which were assessed as medically significant. The clinical course was reported as follows: the fever and chills began about one hour after vaccination (as reported). About 18 hours after the vaccination, the patient was getting up to take more paracetamol (TYLENOL) and did not feel well. The patient had a syncope episode in the bathroom (no issues as she sat on the floor before hand). The patient was unconscious for about 1-2 minutes. The patient's blood pressure several minutes later was low, about 90/50; however, the patient took the blood pressure measurement herself, so it may not have been exactly accurate. The patient underwent lab tests and procedures which included blood pressure measurement: low, about 90/50 on 09Jan2021. Therapeutic measures were taken as a result of fever. Prior to vaccination, the patient was diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of all reported serious events cannot be excluded, considering the plausible temporal relationship and the known |

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| 942614 | 1/14/2021 | MD | 42 | F | 1/6/2021 | 1/1/2021 | <p>adverse event profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p> <p>acute onset nausea; diaphoresis; presyncope; left arm weakness with numbness; numbness and tingling of first 3 fingers in left hand (median nerve distribution); tingling of first 3 fingers in left hand (median nerve distribution); significant cervical lymphadenopathy; painful neck; This is a spontaneous report from a contactable physician reporting for herself. A 42-year-old adult female patient received the first dose of BNT162B2 Pfizer-BioNTech COVID-19 Vaccine, Lot number: EJ1686, via an unspecified route of administration, in left arm, on 06Jan2021 at 9:52 am, at 42-years of age, at single dose for COVID-19 immunization. The patient was vaccinated in Hospital. Medical history included overweight and no known allergies. Concomitant medications included the second dose of HPV VLP vaccine rL1 4v (yeast) (GARDASIL) received in left arm on 18Dec2020 and ergocalciferol (Vitamin D). On 06Jan2021 by 10:05 the patient experienced acute onset nausea, diaphoresis, presyncope and concomitant left arm weakness/flaccid arm with numbness and tingling of first 3 fingers in left hand (median nerve distribution). The patient informed vaccine staff of symptoms and advised ongoing observation. Flaccid arm/weakness/numbness continued for more than 24 hours, although at the time of the report it was slowly improving. At the time of the report the patient further reported significant cervical lymphadenopathy and painful neck (specific onset date not provided - captured as Jan2021). The events were reported as non-serious. The reporter specified that the injection was not given anywhere near brachial plexus. At the time of the report the events "Left arm weakness" and "Left arm numbness" were resolving, the outcome of the events "Nausea", "Diaphoresis", "Presyncope", "Tingling of first 3 fingers in left hand", "Cervical lymphadenopathy" and "Painful neck" was unknown.</p> |

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| 943187 | 1/14/2021 | TX | 38 | F | 1/13/2021 | 1/13/2021 | <p>Symptoms - EE reports after vaccine she waited the 30 minute observation period and felt fine. At approximately 7:00 pm EE reports she went to store and when she went to get out of her car she felt really dizzy. EE reports she hadn't eaten much that day so tried to eat some chocolate covered pretzels and coke. EE denied syncope. EE reports she started feeling ?chest tightness? and starting panicking. EE denies airway issues and SOB. EE said she got nervous and went to Hospital across the street for assessment. EE reports at triage her SPO2 was 100% but slightly tachycardiac. EE reports after her triage assessment she called her daughter to come pick her up and did not seek further medical care. EE reports when she got home she started with generalized itchiness, denies rash. EE reports she took 50 mg Benadryl, 25 mg Atarax, and 40 mg Pepcid at 8:45 PM. EE reports not change in itchiness and took 2nd dose of 50 mg Benadryl around 01:30 (1/14). EE reports she woke up around 06:45 (1/14) with bilateral arm bruising from scratching overnight per EE and feeling chilled. Last day of work and shift - ? scheduled to work tonight (1/14) Home remedies? ? see symptoms for home remedies Any improvement? ? mild improvement Recommendation? EE encouraged to continue to monitor symptoms and to contact EH vaccine support line with further questions or concerns. EE encouraged to take Claritin and Benadryl as outline by the Medical Directive at TCH. EE educated to only take Benadryl if she will be at home today and that is she unable to take Benadryl when at work, EE verbalized back understanding. EE educated if she is still feeling unwell for her shift tonight, to notify her manager and to manage per hospital Illness in the Workplace Policy. EE denied further questions at this time.</p> |

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| 942615 | 1/14/2021 | | 21 | F | 1/6/2021 | 1/7/2021 | almost fainted; body pain and chills; body pain and chills; This is a spontaneous report from a non-contactable other health professional (patient). A 21-year-old female patient (pregnant: No) received first dose of BNT162B2 (Batch/lot number: EUA), intramuscularly in left arm on 06Jan2021 12:00 PM at single dose for COVID-19 immunization. The patient's medical history was not reported. Concomitant medication included lisdexamfetamine mesilate (VYVANSE), celecoxib (CELEXA). The patient experienced almost fainted, body pain and chills all on 07Jan2021 03:30 AM. About 15 hours the vaccine, the patient woke up at 3 am with extreme body pain and chills and almost fainted when trying to get paracetamol (TYLENOL). The events were reported as non-serious. The adverse event was not resulted in doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care. No treatment received for the adverse event. The outcome of events was unknown. Facility where the most recent COVID-19 vaccine was administered: Nursing Home/Senior Living Facility. Prior to vaccination, the patient wasn't diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. No follow-up attempts are possible. No further information is expected. |
| 945643 | 1/14/2021 | | 21 | F | 1/14/2021 | 1/14/2021 | Patient felt light headed/faint and flushed. (self reports history of fainting with shots/vaccines) BP 78/41 HR 67 sat 100. Encouraged to lay supine, however, patient requested to sit with head between knees as this helped in the past. Cold back to back of neck. No SOB or trouble swallowing. Patient alert and conversant. Observed x 30 mins and all symptoms resolved. Repeat BP 108/78 HR 85 sat 100 |

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| 944335 | 1/14/2021 | NC | 43 | F | 1/12/2021 | 1/13/2021 | ~~Moderna Covid-19 Vaccine EUA" No problems the day of the vaccine. Overnight I developed a sore arm, chills, and headache, which I expected. The next morning I got up to get ready for work and I passed out, hitting my forehead on the tile floor very hard. I woke up on the floor, then got in shower and immediately passed out again, hitting the back of my head on shower wall. My husband found me sitting on shower floor still groggy. He called primary care provider, who said to take me to emergency department. He took me to emergency department. |
| 942909 | 1/14/2021 | PA | 68 | M | 12/28/2020 | 1/12/2021 | Chief Complaint Patient presents with ? Vomiting pt reports dry heaving and nausea that started an hour ago Patient is an 68 y.o. year old male with PMHx significant for HTN, BPH, who presents to the ED today with nausea and dry heaving for one hour PTA. States that he was at work as a courier when he had onset of sensation of room spinning, nausea, and dry heaving. Also having tinnitus which he thinks is b/l. This happened once about two weeks ago and resolved spontaneously overnight when he was asleep. No preceding illnesses, medication changes, or other associated symptoms. Vertigo has no clear exacerbating or relieving factors. Has not yet taken anything for symptoms. The patient denies fevers, chills, headaches, syncope, chest pain, shortness of breath, rhinorrhea, sore throat, cough, abdominal pain, changes in usual bowel movements, changes with urination, back pain, pain anywhere else in body. The patient has no sick contacts, recent travel history. |
| 946898 | 1/14/2021 | KS | 40 | M | 1/13/2021 | 1/13/2021 | About 1 minute after receiving vaccine, pt fainted while on the way to recovery area. Pt was standing in entryway when he started to fall down but was caught on the way down by a nurse. While on the floor the pt was asked his name and responded with correct answer, EMS was called and then pt was placed in wheelchair and transferred to cot after. the BP and pulse was taken (63/46, pulse 51) Glucose gel was provided orally. EMS arrived shortly after BP was take but pt refused stating that he was feeling better and he waited out the remainder of his recovery time laying in cot with no other incidents. |

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| 945584 | 1/14/2021 | CA | 27 | M | 1/13/2021 | 1/13/2021 | At 11:00 PM awoke with severe full body chills and subjective fever that lasted about an hour. Woke again at 1:30 AM drenched in sweat with pounding frontal headache and eye aches, got up to use restroom and had vasovagal syncope while standing in front of the toilet. |
| 945548 | 1/14/2021 | TX | 50 | F | 1/13/2021 | 1/13/2021 | 15 minutes after receiving the vaccine I felt like I was going to faint and then called out someone's name and she came and caught me as I fainted. They called for Rapid Response Team. They put me on a stretcher, asked what happened, and took some vital signs - I was tachycardic, BP was 184/108 pulse ox 97 and they also saw nystagmus only in my left eye which I've never had before. |
| 945294 | 1/14/2021 | FL | 36 | F | 1/11/2021 | 1/12/2021 | Approximately 12 hours after receiving the booster dose, she awoke feeling extremely ill and nauseous, roused me to say so, and then immediately became unresponsive and pulseless. She was admitted to hospital for cardiac work up, and all diagnostic tests have found her heart to be normal in structure and function. Cardiology believes she experienced a vasovagal syncope with asystole. She remains hospitalized at this time for initiation of sotalol therapy; she was diagnosed with frequent PVCs approximately 1 year ago. |
| 945147 | 1/14/2021 | GA | 42 | M | 1/12/2021 | 1/12/2021 | States had a syncope event shortly after 2nd COVID vaccine. Vaccine administered approximately 10am then about 40-45 minutes later had a syncope episode and fell from a standing position. |
| 945025 | 1/14/2021 | MN | 26 | F | 1/12/2021 | 1/13/2021 | About 16 hours after second dose of the Pfizer COVID-19 vaccination: - Fever of 101-102F - Chills - Body aches - Joint aches - Headache About 40 hours after time of vaccine: - Fainting spells x2 (shakiness, blurry vision, ringing in ears, loss of balance) |
| 945019 | 1/14/2021 | MN | 68 | F | 1/7/2021 | 1/8/2021 | Most concerning was dizziness to the point of almost fainting. This happened 2 times. Once on the first day after injection and once on the second day after injection. Other S.C. were fatigue, muscle aches, chills, indigestion and sore arm. No fever noted. |
| 944943 | 1/14/2021 | CO | 71 | F | 1/12/2021 | 1/12/2021 | Systemic: Fainting; symptoms lasted 1 day |

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| 944477 | 1/14/2021 | NJ | 75 | F | 1/14/2021 | 1/14/2021 | Patient given vaccine. Within 5 minutes husband said she?s having another spasm. She was being monitored for 15 minutes after the injection. After the spasm it appeared to. become a seizure and passed out for 5 minutes . Husband said she missed her medicine and needed her carbidopa/levodopa. 911 arrived and administered oxygen and took to the hospital. |
| 944807 | 1/14/2021 | FL | 77 | M | 1/12/2021 | 1/14/2021 | Arm was sore starting approximately 4 hours. after the shot. I usually set thermostat to 68, but got so cold last night i pushed it up to 74 and added a blanket. Around 4:00 I woke up to go to the bathroom. Problems similar to Cirpro. Did not have control over direction I was walking.. Had to rock back and forth to sit up so I could get out of bed. I estimate this was a 3-5 minute ordeal. Drank some Powerade and went back to bed. I had gone to bed just before midnight. Slept till 10:30 because maid was coming at 11. I was totally unstable. When she saw me she immediately made me sit in a recliner. Said my face was pale and my eyes were blood shot. I would have fainted within seconds. |
| 944456 | 1/14/2021 | WA | 27 | F | 1/7/2021 | 1/7/2021 | Pt. received vaccine at 1520. At 1530 pt. started with itching, burning pain and patchy erythema without urticaria. No dyspnea, angioedema or wheezing. Pt. also experienced mild anxiety with O2 sat at 99, pulse 90 and BP 120/84. At 1535 50 mg diphenhydramine given IM in R deltoid and ice pack applied to L shoulder. At 1550 pulse 90, O2 sat 99%, BP 130/90, respirations unlabored and pt. reported mild dizziness, but not feeling like fainting. At 1615 itching reduced, pt.'s primary care provider, contacted and situation was reported to triage nurse and on-call provider. Provider advised pt. okay to go home if responding to the diphenhydramine. |

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| 944517 | 1/14/2021 | | 44 | F | 12/23/2020 | 12/25/2020 | Myalgia chills, fatigue, syncope vs seizure 43 yo employee falt fatigue on 12/24 and again on 12/25/20. The patients husband reports she was walking down the stairs, seemed "off" and missed the step/slid on step injuring both feet/ankles. Pt got up and was able to stand for a few minutes. Husband reports that he than sat her on the steps-few minutes later she had syncope with convulsions vs seizure. Per his report this lasted over a minute, she stopped breathing and was unresponsive. He reports she was confused while he was on the phone with 911 operator (3 minutes). Patient was taken to Health Center for work up. The head CT, labs, X-rays, EKG were unremarkable. Followed up her physician Dr. and was referred to neurologist. She had a MRI without contrast which was unremarkable and is scheduled to undergo a sleep deprived EEG. She is undergoing physical therapy at this time for injury to bilateral feet/ankles. |
| 944554 | 1/14/2021 | ME | 37 | M | 1/13/2021 | 1/13/2021 | Rapid heart rate, severe sweating, inability to breathe, narrowing vision, fainting, anxiety |
| 944601 | 1/14/2021 | NY | 42 | F | 1/11/2021 | 1/11/2021 | Monday, 1/11/2021 (8:30a): 2nd dose administered ? I felt fine the rest of the day and when going to bed. Overnight, I started to experience chills followed by extreme perspiration and weakness to the point that I struggled to open a bottle of water I had by my bed. Tuesday, 1/12/2021: Headache, weak and tired but attempted to work. I had to leave shortly after arriving because my symptoms were becoming progressively worse to the point I almost passed out from standing. Upon arriving home, I started to experience nausea and vomiting x 3. Intense chills followed by the extreme perspiration still existed. Most of these symptoms subsided by 9:30p that evening. Wednesday, 1/13/2021: Intense headache, weakness and dizziness. Of note, my left underarm/armpit (the arm where the vaccine was administered) is sensitive to touch. |

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| 944605 | 1/14/2021 | PA | 51 | F | 1/13/2021 | 1/14/2021 | Arm soreness, unable to sleep, patient is hypoglycemic - felt like having an episode, dizziness, patient loss consciousness for about 2 min, spouse called 911, patient had food then milk and ham, patient was pale, sweating, hands cramping, dizzy, shaking. Paramedics checked BP 118/76, sugar levels back up and oxygenation normal. Patient refused offer for transport to ER. Doctor visit in the AM ? EKG test: normal. Doctor requested for F/U prior to receiving 2nd COVID19 vaccination. Doctor unable to determine cause of low blood pressure that caused patient to faint. Previous TB test 20 years of age, 1988, caused fainting spell- blood pressure dropped and sugar levels for patient in the past. Patient today 1/14/21 is feeling foggy, dizzy, and fatigue blood pressure is still low, arm still sore. |
| 944637 | 1/14/2021 | OH | 37 | F | 12/31/2020 | 12/31/2020 | Tachycardia, palpitations, lightheadedness/near syncope, and numbness/tingling to tongue and lips 10 minutes after receiving vaccine. All symptoms resolved in about 15 minutes with the exception of numbness/tingling to tongue and lips which lasted 3 hours. Symptoms resolved on their own without treatment/medication other than lying flat with feet up and drinking a bottle of water. I was assessed by medical professionals at the vaccine clinic which was located inside of the hospital. I consulted with an ED physician but did not require any additional treatment. |
| 944688 | 1/14/2021 | MI | 36 | F | 1/12/2021 | 1/13/2021 | My first dose of COVID vaccine I didn't have any symptoms (1st dose: 12/23/20). Received 2nd dose at 0800 on 1/12/21. First symptom was on 1/12 at 2000 when I had a headache and malaise so I went to bed early. Woke up at 0200 on 1/13 with nausea, body aches and chills. My temp felt fever-ish (100.4 via temporal scan). So I took Tylenol and Pepto to go back to sleep. Same symptoms carried throughout the morning of 1/13. By noon 1/13 = my L arm where the injection had occurred was swollen, painful and hard to move. That evening I had a presyncopal event where I felt flushed and nearly passed out. My L arm continued to hurt but the swelling moved down into my lymph nodes where lymphadenopathy continues to be a problem until now. |
| 944442 | 1/14/2021 | MA | 63 | F | 1/11/2021 | 1/11/2021 | 30 seconds of near syncope |

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| 941422 | 1/13/2021 | FL | 48 | F | 1/8/2021 | 1/10/2021 | Brief but very severe abdominal pain waking me from sleep. Pain was so intense I almost passed out. It restocked just as quickly, lasted 3-5 min |
| 940105 | 1/13/2021 | AL | 54 | F | 1/12/2021 | 1/13/2021 | 14 hours after vaccination, woke up to slight body aches so went to take Tylenol and sudden wave of nausea hit and passed out falling on floor. Had slight stomach upset and significant chills. Took Tylenol and was recovered by 8 a.m. |
| 940808 | 1/13/2021 | AZ | 37 | F | 12/28/2020 | 12/28/2020 | Systemic: Exhaustion-Medium, Systemic: Fainting-Medium, Systemic: muscle tightness and weakness-Medium |
| 941370 | 1/13/2021 | FL | 39 | M | 1/13/2021 | 1/13/2021 | Pt received doe #2 to left deltoid at 1300. Immediately he began profusely sweating. he was observed for ~ 1 hour and continued to be diaphoretic. No CP, SOB, lightheadedness or syncope. Vital signs normal. Brought to employee health clinic. Remained slightly diaphoretic but normal exam/ vital signs stable |
| 941165 | 1/13/2021 | PA | 55 | F | 12/30/2020 | 12/30/2020 | Systemic: Fainting-Medium |
| 941018 | 1/13/2021 | MD | 53 | F | 12/29/2020 | 12/29/2020 | Systemic: Fainting-Severe |
| 941002 | 1/13/2021 | MA | 35 | M | 1/13/2021 | 1/13/2021 | After receiving the Moderna vaccine the patient was observed in the monitoring area (he was designated 30 minute in pre screening). He complained of fainting symptoms and described past similar episodes related to vasovagal type stimulus (IV insertion) as well as panic attacks. The patient was placed supine, vitals signs were monitored and IV normal saline bolus administered by on site paramedics. The patient rapidly improved and refused transport and further care against medical advice. He was advised to seek immediate medical evaluation at a hospital and advise his physician and he was picked up by another party and di not drive. |
| 940831 | 1/13/2021 | IN | 31 | F | 1/11/2021 | 1/12/2021 | Fever,chills, body ache, headache, fatigue, near syncope |

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| 940806 | 1/13/2021 | | | F | 1/4/2021 | 1/1/2021 | passed out; blood pressure was lowered; blood sugar high; weakened; feeling tired and her legs are heavy; feeling tired and her legs are heavy; This is a spontaneous report from a contactable consumer (Patient's Mother). A 23-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 04Jan2021 Monday at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient experienced passed out 12 hours post injection (Jan2021). She specified that her daughter was therefore brought to hospital by ambulance. She continued explaining that her blood pressure was lowered, her blood sugar high and that she was weakened (Jan2021). On 08Jan2021, "day 4", she said that her daughter had been feeling tired and her legs are heavy (Jan2021). The event outcome was unknown. She then asked if those side effects were experienced after the vaccine. It was not reported as serious. Information on the batch number has been requested. |
| 940674 | 1/13/2021 | NY | 31 | M | 1/12/2021 | 1/12/2021 | Pre syncope symptoms - 5-10 minutes after injection: Warmth Turning pale Getting sweaty palms Feeling dizzy or lightheaded Blurred vision Lasted 10 minutes; was observed for 30 minutes, given a snack and drink and slowly began to subside. |
| 940654 | 1/13/2021 | WA | 46 | F | 1/8/2021 | 1/8/2021 | headache nausea syncope |
| 939666 | 1/13/2021 | DC | 40 | M | 1/12/2021 | 1/12/2021 | After patient received the vaccine while waiting 15 minutes, the patients blood pressure dropped. The patient fainted and hit his head. He was conscious during the event. The EMS was called and they check the patient. The patient was offered and opportunity to go to the hospital but he declined. |

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| 940127 | 1/13/2021 | OH | 39 | F | 12/30/2020 | 12/30/2020 | per patient "12/30 9:30 am(approximate 1 hour after Moderna COVID19 vaccine) was home became woozy passed out 2 mins recovered in 5-10 mins. 11:30 am fixing lunch no warning passed out hit floor out 1-2 hours not responding BP 60/40 has POTS and family treated with IVF and pickle juice she was out of it in bed until 6pm. Did no take am meds prior to 08:30 vaccine but on Colanar 4mg bid, Cymbalta 40mg qd, Omeprazole 20 mg qd, Lisinopril 20mg qd, Benadril 50mg IV via port bid, Motegrity 2mg qd, Ducolox 30 qd, Senna 2 tabs qd, Zanaflex 4mg tid prn, Clonazepan 1mg q12 hour prn, Ibuprophen 800mg prn. |
| 939865 | 1/13/2021 | CO | 46 | F | 1/12/2021 | 1/12/2021 | Around 11:30pm on 1/12/2021, began having pretty serious chills (fever not measured but felt very warm). At about 1:45am on 1/13/2021, was feeling very achy and uncomfortable, so I went downstairs to get some Tylenol. Rapid heart rate and sweating, so much I had to sit down in the kitchen for a few minutes. Eventually took the Tylenol, and as I was heading back upstairs, I passed out (I don't remember going down to the floor) and dropped the cup of water I was taking with me. Was out for less than 30 seconds. A couple episodes of heaving/vomiting small amounts of liquid while on the floor. Made it back to bed and was starting to feel improved around 4:00am. |
| 939847 | 1/13/2021 | CO | 46 | F | 1/12/2021 | 1/12/2021 | Around 11:30pm, I woke up with incredible chills and had them for about 1.5 hours. Around 1:45am/2:00am on 1/13/2021, aches began, so I went downstairs to take acetaminophen. Increased heart rate and sweating while in the kitchen (had to sit down on the floor), eventually took Tylenol, and as I was heading back upstairs with cup of water, I passed out (less than 30 seconds) dropping the cup of water. Heaved/vomited small amount of liquid two or three times. Made it back to bed and began to feel better around 4:00am 1/13/2021. |
| 939788 | 1/13/2021 | | 25 | F | 12/22/2020 | 12/26/2020 | near syncope |
| 941487 | 1/13/2021 | NY | 23 | F | 1/9/2021 | 1/10/2021 | Almost passed out at work around 12 pm on Sunday. After that I had a persistent headache for 12 hours, I was fatigued, nauseous and had a persistent fever. |

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| 940331 | 1/13/2021 | TX | 71 | F | 1/4/2021 | 1/4/2021 | Very nauseous all night long. Ate a breakfast bar in the morning, threw it up, had dry heaves for a while, then seemed to be OK. About an hour or so later got up to go to the restroom and just remember walking thru the door. Next thing I knew I was on the floor bleeding, passed out approx. 24 hrs after receiving shot. No way to know how long I was out, received head cut. |
| 942458 | 1/13/2021 | AZ | 44 | F | 1/1/2021 | 1/12/2021 | Syncope |
| 941456 | 1/13/2021 | MI | 20 | F | 12/30/2020 | 12/30/2020 | Systemic: Fainting-Medium |
| 939601 | 1/13/2021 | WA | 33 | F | 1/10/2021 | 1/11/2021 | Moderate-Severe chills, fever (maximum temperature: 101F), moderate body aches/joint pain, moderate headache, moderate fatigue, fainted twice |
| 941437 | 1/13/2021 | NC | 39 | F | 12/29/2020 | 12/29/2020 | within 5-10 minutes of injection, felt light-headed and fainted, support was with her and we helped her to the floor until stretcher could be moved over to her, immediately came to, placed on stretcher, rested for 10-15 minutes, drank water, felt well and got up from stretcher, no issues |
| 942377 | 1/13/2021 | CT | 47 | M | 1/7/2021 | 1/7/2021 | Approximately 13 hours after receiving the vaccine I became overwhelmingly tired. Went to get ready for bed by first going into the bathroom. While getting ready I passed out (micturition syncope). Hit my head on the floor and sustained a concussion. I am still experiencing post concussive symptoms but this is to be expected as it has been less than a week. |
| 942354 | 1/13/2021 | CT | 33 | F | 1/13/2021 | 1/13/2021 | Within minutes of receiving the vaccine Pt said she developed a "fruity" taste in her mouth. She said she got dizzy, extremely hot and felt like she was "swaying" She said she also got what she described as "menstrual like cramps" that radiated all around her abdomen and back. She was under observation as advised per Pfizer protocol. An associate of the Pt noticed she passed out for a second she then turned beet red from her head to her neck as we could see. The associate yelled for us to grab a BENADRYL. They hooked her up to a BP machine and she did present with a spike in BP. After a few minutes, the redness and symptoms subsided. She was observed by the medical staff at the facility. |

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| 942074 | 1/13/2021 | CA | 38 | F | 12/28/2020 | 12/29/2020 | The next morning (12/29/20) - I had typical symptoms --> minimal body aches/fatigue and a sore Left arm At 6pm (12/29/20) --> I just finished dinner and all of sudden I felt like I zoned out/passed out for a minute. When I came to --> my sight was blurry, I felt very nauseous, dizzy, light-headed and felt like I was going to pass out. I ran to the kitchen and drank some water to try and calm it down, the sensation of passing out was still there with palpitations. I called out to my roommate who called an ambulance. My bp/hr were a bit on the lower side initially when the EMTs got to my apt. I was still feeling like I was going to pass out. My labs, vs, and tests all came back WNL when I got to the ED and by that time, I had a severe migraine and nothing else. From that night (Tuesday night 12/29) until the following Tuesday (1/5/21), I had a migraine, severe lethargy, body aches, and a swollen left armpit lymph node. |
| 941983 | 1/13/2021 | WA | 37 | M | 1/12/2021 | 1/12/2021 | Patient received the Covid vaccine on 1/12/2021 at 11:18 am. He felt light headed a minute or two post vaccination. He then lost consciousness for about <30 seconds. The staff eased him down the floor from the chair he was sitting on. He regained consciousness at 11:21am. He was diaphoretic and very pale. BP was 128/73 and HR was 46. Patient was given O2 at 2L/min and Gatorade which he tolerated well. At 11:26 am BP was 121/75, HR 53, O2 Sats at 99%, and RR 16. At 11:40am, patient stated he felt well and at this time, his color had returned. Patient stated he has a history of fainting with blood draw in 2003 but no issues with vaccines in the past. Also stated his HR usually runs in the 50's range. |
| 941882 | 1/13/2021 | MI | 34 | F | 1/13/2021 | 1/13/2021 | Pt experienced tachycardia, lightheaded, sweaty, nausea, and near syncope. Pt says she is anxious and feels this was anxiety-related. |
| 941876 | 1/13/2021 | NC | 89 | F | 1/7/2021 | 1/8/2021 | Patient was hospitalized within 24 hours after a syncopal episode due to hypotension. She was found to have a UTI due to E.coli and subsequently treated for the infection. It was felt, that the syncope was due to sepsis related to the UTI caused by known chronic constipation rather than the vaccine. |

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| 941499 | 1/13/2021 | CA | 36 | F | 1/11/2021 | 1/11/2021 | Patient experienced a syncopal episode post vaccination, accompanied by feeling hot and tachycardic. Prior to the syncope, she reported hyperventilating. She remained unresponsive for about 10 minutes and was brought to the ED. There she became responsive, and reported chest pain and had sinus tachycardia episodes. She also had lower extremity weakness. This has improved per the latest neurology notes. She also had a negative EEG. Unsure if this is an allergic reaction or if the syncope was due to hyperventilation. Patient is currently on day 3 of hospitalization. |
| 941839 | 1/13/2021 | CO | 31 | F | 1/7/2021 | 1/7/2021 | near syncope, relieved by rest |
| 941473 | 1/13/2021 | CA | 48 | F | 1/1/2021 | 1/1/2021 | Systemic: Nausea-Mild, Systemic: Vomiting-Mild, Systemic: Fainting-Mild |
| 941513 | 1/13/2021 | PR | 37 | F | 1/4/2021 | 1/5/2021 | Immediately after IM injection of the vaccine, patient start with an ascending muscular pain through shoulder and neck (left side). Didn't take any analgesic and went to sleep that night as usual. When she woke up next day felt dizzy and fainted. Husband held her and give alcohol to smell, what caused patient to respond. Took her BP and found it low (100/60). The person lay down and rested for an additional 2 hours and then continues her day as usual. |
| 941515 | 1/13/2021 | | 44 | F | 1/7/2021 | 1/8/2021 | nausea, syncope, LOC, fatigue |
| 941576 | 1/13/2021 | KY | 23 | F | 1/12/2021 | 1/13/2021 | Employee was awoken at 5:30 am on 1/13/2021 by chills and a feverish feeling. She then became nauseous and faint. She passed out and was noted by her mother who is a RN to have a seizure. She remained out for several minutes and then aroused. She has remained groggy the rest of today but has improved. She has a history of non-epileptic seizures since she was 14 and has been on medications for this. Employee stated she has not has any seizure activity in over a year. She did not see medical attention due to recovering quickly from this. |
| 941599 | 1/13/2021 | NY | 27 | F | 1/8/2021 | 1/8/2021 | Reported decreased sensitivity to touch in mouth and on face, mixing heat and cold (hot shower felt cold, cold raindrops felt scalding, trouble thermoregulating) couldn't tell where arms were, dizziness, passed out. |

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| 941799 | 1/13/2021 | AZ | 40 | F | 1/7/2021 | 1/9/2021 | Patient experiencing moderate-severe body aches, chills, feeling of burning all over skin, skin flushing, nausea, headache, dizziness, near syncope, and bouts of being tachycardia. acetaminophen 1gm q6 hours x 4 doses for 2 days ondansetron 4mg x 1 dose |
| 941828 | 1/13/2021 | MA | 31 | M | 1/13/2021 | 1/13/2021 | Vaccine was given at 1250 pm. Approximately 20 min. after receiving the vaccine patient became general weak accompanied by near syncope, nausea. He was transported to hospital for treatment. |
| 936909 | 1/12/2021 | TX | 48 | F | 12/23/2020 | 12/23/2020 | I got the vaccine and had a headache that lasted 2-3 minutes. I then got in my car and I felt little bit sick and I picked up food and I started to feel sick. I went to work and my symptoms got worse and I sat in my desk and I felt like fainting. I just felt so sick and I thought it was my diabetes. A coworker saw me and told me i looked deathly pale and felt fainting and they took me to a ER room. They gave me Benadryl and IV fluids. I started seeing the floor and ceiling warped out, I was hallucinating. My legs felt numb as well. My eyes were twitching constantly. My blood pressure 147/95 and pulse was 112. I went home, ate and went to sleep. On Saturday I felt better and went back to work 12-28-2020, I felt weak and stayed working at my shift. On Tuesday I worked 1 hour and still felt super weak. Today I am starting to feel like myself again. I will not get my second dosage due to my symptoms I have experienced. |
| 937674 | 1/12/2021 | NC | 50 | F | 12/22/2020 | 12/22/2020 | Received 1st dose vaccine and became nauseated, dizzy, lightheaded and almost passed out. |
| 938141 | 1/12/2021 | OR | 33 | F | 1/11/2021 | 1/12/2021 | Fainted twice and hit her head when falling, has head ache and abrasions on her face. |
| 938114 | 1/12/2021 | | 30 | F | 1/12/2021 | 1/12/2021 | Syncope and seizure |
| 937926 | 1/12/2021 | NY | 34 | F | 1/7/2021 | 1/9/2021 | Vaccine given Thursday afternoon. Saturday morning had fainting spell. Vision and hearing lost before collapsing and fainting. After a few seconds came to and was disoriented and tired and then shortly recovered. I have no prior history of ever fainting or loosing consciousness. |
| 937842 | 1/12/2021 | ID | 56 | F | 1/11/2021 | 1/11/2021 | Sweating. Dripping sweat. Nausea. Passed out last night. |

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| 937769 | 1/12/2021 | MN | 22 | F | 1/11/2021 | 1/12/2021 | Vasovagal syncope |
| 938163 | 1/12/2021 | AL | 59 | F | 1/12/2021 | 1/12/2021 | pre syncope; difficulty breathing; dizzy - after 20 minutes of monitoring patient refused emt |
| 937647 | 1/12/2021 | IL | 45 | F | 1/8/2021 | 1/8/2021 | About 15 min ?icy hot? numb feeling hands feet, lips mouth, dizzy, difficulty thinking, heart pounding, tongue felt big, nausea, tightness back throat that progressed down neck, paramedics reported near syncope decreased pupil& verbal response, tachycardia, red neck chest, spots on face. On site ambulance IV meds Epi? Benadryl 50mg and o2, transferred to ER- IV meds Pepcid and solumedrol, and home 5 days oral prednisone, Benadryl, Pepcid, albuterol |
| 937556 | 1/12/2021 | NC | 42 | F | 1/2/2021 | 1/2/2021 | EXTREME VERTIGO, HIGH FEVERS, SYNCOPE, BODY ACHES, CHILLS, MEMORY LOSS |
| 937158 | 1/12/2021 | TX | 83 | F | 1/6/2021 | 1/8/2021 | Patient on phone call follow-up noted that she fainted and vomited about ~1.5 days after vaccine administration. Patient was in a public area and EMS was called. Patient noted she felt fine after event and refused transport to another facility. No other issues noted after this episode per patient. |
| 938169 | 1/12/2021 | | 37 | F | 1/7/2021 | 1/8/2021 | Experienced chills, headache, tachycardia, fatigue, dizziness, syncope |
| 937128 | 1/12/2021 | FL | 68 | F | 1/4/2021 | 1/5/2021 | MODERNA COVID-19 Vaccine EUA I took the vaccine on Monday Jan 4 at around 9 AM. During the day only pain in the left arm. On Tuesday I felt tired all day long. At 7 PM, I took a Coke inside the fridge and I noticed and told my husband I was not feeling well. I put the coke in the glass, after I took the glass in my hand and then I fainted. Never in my life I have fainted before. I hit my head in the floor. Now I have some bruise in my face, mainly around my left eye. Feeling a little dizzy, I am in quarantine I and my husband are staying home all the time. I have my doctor scheduled for next Thursday. |

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| 936192 | 1/12/2021 | NJ | 24 | F | 12/26/2020 | 12/26/2020 | Passed out twice; Pain in the injection site; Slight headache; A spontaneous report was received from a consumer concerning a 24-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced the events, passed out twice, pain in the injection site, and slight headache. The patient's medical history was not reported. No concomitant medications were reported. On 26 Dec 2020 at 1:58 pm, approximately three hours prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: 026L2DA) intramuscularly for prophylaxis of COVID-19 infection. On 26 Dec 2020, at 5:00 pm, the patient passed out. She also had pain in the injection site and a slight headache. On 27 Dec 2020, at 8:30 am, the patient passed out again. No treatment information was provided. The Action taken with mRNA-1273 in response to the events was not reported. The outcome for the events, passed out twice, pain in the injection site, and slight headache was unknown.; Reporter's Comments: This case concerns a 24 year old female patient, who experienced a serious unexpected event of loss of consciousness and non-serious expected event of injection site pain and headache. The event occurred apparently few hours after first dose of mRNA-1273 (Lot # 026L2DA) administration. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. |
| 936702 | 1/12/2021 | LA | 62 | F | 1/11/2021 | 1/12/2021 | Chills, dizzy (nearly fainted), headache and joint (hip) pain. All symptoms manifested approximately 21 hours after injection |
| 937131 | 1/12/2021 | TX | 83 | F | 1/6/2021 | 1/8/2021 | On phone follow-up after vaccine patient noted that she fainted and vomited ~1.5 days after vaccine. Event occurred in the public. EMS was called but patient declined transport to ER facility. Patient said she felt fine after event and no further issues after episode. Patient has had no further follow-up with another health care provider for event. |
| 939204 | 1/12/2021 | PA | 42 | F | 1/6/2021 | 1/6/2021 | Flu like symptoms, syncope, lymphadenopathy, nausea, fatigue, weakness. |

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| 938212 | 1/12/2021 | NY | 66 | F | 1/3/2021 | 1/3/2021 | ~~45up to void min later sweat, 12hrs later when I woke up to void, I felt warm ,severe fatigue , ,muscle aches , pain some Syncope, nausea, sweating on and off, oral herpes outbreak just like I did when I had Covid -19 in April~~ |
| 939164 | 1/12/2021 | VA | 63 | F | 1/11/2021 | 1/11/2021 | Possible vasovagal syncope 6 hours past the administration. Lasted for 30 minutes. Symptoms included extreme warmth (felt like whole body was on fire), dizziness - laid down immediately so did not faint, nausea, lowered heart rate (44), unsure of blood pressure, paleness. Cold compresses and laying down and raising legs was helpful. |
| 939129 | 1/12/2021 | | 31 | M | 1/6/2020 | 1/6/2020 | dizziness, SOB, fainting - 5 minutes post vaccination. Symptoms resolved without intervention. Taken to the ED for eval. |
| 939121 | 1/12/2021 | CA | 50 | F | 1/8/2020 | 1/9/2021 | About 12 hours after vaccine, I had high fever of 102, severe body aches, severe chills, minimal nausea, even with two extra strength tylenols. I went to the restroom around 5 am and had lightheadedness and FAINTED. My husband helped me up and helped me to bed. I was still mildly lightheaded for about 30 minutes. I took two extra strength tylenols and two Advils. My fever broke about 30 minutes later. I slept. Then about 2 pm had fever and aches again, but took two Advils and fever broke. |
| 939004 | 1/12/2021 | WA | 38 | F | 1/9/2021 | 1/10/2021 | 12:20 spouse woke PT up because she was gargling. Passed out twice when trying to walk. |
| 938945 | 1/12/2021 | CA | 21 | F | 1/9/2021 | 1/9/2021 | Recipient experienced dizziness, lightheadedness, and fainted within 15 min of vaccination. She was given a sandwich and orange juice, which she consumed. She felt better within 1 hour. She was picked up by her mom and was driven home. |
| 938861 | 1/12/2021 | IL | 42 | F | 1/8/2021 | 1/8/2021 | Developed syncope within a few minutes of receiving vaccine. Taken to the ED for treatment. given IV fluids, Benadryl, famotidine, methylprednisolone, IV fluid bolus and O2 along with reglan and Zofran. Total ED stay approximately 4 hours |

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| 938270 | 1/12/2021 | | 25 | F | 12/22/2020 | 12/26/2020 | Near syncope, tachycardia with palpitations, nausea, dizziness, shakiness, pallor, fever |
| 938750 | 1/12/2021 | FL | 66 | F | 1/9/2021 | 1/9/2021 | Felt very much like I was going to faint. Had nausea and without proper breathing and fighting through it, I would have passed out. And I was driving. The pain during the injection was one of the most severe I've ever had. It was injected in the top part of my shoulder where there is nothing but bone. |
| 938740 | 1/12/2021 | SC | 42 | F | 1/6/2021 | 1/7/2021 | The day after the vaccine was given, 01/07/2021, I had a headache and nausea around 10:00am. I had to leave work early. I fainted when I got home on Thursday. Felt very tired. So I rested the remainder of the day and that night. On Friday 01/08/2021, I felt very tired and had a temperature of 100.6. I slept most of the day. Friday night I fainted again around 8:00pm. Slept all night. Felt much better on Saturday. Felt normal from Sunday on. |
| 938719 | 1/12/2021 | FL | 77 | F | 1/11/2021 | 1/11/2021 | Dizziness/light headed (almost passed out) Vomiting Diarrhea Exhaustion (slept for 5 hrs) High blood sugar (300) |
| 938695 | 1/12/2021 | MN | 22 | F | 1/11/2021 | 1/12/2021 | dizziness then syncope. loss of consciousness lasted a couple minutes. Patient sustained minor superficial abrasions to her face. evaluated in clinic |
| 938484 | 1/12/2021 | NY | 39 | F | 1/12/2021 | 1/12/2021 | patient fainted, 10 sec seizure, diaphoretic |
| 938340 | 1/12/2021 | NJ | 25 | F | 1/11/2021 | 1/12/2021 | At 12am on 1/12/21, I experienced extreme hot flashes and nausea while sleeping. I was unable to walk at first, but after standing up I fainted and became extreme cold. This same exact feeling happened again at 7am on 1/12/21 without loss of consciousness. |
| 939171 | 1/12/2021 | PA | 35 | F | 12/31/2020 | 12/31/2020 | right arm numbness/tingling chest tightness dry heaving passed out lips and tongue tingling then swelled. 50mg IM Benadryl administered, vitals monitored, RR called and I was transported to the ER and given more medications. |

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| 938813 | 1/12/2021 | | 34 | F | 1/8/2021 | 1/8/2021 | Patient is a 34 y.o. female who was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. She denied any history of previous adverse reactions to vaccines. She was given the Moderna vaccination in the right deltoid muscle. During her 15 minute waiting period after the injection, the patient began to experience dizziness and diaphoresis. She denied difficulty breathing, throat tightness and facial swelling. This provider was notified of patient reaction and she was then assessed in the emergency bay area. Monitored patient for severe reaction symptoms, including but not limited to blood pressure abnormality , rapid progression of symptoms and syncope. Patient states she last ate an apple with PB around 1pm today, but has not had much else today. Denies drinking much water today. She was working in surgery a majority of the day. |
| 933500 | 1/11/2021 | | 52 | F | 1/8/2021 | 1/9/2021 | ~~Pfizer-BioNTech Covid 19 Vaccine EUA" // reaction: syncope, nausea, drowsiness, headache, weakness, flu like symptoms- lasting for 1.5 days. treatment: rest, advil, Tylenol, soft diet with small meals, liquids, bedrest. 2 days after vaccine, still tired- arm not sore but axillary lymph nodes are swollen. |
| 934597 | 1/11/2021 | GA | 42 | F | 1/10/2021 | 1/11/2021 | Headache, chest pain, fatigue, feeling of near syncope |
| 934740 | 1/11/2021 | TX | 37 | F | 12/19/2020 | 12/19/2020 | extreme fatigue with, headache. Went to ER And Received fluids And meds for headache. SEEN IN E.D 1/7 & 12/19 (after both 1st & 2nd vaccine) ZOFRAN & FLUIDS IN E.D. DIAGNOSIS "NEAR SYNCOPE~~ |

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| 934899 | 1/11/2021 | | | F | | | difficulty of breathing; chest pain; nearly passing out/fainting; This is a spontaneous report from a contactable consumer. A 50-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiry date unknown) via unspecified route of administration on unspecified date at single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. The reporter called in behalf of her friend that has been experiencing serious adverse event. The patient experienced difficulty of breathing, chest pain, nearly passing out/fainting on unspecified date. They felt that the vaccination provider did not provide enough support about the adverse event that happened. Follow-up activities are possible, information on the batch number has been requested. |
| 934526 | 1/11/2021 | NC | 22 | F | 12/22/2020 | 12/23/2020 | Woke up during the night and experienced vomiting and diarrhea followed by syncope |

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| 934919 | 1/11/2021 | | | M | 1/5/2021 | 1/1/2021 | <p>syncope; diaphoresis; varying HR; blurred vision; This is a spontaneous report from a contactable physician (patient). A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on 05Jan2021 as single dose for COVID -19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced syncope, diaphoresis, varying HR (heart rate) and blurred vision in Jan2021. The patient underwent lab tests and procedures which included heart rate: varying in Jan2021. Details were as follows: Patient received the vaccine in the morning. He reported diaphoresis, syncope, varying HR, and blurred vision within 10 minutes of receiving the vaccine. He was taken to the emergency room and therapeutic measures were taken as a result of the events; he was given fluids. The patient generally tolerated vaccines and has recovered from the episode. The events, syncope, diaphoresis, varying HR (heart rate) and blurred vision recovered in Jan2021. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up .; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event due to temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators as appropriate.</p> |

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| 933808 | 1/11/2021 | VA | 33 | F | 1/7/2021 | 1/8/2021 | Summary: syncopal event, hypotension, leukocytosis About 22-24 hours after receiving the first dose of the vaccine (1/8/21), the patient became nauseous and lightheaded, sat down in a chair for at least 30 minutes, felt worse and let a coworker know, then had a syncopal episode lasting 5-10 minutes, coworkers witnessed patient had stable vital signs but unresponsive, diaphoretic, pale, and shaking, a hospital rapid response was called (patient works at the hospital). Patient was taken to the ED for observation, remained hypotensive (90's/50's) for about an hour, then slowly returned to normal BP (110's/80's) over another hour. Patient likely did not require going to the ED, however was taken there as a precaution due initially to the length of time passed out and hypotension. Prior to this episode, the patient only experienced soreness at the injection site. Following this episode, the patient felt some weakness and had a mild headache for another 24 hours before returning to baseline. |

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| 934910 | 1/11/2021 | CA | 53 | F | 12/28/2020 | 12/28/2020 | chest pressure; tightness /pressure in throat; Face red; BP 186/90; within 2 min. of injection had near syncope that would come in waves every 2-3 minutes; Headache; rapid HR; Chills; mild cough; Dizziness; fatigue; This is a spontaneous report from a non-contactable health care professional nurse, the patient. A 53-years-old non-pregnant female patient (nurse) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: EJ1685), in the right arm on 28DEC2020 08:15 as a single dose, for COVID-19 vaccination. Facility where the most recent COVID-19 vaccine was administered was a Hospital. Medical history included asthma and gastroesophageal reflux disease from an unknown date and unknown if ongoing. Known allergies include Tape, Walnuts, and Cat hair. Concomitant medication received within 2 weeks of vaccination included acyclovir [aciclovir] (ACYCLOVIR [ACICLOVIR]), ferrous gluconate, herbal nos, vitamins nos (FLORADIX), lansoprazole (PREVACID), cholecalciferol (VITAMIN D [COLECALCIFEROL]). No other vaccines were given within 4 weeks. Prior to vaccination, the patient was not diagnosed with COVID-19. On 28DEC2020 08:15 within 2 min. of injection had near syncope that would come in waves every 2-3 minutes, face red, chest pressure, tightness /pressure in throat, headache, BP 186/90, rapid HR. The patient Spent 1 hour in ER. Later in day 28Dec2020, continued to have dizziness, chest pressure, chills, headache, fatigue. This continued for 4 days and had mild cough. The adverse events resulted in an emergency room (ER) visit. and Physician Office Visit. Treatment included Xyzal which relieved majority of symptoms. Laboratory test and procedures on 28Dec2020 include Electrocardiogram (EKG) with normal results, Blood Pressure Measurement 186/90 and Heart Rate Rapid. Treatment was given for chest tightness, throat tightness and red face and No treatment was given for chills, cough, dizziness, fatigue, headache, heart rate increase, blood pressure high and near syncope. The clinical outcome of near syncope that would come in waves every 2-3 minutes, face red, chest pressure, tightness /pressure in throat, headache, BP 186/90, rapid HR, dizziness, chest pressure, chills, headache, fatigue, mild cough was recovered. No follow-up attempts are possible. No further information is expected.; Sender's Comments: The Company cannot |

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| | | | | | | | completely exclude the possible causality between the reported face red, chest pressure, tightness /pressure in throat, blood pressure increased (BP 186/90), near syncope and the administration of BNT162B2, based on the reasonable temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate. |
| 934503 | 1/11/2021 | AL | 38 | F | 1/6/2021 | 1/7/2021 | During the middle of the night, fever, headache, chest pressure/shortness of breath. By early morning the following day, severe dizziness and fainting. Felt like orthostatic hypotension. Could not even sit up in bed without blacking out. Lasted for hours until about midday |
| 934306 | 1/11/2021 | MI | 45 | F | 1/9/2021 | 1/10/2021 | Vasovagal syncope episode - passed out a total of 3 times Drop in pulse ox and heart rate |
| 934201 | 1/11/2021 | | 49 | F | 1/8/2021 | 1/8/2021 | Got shot waited 15 minutes, walked to elevator, felt dizzy returned to vaccine admin area. Headache, vitals checked and were okay. Continued to feel weird rubbing chest and short of breath but no chest pain. Decided to take her to the ED. On the way she passed out and was not responsive still had a pulse. In ED became responsive, reports numbness in both arms and short of breath. Received Benadryl complete assessment, doesn't appear to be an acute allergic reaction. ECG & vitals were okay. Patient observed for 4 hours and seemed to improve so discharged. |
| 933877 | 1/11/2021 | OH | 50 | F | 12/30/2020 | 1/2/2021 | Felt dizzy and nauseous and then passed out for 30-60 seconds. Vomited after I came to about 5 minutes after and have been fine since |
| 933438 | 1/11/2021 | FL | 23 | M | 1/11/2021 | 1/11/2021 | Near-fainting, Lightheaded, chest tightness cold sweat |

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| 934924 | 1/11/2021 | OH | 58 | F | 1/4/2021 | 1/4/2021 | tired; no energy; low back pain; her fingers are hurting; passed out on toilet; Nauseated; hit head on wall, head just hurts; hit head on wall, head just hurts; Chills; she was very cold; could not sleep good; site of vaccine was sore; Muscle pain; Joint pain; This is a spontaneous report from a contactable consumer. A 58-year-old female patient started to receive first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Batch/lot number: EK9231) by injection once to left arm, via an unspecified route of administration on 04Jan2021 12:30 at single dose for covid-19 immunisation. Medical history included thyroid disorder. Concomitant medication included levothyroxine sodium (SYNTHROID) for thyroid disorder; patient started it after she had her son, and her son is 18 years old. The patient had her vaccine yesterday (04Jan2021) at 12:30, and at nighttime, around 22:00, she started having chills, she was very cold, so she went to bed, she could not sleep good, she kept waking up, and the site of vaccine was sore, she had muscle pain, joint pain, she didn't have fever, but she got up late today (05Jan2021), around 11:00, and had breakfast and felt nauseated, so she stopped eating, and she went to the bathroom and passed out on the toilet, when she woke up, she had her nightgown inside the toilet, it was all wet, she felt better, so she stood up and then she woke up again, and was inside the tub, her legs were inside the basin, she was lying down with her back inside the tub, she thinks she hit her head on the wall, and it just hurts, it didn't bleed or nothing. The patient stated she had the paper she was given. Again stated she can not even function. Patient still feels Chills a little bit, not as bad as last night. She is awake now, but she feels very very tired, like she has no energy, she is laying down on couch right now. She kept waking up and noticed this morning, she had low back pain, in the muscles, even her fingers are hurting. Regarding hitting her head on the wall, states she has a terrible headache, not a little pain, she thinks it is because she hurt her head. The patient is supposed to get second vaccination on 25Jan2021. The outcome of events Chills, Joint pain and nauseated was recovering; of events site of vaccine was sore and muscle pain was not recovered; of other events was unknown. |

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| 935764 | 1/11/2021 | NM | 76 | M | 1/9/2021 | 1/10/2021 | Headache, Dizziness, Nausea, Fainted and hit my head on tile floor. Started at 2:30 a.m. on 1/10/2021 and culminated with fainting on same day at 12:30 p.m. Have continued with weakness, tiredness and dizziness. Other reactions have subsided. |
| 934099 | 1/11/2021 | IL | 41 | F | 12/28/2020 | 12/28/2020 | Patient is a 41 y.o. female who presented to the ED with complaints of a reaction after she took the COVID vaccine. Patient is an RN here and had earlier received COVID-19 vaccination (Moderna) around 0130 this afternoon. Soon after she experienced rash which was burning and itchy on her arms thighs and back. She reported to Occ health and was directed to the ED. While in the ED she experienced throat tightness and nausea. She had one episode of diarrhea. No tongue, lip swelling, SOB or difficulty swallowing. Denies any chest pain, palpitations, pre-syncope/syncope. No vomiting abdominal pain. H/o of allergy to fish mix and dust mite. |
| 935927 | 1/11/2021 | | 48 | F | 1/11/2021 | 1/11/2021 | After vaccination, patient was ok, talking and eating. Suddenly, patient complains of dizziness, and "didn't feel right". Patient was laid flat on a couch, but then passed out and was not responsive to sternal rub. After a code was called, the patient woke up. At no time was there a loss of pulse or SOB. Patient was transported to the ER and was subsequently discharged same day. Patient did report that prior to the vaccination, she ran 13 miles in the morning, which may have had something to do with the reaction. |
| 936133 | 1/11/2021 | VA | 40 | F | 1/11/2021 | 1/11/2021 | lightheaded ness and near syncope bradycardia as hypotension started about 10 minutes after vaccine administered. about 1 hour later had wheezing and chest tightness lasting about 4 hours |

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| 935993 | 1/11/2021 | OR | 55 | F | 1/7/2021 | 1/8/2021 | On 1/8/21, the day after the vaccination I developed a headache, nausea, fatigue, chills and cognitive impairment. I quickly started vomiting which was intense and persistent. I had no food in my system so vomiting was mostly dry heaves, bile and what ever water I could drink. Shortly after the vomiting began, I believe I passed out, fell and hit my head on the floor. I don't remember falling but my husband said he heard the fall and I developed a large lump/bruise on my forehead. The persistent vomiting lasted about 4-5 hours and other symptoms gradually improved. 1/11/21 I still have a milder headache, slight nausea and some fatigue. |
| 935968 | 1/11/2021 | OR | 55 | F | 1/7/2021 | 1/8/2021 | On 1/8/21, the day after the vaccination I developed a bad headache, nausea, fatigue, chills, cognitive dysfunction. No fever. I quickly started to vomit intensely and repeatedly for several hours. Towards the beginning of the vomiting, I believe I passed out and hit my head on the floor. I don't recall hitting my head at all but had a large swollen bump on my forehead. My husband said he heard the fall. I had no food in my system so vomiting was dry heaves, bile and any water I was able to drink. Symptoms decreased over the next 4-5 hours. I still have a more mild headache and slight nausea on 1/11/21. |
| 935700 | 1/11/2021 | IL | 58 | F | 1/8/2021 | 1/9/2021 | Fatigue, muscle aches, mental fogginess, syncope, cold hands |
| 935941 | 1/11/2021 | WV | 83 | M | 1/11/2021 | 1/11/2021 | Patient passed out while driving, the patient called me when they got home. His wife stated that he felt fine and I advised them to get him checked out as their earliest convince. |

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| 934925 | 1/11/2021 | | | U | | | Fainting; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for 2 patients. This is 2nd of 2 reports. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient experienced fainting on an unspecified date with outcome of unknown. The action taken in response to the event for bnt162b2 was not applicable. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021006219 same reporter/drug/event, different patient |

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| 935797 | 1/11/2021 | NY | 38 | M | 1/10/2021 | 1/11/2021 | Felt completely normal at time of injection, and for several hours afterward. Began feeling pain and soreness at injection site around 11PM. Felt overall coldness and increased soreness at injection site when retiring to bed at 11:30PM. Experienced extremely vivid dreams prior to awaking at ~4AM with the need to urinate. Felt extremely hot, and somewhat concerning shortness of breath. Sat up in bed for 45-60 seconds prior to standing vertical. Felt normal when walking to bathroom and while urinating, no straining or abnormal effort required. Upon nearing completion of emptying bladder, ears began increasing intensity of ringing, followed immediately by cascading sensation of weakness. Realizing I was probably rapidly losing consciousness, I grabbed sink for support, in order to get as close to the ground as possible. Regained consciousness an unknown period of time later, though believed I was in bed. Upon noticing how cold my "bedsheets" were, I realized/remembered that I had lost consciousness. Felt completely weak and rested on floor for 30(?) minutes; attempts to move to a more vertical position were met with vague sensations of nausea. Eventually felt strong enough to drag myself to a nearby couch, where I slept on and off until 11:30AM, and gradually woke up to eat breakfast. I have experienced 1-2 episodes of syncope in my lifetime, and this instance aligns with how I felt at those times. Have never experienced micturition syncope at any point before, though. |

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| 935780 | 1/11/2021 | OH | 61 | F | 1/5/2021 | 1/5/2021 | Extremely tired went to bed at 8:30. At 11:00, tossed and turned until 12:16 a.m. Did not think she could stand up. Walked in the bathroom had pain in stomach, was very hot and freezing at the same time, was shaking. Head hurt was hurting so bad. Tried standing up from toilet, was passed out. Eye, half of face is bruised and swollen , eye shut for two days. More than forty minutes passed before she could call her husband. Does not remember anything because she was passed out. Husband came in and grabbed her, to get her back into bed. she could not stand. Went to ER at Hospital. Had CT scan, blood work , EKG, chest xray. Was still kind of out of it but was able to communicate with nurses. Face is still black and blue. Last night got up at 4:00 a.m. something was wrong with her throat. Felt like a walnut was in her throat. Went to doctor this morning. They said it was a reaction from the shot. Got an EpiPen, prednisone. Call them in 2 days to let them know how she's doing and also wear a heart monitor because they do not know how to take care of her, Has had vision blurriness in both eyes. Has not felt well at all. |
| 935742 | 1/11/2021 | CO | 32 | F | 1/7/2021 | 1/8/2021 | Vaccine at 600pm on 1/7. Waking up every hour from 330am-800am. Woke up 8am chest scratchiness/itchiness, generalized joint pain, and body aches, and fatigue. Episode of lightheadedness at around 6pm and near syncope. Started experiencing axillary swelling and pain. All symptoms resoled by 1/9 except for L axillary swelling which persisted until 1/11. |
| 935519 | 1/11/2021 | | 34 | F | 1/11/2021 | 1/11/2021 | Patient is a 34 y.o. female who was seen at COVID Vaccine Clinic today for her dose of the COVID 19 vaccination. She denied any history of previous adverse reactions to vaccines. She was given the Moderna vaccination in the left deltoid muscle. During her waiting period after the injection, the patient began to experience dizziness / lightheaded. She denied syncope, N/V, visual changes, headaches. This provider was notified of patient reaction and she was then assessed in the emergency bay area. Monitored patient for severe reaction symptoms, including but not limited to shortness of breath, swelling of the throat, Difficulty breathing, chest pains. Patient did not experience any of these symptoms She is 18 weeks pregnant. No complications with pregnancy. |

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| 935498 | 1/11/2021 | CA | 54 | F | 1/11/2021 | 1/11/2021 | 30 min after vaccine she became hot, flush, dizzy, heart pounding, hands face and feet were numb and tingly, she passed out at her desk and was taken to the ER for evaluation. Benadryl & Solumedrol Admin with hydration with NS. Pt discharged from ER. Pt in ~10am discharged from ER ~2hrs later. |
| 935153 | 1/11/2021 | TX | 83 | F | 1/10/2021 | 1/10/2021 | FAINTING EPISODE CONFUSION |
| 935948 | 1/11/2021 | CA | 23 | F | 1/11/2021 | 1/11/2021 | Patient was screened for COVID-29 vaccine and since no contra indications was given vaccine around 1:10 pm. Around 1:30 pm patient told facility staff she was feeling numbness, tingling, short of breath, weakness, dizziness and felt like fainting. The patient appeared shaky, and clammy. Blood pressure taken at 1:35 pm was 172/100 mmHg, then repeated 168/101 mmhg, then 164/106 mmHg. Facility staff called EMS and they arrived and assessed patient. BP reading 160/100 mmHg, HR 120 bpm, and O2 SAT was 100%. Patient was taken to ER at 1:55 pm. Patient was alert and answering questions. |
| 932771 | 1/10/2021 | TN | 36 | F | 1/9/2021 | 1/10/2021 | Syncopal episode at approximately 5:20am this morning. I had been awake and active for about 30 minutes getting ready for work. As I was walking to my kitchen, I suddenly became very dizzy with blurred vision, tingling hands, nausea, ringing in my ears, and I felt like I was going to lose control of my bowels. I became very weak in the legs and I made it to the couch before I fell. Episode lasted approximately 2 minutes. As I laid down, my symptoms recovered. My husband gave me some juice and toast. After about 20 minutes, I got up and was able to walk without symptoms. I felt perfectly normal prior to this event. Last night, I ate a full dinner and drank about a liter of water. This event did not seem to be precipitated by hypoglycemia or dehydration. For the rest of this day, I have felt normal. |
| 932519 | 1/10/2021 | CA | 29 | F | 1/10/2021 | 1/10/2021 | About 8 minutes after receiving injection, Pt stated that she wasn't feeling well. She passed out for about 2 minutes. Pt came too and was taken to ER via wheel chair. at ER pts bp was 69/33 HR:42 O2 was 100%. pt was pale and diaphoretic. |

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| 932200 | 1/10/2021 | IN | 51 | M | 1/8/2021 | 1/8/2021 | 3 hours after 2nd dose almost fainted when exercising. 4 hours after injection started to feel achey, headache, and stiff neck. 12 hours after injection started shivering and increased heart rate. Took advil which helped, but shivering resumed 18 hours later. Took more advil. Body aches, sore arm, and headache continued for 48 hours. I still don't feel great 48 hours later but much better |
| 932315 | 1/10/2021 | IN | 61 | F | 1/8/2021 | 1/8/2021 | Numb hands, numb face, lightheaded, almost passed out, spike in blood pressure, unsteady walk. Ambulance called, tested to rule out stroke and blood sugar issue but tested ok. Determined I had allergic reaction to vaccine. |
| 932406 | 1/10/2021 | NY | 39 | F | 1/7/2021 | 1/7/2021 | Hypotension and presyncope within 2 min of receiving the vaccine Tingling on face and both hands lasted for 2 hrs Following day- chills and abd cramping Day 3 - headache |
| 932510 | 1/10/2021 | NM | 23 | M | 1/9/2021 | 1/9/2021 | Patient fainted after receiving vaccine/ Pt was monitored in observation chair for 15 minutes, blood pressure, and heart taken within normal limits/ Patient stated he wasnt concerned because this happens to him everytime |
| 932663 | 1/10/2021 | NY | 41 | F | 1/9/2021 | 1/9/2021 | Feeling fine in morning. Had cup of tea, went for vaccine at 10AM. Did fine with injection, sat down for observation, 8-10 minutes later started feeling sweaty, then passed out. Woke up on the floor with nurses around me feeling tightness in chest, numbness in fingers, body shaking off and on, started to feel like tongue was swelling. Nurses gave IV fluids, oxygen and 2 Epi-Pens. Transported by ambulance to Buffalo General Hospital. Symptoms resolved not long after arrival at hospital. Remained in EMT bay hallway for observation., seen there by ER doctor. Another EGK done, additional half bag of IV fluids, released after 4 hours observation. |

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| 932955 | 1/10/2021 | VA | 44 | F | 1/7/2021 | 1/7/2021 | I had throat & tongue swelling in the 15 mins after 1st covid vaccine/moderna..... EMS walking me out of school to ambulance & I passed out on sidewalk. And even I could not talk due to throat and tongue swelling and was getting weak. I was checked BP , it was over 150. I was transported to LG Alleghany - I received 1 epipen at the ambulance and another epipen in the ER. total got 2 Epipens. --- heart racing & shaking all over -- At the ER, took x-ray on lung and thorat , did EKG, and got Benadrly then slept for 40 mins or 1 hour. |
| 932727 | 1/10/2021 | PA | 65 | F | 1/7/2021 | 1/9/2021 | 2 days after injection, nausea, projectile vomiting, 1 episode of unwitnessed syncope |
| 932775 | 1/10/2021 | CA | 50 | F | 1/8/2021 | 1/9/2021 | Chills/shivers, injection site pain, back pain/body aches, nausea, syncope, low blood pressure Started getting chills at 0300, back pain started and injection arm became very painful. at 0430, got out of bed, nausea became severe and I passed out for 2 minutes. Subsequently fractured my nose from the fall after passing out and ended up in the ER for 6 hours with low blood pressure. |
| 932861 | 1/10/2021 | MS | 49 | F | 1/8/2021 | 1/8/2021 | About 15 to 20 minutes after injection I began feeling weak, warm & ?tingly?. I then became dizzy & very weak & almost passed out. They laid me from the chair onto the floor & lifted my legs. They took me to the ER & I received IV fluids, IV benedryl & Pepcid. (I received the vaccine at 12:15 & received the IV & meds at 12:57. I have never had an allergic reaction to anything. I?ve also had 4 children, surgeries & blood drawn several times & never fainted or had an episode such as this. |
| 932534 | 1/10/2021 | LA | 28 | F | 1/7/2021 | 1/7/2021 | Systemic itching, systemic tingling, Hypotension, syncope, Bradycardia, injection site swelling |
| 931573 | 1/9/2021 | NC | 42 | M | 1/1/2021 | 1/6/2021 | Vasovagal syncope about 5 minutes after shot. Symptoms lasted about 5-7 minutes. Hypothensive. Diapharetic, Nausea, |

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| 931559 | 1/9/2021 | FL | 36 | F | 1/8/2021 | 1/8/2021 | Fever and chills starting 5 hours after dose, joint pain, myalgia, anxiety, palpitations, loss of appetite, fatigue, abdominal pain, dizziness, near syncope, headache, insomnia, arm soreness, tingling and numbness in my face and mouth about 10 hours after dose and lasting about 30 min, taking ibuprofen one tablet q6 hours for fever and pain. 26 hours dose symptoms are improving |
| 931381 | 1/9/2021 | SC | 73 | F | 1/8/2021 | 1/8/2021 | Patient fainted at 15 min mark after receiving vaccine. She was out for about 2 minutes. Her oxygen level dropped and blood pressure increase. Patient was given one dose of Nitro 0.4 mg SL and one tablet of Diphenhydramine 25 mg . |
| 931339 | 1/9/2021 | IL | 55 | M | 1/7/2021 | 1/9/2021 | Patient fainted and experienced a hard time breathing for 10 mins. Vital signs: BP: uncooperative HR: 110 RR: 24 O2: 90% and Temp: 97.5. He received 3 Ls of oxygen and 911 was called. He was sent to the ER. |
| 931230 | 1/9/2021 | IL | 32 | F | 1/7/2021 | 1/9/2021 | extreme tiredness, headache, left side tingling/numbness (left arm to left jaw), dizziness and near syncope, body spasms, and left sided chest pain (worse with palpation) |
| 931653 | 1/9/2021 | IL | 30 | F | 1/6/2021 | 1/6/2021 | Dizziness, increased heart rate, feeling like fainting, and headache. |
| 931029 | 1/9/2021 | MD | 51 | F | 1/8/2021 | 1/8/2021 | c/o dizziness, near-syncope 10 minutes post-vaccination |
| 931174 | 1/9/2021 | CT | 28 | M | 12/28/2020 | 1/8/2021 | 11 days after initial vaccination: vaccination site became warm swollen and red. Physically felt lightheaded/dizzy with near syncope episode and heart palpitations. Took Zyrtec, Benadryl and went to emergency room. |
| 930974 | 1/9/2021 | MD | 51 | F | 1/8/2021 | 1/8/2021 | Hypotension 90/60 experienced; Dizziness; almost passed out; rapid heart beat and unable to breath |
| 930941 | 1/9/2021 | CT | 45 | F | 1/8/2021 | 1/8/2021 | Elevated temp 102.3, near syncope x4, chills, joint pain especially in back and neck, nausea 12 hours, pulse 100, night sweats, dizziness and slight headache after Tylenol |
| 931147 | 1/9/2021 | WA | 39 | F | 1/1/2021 | 1/1/2021 | tachycardia (130-140's), HTN 140/100's, near syncope, nausea, temp 99.0 within minutes. That evening face rash and itching. Following day flu like symptoms as well as sore throat and congestion. |

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| 981512 | 1/9/2021 | | 39 | F | 12/28/2020 | 12/28/2020 | Syncope vasovagal syncope at time of vaccination |
| 931044 | 1/9/2021 | NH | 27 | F | 1/8/2021 | 1/9/2021 | Fever and chills began about 1 hours after vaccine, about 18 hours after vaccine I was getting up to take more Tylenol and did not feel well, I had a syncope episode in the bathroom (no issues as I sat on the floor before hand). I was unconscious for about 1-2 minutes. My blood pressure several minutes later was low (about 90/50 but I took it myself so may not be exactly accurate) |
| 931797 | 1/9/2021 | KY | 38 | F | 1/6/2021 | 1/7/2021 | Woke up at 2:30 am feeling nauseous, broke out in cold sweat, got out of bed, went to restroom, everything went black and felt like I was going to pass out. Husband got to me and laid on the floor. Never passed out completely, but it was a very weird and odd feeling. Felt better after about 20 mins. Have felt great since. So did not go to primary care physician but felt the need to report. |
| 981697 | 1/9/2021 | | 33 | F | 12/30/2020 | 12/31/2020 | Headache, Myalgia, Arthralgia, Fever, Cough/Wheeze & Syncope Narrative: |
| 1011344 | 1/9/2021 | | 53 | F | 1/7/2021 | 1/7/2021 | Dizziness, HYPERTension, Syncope, Tachycardia, DIZZINESS AND LIGHTHEADEDNESS AFTER VACCINE THIS AM AROUND 8:30. AT 12:30, WAS VERY PALE, WARM, DRY AND FEELING FAINT. 165/87, 104, 96.2, 98%, BLOOD GLUCOSE 158. NO SOB, RASH, OR ITCHING. AFTER 30 MINUTES WAS 112/69, 73, 18, 98%. Narrative: |
| 981511 | 1/9/2021 | | 47 | M | 12/24/2020 | 12/24/2020 | Syncope vasovagal syncope at time of vaccination |
| 978083 | 1/9/2021 | | 47 | M | 1/5/2021 | 1/5/2021 | Dizziness, Seizures, Syncope, Bradycardia, cold, clammy Narrative: 10 mins after administration, Employee began expressing lightheadedness, Employee assessed, employee was cold and clammy. Employee then began to have a seizure which last approx 30 sec. Vital signs assessed BP 110/80 HR 87 then dropped to 50 which is unusual for employee. o2 sat 94% on room. Employee regained consciousness and was able to state name, time and place. Reported no previous history of seizures. Employee handed off to ER staff for further eval. |

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| 977484 | 1/9/2021 | | 30 | F | | 1/5/2021 | BlurredVision NauseaVomiting & Syncope Narrative: 15 minutes after vaccine was given, employee reported visual changes and nausea. Then she lost consciousness for several seconds while seated. Emergency response team was called, no treatment was provided except supportive care and ginger ale when she regained consciousness. She was placed on cardiac monitor and observed for 30 minutes, initial HR was in 50's sinus bradycardia and BP 102/62. No further issues after 30 mins of observation time and employee was released to return to work. Employee reported having a similar reaction after giving blood in past. |
| 951519 | 1/9/2021 | MN | 78 | M | 1/5/2021 | 1/5/2021 | Narrative: Symptoms: Palpitations & Syncope Treatment: EPINEPHRINE 1 MG ONCE ,EPINEPHRINE 1 MG ONCE ,SODIUM BICARBONATE 50 ML ONCE |
| 931939 | 1/9/2021 | AZ | 41 | F | 1/8/2021 | 1/8/2021 | Fever, chills, weakness, myalgias, near syncope, increased heart rate. |
| 931825 | 1/9/2021 | NC | 42 | F | 1/9/2021 | 1/9/2021 | Palpitations, presyncope, tachycardia, elevated blood pressure, sweating, chest pain |
| 990748 | 1/9/2021 | | 38 | F | 12/23/2020 | 12/25/2020 | BlurredVision, Headache, CoughWheeze, Hypertension, Syncope, shortness of breath |
| 928757 | 1/8/2021 | IL | 34 | M | 1/7/2021 | 1/8/2021 | Nausea/ dizzy, Syncope 12 hours later. |
| 928772 | 1/8/2021 | NY | 52 | F | 12/22/2020 | 12/22/2020 | Patient felt warm with palpitations 5 minutes after vaccine administered. was monitored for 30 mins & then returned to work. on 12/30/2020 patient was at work in Presurgical testing dept & experienced near syncope, dizziness & elevated BP. reported to ED & was admitted to telemetry unit. |
| 928819 | 1/8/2021 | CT | 25 | F | 1/8/2021 | 1/8/2021 | Syncope 30 min after injection. Severe right arm pain radiating to fingertips 1 hour after injection. |
| 928867 | 1/8/2021 | SC | 52 | F | 12/28/2020 | 1/1/2021 | HEADACHE, NAUSEA, VOMITING, SYNCOPE, JOINT PAIN, WEAKNESS, EXTREME FATIGUE. STARTED ON 1-1-21, NAUSEA AND VOMITING STOPPED ON 1-2-21 BUT RETURNED ON 1-8-21. |

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| 928934 | 1/8/2021 | NY | 32 | F | 1/6/2021 | 1/7/2021 | I woke up to use the bathroom around 2:30 am and felt light headed, dizzy, fatigue and sweaty. I walked back to my bedroom and passed out on the floor. I believe I was only blacked out for a minute or less but I did hit my nose and bruise it. The next morning I was very tired and had a headache. Along with the sore arm. |
| 929124 | 1/8/2021 | | 26 | F | 1/3/2021 | 1/4/2021 | drop in blood pressure resulting in fainting; drop in blood pressure resulting in fainting; Severe headache; fever; This is a spontaneous report from a contactable other healthcare professional (patient). A 26-year-old female patient (non-pregnant) received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number EK9231), via an unspecified route of administration on 03Jan2021 at single dose at left arm for immunization. Medical history included allergies to Penicillins. The patient's concomitant medications within 2 weeks of vaccination included birth control pill, prenatal vitamin. Patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, patient was diagnosed with COVID-19. Since the vaccination, patient has not been tested for COVID-19. The patient experienced severe headache, fever, and drop in blood pressure resulting in fainting the morning following receiving the vaccine on 04Jan2021 with outcome of recovering. Patient didn't receive treatment for events. Adverse events resulted in doctor or other healthcare professional office/clinic visit. This report is considered non-serious. No follow-up attempts are possible. Information about Batch number cannot be obtained. No further information is expected.; Sender's Comments: Based on the close temporal relationship, the association between the event fainting with BNT162b2 can not be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate. |

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| 928707 | 1/8/2021 | CA | 22 | F | 1/5/2021 | 1/5/2021 | Moderna COVID-19 Vaccine Chills (approximately 4 hours), muscle and joint ache (approximately 12 hours), fever (approximately 8 hours), syncope and ears ringing (momentary) |
| 929182 | 1/8/2021 | | | F | 12/23/2020 | 12/31/2020 | Fainting; This is a spontaneous report from a non-contactable consumer (patient). This consumer reported similar events for 02 patient. This is the 1st of 2 reports. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 23Dec2020 at single dose for COVID-19 immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient experienced fainting on 31Dec2020. The patient went to the emergency department in regards to fainting and was told the fainting couldn't be related to the COVID-19 Vaccine. Then she heard about someone else fainting. Outcome of the event was unknown. No follow-up attempts are possible, information about lot/batch cannot be obtained. No further information is expected; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021006463 same reporter/drug/event, different patient |
| 929266 | 1/8/2021 | FL | 42 | F | 1/7/2021 | 1/7/2021 | Approximately 30 minutes post vaccination, patient became c/o of palpitations and confusion with syncope and loss of consciousness. Later the patient developed hives. |

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| 929132 | 1/8/2021 | NJ | 25 | M | 12/24/2020 | 12/24/2020 | Patient fainted in the ICU setting.; dizziness; hypotension; This is a spontaneous report from a contactable Other HCP. A 25-year-old male patient received BNT162B2 (Lot number: eh9899) via an unspecified route of administration on 24Dec2020 13:00 at single dose for covid-19 immunisation. The patient did not have any known allergies or medical history. Prior to vaccination, the patient was not diagnosed with COVID-19. There were no concomitant medications. On 24Dec2020, patient experienced dizziness and hypotension. Patient's blood pressure (BP) was 50/30 and heart rate (HR) 45. Patient fainted in the intensive care unit (ICU) setting. This happened during work hours while treating a patient. Patient was treated in the emergency department (ED). The adverse events resulted in emergency room/department or urgent care. It was unknown if treatment was received for the adverse event. Since the vaccination, the patient has not been tested for COVID-19. The outcome of events was recovered.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate. |
| 928705 | 1/8/2021 | IL | 30 | F | 1/6/2021 | 1/7/2021 | I developed nausea the night of the vaccine, the next morning I woke up with a headache behind my eyes, and fainted while getting ready for work that morning. I then had a really bad headache and slept the entire day. I was unable to go to work or care for my house or children. |
| 928704 | 1/8/2021 | NM | 42 | F | 1/6/2021 | 1/6/2021 | BP: 120/70 - Lightheadedness, syncope. Outcome: rested, stabilized. |

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| 928627 | 1/8/2021 | NC | 38 | F | 1/6/2021 | 1/6/2021 | Today morning one of the employee at nursing home had a reaction to Covid vaccine. I or technician gave the shot to her around 9 am to 9:15 am this morning initially she had no reaction to shot but around 10:30 am (by this timewe were at the another clinic) She called the nurse who was with us and informed us that she is having dizziness and feeling weird (we asked her to measure the blood pressure the reading was 122/99) then she mentioned she is feeling good butin next 2 minutes she fainted and fell and hit her head on countertop then they called 911. My last conversation related to this incident was she is diagnosed with low blood pressure and they will do other test to make sure she is fine. |
| 928616 | 1/8/2021 | FL | 32 | M | 1/8/2021 | 1/8/2021 | Patient had vasovagal syncope 10 minutes after Moderna vaccine administration. Patient was bradycardic (~40 HR) , pale, diaphoretic, and vomit x1 . Oxygen saturation at 100% at room air. |
| 928497 | 1/8/2021 | FL | 66 | F | 1/7/2021 | 1/7/2021 | Patient felt dizzy and experienced syncope. Left leg felt weaker than normal. Lactated ringers and meclizine 25 mg PO once provided in the emergency department. Patient was discharged from the emergency department. |

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| 928475 | 1/8/2021 | NJ | 40 | F | 12/22/2020 | 12/23/2020 | Around at 7AM when I arrived at work I started feeling chills, took temperature 99.5F that is already elevated for me. About 9:30 my temp was 101.8F and they sent me home. I just had the chills and fever. I got home and developed a headache and around 1PM I started feeling really dizzy. The temperature did not subside and the next day I woke up and I couldn't function, I felt really dizzy I kept laying down and drinking water, I could not keep anything down my stomach did not feel well. I felt like I had to vomit. When I sat down in the toilet then my ears started ringing pretty bad all of a sudden I could not hear anything and I passed out in the toilet. My husband found me and tried to wake me up. After that I still feel dizzy. I did not have any appetite either. I could barely hold water. The next day I was not as dizzy but my stomach was still upset but I could hold some soup down but then started with diarrhea. Employee health kept calling me everyday and I did the the telehealth appt and I also had a little bit of a rash in my chest that appeared all of a sudden red like a streak. The dizziness I had for the first 4 days, diarrhea did not come until the 3rd day and I had it for 2 days and my temperature was back to normal on the 4th day. Everything started to get better (my stomach stopped feeling queezy) around the 4th day but still felt fatigued until about 12/29/2020. |

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| 927603 | 1/8/2021 | CO | 34 | F | 12/20/2020 | 12/20/2020 | Near syncope; lightheaded/dizzy; vision narrow; Tingling in lips; This is a spontaneous report from a contactable physician. A 34-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: Eh9899), via an unspecified route of administration on 20Dec2020 09:00 in left arm at single dose for COVID-19 immunization. Medical history was reported as none. The patient's concomitant medications were not reported. The patient experienced near syncope, lightheaded, dizzy, vision narrow and tingling in lips on 20Dec2020 09:30 AM. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. No treatment given to the patient for the events. The outcome of the events was recovered on unspecified date. The event was considered non serious as it did not results in death, was not life threatening, did not cause/prolonged hospitalization, was not disabling/Incapacitating and had no congenital anomaly/birth defect. |

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| 927517 | 1/8/2021 | NJ | 62 | M | 12/30/2020 | 12/1/2020 | Felt pinched when the vaccine was administered; soreness at the muscle site; little muscle soreness from the vaccine; Postnasal drip in throat; Feeling warm then really hot; Feeling weak; Clammy; sweaty; As if he was going to pass out; almost like a vagal reaction if you got a needle or were scared; vagal reaction but delayed; Heart might have been beating fast; Experience is like the dizziness related in the signs of a severe allergic reaction; Experience is like the dizziness related in the signs of a severe allergic reaction; Anxiety; anxious; This is a spontaneous report from a contactable physician (patient). A 62-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot Number and Expiration Date were not reported), intramuscular in left deltoid, on 30Dec2020 10:30, at a single dose, for COVID-19 immunization. The patient's medical history included ongoing mild intraocular pressure. The patient's concomitant medication included unspecified eye drops for a mild intraocular pressure. The patient previously took tetanus vaccine and experienced vagal reaction and passed out (in his childhood). The patient's past COVID tests were always negative. On 30Dec2020, the patient received it at a facility where he is a physician on staff, and they started giving it that day. It was administered by a pharmacist who was very clean and professional, and everything was fine. The patient received the COVID-19 vaccine in the left deltoid and felt pinched when the vaccine was administered, and he felt fine. He did not have any immediate reaction. He sat down, then got up and was standing talking to some colleagues, and about 10 to 15 minutes later, they were talking and felt a little postnasal drip in throat. His colleagues said that is what they felt as well. About 10 minutes later, the patient was feeling warm then really hot to the point where he felt the need for cool air. He added feeling weak and clammy as if he was going to pass out. He started to feel weak and warm and almost like a vagal reaction if you got a needle or were scared. It was almost like he felt hot, sweaty, and weak and feeling like he needed to get to a cool place and sit down. The patient's heart might have been beating fast, but he did not check his pulse. The patient went outside where the temperature was in the thirties and cold. The patient broke out in sweat and felt weak. The patient sat down, and it was cold outside, and he felt |

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better. It passed and he felt fine after that. The symptoms lasted 10-15 minutes top, and it was resolved after the peak. The patient had soreness at the muscle site which got better overnight; little muscle soreness from the vaccine. The patient then got better and felt no other symptoms. He looked up the side effects and talked to the pharmacist. He spoke with a pharmacist, who provided the information on the reported adverse reaction of the COVID-19 vaccines and the signs of a severe allergic reaction included in the PI. He is not an allergic type person. He is familiar with those reactions and never had any trouble. He wasn't quite sure if it was related but then said it is probably somewhat related. The patient explained that he doesn't have any of the reported adverse reactions in the PI; but his experience is like the dizziness related in the signs of a severe allergic reaction in the PI, and he did feel that his heartbeat was fast. He is fine now though. The patient asked if his event is related to the vaccine and what is the impact on getting the second dose when reacting to the first. The patient was thinking that this event is a vagal reaction but delayed. He also explained that he was speaking with his colleagues, right after receiving the COVID-19 vaccine, regarding postnasal drip reaction. The patient also wondered if anxiety related to this discussion could have triggered his symptoms. Originally, he thought it was just him. But after talking to colleagues, maybe he was just a little anxious. He did not feel anxious going in. He did not need any intervention. He did not take any diphenhydramine hydrochloride (BENADRYL) or anything. He sat and rested, and it passed. He has been fine since. He needs a second dose in 3 weeks. There is not a lot of information about the side effects. It was not like he got a rash. He did not have any swelling of the tongue or throat. He just wanted to find out about if he should get the second dose. He really wanted to get the second dose. He just wanted to know if this was common or a concern and should he take the second dose. There were a lot of people getting the vaccine and this was not anything that stopped anyone from getting it. He is just trying to make sure and see how likely it was that it was related to the vaccine and how does it affect him getting the second dose. The patient was recovering from "Felt pinched when the vaccine was administered; soreness at the muscle site;

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| | | | | | | | little muscle soreness from the vaccine". The outcome of "Postnasal drip in throat" and "Anxiety; anxious" was unknown. The patient recovered from the other events on 30Dec2020. Information about lot number and expiration date for the suspect product will be requested in follow-up attempts. |
| 928569 | 1/8/2021 | MA | 39 | M | 1/8/2021 | 1/8/2021 | Pt c/o feeling lightheaded, "seeing spots" 10min s/p covid-19 vaccine. Pt notes that sx exactly the same as he experiences with blood draws, blood donations. NO LOC. EASED TO SUPINE POSITION. VITALS AS NOTED. SX RESOLVED W/O TX, VITALS AS NOTED. ADVISED TO NOTIFY STAFF OF THIS NEAR SYNCOPAL EPISODE WHEN HE RETURNS FOR DOSE #2. 10:50 BP 89/52 10:55 BP 92/56 IMPROVED 10:59 BP 116/74 ASYMPTOMATIC DX: NEAR SYNCOPE POST VACCINATION. RESOLVED. |
| 927410 | 1/8/2021 | FL | 28 | F | 1/7/2021 | 1/8/2021 | I received the COVID 19, vaccine January 7, 2021. Around 12:30 AM on January 8 I felt nauseous, was very clammy and ending up fainting. I will be calling out my primary due to this issue. I still need a second dose and unsure if I should get one now. |
| 951314 | 1/8/2021 | | 60 | F | 12/23/2020 | 12/23/2020 | RespDepression, CoughWheeze & Syncope Narrative: Patient started having shortness of breath about 20 minutes after injection. First reported as a cough then asked for water and was having difficulty breathing. |
| 928480 | 1/8/2021 | IA | 61 | F | 1/7/2021 | 1/8/2021 | patient reports fasting high blood sugar >200 12+ hours after vaccination - she is diabetic on oral metformin and has never had elevated blood sugar >140 with fasting; controlled HgA1C at 6.1%; felt dizzy, nauseated, HA and sweaty as if she may pass out - never passed out |
| 971293 | 1/8/2021 | | 35 | M | 12/23/2020 | 12/23/2020 | Syncope Narrative: Complaint of lightheadedness 15 seconds after administration of vaccine. Patient lowered to floor safely by RN, followed by syncope and loss of consciousness. EMS called. Patient returned to baseline oriented with stable vital signs following event. Patient left clinic in stable condition after monitoring by RN for approximately 1 hour. |

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| 930866 | 1/8/2021 | TX | 39 | F | 12/22/2020 | 12/22/2020 | Vagal presyncope. Tachycardia. Cold sweat, lightheadedness about 15min post injection. Having had multiple vagal episodes before, including with other vaccines, I oncreased my SVR by kneeling down. Symptoms resolved after 15min of continuous kneeling. |
| 930817 | 1/8/2021 | GA | 41 | F | 1/6/2021 | 1/6/2021 | About 5minutes after vaccination had syncope episode, in and out for about 5-10, malaise, feeling like ? under anesthesia since then. |
| 930668 | 1/8/2021 | CA | 43 | F | 1/8/2021 | 1/8/2021 | This morning Friday 1/8/21 pt was given injection at 0912. At about 0930 pt C/O diaphoresis, lightheadness. Water was offered. BP taken manually in 80s. 911 was called. Pt suffering substernal pain. A/OX4 no fainting. Paramedics arrived at 0940, assessed pt and EKG performed. Paramedics encouraged for pt to go to her hospital, Pt declined and exited clinic on her own. |
| 930617 | 1/8/2021 | FL | 45 | F | 1/8/2021 | 1/8/2021 | PT HAD A VASOVAGAL SYNCOPE EPISODE: (SWEATING, NAUSEA, AND BLOOD PRESSURE DROPPING). PT WAS LAYED ON THE FLOOR IN A SUSPINE POSITIION WITH FEET ELEVATED. PT WAS PLACED ON A BLOOD PRESSURE MONITORING MACHINE. COLD COMPRESSIONS WERE APPLIED TO THE PATIENT'S BODY. PT WAS GIVEN A FEW CRACKERS AND SODA TO INCREASE BLOOD SUGAR. WITHIN MINUTES THE PT BLOOD PRESSURE BEGAN TO RISE AND PT FELT FINE. PT WANTED TO DRIVE HOME AND WAS ADVISED NOT TO DRIVE. PT CALLED FOR HER PARENTS TO COME AND PICK HER UP. |
| 930603 | 1/8/2021 | TX | 50 | F | 1/8/2021 | 1/8/2021 | employee felt near syncope[al episode post vaccine administration |

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| 930596 | 1/8/2021 | HI | 38 | M | 1/7/2021 | 1/7/2021 | Officially I fainted, but I describe in detailed events of occurrence below. I was using my laptop doing some busy work while I waited the 15 minutes after taking the first shot of the Pfizer/BT Vaccine. I had the feeling that I could feel the vaccine coursing through my chest but I thought that was irrational and my mind and nerves playing tricks. I continued to work and let my mind wander for a moment. Next thing I know I was dreaming for a time and then I slowly awakened by the staff calling my name asking "are you OK, do you know where you are?" I was able to answer correctly, but my mind felt fuzzy/foggy where I felt as if I was running on automatic but my conscious mind was not in full control. At the time, it was hard to describe at the time how I was feeling as I was trying to note it down for future reference. All I could put down were simple words and I could not form full statements. Though I was very present in the moment. I can remember the name of the Nurses who I was talking to, and what we were talking about. They took me to be observed for about an hour longer. While I waited, I felt warm, especially in the areas of the back of my head and chest. I was not in any pain, but I was very thirsty. I was also getting pretty hot sitting there, but that may be because of the fact the ER Triage room has full glass wall in full sun. At the end of the hour the sun dropped lower in the sky I felt the normal cold refrigerated Hospital I am used to. I felt weak initially but by an hour I had regained most of my strength by the time the triage nurse took my vitals. After the physician looked over me and my report, they did not give me a reason of concern that would warrant keeping me and let me go home to rest. |
| 930588 | 1/8/2021 | | 52 | M | 1/2/2021 | 1/8/2021 | Patient had severe nausea/vertigo episode upon awakening on 1/8/21. Patient fainted and collapsed onto bathroom floor. He hit his head on the wall during the fall. Patient was found barely conscious by his wife right after the fall. Patient temperature, O2 sat and BP all within normal limits measured within 5 minutes of fall. Patient does have history of Meniere's disease x 5 years, but is well-controlled with medication and middle ear steroid injections. Patient has not had severe vertigo episode in 2+ years. |

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| 930402 | 1/8/2021 | | | U | | | Throat felt clogged, almost passed out, This lasted about 30 secs about 10 mins after injection. Then became very hot and sweaty and started itching all over. This happened about 15 mins after injection and lasted all day. There is now a rash all over my face and small hives on my chest. I have taken 2 benadryl. This is now 7 hrs post injection |
| 929655 | 1/8/2021 | FL | 40 | F | 12/28/2020 | 12/28/2020 | After receiving the vaccine, I went into a waiting room for the post-vaccine 15 minute observation. Approximately 2 minutes after sitting down I felt a sensation that can be described as a wave through my body. It only lasted for 10 seconds; however, it was immediately followed by a rapid heartbeat. It almost felt as though I might pass out (I have never passed out before). I alerted a nurse, and she monitored me for the 15 minute duration. After about 2 minutes, I felt 'normal' again. |
| 930277 | 1/8/2021 | CA | 50 | M | 1/8/2021 | 1/8/2021 | patient described feeling lightheaded, near syncope, 'almost passed out' 15 minutes after vaccine administration |
| 930247 | 1/8/2021 | WA | 31 | F | 12/31/2020 | 1/2/2021 | 15 min after vaccine administration I was extremely dizzy/nearly fainted this lasted for 25 minutes. 2 days later I developed some redness at the sight of injection/itchiness. This got better. On day 7 after getting the vaccine I developed a firm, raised, HOT and extremely itchy area at the site of injection. This is measuring at 5cm by 5 cm on my Left deltoid. This continues to get larger and larger. I have also had daily headaches since the vaccine was given. I seen a doctor who recommended calling the CDC who then advised me to complete a VAERS report. |
| 930005 | 1/8/2021 | AZ | 26 | F | 12/22/2020 | 12/22/2020 | initial; swelling of tongue, tingling and numbness in legs, syncope. later; HA |
| 929938 | 1/8/2021 | FL | 36 | F | 1/7/2021 | 1/8/2021 | Started with just a very sore arm. Swelling of axillary lymph nodes. Woke up and blood pressure dropped (fainting). Then felt extremely hot and feverish (no actual fever).mild constant dizziness accompanied with nausea. |

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| 929937 | 1/8/2021 | FL | 25 | F | 1/8/2021 | 1/8/2021 | Patient states that she got her coronavirus vaccine and about 10 min later she felt very weak diffusely, felt her ears ringing and passed out. Patient was caught and lowered to a chair, thus did not hit her head. Patient states she has passed out before but this felt different. Patient felt her heart racing prior to passing out. |
| 929774 | 1/8/2021 | | 31 | M | 1/7/2021 | 1/7/2021 | I felt fine the rest of yesterday but started to feel really tired and worn down late last night. I took my sleeping pill like normal and went to bed. I woke up feeling really achy and cold so I went to take some Tylenol in case I had a fever. Started feeling dizzy and light headed and I passed out. I cut my foot on the glass I dropped and scraped my back as I fell. I don't remember being blacked out very long. I just remember sitting on the floor feeling really lethargic. My whole body felt tingly and my ears were ringing really bad. Was able to get up and get back to bed. Decided to go back to sleep and not go to the ER. This morning I'm still a little dizzy but mostly just have a headache and am extremely tired. I plan to get into my doctor today so I will keep you updated. Just wanted to let you know what happened so you could report it. |
| 929695 | 1/8/2021 | DC | 26 | F | 12/30/2020 | 12/31/2020 | Hives, started 24 hours after vaccine administration, present for about 1 week after vaccine dose, improved with antihistamine therapy. no lip/tongue swelling, shortness of breath, vomiting, syncope, hypotension |
| 929300 | 1/8/2021 | WI | 70 | F | 1/7/2021 | 1/7/2021 | Allergic reaction / Syncope and collapse Patient reports feeling dizzy, hot, and that her eyes felt funny. Patient was sweaty, heart rate within normal rhythm. Patient lost consciousness and began seizure-like activity and was assisted to the ground. Patient regained consciousness about 20 seconds later. At 12:48: BP was 91/44 upper right arm, HR 78, O2 sat 100%. At 12:50 BP was 76/50 and patient report shortness of breath and the sensation that her throat was closing up. She was assisted to supine position again. at 12:54 Epinephrine 0.3ml was administered IM. At 12:56 NS administered wide open with pressure. Blood glucose 109. at 12:59 BP was 133/67. Taken to Emergency Department where she received famotidin 20mg IV, Methylprednisolone 80mg IV and KCL 20mEq po due to Potassium level of 3.4. |

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| 929384 | 1/8/2021 | PR | 32 | M | 1/8/2021 | 1/8/2021 | Fifteen minutes after vaccine administration, patient was sitting outside and had an episode of vasovagal syncope. He became diaphoretic, thousand yard stare, limbs stiff, and then slumped for less than 5 seconds while sitting. He was lowered to the ground and legs elevated, supplemental oxygen provided. He came to within 15 seconds of initial symptoms. He stated he felt hot and ?woozy.? Vital signs: BP 107/69, HR 88, SpO2: 99, Resp: 16, temp 98.8. Blood glucose 127. Patient states he was out in the sun the day prior and did not hydrate as he should have. Cool water was provided and he received 500mL of saline IV. Patient was monitored for 2 hours post episode and was released back to work feeling good without any further issues. Patient stated he had a previous syncopal episode upon receiving some anxiety producing news in the past and states that this episode felt similar. |

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| 930297 | 1/8/2021 | RI | 29 | F | 1/7/2021 | 1/7/2021 | 29-year-old previously healthy female presenting today with difficulty sleeping, sore throat, and nausea after receiving the second Pfizer COVID-19 vaccine around 10 AM. Patient says that after her first dose of the vaccine she had mild sore throat and hoarse voice that resolved spontaneously. She had her vaccine around 10, several hours later before coming to the emergency department between 2--230 she had the sudden onset of difficulty speaking with associated sore throat and nausea. She has had dry heaving but no large amounts of vomiting. She has not had stridor, wheezing, shortness of breath, syncope, or the development of a rash or hives. She has not had a reaction to her prior vaccines she does not have any other allergies in general. She has otherwise been well recently without infectious symptoms including fevers, chills, cough, and has not been exposed to Covid to her knowledge. Medications administered in ED included diphenhydramine 50 mg IV once, dexamethasone 10 mg IV once, famotidine 40 mg IV once, ondansetron 4 mg IV once. Had brief episode of shaking and R arm rigidity in the ED. Patient denies LOC during the episode, did not have a post ictal state, no tongue biting or episodes of incontinence. Given single event without LOC, less concern about episode being a seizure. Patient has had no further episodes of shaking since admission. CT brain was wnl, no FNDs noted on exam. |
| 925842 | 1/7/2021 | FL | 48 | F | 1/7/2021 | 1/7/2021 | Patient felt warm and dizzy and fainted twice during monitoring period. |
| 925883 | 1/7/2021 | SD | 41 | F | 1/7/2021 | 1/7/2021 | Light headedness, skin flushing, syncope |
| 925916 | 1/7/2021 | KS | 27 | F | 1/4/2021 | 1/5/2021 | Vasovagal Syncope w/ orthostatic hypotension for ~5 hours following. |
| 925954 | 1/7/2021 | AK | 32 | F | 1/6/2021 | 1/7/2021 | Fatigue, Aches and myalgias, shoulders, neck and back, and syncopal episode (passed out in bathroom no injuries continues to monitor) recovered well |

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| 925759 | 1/7/2021 | CA | 21 | F | 1/6/2021 | 1/6/2021 | 1825 Pt received the Pfizer vaccine. Patient sat in chair being monitored for 15 minutes. At 1832 pt felt lightheaded and fainted, emergency response CALLED. Patient appeared pale and diaphoretic. RNs assisted patient down to the floor with head supported with jacket and legs elevated. 1837 Patient's vital signs BP: 101/59, HR: 60, o2: 97%. Patient woke up stating that she is ok. Emergency response arrived 1838. Continued to monitor patient, @ 1845 BP: 110/71, HR: 64, o2:98%. Pt states feeling better, offered juice, pt able to tolerate 1 cup of apple juice with no complications. 1850 patient states feeling better, assisted patient to sitting position from lying down. VS obtained BP: 96/57, HR: 72, o2: 97%. Emergency response recommended patient to to the Emergency Department, but patient refused. States that she is going to go home. Advised that she call for a ride, and patient agreed. 1855 Assisted patient in the standing position, BP: 99/63, HR: 65, o2: 96%. Pt was able to tolerate more apple juice, denies any lightheaded, dizziness or headache. Patient stated that her ride was on the way. Patient agreed and continued to be monitored for another 15 minutes. Pt discharged @ 1915 in stable condition. |
| 926110 | 1/7/2021 | IA | 44 | F | 1/6/2021 | 1/6/2021 | tingling in both hands - along ulnar nerve to 4th/5th fingers - severe - reports 8/10 discomfort BILATERALLY - felt like she was going to pass out and have diarrhea and vomit at same time - these symptoms awakened her from sleep at 11:45pm; sxs lasted about 15 minutes and then abated; tingling in 4th/5th fingers BILATERALLY persists today- though much less intense - reports at level of 1/10; never did vomiting and never had diarrhea; never passed out; feeling well today - able to run 4 miles and teach yoga and work at a physical therapist |

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| 924892 | 1/7/2021 | FL | 89 | M | 12/30/2020 | 12/30/2020 | <p>extremely lightheaded; like he was about to fall down; This is a spontaneous report from a contactable physician. This physician reported similar events for 2 patients. This is the 1st of 2 reports. An 89-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number; EL0140), intramuscular on the right arm on 30Dec2020 10:10 at single dose for vaccination. Medical history included covid-19 on Jul2020 and had it fairly severe and almost died and he mentions he was overweight. There were no concomitant medications. The patient previously took flu shot (INFLUENZA VACCINE), a couple of months ago. He mentions he was in the military so he had a lots of shots in his life but he has never had a reaction like this. The patient stated that on 30Dec2020 10:30, "he became extremely lightheaded, like he was about to fall down. He sat down and is currently sitting down. This lightheadedness started about 20 minutes after the injection. When probed for the outcome, the caller explains it might be improving a little. The lightheadedness is not still not gone, but it has not worsened. When probed for seriousness criteria, the caller explains he is just resting and sitting. He would say its not serious but it could be medically significant. He states he isn't sure if this is something that happens to just people who have had COVID before. He states none of his friends or relatives have this type of reaction. He lives in a retirement home and everybody is getting the injection. This is the second day of injections. He doesn't know if anybody had a reaction to the COVID-19 vaccine here". The outcome of the events were recovering.;</p> <p>Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of lightheadedness and pre-syncope due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern</p> |

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| 925988 | 1/7/2021 | MO | 35 | F | 12/27/2020 | 12/28/2020 | identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2020520862 same reporter/drug, similar event, different patient. Woke up with chills, headache, weak, felt like fainting, arm pain. Called off work. Fever of 100.4. |
| 925753 | 1/7/2021 | NY | 46 | F | 12/28/2020 | 12/28/2020 | Fainting; Red Palms; blotching; sweating profusely; heart palpitations; Chest pain; Elevated BP; This is a spontaneous report from a contactable consumer (patient). A 46-years-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 28Dec2020 09:15 at single dose on left arm (Lot number: ek9231) for COVID-19 immunisation. Medical history included asthma, bronchitis, mitral valve regurgitation, herpes, depression, ADHD. COVID prior vaccination: Yes. Known allergies: tramadol, milk products. No other vaccine in four weeks. Concomitant medication included amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL), bupropion, and, losartan/hydrochlorothiazide. The patient experienced red palms/blotching, sweating profusely, heart palpitations, chest pain and fainting, elevated BP, all on 28Dec2020 09:15. All these events required Emergency room visit. Therapeutic measures were taken as a result of the events included 50 mg of Benadryl, 60 mg of Prednisone, omepresol. No COVID tested post vaccination. Outcome of events was recovered with sequelae. |

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| 925649 | 1/7/2021 | | | F | 12/1/2020 | 12/1/2020 | <p>It sounds like to be an allergic reaction; She passed out; Tachycardia; Nausea; Lightheadedness; This is a spontaneous report from a non-contactable physician. A 32-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) in Dec2020 at single dose to be vaccinated for her protection. Medical history was none. The patient's concomitant medications were not reported. Patient took the Pfizer COVID-19 vaccine and next day she had a very serious reaction. She did not know that if it was due to the vaccine. But she had tachycardia requiring her to go to the emergency room and she passed out and she had nausea and lightheadedness as well. It sounds like to be an allergic reaction. Given the seriousness of tachycardia and passing out as well as the lightheadedness and nausea it sounds too severe just to be a mild immune response. So, it was sort of rare immune response or it was unrelated it was unknown at this time. Outcome of event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Based on the compatible time association, the contribution of suspect BNT162B2 to the events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p> |

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| 925442 | 1/7/2021 | MA | 67 | F | 1/6/2021 | 1/7/2021 | I received the vaccine yesterday 1/6/21. Today, 1/7/21, I went for my walk this morning and felt off balance/swayed to the right a bit at one point. I don't think lightheadedness precipitated this, but it unnerved me. I steadied myself and finished the walk without a problem. I checked and surface/pavement was uneven. My temp is 97.5 and I feel fine now but am just a little nervous that is a possible reaction to the vaccine. I had a reaction to the second dose of the hepatitis B vaccine 10 yrs ago, I fainted in early morning hours after getting up to go to bathroom. I had received the second dose at about 11:30a the day before, and developed flu like symptoms by afternoon with a fever and ended up dehydrated which I think contributed to my fainting at about 3a when I got up to void. I had a concussion and was treated with IV fluids at the local ED. |
| 925218 | 1/7/2021 | VA | 28 | F | 1/6/2021 | 1/7/2021 | 06Jan21-Unable to sleep, increased heart rate, headache. 07Jan21- Increased heart rate, headache, back pain, neck pain, passed out, weak, fever, chills, hot, dehydrated (even after consuming lots of water all day). Took motrin and one hour nap, decreased symptoms severity but did not get rid of them. |
| 925159 | 1/7/2021 | VA | 28 | F | 1/6/2021 | 1/7/2021 | Moderna COVID-19 Vaccine EUA. Around 7pm on 06Jan21, symptoms began with a headache, increased heart rate, inability to sleep/relax. On 07Jan21, Migraine headache, inability to sleep/relax, increased heart rate, passed out, lightheaded, back pain, neck pain, weak, fever, chills, hot, dehydrated (even with large consumption of water). Took two motrin and an hour nap, which severely decreased above symptoms but still experienced them. |

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| 924817 | 1/7/2021 | TX | 32 | F | 12/22/2020 | 12/22/2020 | As soon as I received my shot it was like an electric shot from the injection shot, up the back of my neck, into my brain. I was instantly woozy and disoriented. They moved me to observation. My hemiplegic migraine started within 10 minutes of the vaccine. I take a preventative every day, and to be honest after the vaccine it was like I had never, ever taken my preventatives. The migraine I got that day is the worst one I have experienced since the first one I ever got. Now on top of the migraines, the vaccine gave me waves of new symptoms. I was having spells of intense heat flashes, with wooziness, and nausea. So the new symptoms were paired with the hemiplegic migraines that, if you aren't familiar with, mimic strokes because my whole left side tends to go limp, and I struggle with speech, and cognitive issues. So it really wasn't all too long before the nurse kindly suggested that I didn't look great and we should head to the ED. They treated the migraine, gave me a CT, everything came back fine. They reached out to my neurologist, gave me some fluids, really they wanted to keep me a little longer, but I know the migraine drill and just wanted to go home and sleep and eat. I promised to follow up with my neurologist and fill out my CDC form. Over the next week the migraine and extra symptoms seemed to slowly but surely let up. The only note worthy thing was really that my left side would get extra tender at times. Not just my injection site, but it was almost like all my nerve endings all over my left side were on fire at times and a pinch on the thigh may as well have been a stab, or a pat on the back a punch. It was pretty intense at times. And just when I thought it was all over my menses started, you see my hormones trigger my migraines. And once again it was like I wasn't on a preventative. I had an intense Migraine start. I was able to take my bail out medication (sumatriptan) though and get to work. I moved forward with my day, and just when I thought all was normal, I got one of those brutal heat flashes, the room started moving, and I was nauseous. Unfortunately I was in full PPE, I almost passed out, I had to get a coworker to help, they had to get my supervisor. It was a big, unnecessary-necessary, pride-wounding scene. Now I am not a scientist or a doctor, but I might speculate that people with neurological deficits, like myself, are going to have a harder time with this inactive Covid strand. I would much rather be immune to Covid |

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| | | | | | | then catch it though, so whatever I can do to help, and protect myself and family and friends and neighbors, I will absolutely do... But I imagine there is probably an adjustment to be made here for the neurologically impaired. Thanks for your time, and let me know if you have any questions. | |
| 924808 | 1/7/2021 | AK | 22 | F | 1/6/2021 | 1/1/2021 | Patient passed out about 3 minutes after Moderna Covid19 vaccine EUA administration and came to really quickly and decided to move to a chair. No difficulty breathy per paramedics but when they arrived she passed out a second time and paramedics opted to take patient to hospital for observation. |
| 926247 | 1/7/2021 | KY | 64 | F | 1/5/2021 | 1/6/2021 | I was feeling fatigue night after injection. Next morning I passed out, woke up sweaty. Then started vomiting and having severe leg cramps. Called employee health and they said to go to emergency department. |
| 926948 | 1/7/2021 | NY | 38 | F | 1/7/2021 | | post vaccine syncope episode rule out out cva |
| 925162 | 1/7/2021 | NC | | F | 12/31/2020 | 1/5/2021 | Patient was riding in a car and began feeling dizzy and passed out, this happened ten times and over the evening and decided to go to the ER the next morning at 7am. These episodes lasted 5 minutes or so and then she was able to regain consciousness. |
| 937553 | 1/7/2021 | | 63 | F | 12/29/2020 | 12/30/2020 | Headache, Myalgia, CoughWheeze, Syncope, Fatigued, chills, night sweats, mild shortness of breath, cough. Takes coumadin for protein s deficiency. Tested + for COVID on 1/4/21 Narrative: Fatigued, chills, night sweats, mild shortness of breath, cough. Takes coumadin for protein s deficiency, sees hematology. Currently taking prn tylenol, scheduled to see hematology. Tested positive for COVID on 1/4/21. |
| 952333 | 1/7/2021 | | 55 | F | 12/29/2020 | 12/29/2020 | Headache, Myalgia, CoughWheeze, NauseaVomiting, Palpitations, Syncope, Arm pain, chills and overall weakness Narrative: Employee was unable to work second to symptoms, missing >1 days of work at time of this report. |

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| 947418 | 1/7/2021 | | 63 | F | 12/22/2020 | 12/22/2020 | HYPERtension, Syncope Hx. HTN and did not take BP meds in the morning. also anxious about immuniation. Narrative: History of recent stress test with pending results. pt. c/o lightheadedness while seated in recliner during observation. Per pt., she feels anxious after witnessing another person have a syncopal event. BP 240/98, P 76, R 22, O2 sat. 99% at 0935. RRT in the area so they assessed the pt. and convinced her to go to ED to be checked out. D/c'd per w/c to the ED with RRT. ED reported BP 190/108 in the ED. States she did not take BP meds in the morning and was anxious about her immunization today. ED reported she took her Losartan at 4pm. Discharged from the ED. Recorded on employee medical file on database. |
| 926881 | 1/7/2021 | IL | 56 | F | 1/7/2021 | 1/7/2021 | Patient was feeling nauseous after the vaccination. Went and ate lunch. When she came back from lunch, she passed out and a code blue was called. She never lost a pulse, but when in the ER she could not speak. She responded to commands without speaking. About 30 minutes later, she finally spoke. |
| 940763 | 1/7/2021 | | 37 | F | 12/28/2020 | 12/30/2020 | Dizziness, Headache, NauseaVomiting, 12/30 worst migraine 12/31 migraine, severe nausea, lightheaded, dizziness 1/4 felt like fainting and went home from work 1/6 head heavy, dizziness. Narrative: 12/30 worst migraine took Midol and then Excedrin with no relief, 12/31 migraine, severe nausea, lightheaded, dizziness 1/4 felt like fainting and went home from work 1/6 head heavy, dizziness. |
| 926444 | 1/7/2021 | NC | 64 | F | 1/5/2021 | 1/5/2021 | Flu-like illness (fevers, rigors, chills) and one episode of presyncope due to orthostatic hypotension upon getting up the day after the vaccine |
| 933619 | 1/7/2021 | | 62 | M | 12/18/2020 | 12/18/2020 | Syncope Hx of syncopal episodes during any procedures, per ED note. Narrative: c/o of feeling flushed and pt. asked to lay down @11 am in the observation area. Staff able to get pt. to cart before she "passed out." She immediately responded but RRT was called to assess the patient. BP low, per RRT (84/54 P 53, 108 /65 P 51) and pt. was taken to the ED at 1112. No SOB, nausea noted. Per ED and final report was that the reaction was not an allergic reaction nor a side effect of the injection. |

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| 933533 | 1/7/2021 | | 52 | F | 12/29/2020 | 12/29/2020 | Myalgia, CoughWheeze, UrticariaPruritus, NauseaVomiting, Syncope, itching; chest congestion; fatigue body ache; n/v for the first 24 hrs of vaccinating employee Narrative: 12/29 developed itching and chest congestion that flared up my asthma. 12/30 still itching and chest congestion/ having bad fatigue, body aches, nausea and diarrhea lasted for 24 hrs. |
| 931853 | 1/7/2021 | | 50 | M | | | Patient received Pfizer Covid 19 vaccine at 1400. He felt fine initially. At 1600 developed lightheadedness, slight headache and intermittent tingling to his left fingers. He reports itching to his extremities. He has not noticed a rash. He denies syncope, nausea, vomiting, sore throat, congestion, chest pain, SOB, palpitations, weakness, slurred speech, abdominal pain, diarrhea. He denies history of prior allergic reactions. No new medications. he is not anxious. Denies rash likely related to vaccine administration at 1400; seen in the urgent care at 1600 and discharged after treatment and evaluation at 1858. Inventions: ekg no acute findings; methylPrednisolone 125 mg IV; diphenhydramine 25 mg IV; famotidine 20mg po; odansetron 4mg IV home with Benadryl 25 mg Q6 hours for 5 days. |
| 927222 | 1/7/2021 | NV | 52 | F | 1/6/2021 | 1/6/2021 | Received vaccine, went to observation area, sat down, 2 minutes later felt very flushed, hot, skin became red, and almost fainted. Similar to vasovagal experience without nausea at that time. Staff took me to nursing station, and I felt better within 10 minutes of laying down on ice pack, drinking water. Stayed there for an hour and got a ride home in case. Blood pressure was very elevated afterwards for several hours. |
| 927036 | 1/7/2021 | KS | 34 | M | 1/6/2021 | 1/7/2021 | Body aches overnight then a spell of dizziness, nausea and almost fainting and sweating profusely around 9:30am the following day. Continued body aches and headache for remainder of the day. |

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| 926892 | 1/7/2021 | WA | 55 | M | 12/30/2020 | 1/2/2021 | Patient received 0.5mL Moderna Covid19 vaccine at mass vaccine clinic on 12/30. This patient was a walk thru and not a patient of HP at this time. Daughter reported to ARNP, RN Director Clinical Support on 01/03 the following outcomes: Patient first exhibited the first signs of reaction started about 60 hours after vaccine: hives only (no difficulty breathing, dizziness, lightheadedness); applied hydrocortisone cream, took diphenhydramine. Patient slept for a few hours then woke up for lunch. Around 12:30-1:00 the patient exhibited three episodes of syncope. Emergency services was called after the first. Firefighters couldn't find BP, was in 70s by doppler only. Patient taken to hospital for care. Discharged from ED around 5, suspecting hypotension 2/2 to diphenhydramine use. Monitored vitals at home; became severely hypotensive (BP 70s/40s both with automatic monitor and manual read) and lethargic again about an hour or so after, but normotensive again right before about to call ambulance. Pt claimed to be okay and had some dinner. Fourth episode of syncope, ambulance was called. Patient remains at hospital ED since, still in observation unit. BP's normalized but itching returns periodically. IV steroids and diphenhydramine. Took head CT yesterday; no word on the results. Stable and alert enough since yesterday to communicate with us with his phone. Patient is scheduled for an echo to be done today. No hx of severe allergic reaction. Treated for active TB 30 years ago, shingles x2 in the past few years; otherwise healthy 55 y/o male. Pt discharged 01/04 to home with fatigue and malaise. Not additional symptoms reported since then. Provider doing full cardiac and neurologic work up. |
| 926805 | 1/7/2021 | CA | 42 | F | 12/23/2020 | 12/23/2020 | 12 minutes post vax felt warm, dizzy, hypotensive, syncope. Transferred to ED, monitored and discharged. On 12/24/2020 developed cyanosis to lips. Returned to ED and placed on 5 day steroid therapy and diphenhydramine. Mildly improved. |

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| 926801 | 1/7/2021 | IL | 41 | F | 1/5/2021 | 1/5/2021 | I received the injection around 2:15 pm. There were no immediate effects. By late afternoon/early evening, my arm was a bit sore and later started to feel warm near the injection site. However, I otherwise felt fine. At 9 pm, I suddenly became very dizzy and passed out for several minutes. When I regained consciousness, I felt a little short of breath, which resolved within 20 minutes or so. However, I was also extremely nauseous, which got worse any time I tried to move. This continued for several hours. I also alternated between being very warm and chills during this time - it was like waves of heat. I did not have a fever. Later, my head began to hurt and I took tylenol to help with that. I also had diarrhea. These symptoms began to gradually lessen after a couple of hours and I was able to fall asleep around 12:30 pm. I woke up hot and sweaty several times throughout the night. The following day, 1/6, I was very tired and had a headache and could not eat much, but otherwise felt much better. |
| 926779 | 1/7/2021 | OH | 28 | F | 1/5/2021 | 1/6/2021 | After receiving vaccine, woke up around 3 am experiencing nausea, loss of vision x 1-2 minutes, syncope, difficulty breathing, numbness & tingling in hands and feet. Measured temperature of 102 F. Slept most of the next day and missed work x 1 day. The following day was improved but still with moderate fatigue and nausea. Took ibuprofen with some improvement. |
| 926500 | 1/7/2021 | IL | 45 | M | 1/7/2021 | 1/7/2021 | Patient received vaccination approximately at 10:45 am, he had told immunizer he had felt nervous and had fainted previously with other vaccinations. Patient was monitored after vaccination patient said he felt dizzy, approximately 11:15 am he fell forward from chair and was attended to by staff. EMTs were called and patient was taken to hospital for observation. After vaccination pt had blood pressure readings of 130/80 5 min after 150/80 15 minutes after his blood sugar readings reported by family member on scene were 325 the previous evening and 255 the morning before he came in. EMTs took a blood sugar reading 365 upon their arrival. |
| 929355 | 1/7/2021 | | 35 | M | 12/23/2020 | 12/23/2020 | Dizziness, RespDepression, passed out Narrative: |

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| 940886 | 1/7/2021 | | 56 | F | 12/22/2020 | 12/23/2020 | SkinRash, CoughWheeze & Syncope |
| 922444 | 1/6/2021 | CA | 44 | F | 12/29/2020 | 1/3/2021 | increased frequency of known recurrent syncope |
| 924031 | 1/6/2021 | MD | 56 | M | 1/5/2021 | 1/6/2021 | 15 hours after shot experianced, dizziness, feeling of fainting, difficulty breathing mild pressure chest pain. Was taken to local Er. Ekg, cat scan chest xrays all negitive. Blood work negitive. No past history of symptoms |
| 922316 | 1/6/2021 | | 27 | F | 1/4/2021 | 1/5/2021 | Sudden onset shakiness and became light headed with tunnel vision. Almost passed out. Episode lasted about 5 minutes but generalized weakness lasted for about an hour. |
| 923780 | 1/6/2021 | IA | 39 | M | 1/5/2021 | 1/5/2021 | Pt's only real complaint: mild lightheadedness/dizziness. No CP, SOB, cough, throat swelling, difficulty swallowing, stridor, syncope, neuro deficits, HA, fever, chills, nausea, vomiting or pain of any kind. Patient was evaluated and workup was done in ED: EKG, CXR, labs. Patient was observed for ~2 hours after which his symptoms were totally gone and patient was sent home with normal vitals and without complaints of any kind. |
| 923626 | 1/6/2021 | GA | 31 | F | 12/30/2020 | 12/31/2020 | Arm soreness; headache; shakiness; nausea; diarrhea; This is a spontaneous report from a contactable other health professional reported for herself. A 31-year-old female patient (not pregnant at time of the report) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number EJ1685), intramuscularly on left arm on 30Dec2020 14:30 at single dose for COVID-19 immunization. Facility type Vaccine was reported as Doctor's office/urgent care. Medical history included SVT, neurocardiogenicy syncope, PVCs, known allergies: PCN. Concomitant medications were not reported. The patient experienced arm soreness, headache, shakiness, nausea, diarrhea on 31Dec2020. No treatment was received for the events. The outcome of the events were not resolved. |

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| 923412 | 1/6/2021 | CO | 25 | F | 12/30/2020 | 12/30/2020 | she got tunnel vision; almost passed out; Blood pressure dropped to 70/50; heart rate went up to 140; whole body got cold and tingly; whole body got cold and tingly; This is a spontaneous report from a contactable pharmacist (patient) reported for herself. A 25-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; brand: Pfizer Biotech; lot number: EL0142) via an unspecified route of administration at left arm on 30Dec2020 at 12:45 PM at a single dose (dose number: 1) for COVID-19 immunization. Facility where the most recent COVID-19 vaccine was administered was workplace clinic. Medical history included premature ventricular contractions (PVCs). No known allergies (no allergies to medications, food, or other products). The patient was not pregnant. No other vaccine in four weeks and no other medications in two weeks. The patient experienced adverse events included blood pressure dropped to 70/50, heart rate went up to 140, whole body got cold and tingly and she got tunnel vision and almost passed out. The events all started on 30Dec2020 at 12:45 PM. The events were reported as non-serious. No treatment received for events. The outcome of events was resolving. Prior to vaccination, the patient was not diagnosed with COVID-19, and since the vaccination, the patient had not been tested for COVID-19. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Based on the close temporal relationship, the association between the event tunnel vision with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate. |

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| 923402 | 1/6/2021 | CA | 39 | F | 12/30/2020 | 12/30/2020 | blood pressure went up to 150/101; feeling like fainting; feeling really tired; Weakness; irregular heart beat; sob; feeling like flushing in the body; chills; This is a spontaneous report from a contactable healthcare professional. A 39-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL1284), intramuscular on the left arm on 30Dec2020 07:15 at single dose for COVID-19 immunisation. Medical history included hypothyroidism, depression, cardiac murmur and pvc. The patient had no known drug allergies and had not tested for COVID-19 prior and after vaccination. Concomitant medication included levothyroxine sodium (SYNTHROID), ergocalciferol (VITAMIN D), tocopherol (VITAMIN E) and sertraline hydrochloride (ZOLOFT). The patient experienced weakness, irregular heart beat, feeling like fainting, sob, blood pressure went up to 150/101, feeling like flushing in the body, chills, feeling really tired, all on 30Dec2020 07:15. The patient received treatment. The outcome of the events was recovering.; Sender's Comments: Based on the close temporal relationship, the association between the event "blood pressure went up to 150/101" with BNT162b2 can not fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate. |
| 922600 | 1/6/2021 | IL | 35 | M | 1/4/2021 | 1/4/2021 | Patient tolerated injection well. Post vaccination the patient was scheduling his second appointment when he passed out at our clinic. He fumbled around the room and hit his back on the chair. After patient came to we called his wife and contacted MD. Patient's wife drove him to medical facility to be examined and cleared. |

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| 922524 | 1/6/2021 | FL | 62 | F | 1/5/2021 | 1/5/2021 | Within 30 seconds to 1 minute, I had a strange taste in my mouth. It was neither pleasant nor unpleasant, just different. Following this I began to feel bad. It felt as if my blood pressure dropped. I became dizzy and had to hold my head up with my hands. Thank God, I was in my car when I got this injection, or I would have fainted. I felt my temp increase, and my breathing and heart rate became rapid. I used meditation to get my breathing under control, and within a few minutes, I broke out in a cold sweat all over. Then these symptoms subsided and I felt much better. This entire reaction was under 5 minutes. 15 minutes after the injection, a nurse returned to my car and I told her that the vaccine triggered a hot flash or something. My arm became very sore, and that night I felt a goose-egg lump, very warm at the injection site. Also, the left side of my throat felt tight, and it hurt. This morning my arm is still very sore, but no lump, and my throat feels better. |
| 924324 | 1/6/2021 | MI | 44 | M | 12/19/2020 | 12/19/2020 | PRESYNCOPE, RIGHT SIDED FACAIL NUMBNESS |
| 922533 | 1/6/2021 | FL | 38 | M | 1/5/2021 | 1/5/2021 | Pt received vaccine and was sitting in observation for 10 minutes when he started to complain of feeling really warm, skin was flush and he was sliding out of his chair. Pt was assisted to stand and move to another room to lay down and have vital signs taken. During this move he passed out and was assisted to the ground. Pt did not hit his head and was laid flat. At this time emergency protocol was activated and Epi Pen was given to left thigh at 10:42. BP 127/64 P. 64 SPO2 100%. respiration shallow at 18. Pt opened eyes immediately after Epi pen administration. He had no recall of syncopal episode. Pt was transported to ER via ambulance for further evaluation. |
| 932381 | 1/6/2021 | | 59 | F | 1/4/2021 | 1/4/2021 | Headache, Myalgia, Arthralgia, Fever, CoughWheeze & Syncope |
| 924215 | 1/6/2021 | | 37 | M | 1/6/2021 | 1/6/2021 | Within minutes patient experienced light headedness, flushing, reports that he felt like fainting and he felt his heart racing He was taken to ER and only finding was elevated BP. Pt was interviewed an hour after incident and reported that all sx had resolved. Pt was discharged and came by vaccine clinic to report he had recovered. |

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| 927940 | 1/6/2021 | SD | 91 | U | 1/6/2021 | 1/6/2021 | I was informed by the staff that pt. had fainted about 1/2 hour after receiving The Covid vaccine. The staff immediately called 911 & EMS arrived in about 15 minutes *Collapsed approx. 30 min after shot Arrived 11:45AM & she was responsive WEIGHT: 149.8 as of 12/20/20 |
| 924723 | 1/6/2021 | MI | 29 | F | 12/27/2020 | 12/27/2020 | PRESYNCOPE BP 70 SYSOTLICALLY, IV INITIATED AND TAKEN TO EMERGENCY DEPT |
| 924617 | 1/6/2021 | WA | 59 | F | 12/26/2020 | 12/27/2020 | Extreme Dizziness, Blurry Vision, Near fainting and Nausea |
| 924611 | 1/6/2021 | IL | 38 | F | 1/3/2021 | 1/3/2021 | I couldn't breath and my blood pressure was abnormally elevated for a prolonged time. It made my head spinned and pressured. My heart was racing rapidly and feeling fainted |
| 924587 | 1/6/2021 | CA | 36 | F | 12/28/2020 | 12/28/2020 | She arrive at 3:43 and she was nervous before the vaccination for COVID19 (Morena) because has had anaphylactic reactions to Flonase. She was feeling well up to 15 min post vaccination when she felt she is going to pass out w/o loosing consciousness. She felt weak and feeling fainted when we transferred her to the stretcher. Her BP was 163/106 P=112, Pulse Ox 100% at 16:09. She was resting, received O2 lit per min, she was feeling chest tightness when she used her inhaler Albuterol 2 puffs X2 within 5 min. She was feeling weak and stating "I am going to pass out." Her repeat BP=152/110, P=94 with pulse Ox 100% at 16:12 911 called and arrived at 1643 |
| 924541 | 1/6/2021 | WV | 61 | F | 12/29/2020 | 12/30/2020 | Diarrhea, near syncope, extreme fatigue. Started 30 hours post injection & continued x 48 hours. Site soreness/edema 24 hours after injection that increased to extreme sensitivity at site after 30 hours which lasted 24 hours. Left deltoid swollen x 1/2 more than usual size started 36 hours after injection and lasted 36 hours. |
| 924396 | 1/6/2021 | AZ | 62 | F | 1/6/2021 | 1/6/2021 | Syncope |
| 924322 | 1/6/2021 | PA | 61 | M | 1/5/2021 | 1/6/2021 | Presyncope, temporary dizziness and vertiginous sensation lasting 5 seconds. |

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| 924109 | 1/6/2021 | CA | 50 | F | 12/30/2020 | 1/5/2021 | The mentioned individual began to feel she had trouble concentrating, felt cold and hot, tingling on scalp and hands, nausea and felt like fainting. |
| 921091 | 1/5/2021 | NH | 54 | M | 12/31/2020 | 12/31/2020 | Pt received vaccination and left after 15 min. observation symptom free. He drove a short distance away from the clinical site when he felt profuse sweating and had syncope (seconds) crashing into curb. He was aroused from impact and was able to stop car. He then developed profuse nausea and sudden urge to defecate. He went to restroom. Given these events he returned to the clinical site in another vehicle. Upon arrival he denied chest pain, shortness of breath or ongoing nausea or abdominal pain. He reported his AM blood sugar was 72 and does not take insulin. No history of coronary disease or syncope. EMS was activated and assumed care. |

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| 920968 | 1/5/2021 | CT | 30 | F | 12/22/2020 | 12/23/2020 | <p>It looks like one of the ingredients may have an animal cell lipid; Syncope; Dizziness; feeling faint; like going to pass out now and then; overall achiness, severe headaches, fever; overall achiness, severe headaches, fever; overall achiness, severe headaches, fever; This is a spontaneous report from a contactable nurse reporting for herself. This A 30-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot # EH9899), intramuscular at single dose in the left arm on 22Dec2020 09:00 for covid-19 immunisation. Medical history included reaction to pork, porcine and/or if she ever was exposed to exposed to heparin. There were no concomitant medications. On 23Dec2020, the patient experienced syncope (medically significant), dizziness (medically significant), feeling faint; like going to pass out now and then (medically significant), overall achiness, severe headaches, fever. The outcome of the events syncope, dizziness, feeling faint; like going to pass out now was recovering and outcome of overall achiness, severe headaches, fever was recovered on 24Dec2020. The patient ask: are there any animal products, pork gelatin or a lipid form of that contain in the vaccine? The events were described as follows: She experienced a significant amount of syncope and dizziness, for greater than 4 or 5 days post-receiving the vaccination. Also feeling faint like she is going to pass out every now and then. Has a more important question, wondering along with the doctors if one of the ingredients may have an animal product, like pork gelatin or a lipid form of that. It looks like one of the ingredients may have an animal cell lipid and was wondering if she was having a reaction to that. Declines to provide primary care provider details. States she received this first dose at occupational health in her workplace. Received the vaccine on the 22Dec2020 at 9am. 24 hours post vaccination, 1 day after, the syncope, dizziness, feeling faint started. Also the other symptoms, overall achiness, severe headaches, and fever were also experienced, but they stopped after that 24 hours. Those were expected since it was listed as side effects that popped up, so she expected those and they stopped after 24 hours. The syncope, dizziness, and faint feeling are not any worse and are very slowly improving, but she still has it and had to call out of work today because of it. That's consistent. Mentions it takes her a while to get down the stairs when</p> |

VAERS_ID RECVD STATE AGE_YRS SEX VAX_DATE ONSET_DATE SYMPTOM_TEXT

| <u>VAERS_ID</u> | <u>RECVD</u> | <u>STATE</u> | <u>AGE_YRS</u> | <u>SEX</u> | <u>VAX_DATE</u> | <u>ONSET_DATE</u> | <u>SYMPTOM_TEXT</u> |
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| 920382 | 1/5/2021 | IN | 28 | F | 1/4/2021 | 1/5/2021 | Fainted at 6:30 a.m. the next morning |
| 920514 | 1/5/2021 | ME | 57 | M | 12/31/2020 | 12/31/2020 | \$ hours following the vaccination, I felt very faint and dizzy and nearly passed out. I checked my blood pressure, which was normal. My pulse rate was low (58). I remained dizzy and weak for the rest of the day, with some nausea, but no vomiting. My dizziness and weakness gradually dissipated over the next 3 days. |
| 920522 | 1/5/2021 | MI | 48 | F | 12/31/2020 | 1/1/2021 | 1/1/21 thru 1/3/21 body chills fever 101-102 temp 1/3/21 @ 4am fainted with temp of 101.5 |
| 920555 | 1/5/2021 | MD | 44 | F | 1/3/2021 | 1/3/2021 | 1/3: near syncope about 4 hours after receiving vaccine 1/4: near syncope around 6pm, followed by joint pain, chills, fatigue, nausea, headache injection site extremely sore on movement. |

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| 920569 | 1/5/2021 | GA | 38 | F | 12/18/2020 | 12/18/2020 | It was extremely painful when I received the vaccine and I immediately felt my fingers tingling. In about 10 min I felt very hot in my face, back and felt like I was going to pass out. My heart was racing, it was about 130. My BP initially was 139 and then 160 after that. I never passed out but I felt those waves with a tingling to my face and my neck as I was going to pass out and I started shaking and my heart was racing and my BP was up and it lasted about 45 min before it started going down. They gave me some Ibuprofen at the Employee health and they kept observing me and it started getting better after 45 min. I still felt the waves of feeling flush and hot and cold and very fatigued. |
| 920701 | 1/5/2021 | IL | 27 | F | 12/17/2020 | 12/18/2020 | 12/18/20- reports suddenly got sweaty, hands felt cold, then got nauseous. Reports vomitted x 1. Reports the rest of the day felt tachycardiac for a few hours (HR 120-140) and dizzy. Started getting muscle aches/joint aches. Denies any recent COVID exposure. Tested positive for COVID In 8/2020. Reports hips/knees are throbbing today; Heart rate WNL. /// Presenting today due to intermittent presyncope and palpitations. Also notes generalized weakness. Patient evaluate 2 L of fluid given her Mirena IUD D-dimer was sent which was negative patient with no pleuritic symptoms or dyspnea to suggest pulmonary embolism. Otherwise hemodynamically stable on exam ambulates with no difficulty no focal neurologic deficits. Patient did describe on her initial presentation that she noted some weakness of her bilateral legs. Given her possible viral reaction and description of weakness it is possible the patient is developing an early autoimmune reaction however she has no evidence of GuillainBarré or transverse myelitis on my exam. We will plan to discharge with neurology follow-up as outpatient. |

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| 920814 | 1/5/2021 | CA | 38 | F | 12/28/2020 | 12/28/2020 | She received the Moderna vaccine on 12/28. She then started to feel some itching in her throat within 5 minutes. It then started to get worse and then she started to cough. Vital signs show blood pressure 152/89 with pulse 72 oxygen saturation 100% with respiratory to 16. She was given liquid Benadryl and the coughing and itchiness in her throat lasted for three hours. She went to sleep as the Benadryl caused her to be drowsy. When she awoke she had no symptoms. She then had a fever later in the day. she had no hives, lip swelling, tongue swelling, shortness of breath or presyncope associated with these symptoms. |
| 922037 | 1/5/2021 | CA | 37 | F | 1/5/2021 | 1/5/2021 | Patient received vaccine and started to feel lightheaded and flushed about 5 minutes after the dose. She fainted and was assisted to the ground. She did not lose consciousness. She was asked about her recent insulin dose and it was suspected that she did not eat enough food after taking her morning insulin. |
| 921059 | 1/5/2021 | NH | 34 | F | 1/2/2021 | 1/2/2021 | 1310:Pt received vaccine. 1315: Pt's husband honked horn as patient reports feeling dizzy, lightheaded, and nauseous. Pt has history of neurocardiogenic syncope and states this often happens to her with vaccine administration. HR 130 BP 120/70. Pt with seat reclined. 1320: Pt extracted from car by RNx2, assisted to cot to lay flat. Pt states feeling much better laying on cot. Pt observed 1:1 by this RN. Pt reports feeling better. Offered to call ambulance for patient, pt declines. States this is very normal for her. 1330: Pt able to sit up. 1345: Pt stands and assisted back to car with slow transition. Pt observed for additional 10 minutes in parking lot. Pt states she feels comfortable going home and resting. educa educated regarding reasons to go to Emergency Department or call 911, pt verbalizes understanding. education provided to patient's husband regarding things to monitor for. Both are agreeable and feel safe with plan. Pt encouraged to speak to Agency regarding second dose plan. Recommend patient recieves dose #2 at a healthcare facility while being continuously monitored by healthcare personnel and with the ability to provide immediate intervention. Pt verbalizes understanding. |

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| 921588 | 1/5/2021 | TN | 36 | F | 12/22/2020 | 12/22/2020 | I have learned that it was syncope. I felt like time was moving quickly. I was jittery and felt like my heart was beating quickly. I was taken to a separate area and felt warm and flush in my chest. They laid me down on the cot and said I looked pale. My hands were cold and within minutes I was shaking uncontrollably. I think it was an anxiety related to my research I've done at my job related to COVID. I don't think it was an allergic reaction, but I do have an appt on Thursday. I was monitored for about an hour. Symptoms went away but I wasn't totally ok until the next day besides soreness in next arm. |
| 921615 | 1/5/2021 | PA | 38 | F | 12/28/2020 | 12/28/2020 | Within first 5 mins - Sudden onset of warm sensation (similar to the feeling of IV contrast administration), flushed feeling, pale, near syncope followed by nausea and dry heaving. Lasted 30 mins. Felt fatigued and mild headache for next 24-48 hours. |
| 921631 | 1/5/2021 | MI | 83 | F | 1/3/2021 | 1/5/2021 | ~~Patient with seizure this am during 1 assist transfer, resident passed out, lowered to shower chair next resident with incontinent episode and was sent to Emergency Department emergently and currently under evaluation with possible admission. ~~ |
| 921646 | 1/5/2021 | | 40 | M | 12/22/2020 | 12/22/2020 | syncope 4 hours after chills 2-5 hours after body aches off and on for 7 days |
| 921836 | 1/5/2021 | CT | 25 | F | 12/29/2020 | 12/30/2020 | Fatigue, chills, nausea, headache. Next morning, felt dizzy. Tried to get up. Sat at table, felt dizzy again, passed out, felt like she was deep sleep, was told she was foaming at the mouth. Felt better afterwards. |

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| 921029 | 1/5/2021 | LA | 31 | M | 12/23/2020 | 12/23/2020 | After receiving the vaccine, I was instructed to wait i for 15 minutes to ensure there were no reactions. I sat down in the provided chair, put my headphones in my ears, and started my timer on my watch for 15 minutes. after about 5 minutes I began to feel like my injection arm was a little weak, as if perhaps my arm was stiffening from the injection sore. I remember feeling slightly warm and started to read over the COVID-19 Vaccine symptoms sheet and then I blacked out (Fainted). The nurse in the hallway woke me up and was asking me if i was alright and then rushed me in the back room where they tested me and ensured I was ok. I had not eaten anything the morning of the vaccination shot and barely anything the night before. I have been experiencing higher levels of anxiety recently due to pressures of day to day life; school, work, etc. The nurses are thinking it is likely I had more of a reaction to the anxiety and low food or blood sugar (I am not diabetic), than a reaction to the vaccine itself. They did refer to my experience as sounding like Vasovagal syncope. I have never had this experience with any flu vaccine or shots before; I do not have a fear of needles or shots. |
| 922082 | 1/5/2021 | CA | 21 | F | 1/5/2021 | 1/5/2021 | Patient received Moderna covid 19 vaccine on 11:15am 1/5/2021. Patient had rested for 15 minutes after vaccination and reported felt fine. Patient went back to work. Patient fainted around 3:30pm. Patient regained the conscious quickly and the Paramedics said her blood sugar was normal and she had little orthostatic hypotension. The Paramedics gave her some fluid. |

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| 918799 | 1/4/2021 | NY | 67 | F | 12/23/2020 | 12/24/2020 | disoriented; hit her head and cut herself; hit her head and cut herself; Passed out at night; This is a spontaneous report from a contactable consumer (patient). A 67-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), via an unspecified route of administration on 23Dec2020 at single dose at left arm for COVID-19 immunization. Medical history included Atrial fibrillation/heart problems diagnosed prior to the vaccine, got the COVID virus on 18Nov2020, disoriented in Nov2020. Concomitant medications included her heart medication every day and vitamins, nothing out of the normal. Caller stated she had heart problems. The heart problems were diagnosed prior to the vaccine. Caller also stated that she got the COVID virus this year before the vaccine as well and she was off, of work for like a month. On 23Dec2020 she got the vaccine. Then on Thursday 24Dec2020 and Friday 25Dec2020 she had a reaction. She had passed out in the night, hit her head and cut herself, she was then disoriented for 1 full day. Caller stated that the last time she was disoriented like this was when she had the COVID Virus, because she had heart problems. Caller stated that she was fine now. Caller stated that she had been off, of work so much. The heart problem she had was Atrial Fibrillation. Caller clarified that she had the COVID virus this year in Nov2020, it was before thanksgiving, on 18Nov2020 she had the virus, then on 19Nov2020 she got tested and it was positive. She got the vaccine on the 23Dec2020 Wednesday then on 24Dec2020 at night she passed out and on 25Dec2020 she was disoriented all day. Investigation Assessment: No. On 24Dec2020 she was going to bathroom, and found herself on the floor, then the following day 25Dec2020 was when she was disoriented. She knew this because when she had the actual COVID virus previous in Nov2020 this happened previously. When queried outcome of being disoriented she stated that she still felt a little weird but if getting better very, very slow. The Second dose was schedule for 13Jan2021. Caller confirmed that she did have a Positive Test for Covid Previously. Her treatment at the time was in the Emergency Room, they gave her an Antibody infusion, she had to schedule it because it was actually a clinical trial. Caller was asked if she knew the name of covid test, she stated that she does not know, |

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| 918660 | 1/4/2021 | IL | 27 | M | 12/28/2020 | 12/29/2020 | she only recalled that she opened her mouth and they test her that way. The outcome of the event "disoriented" was recovering, of the other events was unknown. |
| 918602 | 1/4/2021 | IL | 38 | M | 12/31/2020 | 12/31/2020 | Myalgias in bilateral thighs, left shoulder, and right shoulder- Worst at 24 hours later. Headache-24 hours later. Poor thermoregulation with near vasovagal syncope while in the OR-24 hours later. |
| 918574 | 1/4/2021 | TX | 31 | F | 12/21/2020 | 12/22/2020 | Patient passed out. Blood pressure was low and pulse was low |
| | | | | | | | Immediately I got nauseas and headache. Next day my whole lower back was spasm and had horrible body pain/back pain. I almost passed out putting pants on. A friend took me to an Urgent care they gave me Shot of tramadol and given Tylenol 3. They also did a test on my kidney. About 50 hours after the shot I was feeling better. |

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| 918081 | 1/4/2021 | NY | 26 | M | 12/30/2020 | 12/31/2020 | I received the shot around 0730 on 12/30/2020. Went home and got ready for work. Around 12am 12/31/2020 my arm started to radiate at the injection site and was very tense. I placed a heat pack on the right arm but the pain did not dissipate. My arm continued to be in pain for the rest of the night. Around 0240 I ate dinner, had water and still had some arm pain. Around 0345 my arm started to flare up and sent pain sensations throughout my body. My right arm was increasingly discomforting, I could barely move it. The sensations spread to my legs, numbing them and my throat had felt as if it were closing up. I got up to get the attention of the nurse and was able to flag her down. She said I was pale as a ghost. My vision was very blurry, I could not hear anything because my ears had filled up and everything was muffled. My head had begun to ring and I was on the brink of fainting when a chair was given to me. My eyes had become extremely sensitive to the light, I was given water and spoken to about what had happened leading up to the event. I was greeted by the paramedics who drew my blood, placed an IV and transferred me to the Acute Care portion of the Emergency Department. My vitals were 76/49, 80/50, 90/56, 100/60 before being brought to the ER. On 1/1/2021 My thighs have been sore/tense, my knees and ankles have been stiff and just feeling sickly. On 1/2/2021 much of the same symptoms are present. The soreness in the muscles isn't as prevalent, however joints still are stiff On 1/3/2021, congestion and runny nose are still present, stiffness in ankles and now shins are prevalent. |

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| 918541 | 1/4/2021 | UT | 43 | M | 12/30/2020 | 12/30/2020 | 10 min after injection, my mouth started getting hot, then it moved down my throat and it was difficult and painful to swallow. I got quite dizzy. They initiated rapid response, when they came they simply monitored symptoms and Vitals. Blood pressure and Heart rate were elevated. after about 10 min the symptoms eased, but swallowing was still difficult and slightly painful. then a second wave of dizziness hit me and I nearly passed out. my heart rate was elevated once again and had ringing in ears. these symptoms lasted another 5-10 min then eased. I then had a headache. The symptoms didn't return, just a headache and fatigue the rest of the day. i was then given option to go to ED, which i didn't feel at that time I needed, so I left. The next day, i had some standard symptoms of pain in left arm from injection, and fatigue, but then toward the evening i developed a fever of 101 deg F than continued for a couple of hours. I used ibuprofen and Tylenol rotating to keep the fever down. On day 3 only mild fatigue. |

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| 918200 | 1/4/2021 | FL | 27 | F | 12/23/2020 | 12/23/2020 | Pfizer-BioNTech COVID-19 Vaccine EUA - Patient witnessed another patient with syncope prior to her injection. She was already anxious about receiving vaccination and this increased her anxiety, though she proceeded with immunization. Patient was in 15 min observation window in a chair and began to feel light-headed like she may pass out. A SWAT was called. With RN assistance, patient was lowered to the floor, with no loss of consciousness. Patient was pale and reported anxiety, racing /pounding heart, and felt hot with facial flushing. Patient was transferred to ED and was noted to be tachycardic (120s), but dropped to 80s. She noted that this episode felt different than her prior syncopal episodes associated with anemia. Patient was observed for 5 hours and discharged to home. Patient returned to ED roughly 2.5 hours later complaining of continued dizziness and unsteady gate. Patient was pale and anxious. Patient reported had not eaten/drunk enough during her shift and received vaccine immediately post a stressful shift. Additionally, patient witnessed another patient have syncopal episode prior to her receiving her vaccine which made her anxious. Patient was given IV fluids and had electrolytes replacement. Patient additionally received diazepam. Patient was discharged at 2358 on 12/23. Patient returned to ED on 12/24 at 0239 complaining of near syncope and lightheadedness. Patient had tachycardia and self-reported palpitations. Received IV fluids and observation on telemetry with no rhythm disturbance. Patient discharged 1428 on 12/24. On 12/29, patient returned to ED at 0326 for continued dizziness, fatigue and near syncope. Was admitted for cardiac evaluation. Noted to have unprovoked tachycardia and was discharged with a Halter Monitor to evaluate cardiac symptoms. patient was discharged 12/31 at 1619 |
| 918809 | 1/4/2021 | OK | 26 | F | 1/3/2021 | 1/4/2021 | Severe headache, fever, and blood pressure drop leading to fainting starting the day after receiving the Pfizer-BioNTech COVID-19 Vaccine EUA. |

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| 919640 | 1/4/2021 | TN | 26 | F | 12/26/2020 | 12/27/2020 | got the shot around 11 am on 12/26 and my mouth became immediately parched. My arm was super sore as the day went on and around 4:30 am I woke up shivering with chills and aches and a mild temp of 99. Passed out and BP was extremely low. Parents called an ambulance and I went to Emergency room. |
| 918338 | 1/4/2021 | MI | 64 | F | 12/31/2020 | 12/31/2020 | about 4 hours after vaccine, patient passed out and when came to, vomited profusely. Transferred to hospital ED. |
| 919112 | 1/4/2021 | NM | 42 | F | 12/31/2020 | 12/31/2020 | 45 minutes following the injection, dizziness and near fainting. Within a few hours, severe arm pain, limiting range of motion to about 30%. The day after the injection experienced diarrhea all day, as well as ongoing severe arm pain, limited range of motion to approx 30%. |
| 919171 | 1/4/2021 | CA | 57 | F | 1/4/2021 | 1/4/2021 | After sitting for 10 minutes, I became very nauseated and lightheaded and walked self to gurney near by to lie down. Medical attention was rapid and blood pressure was super low, 70/50 ish and returned to better number in Trendelenberg position. I was sent to ER for further monitoring and all is fine now- Dx with near Syncope due to orthostatic hypotension. |
| 919370 | 1/4/2021 | TX | 28 | F | 1/2/2021 | 1/3/2021 | Saturday midnight started with a headache, Sunday morning woke up around 9:30 to get milk for my 2 year old boy, wanted to take a Tylenol for the headache when I started to feel really nauseous and fainted. I remember waking up laying down on the floor, I screamed at my husband I couldn't get up. And my husband got me up from the floor when I fainted again in his Arms. He states I was unconscious for 10-15 seconds. After I wake up my headache and nauseous went away. I was fine the whole day. |
| 919501 | 1/4/2021 | AZ | 56 | F | 12/30/2020 | 12/30/2020 | Light headed, almost passed out several times accompanied by nausea. It would come and go and lasted about 2 hours. Blood pressure spiked and then returned to normal within an hour. Injection site painful for 2 days, extreme tiredness accompanied by headache lasted for 4 days. |

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| 919624 | 1/4/2021 | PA | 29 | F | 12/29/2020 | 12/29/2020 | Around 10 or 11 pm, arm pain, chills, fatigue, headache, nausea, swollen lymph nodes, lightheadedness, fainted in tub. Next day, fatigue all day, couldn't talk, or eat. Went back to bed again. The following day hot flashes, weakness. went to ER. Felt like blood pressure was dropping, tingling in legs, difficulty lifting her head. |
| 919646 | 1/4/2021 | OH | 64 | M | 12/29/2020 | 12/30/2020 | Patient began having headache and fatigue 12/29. Early morning of 12/30 patient reported severe chills. Felt better during the day of 12/30 with only a headache. Night of 12/30 patient reported severe chills again and wanted to call the doctor in the morning, but the felt better on 12/31. The night of 12/31 patient again had chills, but less severe (rated 3/10 on scale). Night of 1/1 patient reported slight hive like rash that went away with warm Epsom salt bath. 1/3 0100 patient woke up with severe hives down back of legs and lower back. Got into a hot tub to soak and once the patient got out he was standing at the sink and passed out. His wife got him back to bed. Around 0700 on 1/3 patient woke up to urinate and he passed out again. He states both times he passed out felt the same stating "I felt like I was going to vomit and then all of a sudden I couldn't breath, almost like I was choked out.~~ |
| 919689 | 1/4/2021 | CA | 57 | F | 1/4/2021 | 1/4/2021 | Pt reported feeling dizziness, lightheaded, near syncope, numbness/tingling up neck into chest area, numbness and tingling in extremities. Feeling of impending doom, chest pressure with SOB. Pt was given Epi-Pen 0.3mg in clinic, transported via EMS to local ER at which time 50IV Benadryl given while in Ambulance, and 4mg decadron in ER. Pt was discharged from ER at 3:00pm |
| 918873 | 1/4/2021 | | 33 | F | 1/4/2021 | 1/4/2021 | lightheaded, sweaty, BP113/77. Administered vaccine supine as patient indicated history of fainting with injections. Symptoms resolved shortly after administration. |

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| 919504 | 1/4/2021 | MT | 54 | M | 12/29/2020 | 12/29/2020 | About an hour after being vaccinated, I got very pale, and almost had a syncope episode at work. I felt weak kneed for about 2 hours afterwards, and was still wobbly knees the next day. I also had muscle/joint aches the same day, which went away within 24 hours. In the past 6 days, I have had reoccurring headaches, fatigue, and this morning, had a severe enough headache to bring on nausea. I am med compliant with all my meds and I take care of my Type II diabetes, I am also a volunteer firefighter - advanced EMT, so I know when there is a problem. |
| 917667 | 1/3/2021 | AL | 47 | F | 12/30/2020 | 12/31/2020 | Most horrible fever, chills, body aches, near syncope. |
| 917804 | 1/3/2021 | IL | 21 | F | 12/26/2020 | 12/27/2020 | Dizzy, fainting, numbness on right leg/ face, nausea |
| 917803 | 1/3/2021 | AL | 31 | F | 12/29/2020 | 12/29/2020 | approx 6 minutes after receiving vaccine to Left deltoid IM site: marked tachycardia HR 180 with associated dizziness, nausea, hypotension and subsequent severe lethargy and feeling of syncope. placed on stretcher at hospital facility and ultimately fell asleep for unknown amount of time. After waking approx 2 hours later majority of severe symptoms subsided but residual tachycardia of 120s and orthostatic hypotension throughout the day for next 16 hours. associated dry flushed skin of face and dry itchy eyes throughout day as well |
| 917672 | 1/3/2021 | IL | 62 | M | 12/28/2020 | 12/29/2020 | whole body muscle aches, chills, fever over 101, light headed/dizzy (fainted), fatigue, some nausea. all disapated within 48 hours of getting shot |
| 917230 | 1/2/2021 | IL | 47 | F | 12/30/2020 | 12/30/2020 | tachycardia hypotension dizziness/lightheaded weakness nausea pre-syncope |

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| 917426 | 1/2/2021 | OR | 52 | F | 1/2/2021 | 1/2/2021 | Caregiver (cg) received Covid vaccine on 1/2/21 @ 0910. Cg was nervous but did ok with vaccine administration. Once in the observation area, cg became nauseous and raised her hand to report. Cg was sitting in one of the back rows so observation RN came to her. Observation RN was walking cg to lower level when she experienced syncope and fell forward down several steps and to the right hitting the front of her head and right shoulder on the wall. Cg was unconscious for approximately 30-45 seconds. Once alert, cg responded appropriately to questions, but slowly. Vitals were 120/82 P 107 at 0915 and 150/84 P 96 at 0920. Cg had 2 events of uncontrollable bilateral arm shaking lasting approximately 5-10 seconds. Rapid Response Code was called and cg taken to ED at 0940. C-collar and back board was used to transfer cg from floor to stretcher. Unknown at this time if caregiver was admitted. |
| 917505 | 1/2/2021 | CA | 39 | M | 1/2/2021 | 1/2/2021 | Patient became lightheaded, clammy and passed out (typical vagal reaction). Patient aroused easily, VS monitored.... patient was able to sit up after about 5 minutes. Monitored for 30 minutes post vaccination. Patient did not need any other intervention or care. |
| 917615 | 1/2/2021 | IN | 42 | F | 12/30/2020 | 12/31/2020 | I had chills, headache, and was nauseous all day but around 630 I passed out and smacked my face when getting out of the shower. |
| 917570 | 1/2/2021 | WI | 46 | F | 12/30/2020 | 12/31/2020 | Acute onset of reactogenicity reaction as patient was leaving grocery store. Almost crashed car driving due to violent rigors. Single episode explosive diarrhea upon arrival home. Patient incapacitated on couch for 3.5 hours due to shaking chills, dizziness, headache, profound weakness, near syncope when attempting to get up. Patient unable to reach phone to summon help for over an hour. (phone was only 2 feet from patient). |

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| 916696 | 1/1/2021 | MI | 20 | F | 12/30/2020 | 12/30/2020 | Patient received first dose of moderna covid-19 vaccine EUA. She is an employee of the nursing home. While waiting for 15 minutes, patient fainted and fell. She became alert immediately after. Patient reports no allergies or chronic medical conditions. No epipen or Benadryl were administered. Her vitals were taken immediately after: bp 128/80, temp98.0, Osat 99%, HR 88. Patient also reports not remembering if she has anything to eat that day . |
| 917086 | 1/1/2021 | WI | 51 | F | 12/26/2020 | 12/27/2020 | Severe fatigue, Gi upset, nausea, near syncope |
| 917073 | 1/1/2021 | CT | 27 | M | 12/30/2020 | 12/31/2020 | 32 hours after my vaccination I fainted. When I came to my body felt weak and heavy and I felt like I could not move my limbs. It took about 45 min before I felt strong enough to get up off the floor and into my bed |
| 917037 | 1/1/2021 | MN | 42 | F | 12/31/2020 | 1/1/2021 | Dizziness, nausea, diaphoresis, syncope/fall. Totally blacked out and fell. Helped back to bed, covered in sweat. No fever. Layed in bed until next morning around 10am, still dizzy and nauseated. |
| 916993 | 1/1/2021 | CA | 48 | F | 12/31/2020 | 12/31/2020 | Pt felt dizzy and nauseous after vaccine administration. When she tried to get up, she experienced syncope for about one minute. We administered Epi-pen and pt regain consciousness. Asked facility and patient if 911 call was needed, but patient refused. We monitored her blood pressure for over 1 hours and she stabilized at her baseline. We released her to go home and she will continue to monitor other potential adverse reactions. |
| 916952 | 1/1/2021 | CA | 25 | F | 12/31/2020 | 1/1/2021 | Fainting possibly due to pain Patient given motrin and sleeping at home |
| 916830 | 1/1/2021 | MT | 29 | F | 12/31/2020 | 12/31/2020 | Had chills all night. Severe headache and body aches started around 10pm (vaccination was around 11am). I felt great for a few hours immediately following vaccination but developed severe light-headedness that evening. Passed out the following morning (01/01/2021) and my daughter called 911/ paramedics. I declined going to the hospital but I still feel horribly dizzy and ache. |
| 916777 | 1/1/2021 | MI | 30 | F | 12/29/2020 | 12/29/2020 | Chills, myalgias and pre-syncope |
| 915981 | 12/31/2020 | NY | 35 | F | 12/30/2020 | 12/30/2020 | syncope, shaking, and right side hand paralyzed |

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| 916580 | 12/31/2020 | NY | 34 | F | 12/23/2020 | 12/23/2020 | High Fevers, Nausea and Vomiting, Severe pain at injection site, Syncope, dizziness, abdominal pain, patchy hair loss. Lasted for 72 hours. |
| 916561 | 12/31/2020 | MI | 47 | F | 12/27/2020 | 12/27/2020 | Shortness of breath, rapid heart beat, weakness, near fainting. Symptoms started after the 15 minute observation period and I left the facility. I took 50 mgs of Benadryl and symptoms were gone within 30 minutes. This could have been an anxiety attack and unrelated to the vaccine. I have never reacted to a vaccine before. Unsure if I should receive the second dose of this vaccine. |
| 916441 | 12/31/2020 | OR | 26 | F | 12/29/2020 | 12/30/2020 | Day of injection patient only had symptom of sore arm, following morning patient woke up at 0330 with chest tightness and increased arm soreness. At 0555 pt woke to take acetaminophen and ibuprofen for muscle and joint aches pains, while standing at counter patient significant other witnessed patient syncope resulting in head hitting floor. Prior to syncope pt had episode of flush feeling with instance of nausea, does not remember falling. Pt continued to have episodes of dizziness when ambulatory, fever, chills. Pt significant other took her to the emergency department for assessment as bruise of face began to show and headache increased after fall. Pt had drank adequate fluids and eaten dinner the night before, dehydration was not a factor. |
| 916291 | 12/31/2020 | GA | 56 | M | 12/18/2020 | 12/20/2020 | Received Pfizer vaccination 12/18/2020. 2-3 days later pt noted itching on palms. Improved with Allegra. One week p injection itching to hands returned, scalp itching, angioedema lips, around eyes, hands, penis as well as urticarial reaction neck, upper chest, arms, and legs, inguinal folds. Pt is an ER physician and reaction developed while at work. Took prednisone 60mg, Benadryl 50mg, Pepcid 40mg, and Allegra 180. Resolved slowly over 5-6 hours. Never any throat or tongue swelling. No difficulty breathing, dizziness or syncope. Has had yellow fever, typhoid, and all routine immunizations without any reaction previously. No other changes in lifestyle- foods, skin products, detergents, supplements. No recent illnesses. No insect bites/stings. |

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| 916276 | 12/31/2020 | SC | 38 | F | 12/29/2020 | 12/30/2020 | nausea, headache, dizziness, near syncope, tachycardia (130-150s), temperature of 101.4 All lasted around 6 hours and left as quickly as they came |
| 916039 | 12/31/2020 | OH | 39 | M | 12/24/2020 | 12/26/2020 | Had dizziness, blurred vision and tunnel vision while driving 2 days after vaccine. He pulled over and called 911 who took him to the hospital. Dx was near syncope/vasovagal episode, but supposedly had a prolonged QT interval on his EKG. Received IV fluids and has been fine. |
| 915536 | 12/31/2020 | FL | 28 | F | 12/29/2020 | 12/29/2020 | At 5pm on day of vaccine she noticed right arm soreness, which worsened and woke her from sleep; Noticed swollen lymph node in right axilla; Took 600mg ibuprofen and pain subsided; Felt fatigued in the morning, went to her physical therapy and during therapy developed nausea, elevated heart rate to 160-170's for 20 minutes, and near syncope - was seen in the ED, EKG and labs unremarkable |
| 915692 | 12/31/2020 | TX | 36 | M | 12/22/2020 | 12/27/2020 | (1) Flashing & feeling warm (2) Palpitation (4) Fainting (5) Moderate Shortness of Breath RX: (1) IV Fluids (2) Monitoring in The ED (3) Blood work & ErG |
| 915571 | 12/31/2020 | FL | 33 | F | 12/23/2020 | 12/23/2020 | sore arm, woke up at 10:10 with severe stomach upset, and gas. took some tums and laid back down, then got up a few minutes later with nausea, tried to vomit however felt dissy/ fainted. got back in bed with fever/ chills, layed down for a few minutes and felt better. entire episode lasted about 20 minutes. woke up the next morning with nausea, and general tired feeling. this lasted for about 12 more hours. |
| 915558 | 12/31/2020 | | 50 | F | 12/26/2020 | 12/26/2020 | I had a presyncope 5-10 mins after COVID vacc #1 on 12/26/20. Required oral fluids and food. Then, was sick for the following 3 days with COVID symptoms, with another presyncopal episode on 12/27 and multiple COVID symptoms. |

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| 915499 | 12/31/2020 | RI | 30 | F | 12/29/2020 | 12/30/2020 | I started to become very tired around 2:00 pm on Wednesday 12/30, with a mild/moderate headache. The fatigue and headache continued through the evening, and at around 7:30 pm I experienced stomachache and indigestion. I went to bed early at 9:00 pm, with the headache, stomachache, fatigue, and my arm feeling very sore. I slept very restlessly with horrible dreams, as if I were sick or had the flu. In the middle of the night, I'm not sure when, I woke up feeling very achy and sore and freezing cold. After using the bathroom, I passed out, and hit my head on the floor or wall, resulting in a bump/cut. My husband heard me fall and found me lying on the floor. I kept repeating "help me" and "water", and he was thinking that I would likely need to go to a hospital. He elevated my legs, put an icepack on my head, and got me water, and I became more lucid and started to feel better. I took 2 ibuprofen and drank water, then was able to get back into bed. I was very very cold but at one point woke up sweating. I slept the rest of the night and woke up this morning at 7:00 am (12/31) feeling fine, aside from tiredness, with no temperature. |
| 915317 | 12/31/2020 | KS | 23 | F | 12/28/2020 | 12/28/2020 | Intractable vomiting and diarrhea along with chills and fainting. Lasted almost 18 hours |
| 916186 | 12/31/2020 | IL | 24 | F | 12/28/2020 | 12/28/2020 | Patient complained of feeling dizzy 13 minutes after vaccine. Symptoms lasted approximately 15 minutes. Patient had not had anything to eat for 18 hours prior to shot. History of migraine headaches. Examined by MD; option of care explained. Note by MD: 24 year old female who complained of dizziness a few minutes after injection. No other complaints. No syncope. Patient did not eat today. Assessment: Normal exam. Plan: follow-up with primary care provider. |

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| 915473 | 12/31/2020 | WI | 30 | U | 12/31/2020 | 12/31/2020 | Patient got vaccine at 8:17am and started feeling nauseous and lightheaded at 8:32am. 8:33 BP was 100/50 and HR of 80. At 8:51 BP was 110/80 and HR 80. At that time, she had some crackers and water. She reported having issues in the past with fainting when seeing needles. We elevated patients legs and put ice packs on head. She started feeling less nauseous after a while of laying down but was still anxious. Patient has a history of anxiety and takes medications for it. Patients husband came in to help patient leave. Told patient we could bring her to the ER to get evaluated and she declined. When walking outside the room and walking around more, she started to not feel nauseous anymore and just felt anxious. Told patient if any other symptoms occur please go to ER. She stated she understood. |
| 913768 | 12/30/2020 | KY | 45 | F | 12/30/2020 | 12/30/2020 | Approx 4-5 minutes after injection patient was seated in a chair. She slumped back in the chair and her head rolled back. Patient did appear to lose consciousness with eyes rolling back. Patient was carefully lowered to the floor to be assessed. She was given one dose of Epi-Pen at 10:53 am. The hospital's code team came to assess the patient. She was able to answer questions. When patient became alert, she reported a history of syncope with injections and had had breakfast yet. Vital signs were stable. She was taken to the ER via wheelchair for observation. |
| 914928 | 12/30/2020 | | 36 | F | 12/23/2020 | 12/23/2020 | Passed out after the vaccine, she felt better after being monitored in the area. |
| 914855 | 12/30/2020 | CA | 35 | F | 12/23/2020 | 12/24/2020 | Fatigue, fever (100.4), tachycardia, lightheaded/near syncope, muscle aches |
| 914767 | 12/30/2020 | RI | 33 | M | 12/30/2020 | 12/30/2020 | Pt within 1 minute after vaccination began to feel lightheaded. No full syncope. I personally evaluated the pt. Icepacks applied and pt given PO. BP systolic on initial eval was 105, improved to 130 within 5 minutes. Pt after 10 min obs ambulatory, feels resolution of symptoms. There was never any c/o SOB/throat tightening or tongue swelling sensation, or N/V. Pt states historically he usually becomes pre-syncope during any blood draws or vaccinations. |

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| 914575 | 12/30/2020 | | 40 | F | 12/20/2020 | 12/29/2020 | Client reports that she had a reaction to the vaccine about 1 hour after the vaccine. Stated she was working at the hospital became diaphoretic, had shortness of breath, all most passed out, had pain in her throat. Stated hospital staff started an IV gave her benadryl. Reported that her blood pressure was low and that she had rigors for a hour after. Stated she was monitored at the hospital then released home where she is doing okay at this time. |
| 914485 | 12/30/2020 | GA | 49 | F | 12/21/2020 | 12/21/2020 | HR and BP suddenly elevated 10 minutes after vaccine and I almost passed out. I was monitored for 30 minutes and released after HR and BP came down with no treatment. I felt dizzy and almost passed out 3 more times that day at home. |
| 914350 | 12/30/2020 | TN | 39 | M | 12/28/2020 | 12/29/2020 | I got the vaccine on Monday for first responders. Everything was fine besides the routine ape was in my left arm. About 1030 last night, I was standing at my fireplace and started to rub my arm where I got the vaccine. That?s the last thing I remember. My wife said as I was walking towards the bed and went completely stiff and fell backwards on our floor. She said my eyes were wide open and I wasn?t breathing. I started to come too while she was on the phone with 911. My body felt very heavy and I couldn?t really feel anything. Cotton mouth and shaking very badly. I was taken to the hospital and spent the night there. All test came back good. Today I feel really lethargic and foggy. I find it very suspicious that immediately after I rubbed my arm that I passed out. My wife thought I was dead, I didn?t know what happened. I?m in shape and workout 4-5 days a week and am very active. I feel it is important to report this adverse reaction. This has never happened before to any other vaccines. |

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| 914179 | 12/30/2020 | NY | 48 | F | 12/22/2020 | 12/22/2020 | lips were tingly and swollen; lips were tingly and swollen; fatigued; allergic reaction; passed out; breathing fast; her brain felt like a rock, like she was there but not there; head was so heavy,wouldn't open her eyes; her throat started to tighten up; chest pain; nauseous; headache; felt a little lightheaded, a little wobbly; palpitations; sweaty; This is a spontaneous report from a contactable consumer (patient) via Pfizer Sponsored Program. A 48-year-old female patient (no pregnant at the time of vaccination) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EH9899) via an unspecified route of administrationon 22Dec2020 on left shoulder at single dose for COVID-19 immunization. The patient's medical history included pernicious anemia and She had problems with B12 and Vitamin D like 10 years ago, she had none in her body, everyone said she was deficient and this year with her new primary care, they sent her to do some antibody tests, and found out she has pernicious anemia, allergy to MRI and CT contrast. MRI and CT contrast NDC, lot, expiry unknown. Her CT contrast allergy happened when she was 9 and 12 years old. It turns out to be her dad has an allergy the same way, his airways close. Whenever she needs a CT, they do without contrast, if she does need, they prep and give her Benadryl and keep an eye on her. This only happened once, that she needed with contrast, and with prep she was ok. With the MRI, this happened 4 or more years ago, maybe like 5 years ago. She needed an MRI, they said she would be fine, they injected contrast, she felt pretty hot, then she doesn't know, 20 minutes into it, she couldn't handle her gown, she looked at her chest, her whole chest was red like a burn. They gave her the IV Benadryl, she guesses, and it went away, now she knows, she doesn't know if her dad is allergic to MRI dye, but she knows she got the allergy from him for the CT contrast. The concomitant drugs was not reported. The patient was taken to ER with a severe allergic reaction. She had an allergic reaction on 22Dec2020: she passed out, said her brain felt like a rock, like she was there but not there, she then received an Epi Pen shot, when she got to the ER, her throat started to tighten up, lips were tingly and swollen, she was breathing fast, she had chest pain, she scaled it from a scale of 1-10, as about a 3 to 4 for chest pain, she felt nauseous, sweaty, and had a |

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headache. She went to bed last night, and woke up, feeling better but a little fatigued on 23Dec2020. She is wondering if she should take the second dose, and wants to be in the clinical trial for this type of reaction. She needs transfer to Regulatory Authority. Caller confirmed details. Caller states she works in a hospital, and all this happened at the hospital, and her doctor was not involved. Outcome of allergic reaction: asks what does lasting effects mean? Right now she has a little fatigue and headache, but she knows they are regular symptoms she can have with the vaccine, are those lasting effects? She was discharged from the ER to home. She mentioned to the nurse she has, she went to get the shot, she told the registration nurse, she said she has a severe allergic reaction to CT contrast, her airway closes and she has a severe reaction to MRI contrast, her skin burns, it turns red and feels like a horrible burn, she cannot handle anything to contact her skin, it burns, and she mentioned that to the nurse, she said, instead of staying 15 minutes, said to stay 30 minutes there to observe just in case. She got the vaccine, and 10 minutes after the vaccine, she felt a little lightheaded, a little wobbly, but she didn't think much, it was mild, and on the mark at 30 minutes, the nurse asked her to stand, and that is when she started feeling, like her head was so heavy, the only way to describe, was like her brain was like a rock, she had to lay down, and when they laid her down, she wasn't there, she was there but wasn't, and they didn't wait at all to give her the Epi Pen, she had a feeling of heaviness that got worse, she wouldn't open her eyes, she was able to answer questions, but it was not her there, it was weird, then she didn't have. she breathed fast, had palpitations, chest pain, so they called a Rapid Response team, they were keeping an eye on her breathing, which was super fast, and they rushed her to the ED, and the doctor did what they were doing, giving her IV of whatever medication, and she was also very nauseous, then at one point in the ED, she started feeling, like imagine if fists were on throat, pushing her throat, a little bit, and she tried to tell to the ED doctor, but guessed she was calling everyone to give her things, and didn't catch it, but it didn't last long, at the same time, she started to feel her lips tingly, so she thinks that, because they gave the Epi Pen so quickly, they wasted no time, she didn't have the airways closing like she does

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| | | | | | | | when she gets the CT contrast, they were quick. NDC/lot/expiry: She reads from the card they gave her: states first dose COVID-19 EH9899, states it doesn't specify lot, but she can find that out, they just gave her a vaccine record card. Epi Pen: NDC, lot, expiry unknown, states everything happened so quickly, she didn't think to get this information before calling, but she can get it. There at the hospital, she went to see the occupational health doctor, and based on guidelines from the CDC, he read supposedly she cannot get the second dose, but the doctor said because it is so new, and she has to wait the 3 weeks she guesses, things can change, and she wanted to be proactive. The outcome of the events, allergic reaction, passed out, throat started to tighten up, lips were tingly and swollen, chest pain, nauseous, headache, lightheaded, palpitations, sweaty was recovering. The outcome of other events was unknown. |
| 914132 | 12/30/2020 | CA | 79 | M | 12/30/2020 | 12/30/2020 | Syncope after 30 minutes from receiving the vaccine |
| 914114 | 12/30/2020 | VA | 54 | F | 12/29/2020 | 12/29/2020 | I received my first Covid vaccine 12/29/2020 around 1 PM. 14 minutes after injection I had a major dizzy spell and I almost passed out. My blood pressure was 184/101. No hx of HTN. They watched me for a while. My blood pressure/HR stayed up all evening and I felt just horrible. Did not have a good night. Bodyaches, low-grade fever, headache, nausea. A lot of pain at the injection site. I have to keep taking Tylenol every four hours in order to control symptoms. Blood pressure improving but still elevated based on my norm. I feel like my immune system is in overdrive. No airway and breathing difficulties, chest pain or shortness of breath or rash. Nausea but no vomiting or diarrhea. Drinking a lot of fluids. It was verified prior to vaccine administration that there was no contraindication receiving the vaccine with a history of having Covid. No timeline was given in between the dose and Covid recovery. |
| 915109 | 12/30/2020 | CA | 35 | F | 12/30/2020 | 12/30/2020 | Vomiting diarrhea nausea fainted shortness of breath 6 hours after vaccination and initial reaction |

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| 913849 | 12/30/2020 | MN | 20 | F | 12/29/2020 | 12/29/2020 | Administered vaccine after asking/talking about screening conditions. This was around 2 PM. Patient proceeded to observatoin area where she fainted around 2:05 PM. After talking to patient, she was afraid of needles and passed out due to "hearing" the needle enter her deltoid. |
| 914513 | 12/30/2020 | | 27 | M | 12/21/2020 | 12/21/2020 | fainted |
| 913590 | 12/30/2020 | TN | 53 | F | 12/29/2020 | 12/29/2020 | after 15 minutes patient stated she began to feel like her heart was racing and she went to stand up and stated she almost fainted. She stated she was experiencing tingling in hands and feeling of heaviness all over. BP 133/92 HR 94 O2saturation 100 resp 20. Patient placed on stretcher,no altered loc, patient alert oriented x 3 skin warm and dry,coloring remained unchanged. Patient given cheese and crackers,water and soda. Patient stated she had eaten that morning. patient kept and monitored x 1 hour. Bp retaken multiple times. Bp at D/C was 111/74 hr 86 resp 18. this was at 1330p. patient stated no complaints. Instructed to follow up with her PCP and was escorted to cafeteria to get lunch. Reported incident to Supervisor of hospital and also Health Dept. |
| 913577 | 12/30/2020 | AZ | 71 | F | 12/29/2020 | 12/29/2020 | HAD CHILLS, FELL ASLEEP GOT UP TO BRUSH TEETH HAD EXTREME NAUSEA, PASSED OUT CAME TO ON FLOOR IN COLD SWEAT. FEEL FINE TODAY |
| 913495 | 12/30/2020 | CT | 20 | F | 12/29/2020 | 12/29/2020 | Nausea, vomiting, vertigo, syncope, chills, headache, body ache |
| 913354 | 12/30/2020 | KY | 24 | F | 12/29/2020 | 12/30/2020 | Chills, nausea, vomiting, severe arm pain, malaise, fatigue, dizziness, lightheaded, and fainting . Symptoms started at midnight 12/30/20 |

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| 913332 | 12/30/2020 | NE | 30 | F | 12/17/2020 | 12/17/2020 | COVID-19 vaccine on 12/17. After waiting 15 minutes, she felt slight dizziness but thought it was a "little panic attack", as she reports being nervous prior to vaccination. She was on the elevator with a nurse when the dizziness increased, she became sweaty and nearly passed out. The nurse assisted, but she felt ok by the time they reached their floor. She drove home and couldn't do anything but lay on the floor because the dizziness had increased and her right arm was swelling and hives on lips. She called Employee Health, but didn't get an answer (after office hours) so she called the house supervisor, who told her to take Tylenol and benadryl. She didn't take benadryl for fear of becoming more fatigued and she wouldn't be able to get help. She had a sore throat and slight SOB. She reports 100.1 fever for a short time and didn't feel well x 36 hours, general malaise, dizziness, swelling in rt arm and hand so bad that she couldn't bend her fingers. She didn't seek medical treatment or evaluation other than calling the house supervisor. hx of: Raynaud's and cold induced urticaria, but denies hx of allergic reactions to anything including vaccines or medications. Denies any current medications. EE was advised to see PCP for evaluation and do not receive 2nd dose. |
| 913328 | 12/30/2020 | NC | 27 | F | 12/29/2020 | 12/29/2020 | About 12 hours after receiving the vaccine, I developed chills and had a near vasovagal syncope event. I also developed cervical lymphadenopathy, nausea, and felt lightheaded. Because I felt so lightheaded I needed to leave work. The chills, nausea, and lightheadedness lasted for at least 10 hours. |
| 913249 | 12/30/2020 | NY | 35 | M | 12/22/2020 | 12/22/2020 | 30 seconds following IM injection, felt warm, flushed, lightheaded, vision dimming., near syncope. Symptoms improved lying supine. Blood pressure measured to be 90's systolic, Heart Rate 60's. NO RASH, NO ANGIOEDEMA, NO Shortness of breath. Symptoms resolved completely within in 3 minutes. |

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| 913246 | 12/30/2020 | OK | 27 | M | 12/28/2020 | 12/29/2020 | On Dec 28th I received the shot & initially didn't feel anything. When I woke up on the morning of Dec 29th I had a really bad headache, felt burning up & cold at the same time. My right arm (shot arm) and my left hip were super soar. I couldn't keep liquids down. I passed out the first time between 6:55 A.M. & 7:05 A.M. Later that morning I passed out a second time for 2 mins. I still plan to get the second dose on Jan 25th 2021. Since I'm a contact tracer I texted my supervisor. I was advised to take the day off & report it just in case it was related to the vaccine. |
| 913243 | 12/30/2020 | IL | 27 | F | 12/29/2020 | 12/29/2020 | Syncope, severe bradycardia followed by 20+ hours of chills, fatigue, weakness, body aches |
| 913162 | 12/30/2020 | AZ | | F | | | near syncope episode, orthostatic; feels a little foggy; This is a spontaneous report from a contactable Physician. A 38-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), via an unspecified route of administration on unspecified date in 2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The emergency medicine physician was monitoring a patient that came in from a vaccination event, stated that it was Pfizer BioNTech Covid 19 vaccine. The patient had a near syncopal episode. They did orthostatics (unspecified) and found that she was orthostatic (near syncope episode, orthostatic). There was no anaphylaxis reaction or allergic reaction. She still felt a little foggy. The physician did a blood glucose, labwork and EKG that look good. The physician wanted to know if there was any data for things that they should looking for with the vaccination and will direct the patient to contact Pfizer to report it. The outcome of the events was unknown. Information on the lot/batch number has been requested. |

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| 913895 | 12/30/2020 | WA | | F | 12/21/2020 | 12/21/2020 | patient got up and woke up on the floor; She never passed out. She got out of her chair, turned off the light and woke; Turned off the light and woke w a bruise to my right cheek; swelling to the right side of my head; This is a spontaneous report from a contactable emergency room nurse (patient). A elderly female patient (also reported as age: 61; unit: unknown) received the first single dose of BNT162B2 (Lot number: EI0249, exp date not reported), intramuscular (vaccine location: Left arm) on 21Dec2020 at 06:15 AM for immunization. Medical history included hypertension (HTN). The patient had no known allergies. Concomitant medication included meloxicam (MOBIC), levothyroxine sodium (SYNTHROID), lisinopril, and metoprolol tartrate (LOPRESSOR). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 21Dec2020 at 08:45 AM the patient got up and woke up on the floor. She never passed out. She got out of her chair, turned off the light and woke with a bruise on her right cheek and swelling to the right side of her head. She was a bit freaked out just worked "another 12" with no side effects. No treatment was received for the adverse events. The events were considered as non-serious by the reporter. The patient did not receive prior Covid vaccination and was not tested for Covid post vaccination. The patient recovered from the events on an unspecified date in Dec2020. |
| 914380 | 12/30/2020 | ME | 33 | M | 12/30/2020 | 12/30/2020 | Lightheadedness and near syncope that lasted about 6 seconds |
| 912946 | 12/29/2020 | VA | 42 | F | 12/29/2020 | 12/29/2020 | After administration of vaccine at 1:00 pm, I looked up and saw patient had fainted in chair, that time was maybe around 1:01 pm. When I rushed over to her, she regained consciousness, noticed she was not able to speak well, nurses removed her mask and we noticed her lips were swollen and was having an anaphylactic reaction, I then administered one dose of Epi-pen at 1:04 pm and called 911. We took her BP but it was high due to the Epi-pen injection, we tested her blood sugar. When the EMT arrived, they took over and took her to the ER. |
| 912112 | 12/29/2020 | MI | 58 | F | 12/23/2020 | 12/23/2020 | Near Syncope, dizziness |

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| 911899 | 12/29/2020 | CA | 27 | F | 12/24/2020 | 12/24/2020 | <p>Pt came in for vaccination for COVID-19 at 4:03 . She received Moderna vaccine at 4:15. She experienced palpitation, worsening chills, headache, and presyncope. No loss of consciousness. Denies chest pain, shortness of breath but feels heavy to push air in and pulse OX 100%, No angioedema, No rash, No pruritus, No throat swelling, denies hoarse voice, or difficulty breathing. She traveled to MD on 12/14/20 to receive antibiotics. She was treated with Erythromycin dose for 6 days from MD.</p> <p>The patient was +COVID19 on 12/11/20 with fever, scratchy throat, congestion, cough, and SOB and was seen in urgent care on 12/13/20 where was DX + for COVID19. She was quarantine for 10 days when she was returned to work on 12/22/20. Her Chest X-ray was negative on 12/13/20. She was negative for nausea, vomiting, diarrhea. She denies any recent vaginal bleeding, or abdominal pain. Denies any history of cardiac disease, or history of arrhythmias. Denies any history of prolonged immobility, or history of clots.</p> |
| 912027 | 12/29/2020 | VA | 20 | F | 12/22/2020 | 12/22/2020 | Increased heart rate and blood pressure, syncope, nausea, sore throat, fever |

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| 912061 | 12/29/2020 | FL | 39 | M | 12/22/2020 | 12/23/2020 | chills all night and syncope; chills all night and syncope; This is a spontaneous report from a contactable other health professional (patient). A 39-year-old male patient received the first dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number and Expiration Date: Unknown), intramuscularly in the left arm (also reported as the right arm) on 22Dec2020 at 15:00 at 39-years-old at a single dose for COVID-19 immunization. The facility where the most recent COVID-19 vaccine was administered was reported as: other. Medical history included Penicillin allergy from an unknown date and unknown if ongoing. Concomitant medications included estrogens conjugated (PREMARIN), progesterone (MANUFACTURER UNKNOWN), estradiol (MANUFACTURER UNKNOWN), montelukast (MANUFACTURER UNKNOWN); all taken for an unspecified indication from an unspecified date to an unspecified date (all of which were received within two weeks of vaccination). The patient did not receive any other vaccines within four weeks prior to the COVID vaccine. On 23Dec2020 at 00:00, the patient experienced: chills all night and syncope. The event syncope was considered medically significant; and the event chills was non-serious. There was no treatment received due to the adverse events. It was reported that prior to vaccination, the patient was not diagnosed with COVID-19; and since the vaccination, the patient had not been tested for COVID-19. The clinical outcome of the events, chills all night and syncope, was recovering. The batch/lot numbers for the vaccine, bnt162b2, were not provided and will be requested during follow up.; Sender's Comments: Based on temporal association, a possible contributory role of suspect BNT162B2 vaccine cannot be excluded for reported event syncope. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate. |
| 912081 | 12/29/2020 | MI | 47 | F | 12/22/2020 | 12/22/2020 | Near Syncope |

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| 913071 | 12/29/2020 | | 45 | F | 12/29/2020 | 12/29/2020 | patient had an episode of syncope/seizure, certainly not clear that is related to the vaccine, admitted for further work-up |
| 913036 | 12/29/2020 | CT | 27 | F | 12/21/2020 | 12/23/2020 | The night of vaccination 12/21 - burning thighs, hot to touch. 12/23 - felt fine most of the day. At around 2 PM, my left hand began to tingle which increased to full body tingling/pre syncope feeling. HR increased to 155. Went to the ER and was treated with fluids. Remained tachycardic around 100 with increasing HR when sitting up/walking. |
| 911766 | 12/29/2020 | OR | 33 | F | 12/28/2020 | 12/28/2020 | called to observation area 10:50 - report that patient passed out, was on stretcher, reported did not fall, 'came to' in less than 1 minute. 108/68, P 70 and strong, alert and oriented. states feels anxious about flu shots. felt lightheaded, hot, sweaty, skin pale and warm. at 1052 rapid response arrived. states feeling better, had had food/fluids today. assessed that not allergic response - vaso/vagal. 1055 sat up and feeling good, skin pink. 1100 to chair. 1115 left area walking. |
| 913023 | 12/29/2020 | CA | 54 | F | 12/28/2020 | 12/28/2020 | physician/patient with history of anaphylaxis to shellfish - symptoms of tingling tongue & syncope. no longer carries epi pen sue to ability to avoid food. 10 minutes post vaccination pt/physician experienced tongue tingling similar to prior anaphylactic events. administered 25 mg. Benadryl po. no further issue, vital signs stable throughout & later in evening. |
| 911715 | 12/29/2020 | NY | 56 | M | 12/28/2020 | 12/28/2020 | I am Health Care worker (Security Officer) at Hospital. On 12/28/2020 around 9am I received my Covid Vaccine (1st) After the shot, I sat the required 15 minutes and felt no ill effects Around 5:30 pm. I was out shopping after work and almost passed out. It was not a gradual feeling - It felt more like someone had punched me in the head. I was too dizzy to walk for 30 seconds or so. After about 5 minutes I felt okay and drove home. I feel absolutely fine today (12/29/2020) |

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| 912930 | 12/29/2020 | MN | 29 | F | 12/29/2020 | 12/29/2020 | Patient was monitored for >15 minutes after vaccination. Patient told a nurse that her knees felt weak. Patient then fainted and was laying on the floor when i arrived. Patient reported she felt like she was "floating" and she did not want to "fall". She was also nausea and wanted to vomit and did not end up vomiting anything up. Patient fainted several more times. Her BP was around 143/80 and unsure about the pulse. Patient then become unresponsive for 20-30 seconds. |
| 912875 | 12/29/2020 | HI | 47 | F | 12/28/2020 | 12/28/2020 | Difficulty breathing sweats then passed out |
| 912803 | 12/29/2020 | NM | 21 | F | 12/14/2020 | 12/14/2020 | So that night throughout I felt feverish around 100.9 the highest was 101F. I would break though and then 1-2 hours later again it would come back. Body chest, couldn't move my arm, the pain was severe. Tuesday I could not even sit down I felt so weak, I had rashes in my face, legs, chest. I was so weak, I fainted and hit my head twice while going to the bathroom and kitchen. I felt like I was constipated, ant then I had diarrhea, I did not have appetite but could not hold anything in, I would throw up. My left side was all numb. I could not feel anything. It was like that the while Tuesday. Wednesday body aches, rashes, numbness, but I had a little bit of a body strength and could walk on my own. Thursday I was able to start eating a little bit and constipation were stating to go way. Friday was just body aches. Sunday the rashes finally went away. |
| 912715 | 12/29/2020 | CA | 46 | F | 12/23/2020 | 12/23/2020 | Near syncope, palpitations, tachycardia, elevated blood pressure |
| 912704 | 12/29/2020 | CA | 26 | F | 12/26/2020 | 12/26/2020 | Pt stated feelings of "fullness of back of throat, palpitations". Patient did not inform of previous vaccine reactions at time of administration when asked (had serious reactions at the time without stating exact symptoms). Sent to ED for observation. ED Note: She denies angioedema/ swelling, stridor, drooling, wheezing, hoarseness, SOB, tongue swelling. No rash or flushing. Denies dizziness or syncope. No itching. No covid symptoms. Meds given: NS 1L, diphenhydramine 25mg IVP, methylprednisolone 125mg IVP |

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| 912165 | 12/29/2020 | CA | 36 | F | 12/28/2020 | 12/28/2020 | <p>She arrive at 3:43 and she was nervous before the vaccination for COVID19 (Morena) because has had anaphylactic reactions to Flonase. She was feeling well up to 15 min post vaccination when she felt she is going to pass out w/o loosing consciousness. She felt weak and feeling fainted when we transferred her to the stretcher. Her BP was 163/106 P=112, Pulse Ox 100% at 16:09. She was resting, received O2 lit per min, she was feeling chest tightness when she used her inhaler Albuterol 2 puffs X2 within 5 min. She was feeling weak and stating "I am going to pass out." Her repeat BP=152/110, P=94 with pulse Ox 100% at 16:12 repeat at 16:30 BP=139/100, P=99 pulse OX 100% She then C/O chills later. Paramedics were called and transferred in to ED. She takes AMLODIPINE 5 MG DAILY FOR HTN. She has family HX of HTN. Negative for headache, + palpitations, + presyncope, + shortness of breath, slight difficulty brathing. She did not experience any loss of consciousness. Never had any chest pain, angioedema, rash, pruritus, throat swelling, hoarse voice. The patient has had no recent illnesses, fevers, chills, nausea, vomiting, diarrhea, or flu-like illnesses. She has had no cough, rhinorrhea, or congestion. She denies any recent vaginal bleeding, or abdominal pain. Denies any history of cardiac disease, or history of arrhythmias. Denies any history of prolonged immobility, recent travels, or history of clots. In ED: 36 year old female presents with dizziness and presyncopal like symptoms approximately 15 minutes after receiving the Medina vaccine at this hospital the patient who is mildly tachycardic mildly hypertensive but otherwise normal and stable vital signs and is overall nontoxic appearing. Of note the patient's oxygen saturation was 97% while I was in the room and not the 2% that is documented here. EKG notable for a rate of 87 normal axis normal sinus rhythm T-wave inversion in V1 otherwise no evidence of Brugada interval abnormality or evidence of electrolyte abnormality that would require further workup at this time. Patient counseled to follow up with her primary care. Patient given EpiPen given her EpiPen has expired. Patient requested to go back to work I feel this is fair given patient will be on campus and can return to the emergency department should she develop any further symptoms. Patient states her symptoms have completely resolved and she has normal vital signs</p> |

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| 912138 | 12/29/2020 | CA | 32 | F | 12/28/2020 | 12/28/2020 | currently heart rate in the 80s blood pressure 138 systolic feeling well and requesting to be discharged. She arrived at 12:30 and was vaccinated shortly after while waiting 15 for observation within the 1st 10 min she C/O tingling of her throat and lower lips, felt palpitation. No chills, No headache, + palpitations, and No presyncope. Tells me that she did not experience any loss of consciousness. Never had any chest pain, shortness of breath, or angioedema, rash, pruritus, throat swelling, hoarse voice, or difficulty breathing. The patient has had no recent illnesses, fevers, chills, nausea, vomiting, diarrhea, or flu-like illnesses. She has had no cough, rhinorrhea, or congestion. She denies any recent vaginal bleeding, or abdominal pain. Denies any history of cardiac disease, or history of arrhythmias. Denies any history of prolonged immobility, recent travels, or history of clots. In ED:32 year old female with PMHx as listed in HPI presents with concern for allergic reaction to mod chair and a COVID-19 vaccine, felt tingling in the back of her throat and lower lip, no swelling, wheezing, shortness of breath, throat tightening, rash, nausea vomit or dizziness. Vitals reviewed found to be within normal limit. Physical exam as per above, no signs of mucosal or oral swelling, no hives or rash and no wheezing on exam. Given above findings, low suspicion for allergic reaction this time but plan to observe patient in the ED for any delayed reaction. |
| 912113 | 12/29/2020 | MI | 58 | F | 12/23/2020 | 12/23/2020 | Near Syncope, dizziness |
| 913031 | 12/29/2020 | PA | 40 | M | 12/26/2020 | 12/26/2020 | 7 minutes after getting vaccine I had a sudden onset of rapid heart beat and near syncope. The rapid heart rate continued and I was seen at urgent care who then told me to report to the ER. Symptoms continued through today 12/29/20. |
| 911625 | 12/29/2020 | NY | 32 | F | 12/26/2020 | 12/26/2020 | I had tingling/swelling in tongue and body itching for 30 minutes post vaccine, then felt light headed/dizzy and almost passed out. Then about 8 hours later I noticed my arm was swollen, hard, red, puffy and hot at injection site. It continued to get worse the next day. I was extremely tired and felt " like I was hit by a truck " for almost 2 days later. Pain in arm continued for a couple days later. |

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| 911696 | 12/29/2020 | MO | 41 | F | 12/22/2020 | 12/25/2020 | Urticaria on day 2 after receiving vaccine. No other symptoms: no wheezing, no facial swelling, no syncope, no headache. Resolved with one dose of Benadryl. |
| 911837 | 12/29/2020 | SD | 30 | F | 12/28/2020 | 12/28/2020 | Dizzy/lightheaded at 8pm 12/28, nauseous. 12/29 6:30am dizzy, lightheaded, fainted in shower |
| 909989 | 12/28/2020 | FL | 32 | F | 12/22/2020 | 12/24/2020 | Dizzy, nauseous, headache, body aches, fatigue, black tary stools., diaphoretic, near syncope |
| 910629 | 12/28/2020 | OH | 26 | F | 12/27/2020 | 12/27/2020 | Patient evaluated and monitored following vaccine. Developed nausea and lightheadedness approximately 20 minutes after dose given. Patient reports that she hadn't had anything to eat or much to drink in the hours leading up to vaccine as she and her husband were going to get lunch after the vaccination appointment. Patient has a history of syncope/presyncope after a blood draw in the past. Patient had no other stx other than very transient nausea and lightheadedness, which improved significantly in the hour that she was monitored. BP at time of discharge from clinic was 105/73; pulse 67 |
| 910636 | 12/28/2020 | | | U | | | Nurse that fainted after the vaccine; This is a spontaneous report from a Pfizer sponsored program received from a non-contactable consumer. A patient of unspecified age and gender received BNT162B2 Pfizer-BioNTech COVID-19 Vaccine, via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that the patient was a nurse who received the vaccine and did a live press conference on TV 15 minutes later and, as a result, she fainted. The event outcome was not reported. No follow-up attempts are possible; information about lot/batch number cannot be obtained. |

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| 910713 | 12/28/2020 | OK | 38 | F | 12/21/2020 | 12/21/2020 | 12/21 SITTING IN CHAIR, FELT TINGLING IN EAR, 'FEELING FAINT'. MOVED TO CHAIR AGAINST THE WALL, TOLD MEDICAL STAFF. FAINTED, SWEATING PROFUSELY, 'WANTED TO GO TO SLEEP'. MONITORED HR, BP. VOMITED. BP WAS STILL ELEVATED 136/100. 'FELT BETTER' AFTER VOMITING, COLOR CAME BACK, 'CAME TO'. ER: BASAL EVENT ABOUT TO DISCHARGE, TINGLING CAME BACK. NOTHING ON MONITOR INDICATED ANY PROBLEMS. EVENTUALLY DISCHARGED AS SYMPTOMS DECREASED. DIAGNOSED; SYNCOPE |
| 910823 | 12/28/2020 | ME | 61 | F | 12/28/2020 | 12/28/2020 | Recipient received her vaccine and was sitting for observation when she reported feeling light headed about 5 min after the administration. 30 seconds after recipient became unresponsive and stopped breathing for 15 seconds, legs were elevated Code blue was called, after about another 30 seconds recipient become aroused and coherent. Vitals were taken- pt. was tachycardic- 120s- came down to 80s, BP 120/80, 90% O2-eventually went up to 98%. Temp 97.3. Med cue was called and took over to evaluate Pt. Pt. did report has had hx of vasovagal syncope. |
| 910844 | 12/28/2020 | CO | 44 | F | 12/22/2020 | 12/23/2020 | Headache, lightheaded, nausea, dizziness, muscle aches, malaise, and chest "squeezing" prior to syncopal episodes x 3. This occurred in OR where she works. "I don't know when I passed out." Rapid Response called s/p sternal rub by MD not effective. Taken to ED via stretcher. In ED, had EKG, IV fluids, Benadryl, and Phenergan. Regained consciousness on arrival to ED. Cleared to return to work on 12/24 by MD in ED. Will follow up with PCP. |
| 911071 | 12/28/2020 | WA | 37 | F | 12/28/2020 | 12/28/2020 | Fainted within a couple minutes of receiving injection. Rapid response team activated and I was lifted onto a bed. Very low blood pressure. And ultimately felt better after 30 to 45 minutes of monitoring by medical team. |
| 910966 | 12/28/2020 | MN | 27 | M | 12/21/2020 | 12/21/2020 | Patient had a vaso vagal event, per the ED notes. Drop in blood pressure and had a fainting spell. Quickly improved after he arrived to the ED |

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| 911035 | 12/28/2020 | AL | 47 | F | 12/22/2020 | 12/22/2020 | Approximately 7 hours after receiving the vaccine patient who is a L&D Nurse return to work in her area. She describes that after finishing with a C-section she felt burning in both of her eyes (she thought this feels like an allergic reaction, but I am not sweating and haven't rubbed my eyes). She went to the restroom to get a cloth to wash her eyes; afterwards she reports her vision went totally black in both eyes. She reports feeling frustrated that no one came to help and some panic in trying to figure out how to get out of the restroom. She did make it out of the bathroom. Her Staff reports she postured and turned arms inward, head going to one side and passed out. They also report ~ 10 minutes of incoherent conversation and stating "I got the vaccine, maybe I was given the wrong thing and now I'm blind". Upon waking, patient vision fully restored and patient does not remember incoherent conversation. Differential diagnosis- TIA vs. CVA > seizure disorder>>> complex migraine |
| 911028 | 12/28/2020 | CA | 53 | F | 12/28/2020 | 12/28/2020 | Became dizzy, warm, tachycardic. Lost consciousness (fainted?), quickly regained consciousness and was taken to the Emergency Department. Before transfer, Benadryl IM 25mg administered. |
| 910998 | 12/28/2020 | NY | 28 | F | 12/28/2020 | 12/28/2020 | Vasovagal syncope episode occurred right after receiving the Pfizer COVID-19 vaccine injection, patient became pallor, not diaphoretic, no c/o CP nor SOB, patient felt dizzy, HR in the 50's, BP 78/50, glucose = 91, pt given water and OJ. After fluids pulse was stronger, bounding in the 60's, color improved, patient was still feeling faint, taken to cardiac intervention area to lay down, patient refused to go to ER, RRT paged and came to pod - escorted patient to lay down. Of note the patient only had 1 egg for breakfast. Patient continued to be pale, starting shaking and was escorted to the ED for IV fluids and monitoring. |
| 910383 | 12/28/2020 | MT | 42 | F | 12/23/2020 | 12/24/2020 | Moderna COVID-19 Vaccine Nausea/Vomiting/Diarrhea upon awakening on 12/24. Lightheaded, near-syncope, diaphoretic. Lasted approximately 3 hours. Vomited then nausea subsided after about 1hr. Chills starting 12/26. Difficulty warming up after being outside in the cold. Prolonged effects that are not normal for me. 12/28 cold/clammy hands despite being in warm environment. |

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| 910309 | 12/28/2020 | | | F | 12/17/2020 | 12/17/2020 | fainted right after taking the vaccine; This is a spontaneous report from a non-contactable consumer (Pfizer company representative). A female patient of an unspecified age received the bnt162b2 (BNT162B2; also reported as COVID-19 vaccine; Batch/lot number, NDC number, Expiry Date: Unknown), via an unspecified route of administration on 17Dec2020 at a single dose for COVID-19 immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient experienced fainted right after taking the vaccine (medically significant) on 17Dec2020. It was unknown if the patient received other products, and any investigation assessment was unknown. The clinical course was reported as follows: The reporter stated they had seen quite a bit on social media and on the (site name), where people have been sending around a video regarding a healthcare worker who fainted. The caller was just wondering " if Pfizer has been made aware of this. "Apparently, this was on the news. This healthcare worker was taking the COVID-19 vaccine and as she was talking to the press, she apparently fainted. It looks as if she fainted as one would do when taking blood tests or faint from fear of a shot or being worried. However, this video has been sent all over social media, as seen as an AE, and telling people to not take the vaccine." The reporter further clarified the healthcare worker was in (city name) and received the COVID-19 vaccine. As the healthcare worker was talking to the press, she fainted right after taking the vaccine. The reporter further clarified she was sent a link via (site name) from the news channel where it had the video recording. The reporter did not have a specific reporter. The reporter explained it was a " whole group that was talking about it." The reporter clarified she was in a (state name) group on (site name) with friends and family. The reporter also saw it on social media. " People are sending it left and right." When probed to determine if the reporter had any patient details or further details regarding the event, the caller stated the only information she had was that on (News name), and click on (City name) news and find the video of the healthcare worker taking the vaccine and fainting. The reporter clarified the news article was dated as 17Dec2020 "so this event must have happened yesterday." From the reporter's understanding from the news, the patient was fine, she |

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| 909917 | 12/28/2020 | PA | 32 | F | 12/19/2020 | 12/19/2020 | got up. "However, people are sending out on social media that she is dead", which the reporter did not think was the outcome. According to the news, when the reporter opened the link, it was just a regular fainting, it was not a death. The reporter felt obligated to report and make sure Pfizer was aware of this since she had been seeing it everywhere on social media. The clinical outcome of the event, fainted right after taking the vaccine, was unknown. No follow-up attempts are possible; information about batch/lot number cannot be obtained. |
| 909917 | 12/28/2020 | PA | 32 | F | 12/19/2020 | 12/19/2020 | Patient reports developing a mild headache post vaccination within 15minutes that progressed in severity with nausea, dizziness and fainting. Occupational Health is following up with patient and recommending comprehensive provider evaluation |
| 909909 | 12/28/2020 | MS | 64 | F | 12/22/2020 | 12/23/2020 | 12/23/2020 0200 Severe Tremors and Chills. Nausea, dizziness, & near syncope. Headache. 0700 Softball size lump(edema), 6"x6" area erythema, hot to touch, and pain at injection site. Difficulty raising arm due to pain. Fatigue. 12/25/2020 0100 Awakened hot and sweating which lasted approximately 6 hours, fatigue. Arm issues continued. 12/26-27/2020 Arm slowly improving but fatigued and headache continued. 12/28/2020-Improved but headache continues. |

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| 910237 | 12/28/2020 | | 23 | M | 12/21/2020 | 12/21/2020 | 23 y.o. male who arrived by to the emergency department for suspected allergic reaction. Patient received his Covid vaccine 3 hours prior to ED arrival. Initially he was asymptomatic however, as the morning progressed, he developed a redness around the injection site. He then noticed a rash all over his face, that was mildly itchy in nature and felt warm. He denies any associated wheezing, shortness of breath, facial swelling, throat swelling, severe abdominal pain, vomiting, lightheadedness, dizziness, or syncope. He has not taken anything for his symptoms, and they continue to worsen. He has no prior history of allergic reaction to vaccines or other known allergies in the past. He states this is mildly itchy in nature. Patient was given 50 mg of p.o. Benadryl and Pepcid for symptomatic control. He was observed in the ED for 2 hours without any progression of his symptoms, no associated facial swelling, wheezing, shortness of breath, abdominal pain, vomiting, or hypotension to suggest anaphylactic reaction. He was discharged home in stable condition |
| 910062 | 12/28/2020 | IN | 28 | F | 12/28/2020 | 12/28/2020 | Diaphoresis, syncope, and hypotension. |

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| 910547 | 12/28/2020 | MO | 45 | M | 12/24/2020 | 12/26/2020 | I'm not sure this is entirely vaccine related, but I wanted you to be aware. I occasionally experience unexplained swelling of my lips. It has been investigated by an allergist, but the cause is unknown -- doesn't appear to be a food allergy (no trigger foods identified, and it has never appeared immediately after eating), and may not even be histamine related. It could be something immune-system related, and my experience this weekend might support that. I had normal, expected symptoms on Friday evening (chills, headache). Those resolved Saturday. Saturday night, my lower lip swelled dramatically. Swelling spread into the upper lip as well. I have seen this before, but this was one of the more severe instances I have experienced. Lips remained swollen overnight. When I woke up Sunday morning and went to the restroom, I became suddenly lightheaded and passed out. That's a symptom I have never experienced before. I consulted with my primary care doctor and took it very easy the rest of Sunday. He and I will follow up to further asses what happened. No further light-headedness on Sunday or today. Lips eventually resolved late in the afternoon. This is all about 72 hours after the vaccine, so I can't be sure it is related, but I do wonder if it is related to having my immune system revved up by the vaccine. I reported it on the CDC check-in app and my primary care physician is noting it on his side as well. |

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| 910367 | 12/28/2020 | MN | 38 | F | 12/21/2020 | 12/21/2020 | I got vaccine tonight ~1750. I felt fine immediately after and stayed for the recommended 15 minutes. During my drive home, ~20 minutes, I had some expiratory wheezing and a sensation of something in my throat. No angioedema or swelling. No skin symptoms. This was mild but made me think twice so I drove back to the er. The wheezing resolved, but I felt like I was going to faint with hot flushing and nausea in the parking lot. I didn?t go in because things seemed better and my stomach was turning like I was going to have diarrhea. Since the wheezing was gone, I decided against going in. I stayed in the parking lot for ~ 15 minutes and feeling of unease and presyncope waxed and waned, but eased. I continued with some nausea. I had waves of nausea, chills, flushing, and presyncope. The wheezing didn?t return. No tachycardia. I had chills and nausea on the drive home and at home. Took Tylenol and Pepcid when I got home and feel absolutely fine now after ~2 hours of fluctuating nausea, chills and sense of unease/anxiety. None were as severe as they were when I was in the parking lot. Throughout, I didn?t have high or low heart rate. After 8 pm or so, I feel just fine. I have zero symptoms now. |
| 909563 | 12/27/2020 | FL | 20 | F | 12/26/2020 | 12/26/2020 | Chest pain followed by Syncope approximately 5 minutes after injection. |
| 909691 | 12/27/2020 | FL | 20 | F | 12/26/2020 | 12/26/2020 | Shortness of breath, chest pain, itching, near syncope, blood pressure spike |
| 909635 | 12/27/2020 | MD | 46 | M | 12/21/2020 | 12/22/2020 | Palpitations, shortness of breath, chest tightness, presyncope, which led to New onset atrial fibrillation with rapid ventricular response and required synchronized cardioversion and hospitalization. Discharged on anticoagulation and beta-blocker. |
| 909590 | 12/27/2020 | CO | 55 | F | 12/23/2020 | 12/24/2020 | Had the expected side effects of arm pain, body aches, headache and chills beginning several hours after vaccination. The morning after the vaccination, I felt like I would be okay to go to work, so got up to take a shower. Felt very lightheaded in the shower and fainted. Fell to the floor outside the shower, hitting my head on the tile floor. Was later able to proceed with going to work. No other ill effects or treatment. |

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| 909791 | 12/27/2020 | CA | | F | 12/27/2020 | 12/27/2020 | syncope, anxiety, nausea, vomiting, diarrhea, perceived tongue swelling although no visible swelling |
| 909511 | 12/27/2020 | AR | 66 | F | 12/1/2020 | 12/27/2020 | Dizziness, syncope, nausea, fatigue |
| 909523 | 12/27/2020 | NJ | 24 | F | 12/26/2020 | 12/26/2020 | Passed out twice - at 5pm on 12/26 & 8:30am on 12/27 |
| 909350 | 12/26/2020 | CT | 30 | F | 12/22/2020 | 12/24/2020 | Dizziness, syncope, nausea, feeling of going to faint. |
| 909311 | 12/26/2020 | CA | 38 | F | 12/22/2020 | 12/22/2020 | Day off sensation going up my left arm to my head Headache dizzy lightheadedness and nausea almost fainting. Bp 115/70 hr 80. Tylenol helped with headache but head still felt heavy. 1st day Chills and extreme fatigue 2nd day fatigue nausea 3rd day fatigue nausea severe headache ?exploding? after getting up from picking up toys off the grown blood pressure 90/60 . |
| 909379 | 12/26/2020 | PA | 28 | F | 12/23/2020 | 12/23/2020 | near syncope, hypotension, nausea/vomiting, tachycardia (120-150) within 5 minutes of administration. did not resolve and worsened within 1 hour. Pt went to ER for workups. Received IV benadryl without improvement. Admitted to hospital overnight for continuous cardiac monitoring. Improved overnight and discharged in the afternoon 12/24/20. |
| 909419 | 12/26/2020 | OR | 37 | F | 12/22/2020 | 12/25/2020 | 57 hours after vaccine, I woke up with stomach cramps, diarrhea, chills/sweats feeling awful and soon after had a sudden syncopal event while walking back from the bathroom. I recovered, laid in bed and then within 15-20 minutes had diarrhea again so went to the bathroom and had another syncopal episode on the toilet (both witnessed by my husband) with diarrhea during this episode. I then went to the ER and was treated with 3L IV fluids for hypotension, IV zofran and bentyl. I left the ER within about 3 hours. still have been fatigued but was up most of that night. my body all hurts but I fell into my bedframe face first during the first syncope so would relate that to those symptoms/injuries. |
| 909433 | 12/26/2020 | NY | 27 | F | 12/26/2020 | 12/26/2020 | Pt began feeling flushed, tremulous, c/o weird sensation in throat. developed rash. Had near syncope. 1-2hrs of symptoms. |

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| 909457 | 12/26/2020 | OH | 39 | M | 12/24/2020 | 12/24/2020 | Day 1/2 - Headache, Pain at injection site/slight arm sweeping, tiredness Day 2 - nausea, tiredness, dizziness, shortness of breath, feeling hot/flushed, fainted (led to a 911 call / ED visit) |
| 909136 | 12/25/2020 | IL | 38 | M | 12/21/2020 | 12/22/2020 | more than usual bowel movements and body tingling all over at random. Body tingling would occur more during strenuous movements and would occur with presyncope sensations without having a syncope episode |
| 909165 | 12/25/2020 | TN | 35 | F | 12/21/2020 | 12/21/2020 | At the time of the injection sharp pain across my back , then at about 5 mins after feelings of light headedness, progressing pain across my back, trouble feeling like I could get enough air in with breathing and dizziness and I tried to get to the floor to sit or lay down but passed out. Then the next event I recall was a sharp pain in my thigh(apparently administered Eli pen) . I regained consciousness and was gasping andl was told I had been given a shot of epi. |
| 908696 | 12/24/2020 | NY | 41 | F | 12/24/2020 | 12/24/2020 | Experienced syncope after receiving vaccine injection. Clinical Assessment Team called but declined going to emergency department. |
| 908625 | 12/24/2020 | CO | 43 | F | 12/21/2020 | 12/21/2020 | Pt received vaccination and immediately afterwards syncope. Pt recalls receiving the inoculation and becoming acutely lightheaded before losing consciousness. No preceding SOB or palpitations noted. |
| 908668 | 12/24/2020 | CA | 30 | F | 12/22/2020 | 12/23/2020 | Chills, myalgia, fever, syncope and vomiting |
| 908761 | 12/24/2020 | CA | 36 | F | 12/22/2020 | 12/22/2020 | On 12/22:First noticed roof of mouth started to itch, back of throat itching, difficult to swallow, noticed hives on chest/torso, difficult breathing, wanted to vomit, close to fainting. Hives around injection site. Placed on gurney and sent to ER. In ER given epi-pen injection, benadryl injection, albuterol, pepcid, toradol, solu-medrol and observed for 4 to 5 hours. On 12/23: Hives still present, injection site has two large bruises on arm; arm in swollen down to elbow. Broke out in hives on chest and face. Re-evaluated in ER. |
| 908877 | 12/24/2020 | NJ | 25 | M | 12/24/2020 | 12/24/2020 | He was fine ate lunch, in a room with a patient, felt light headed and dizziness, passed out, he became unresponsive, he was hypotensive, he is now in the ER. |

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| 908909 | 12/24/2020 | CA | 45 | M | 12/16/2020 | 12/16/2020 | The first 5 mins felt dizzy like small fainting I started relaxed. I went home took shower I had a mild fever took Tylenol. The next day some headache and weakness. On day 2 mildness and weakness again. Then on day 3 fever and weakness was almost gone and headache is sill there. |
| 908942 | 12/24/2020 | MI | 31 | F | 12/24/2020 | 12/24/2020 | Felt a rush in my arm 5 minutes after. Then one hour following the injection I started getting dizzy and vertigo. Driving home I felt like something was very wrong like impending doom. My heart started racing almost pounding out of my chest. I was extremely dizzy and almost fainted. Flushed feeling and tightness in my chest followed. Flushed feeling felt all day. Also had a rash on my neck and chest. |
| 908958 | 12/24/2020 | AZ | 46 | M | 12/23/2020 | 12/23/2020 | Vasovagal syncopal episode, fainted within 10 minutes of vaccine, rapid returned to baseline after episode |
| 909946 | 12/24/2020 | TN | 43 | F | 12/23/2020 | 12/23/2020 | pt received a COVID vaccine of moderna and within 15 minutes pt c/o throat feeling itchy and tight down low. Also, c/o of tingling in fingers and toes. Pt noticeably shaking. Pt has a hx of fainting with needles. Pt become more anxious and requested ambulance to be called. Color was flushed. B/P 169/99 P146 SPO2 99%. For pts comfort gave O2 at 2L/min via NC. Pt remained alert and oriented and talking. EMT administered Benadryl 50mg IM. Ambulance escorted pt to ER where only observation was done. F/U with pt about 2 hours later. Pt states she believes she panicked and was doing fine right now. No other issues. |

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| 908626 | 12/24/2020 | KS | 58 | F | 12/21/2020 | 12/21/2020 | <p>Progress Notes PA-C (Physician Assistant) ? ? Orthopedics Cosigned by: MD at 12/22/2020 9:46 AM Expand All Collapse All 12/21/2020 Patient: Date: 12/21/2020</p> <p>Subjective Patient is a 58 y.o. female who was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. She denied any history of previous adverse reactions to vaccines. She was given the Pfizer vaccination in the left deltoid muscle. During her 15 minute waiting period after the injection, the patient began to experience dizziness/shakiness. This provider was notified of patient reaction and she was then transferred to the emergency bay via wheelchair where she was assessed. Monitored patient for severe reaction symptoms, including rapid progression of symptoms, respiratory distress with dyspnea, increased work of breathing, persistent cough and cyanosis, vomiting, hypotension, dysrhythmia, chest pain and collapse. She denied difficulty breathing, throat tightness and tongue swelling, nausea. She reports a history of atrial fibrillation and states that she had a procedure in the past and the anesthesia provider questioned her about this diagnosis. She reports taking metoprolol and methimazole on a daily basis. She took all of her am medications today, including an 81 mg aspirin. Reports history of watery eyes and blurred vision, takes Zyrtec daily. Denies any worsening of these symptoms outside of her baseline. Denies use of anticoagulant use or diabetes. Last ate and drank about 1130 or noon. Review of Systems Constitutional: Negative for diaphoresis. HENT: Negative for congestion, drooling, facial swelling, rhinorrhea, sneezing and trouble swallowing. Eyes: Positive for discharge. Negative for redness. Respiratory: Negative for chest tightness and shortness of breath. Cardiovascular: Negative for chest pain and palpitations. Gastrointestinal: Negative for nausea and vomiting. Skin: Negative for color change, pallor and rash. Neurological: Positive for dizziness and headaches. Negative for syncope. Psychiatric/Behavioral: Negative for agitation and confusion. The patient is not nervous/anxious. Objective Vitals There were no vitals filed for this visit. Physical Exam</p> |

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Constitutional: General: She is not in acute distress.
Appearance: Normal appearance. She is obese. She is not toxic-appearing or diaphoretic. HENT: Head: Normocephalic and atraumatic. Nose: No rhinorrhea.
Eyes: Comments: Watering of both eyes
Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Comments: At right radial pulse
Pulmonary: Effort: Pulmonary effort is normal. No respiratory distress. Skin: General: Skin is warm and dry. Coloration: Skin is not pale. Findings: No rash.
Neurological: Mental Status: She is alert and oriented to person, place, and time. Assessment/Plan Stress reaction following vaccine administration. Patient was transported to the emergency bay via wheelchair.
Treatment included no therapy, but did continue with vital checks at approximately 5 minute intervals. 1603-blood pressure using the large adult cuff was 154/60 with large adult cuff, heart rate 69 with regular rate and rhythm at right radial pulse, 96% O2 sat on room air. Patient continues to feel slightly dizzy and shaky though denies any chest pain, shortness of breath, swelling of the lips or tongue. 1611 vital signs reassessed with blood pressure of 150/63, heart rate 64, 97 percent on room air, continues to feel slightly dizzy/shaky, though, reports not nearly as bad. Patient continues to answer questions appropriately and is talking without any signs of further decompensation. 1618-reports feeling better. Vital signs rechecked with BP of 121/55, 59 hearty rate and 96% RA. No new complaints. 1624- patient reports a slight headache, but denies chest pain, shortness of breath, chest tightness, lip or tongue swelling. Discharge vitals obtained at 1626-with blood pressure of 135/55, heart rate of 58, 95% on RA. No new complaints, except feeling a bit cold. Patient reports feeling better and feels that she can safely discharge. Discussed need for urgent evaluation at the emergency department or to call 911 if symptoms of chest pain, shortness of breath, angioedema present. Patient expresses understanding and all questions were answered to her satisfaction today. Follow up response to treatment:excellent.
Patient discharge: Stable to go home and follow up with PCP. Orders Placed This Encounter Procedures ? COVID-19 MRNA PA-C Electronically Signed
12/21/2020 4:05 PM

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| 908077 | 12/23/2020 | CA | 64 | F | 12/17/2020 | 12/18/2020 | site soreness and residual headache at base of skull x3 days On 12/18 at 12 noon, I found myself passed out in my office at work laying over my keyboard. My assistant had me on-hold at that time and estimated I was out for 1 minute. Was loopy the entire next day. Just hydrated and rested. Felt great by Monday |
| 907185 | 12/23/2020 | PA | 25 | F | 12/22/2020 | 12/22/2020 | 40 minutes later, I became flushed, hot, sweaty and clammy and tachycardic along with a syncope episode. Nausea came after, and only treatment was fluids. This episode happened after discharge around 9:45pm and then returned to the hospital for the same course of action. |
| 907390 | 12/23/2020 | | 64 | F | 12/22/2020 | 12/22/2020 | 64y/o FEMALE presents to the ED for evaluation of facial itching after COVID vaccine in left arm. The patient states shortly after the vaccine (about 10 minutes) her nose and mouth started itching. She was given PO Pepcid and IM Benadryl PTA in ED. She denies any associated SOB, nausea vomiting wheezes or near syncope. Denies fever/chills, n/v/d or other complaints at this time. IMPRESSION/PROBLEM LIST:-----1. Adverse Reaction to Vaccine for COVID |

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| 907426 | 12/23/2020 | NM | 48 | F | 12/22/2020 | 12/22/2020 | 48 y.o female with history of atrial tachycardia who presents to the ED via EMS for a possible adverse reaction to Covid vaccine. Patient received her Covid vaccine around 1600 today, and soon became diaphoretic, shaky, and lightheaded. She had presented to the emergency department. Currently she denies any chest pain, difficulty breathing, throat swelling, tongue swelling, or any other symptoms currently except for palpitations. Allergic Reaction The primary symptoms are shortness of breath. The primary symptoms do not include cough, abdominal pain, vomiting, dizziness or rash. The current episode started 1 to 2 hours ago. The problem has not changed since onset. The onset of the reaction was associated with a new medication. Significant symptoms also include flushing. 48-year-old female with a history of atrial septal defect, status post atrial septal defect repair in 1980. She works as a nurse at Hospital and has been experiencing increasing rapid palpitations associated with chest pain, and hypertension. With her episodes, she experiences marked lightheadedness, dyspnea, and feeling marked anxiety, as well as chest tightness. She received the COVID-19 vaccine today and while waiting in the observation room, she started feeling unwell, with rapid palpitations, associated with lightheadedness and dyspnea. She last had a sustained episode 2 - 3 weeks ago and had presented to ER and Hospital. No syncope. No orthopnea, PND or increased lower extremity swelling. Active Hospital Problems Diagnosis ? Atrial paroxysmal tachycardia ? History of repair of atrial septal defect 1. Paroxysmal atrial tachycardia in setting of prior atrial septal defect repair - she is having breakthrough episodes through flecainide/digoxin - it is likely her atrial tachycardia is related to her ASD patch. Will hold flecainide/digoxin for now, and try to schedule an ablation during her hospital admission due to highly symptomatic episodes resulting in multiple ER visits. 2. Acute renal insufficiency - most likely pre-renal - iv fluids started. 3. Possible COVID-19 vaccine reaction - she probably had an incidental atrial tachycardia episode post vaccine administration, rather than an actual adverse reaction. Continue to monitor. |

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| 907789 | 12/23/2020 | FL | 52 | F | 12/23/2020 | 12/23/2020 | Patient received vaccine and entered waiting queue. Within 10 minutes, pt requested help from pharmacy vaccination team because she felt severely dizzy. Patient ended up passing out in seated position. Systolic blood pressure dropped to ~80. Patient normalized 5-10 minutes after syncope. Blood pressure normalized. Patient escorted out in stretcher. |
| 907818 | 12/23/2020 | CA | 31 | F | 12/22/2020 | 12/22/2020 | Within 15 minutes after the vaccine patient started to have tachycardia, dizziness, and light headedness with syncope episode. She was taken to the ER where she improved. No further syncope episodes and released. |
| 907915 | 12/23/2020 | MA | 65 | M | 12/22/2020 | 12/22/2020 | Right after patient was given vaccine injection he started to feel lightheaded and woozy. He had just worked the night shift and hadn't eaten anything. No prior illness reported. Patient brought to emergency department to be evaluated. Received 500ml of fluids and symptoms resolved and he went home. Diagnosis of near syncope. |
| 908072 | 12/23/2020 | AK | 28 | M | 12/23/2020 | 12/23/2020 | 5 minutes after administration of vaccine, patient states he does not feel well. He was sitting and passed out. |

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| 908096 | 12/23/2020 | AK | 41 | M | 12/21/2020 | 12/22/2020 | <p> WAS HAVING MYALGIAS AND MILD FEVER STARTING ABOUT 12 HOURS AFTER VACCINE, BUT AT 2 AM, I WOKE UP TO URINATE, FELT SOME DIZZINESS. AT THE END OF VOIDING I COULD TELL I COULDN'T THINK RIGHT AND HAD TROUBLE FLUSHING. TRIED TO WALK BACK TO BED AND HAD A SYNCOPE AS I GRABBED THE DOOR HANDLE. STUMBLED DOWN SLOWLY AND LOSS CONSCIOUSNESS FOR A SHORT WHILE, SECONDS. LAYED IN THE FLOOR FOR A BIT AND WHEN I STOOD UP AGAIN AND WALKED TO MY ROOM HAD ANOTHER SYNCOPE. WOKE UP AFTER SEVERAL SECONDS AND WAS NOT CONFUSED AND DIDN'T REMEMBER THE SECOND TIME I FELL BUT COULD UNDERSTAND I HAD PASSED OUT. MY WIFE SAYS I HAD MY EYES OPEN AND WAS STIFF BUT NO TONIC CLONIC MOVEMENTS. AFTER THE EVENTS I WAS ABLE TO GET BACK IN BED AND AFTER A LITTLE WHILE TESTED FOR ORTHOSTASIS. WHEN I STOOD UP I STARTED FEELING THE LIGHT HEADEDNESS AGAIN AND PRODROME TO FAINTING AND LAYED BACK DOWN. HR 60, MY BASELINE IS 50-60. HAD A FEVER OF 100.7. I TOOK 650 MG OF TYLENOL AND WENT BACK TO BED. I DIDN'T SLEEP WELL BUT NOW (THE FOLLOWING MORNING) I AM FEELING BACK TO NORMAL MINUS SOME MILD SOARNESS. I HAD A RAPID COVID PCR TODAY THAT IS NEGATIVE. NO OTHER LABS. I HAD NEVER FAINTED BEFORE THIS EPISODE. I DID NOT HAVE ANY TRAUMA FROM SYNCOPE. </p> |

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| 907944 | 12/23/2020 | KS | 34 | F | 12/22/2020 | 12/22/2020 | <p>Progress Notes PA-C (Physician Assistant) ? ? Orthopedics Cosigned by: MD at 12/22/2020 9:48 AM Patient: Date: 12/21/2020</p> <p>Subjective Patient is a 34 y.o. female who was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. She was given the Pfizer vaccination in the right deltoid muscle. During her 15 minute waiting period after the injection, the patient began to experience generalized feelings of "not feeling quite right" as well as anxiety/nervousness, nausea and chills. She denied difficulty breathing, throat tightness, dizziness, chest pain, or other GI complaints. This provider noticed her raising her hand from across the waiting area and tended to her where she noted the above complaints. she was then assessed in the emergency bay area. She was monitored for severe reaction symptoms, including rapid progression of symptoms, vomiting, hypotension, chest pain, collapse and Respiratory distress. Past medical history includes anxiety for which she takes Effexor on a daily basis as well as type 2 diabetes, diagnosed approximately seven or 8 years ago during a pregnancy. She is on oral medication during the day and insulin at nighttime. She did take her oral medication today and last ate a pasta lunch right before arriving to the vaccine clinic. Last A1c was 6.5. Patient states that she generally runs a postprandial blood glucose following a heavy meal of about 180. She reported a previous history of anxiety and nervousness following vaccinations in the past. Most recently, she experienced a 30-minute period of anxiety and nervousness following her flu vaccine this past October. These feelings passed without further incidents. Review of Systems Constitutional: Positive for chills. HENT: Negative for drooling, facial swelling, hearing loss, rhinorrhea, sneezing and trouble swallowing. Eyes: Negative for redness and visual disturbance. Respiratory: Negative for cough, chest tightness and shortness of breath. Cardiovascular: Negative for chest pain. Gastrointestinal: Positive for nausea. Negative for vomiting. Skin: Negative for color change, pallor and rash. Neurological: Negative for dizziness, speech difficulty and light-headedness. Psychiatric/Behavioral: Negative for agitation and confusion. The patient is nervous/anxious.</p> |

Objective She ambulates into the emergency treatment bay under her own power and without difficulty. She is seated on the gurney, and continues to answer questions appropriately. Physical Exam Constitutional: General: She is not in acute distress. Appearance: Normal appearance. She is not toxic-appearing or diaphoretic. HENT: Head: Normocephalic and atraumatic. Nose: No rhinorrhea. Cardiovascular: Rate and Rhythm: Regular rhythm. Tachycardia present. Pulmonary: Effort: Pulmonary effort is normal. No respiratory distress. Skin: General: Skin is warm and dry. Coloration: Skin is not pale. Findings: No rash. Neurological: Mental Status: She is alert. Gait: Gait normal. Psychiatric: Mood and Affect: Mood normal. Behavior: Behavior normal.

Assessment/Plan Stress reaction secondary to vaccine administration and history of anxiety and nervousness following vaccinations. Vital signs obtained at 1352 with blood pressure at 154/95, mild tachycardia at 109 and 97% O2 saturation on room air. Patient denies any chest pain, shortness of breath time. She is given a bottle of water and assisted to lie down with the head of the bed slightly elevated. She continues conversating appropriately without any acute distress. Vitals reassessed at 1359 with blood pressure of 133/76, heart rate 97% on room air. Dr. at the bedside now. Suggested obtaining a blood glucose. Blood glucose obtained at 1405, elevated at 234. She continues to deny any chest pain, shortness of breath, chest tightness, swelling in the throat, nausea/vomiting or other GI complaints. Vital signs checked again at 1406 with blood pressure 133/77, heart rate 107 and 97% on room air. Vital signs last checked at 1415 to reveal a blood glucose of 219, blood pressure 127/82, heart rate 100 and O2 saturation of 97% on room air. Patient has no additional complaints at this time and reports feeling well. Her mother has driven her to the clinic today. She felt that she was able to safely walk out with any issues. She was assisted by nursing staff and ambulated out of the treatment bay independently. Treatment included routine surveillance of vital signs at about a 5-minute intervals following notification of her feeling poorly. Vital signs continued to normalize and remained stable through the duration of her 30 minutes following her vaccination. Follow up response to treatment: excellent.

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| | | | | | | | Patient discharge: Stable to go home and follow up with PCP. Recommend to patient that she present to the ED or call 911 should she develop any symptoms up to and including but not limited to chest pain, shortness of breath, chest tightness, signs or symptoms of angioedema, or syncope. She expresses understanding the above and has no further questions today. Orders Placed This Encounter Procedures COVID-19 MRNA PA-C Electronically Signed 12/21/2020 1:51 PM |
| 906272 | 12/22/2020 | CO | 19 | F | 12/21/2020 | 12/21/2020 | 19 y/o fully immunized female with history of anxiety presents for dizziness and nausea x 2 hours. Received COVID vaccine at 14:30. At 16:30 went from sitting to standing, felt dizzy and nauseous. No syncope. No palpitations. Similar reaction to influenza vaccine. No intervention required to previous vaccination. No history of anaphylaxis. BP 125/88, pulse 88, RR 18, O2 95%, temp 37.3. |
| 906778 | 12/22/2020 | AK | 79 | F | 12/21/2020 | 12/21/2020 | Hypotension and syncope without tachycardia, 15 minutes after injection. Patient was repositioned supine, which caused her to regain consciousness. Give 1 liter NS over 2 hours and discharged in good condition. |
| 906228 | 12/22/2020 | FL | | F | 12/20/2020 | 12/19/2020 | fever/chill, extreme fatigue, body aches, headache, near syncope, nausea |
| 906541 | 12/22/2020 | NY | 35 | F | 12/22/2020 | 12/22/2020 | From patient interview: The patient stated feeling dizzy with lightheadedness and seeing spots. She felt like she was going to pass out. She was transported to our emergency department for examination. When I spoke with her she was resting and felt she had returned to baseline. From medical record:Patient Stated Complaint SYNCOPE, Narrative of Presenting Problem Patient is a 35-year-old female with history of vasovagal episodes during her prior pregnancy was in the hospital getting a Covid vaccination and became weak dizzy and sweaty and had a syncopal episode while in a chair. Patient did not hit her head. Upon evaluation patient is awake alert lying supine with no complaints. Patient states she has been suffering with Covid related anxiety and depression. |

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| 906822 | 12/22/2020 | WI | 41 | F | 12/18/2020 | 12/19/2020 | I received the Covid 19 vaccination at 3:00 pm on 12/18 no trouble went home. Upon going to sleep the left arm was numb thought and got up to use the bathroom had diarrhea. While in the restroom hit face had a Syncope episode regain conscience went to ER had 4 stitches in chin. Since 12/20 felt fine and was able to return to work. |
| 906827 | 12/22/2020 | AR | 32 | F | 12/21/2020 | 12/21/2020 | 45 minutes after vaccination felt faint, palpitations, nausea and tremor in hands followed by syncope, after awoke had ongoing muscle spasm/tremor in legs. Taken to ED and labs, IVF, CXR. Observed x 90 minutes and discharged- returned to work as scrub tech in OR. Left early, no further issues that day. Next am on arising had <30 seconds of postural imbalance which resolved spontaneously and no other symptoms since. |
| 906833 | 12/22/2020 | MN | 25 | F | 12/22/2020 | 12/22/2020 | Employee received vaccine and had no signs of adverse reaction after vaccination. Employee went to eat something and fainted. Shortly after employee had an emesis as well. Felt fine afterward and vitals were within normal limits. |
| 906887 | 12/22/2020 | NY | 51 | F | 12/21/2020 | 12/21/2020 | Pfizer-BioNTech COVID-19 Vaccine EUA: Systemic: Anaphylaxis, Fainting |
| 906950 | 12/22/2020 | AZ | 57 | F | 12/21/2020 | 12/22/2020 | Severe headache chills, body aches, arm pain, Nausea, fainted on standing, dizziness |
| 907037 | 12/22/2020 | NY | 31 | M | 12/16/2020 | 12/18/2020 | After injection had L arm pain, the following day (12/17) pain continued . 12/18 onset of fever max temp 38, chills, fatigue, muscle pain and nausea. Treated with Tylenol for symptom relief. Symptoms continue and worsened 12/19 and 12/20. 12/20 underwent video clinician visit for symptoms and inability to return to work for continued symptoms 4 days after vaccination, last day of fever. 12/21 covid and flu swab negative symptoms all continued fatigue very evident going to and from swab exam. 12/22 morning near syncope while getting ready for day, tachycardia, underwent ED eval was given fluids and labs drawn and discharged home with improvement in tachycardia and lightheaded/dizziness with fluids, another covid swab was negative along with negative RVP. Continued to have fatigue 12/22 evening. |

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| 906495 | 12/22/2020 | CA | 51 | M | 12/19/2020 | 12/19/2020 | 11 minutes into the vaccination, patient noted to have tongue and mouth tingling and heart racing. No noted tongue/lip/throat swelling, dyspnea, n/v, abdominal pain, rash, near-syncope. Started to improve after 30 seconds.. H/o tachycardia secondary to salmon, no prior anaphylaxis or use of epinephrine in the past. Sent to ED for evaluation |
| 905551 | 12/21/2020 | CO | 40 | M | 12/18/2020 | 12/18/2020 | Pfizer-BioNTech COVID-19 Vaccine EUA: Allergic reaction after receiving a COVID shot. Pt reports a rush of dizziness, diaphoretic, nausea, and near syncope. Pt appears pale but alert and oriented upon arrival. Patient was given IM epi, IV Solu-Medrol, Benadryl, and Pepcid, placed on a cardiac monitor. He was given 1 L of normal saline. Patient observed here in the ED for almost 8 hours. He has been persistently tachycardic; Admitted as inpt. for observation. Discharged from inpt status on 12.18.2020 @ 2152. |
| 905767 | 12/21/2020 | TN | 52 | F | 12/18/2020 | 12/18/2020 | approx. 10 min after injection felt light headed, flushed, and pre syncope. BP and HR were taken by staff and ER physician,, BP was hypertensive for me 145/90, 145/104, 137/89, 138/86, 132/91. I am normally 116/74. HR was 100. Oxygen was 100%, At 12:33 was given 50mg IM x 1 Benadryl. 12:40 felt loopy and shakey. 12:54 moved to room in PACU and monitored by nurse. BP remained in the 130-140's until appox 1430 BP returned to normal 118/80 and Benedryl had worn off. My co-worker took me home. |

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| 905999 | 12/21/2020 | NC | 49 | F | 12/20/2020 | 12/20/2020 | Employed as a nurse at this hospital. Around 8 PM she received her COVID-19 vaccine. She waited the 15 minutes she was required to wait and then walked to her car. She reports that as she walked to her car she had a pain in her left shoulder which was short-lived but followed by numbness and tingling of her left arm and the left side of her face going up the back of her head. Symptoms started around 8:20pm. She reported back to the clinic to report the symptoms--she lives along and wanted to be assessed before going home. In the clinic, she was assessed by myself. Employee noted that she had not eaten. She ate in the clinic and had something to drink. While in the clinic over the next 10-15 minutes, she noted that she had some numbness and tingling in her feet and calves bilaterally. No leg pain or swelling. Around 9pm, the clinic was closing and she could no longer be monitored under observation. She opted to go to the ER for observation. Per ER note-- She denies any headache. She denies any left-sided weakness. Patient is right-handed. She also reports some mild chest heaviness that lasted for about 20 minutes and then resolved. No shortness of breath. No dizziness, syncope or presyncope. No nausea or vomiting. No rash. No visual or speech changes. No ataxia. Patient continues to have the left-sided numbness and tingling but states that it is less intense than it was. She denies any other complaints. Follow up this AM-- Pt is only fatigued and has some muscle soreness where she had the vaccination. All of her symptoms have resolved and she is not having any further sx's of chest tightness or numbness |
| 905996 | 12/21/2020 | TN | 51 | F | 12/18/2020 | 12/18/2020 | ~1 h 15 min after receiving experienced flushing, dizziness, near-fainting, arrhythmia, progressed rapidly to a rapid heart rate, elevated BP, hives, cool extremities, diaphoretic treatment: NS 1 liter, Benadryl 50 mg IV, Solumedrol 125 mg/ml discharged after 6 h with Rx for Epi Pen experienced dizziness/near-fainting episodes off/on for 3 days, slight headache, chest tightness, green/bloody nasal discharge for 2 days |

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| 905959 | 12/21/2020 | CA | 37 | M | 12/19/2020 | 12/19/2020 | 4 hours after vaccination, patient reports feeling shortness of breath, palpitations, lightheaded, shivering, and almost fainted. Symptoms lasted 30 mins and resolved but returned. He called 911 and went to Hoag hospital. Patient was seen and released but symptoms reoccurred after he got home so he went again. He was administered diphenhydramine 50mg IVP at 12/19, 2136; famotidine 20mg IVP at 12/19, 2136, lorazepam 0.5mg IVP at 12/19 2136 and started on lactated ringers 1000ml bolus at 12/19, 2138. He was discharged on 12/19 after symptoms resolved. |
| 906041 | 12/21/2020 | AZ | 25 | M | 12/18/2020 | 12/18/2020 | Employee, 1st Pfizer COVID19 vaccine today. ~6min s/p shot, he felt a little itchy just @injection site, then got anxious & felt woozy, sweaty. Wearing big mask and a face shield, seemed anxious. Walked independently to go lay down. No syncope. BP up to 140/90, HR 90, RR 20, breathing fine, no itchy throat/swelling/hives. Improved w laying down. To ER out of an abundance of caution-- vitals nL, nL exam, still itchy at shot site. Got 1L NS IV, 25mg PO Benadryl for itchiness- likely anxiety > severe allergy |
| 905423 | 12/21/2020 | IN | 34 | F | 12/17/2020 | 12/20/2020 | On 12/20 at 9am started having left sided facial numbness, tingling, flushing. Near syncope episode (tachycardia, diaphoretic, blurred vision) around 1130am. Took Benadryl seemed to help. On 12/21- around 7a near syncope episode, tachycardia, diaphoretic, facial flushing, itching. Took Benadryl-improvement in facial itching, decreased heart rate. |
| 905165 | 12/21/2020 | TX | 24 | F | 12/21/2020 | 12/21/2020 | Clammy, flush, dizziness, syncope, tachycardia |
| 904605 | 12/21/2020 | | 30 | M | 12/17/2020 | 12/17/2020 | syncope following vaccine |

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| 905463 | 12/21/2020 | CO | 42 | F | 12/17/2020 | 12/17/2020 | Pfizer-BioNTech COVID 19 Vaccine 42 y.o. female had just received her vaccine when she became very lightheaded, was placed on a stretcher and brought to ED further evaluation. Patient has hx of rheumatoid arthritis. Stated that she has not eaten since earlier this morning, did have some nausea vomiting earlier that is now resolved, feels that it was related to "an adrenaline rush just prior to her vaccination. Upon arrival to ED she is denying any headache, fever, sweats, chills, cough, shortness of breath, angioedema, chest pain, palpitations, vomiting, edema, claudication, urticarial. Diagnosed with near syncope. |

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905805 12/21/2020 KS

33 F

12/21/2020

12/21/2020

Date:
12/21/2020

Subjective Patient is a 33 y.o. female who was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. She denied any history of previous adverse reactions to vaccines. She was given the Pfizer vaccination in the left deltoid muscle. During her 15 minute waiting period after the injection, the patient began to experience feelings of hypoglycemia. She checked her blood glucose with her own monitor and had 77 at 1104. She chewed 1 glucose tab that she had in her purse. She noted some difficulty with swallowing it and notified clinic staff. Associated dizziness and was escorted by clinic staff to the emergency bay. This provider was notified of patient reaction and she was then assessed in the emergency bay area. She denied difficulty breathing and chest pain, history of adverse reactions with prior vaccinations or allergies to medications with the exception of spironolactone. Patient had already been given a bottle of water by clinic staff and reported that the glucose tablet went down easier following the water. She took a second glucose tab sometime before 1113. She rechecked her sugar and had slight increase of 79. She did eat breakfast this morning about 0800 and had a protein bar right before her arrival today. Monitored patient for severe reaction symptoms, including rapid progression of symptoms, respiratory distress with dyspnea and increased work of breathing, vomiting, abdominal pain, hypotension and chest pain. Review of Systems HENT: Positive for trouble swallowing. Negative for facial swelling, hearing loss, rhinorrhea and voice change. Eyes: Negative for redness. Respiratory: Negative for cough, chest tightness and shortness of breath. Cardiovascular: Negative for chest pain. Skin: Negative for color change, pallor and rash. Neurological: Positive for dizziness. Negative for syncope and speech difficulty. Psychiatric/Behavioral: Negative for agitation and confusion. The patient is not nervous/anxious. Objective Vitals There were no vitals filed for this visit. Physical Exam Constitutional: General: She is not in acute distress. HENT: Head: Normocephalic and atraumatic. Nose: No rhinorrhea. Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Pulmonary: Effort: Pulmonary effort is normal. No

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respiratory distress. Skin: General: Skin is warm and dry. Coloration: Skin is not pale. Findings: No rash. Neurological: Motor: No weakness. Psychiatric: Mood and Affect: Mood normal. Behavior: Behavior normal. Assessment/Plan Patient is a 33-year-old female who has a 15-year history of type 2 diabetes, and experienced a hypoglycemic event without complaint of chest pain or shortness of breath. Vital signs obtained at 1105 with blood pressure within normal limits at 132/88, heart rate 83 and 98% O2 saturation on room air. Patient continued to compensate appropriately and reported feeling slightly better. Glucose checks repeated by patient at 1117 was 84, vital signs were blood pressure 116/80, heart rate 89, O2 saturation of 98% on room air. She continues to deny chest pain, shortness of breath or difficulty swallowing at this time. At 1117 a 10 mg cetirizine was administered by mouth. Patient was able to swallow this with a small sip of water without any difficulty. 1121, patient continues to deny chest pain or shortness of breath. She continues to be compensating appropriately and sitting at the edge of the bed. She states that she is feeling better. Vital signs obtained at 1123 with blood glucose per the patient's own meter, continuing to elevate at 103, blood pressure within normal limits at 116/91, heart rate at 85 and 100% O2 saturation on room air. At 1126, the patient continues to feel better. She is provided a granola bar to eat. She does note feeling sleepy though attributes this to this being the first day she has had off after working 4 days last week. She notes that she has been sleepy even prior to her arrival at the vaccine clinic today. She is able to eat the granola bar and continues conversing appropriately without difficulty. She continues taking small sips of water without issues. Continues to deny chest pain or shortness of breath. Blood sugar is rechecked at 1138 and continues to elevate to 116. She reports that her meter says her sugar is "stable." Final set of vital signs obtained at 1138 revealed blood glucose within normal limits at 116, blood pressure of 119/84, heart rate 83 and 100% O2 sats on room air. Patient denied complaints of chest pain, shortness of air, nausea, dizziness or blurred vision at this time. She felt much improved and we discussed her leaving the clinic and heading home to have lunch. She had no further complaints. She was able to rise to standing on her own

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| 904385 | 12/20/2020 | TX | 83 | F | 12/16/2020 | 12/16/2020 | without any further issues and ambulated out of the clinic without difficulty. She was advised with strict return precautions should she develop chest pain or shortness of breath to present to the ED or call 911. She expressed understanding of this. LPN, RN, PharmD present through this encounter and assisted as asked of the, by this provider. Follow up response to treatment:excellent. Patient discharge: Stable to go home and follow up with PCP. Orders Placed This Encounter Procedures ? COVID-19 MRNA LNP-S PF PA-C Electronically Signed 12/21/2020 11:17 AM |
| | | | | | | | Patient is a pleasant 83 y.o. female pediatrician with history of Sjogren's, hypothyroidism, hyperlipidemia, hypertension who had been at Hospital to get her Covid vaccine. 30 minutes after doing so she reports being in the lobby and about to walk upstairs and feeling fine. The next thing she knows she wakes up on the stairs with her nose and face bleeding surrounded by healthcare team. She denies any precipitating symptoms such as chest pain, shortness of breath, fevers dizziness, headache. She reports feeling well otherwise in the last few days. I did a thorough bony palpation exam including spine and he only point of tenderness besides on her face was the area above her right ankle. She does not have a history of syncope or collapse |

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| 904585 | 12/20/2020 | AK | 39 | F | 12/19/2020 | 12/19/2020 | About 3-5 min after injection I felt tingling and warmth/flushing in my entire left arm and anterior chest, upper back and achy pain in my left upper trap- felt like a warm IV running through my arm. Associated with tongue tingling. Symptoms lasted about 10 minutes with the exception of the achy upper trap pain which lasted a couple hours - being a health care provider I associated these symptoms with anxiety/excitement about receiving the vaccine but subsequently developed other unexpected symptoms. Over the course of the next several hours noted metallic taste and transient extremity tingling (all extremities) also with some extremity and facial itching - no rash. Now >24 hours after still have the intermittent and transient extremity tingling (most notable in LE's and feet, but also in arms) and skin itchiness/prickly sensation though improved. Had one episode this afternoon (~28 hours after vaccine) of lightheaded, nausea, chills and profound sensation of extremities being "heavy" - felt like pre-syncope - which resolved in about 30 min with rest, hydration . |

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| 904534 | 12/20/2020 | MA | 29 | F | 12/18/2020 | 12/18/2020 | About two to three minutes after the Covid vaccine was administered in the vaccine clinic at my hospital where I work, I began to experience pre-syncopal symptoms (mostly light-headedness and nausea). I stood up to get help and walked to the back of the auditorium where they were observing us for 15 minutes post-vaccine, and due to standing and walking, I became much more dizzy and lightheaded and then sat down on the floor and was eased to a lying-down position on the floor by a nurse as I briefly lost consciousness. I regained consciousness very quickly (maybe 10-20 seconds, but I'm not sure) and was taken care of by a set of nurses who noted me to be hypotensive and pale, with I think a bit of a lower heart rate, though I'm not sure what my vitals were exactly. They had me then stand to do orthostatic vitals and I was orthostatic. I was too dizzy to remain standing and felt very nauseas so I was taken to the ED (in the hospital where I work) to be observed. I had a normal EKG, blood glucose, and urine sample there. After having some juice and lying down, I felt better but was very cold and had some chills. After a little over an hour, they released me from the ED and it seems to have all been an episode of vaso-vagal syncope. I've had vaso-vagal responses before, but not in response to a vaccine since I was about 13, so I was surprised by how quick and severe the vaso vagal response was. Later in the day, I felt better but was fatigued and had a headache. I also had a lot of pain at the injection site. The day after the vaccine I felt tired and had a headache, and for part of the day a mild sore throat. Now two days after the vaccine, I feel much better, and the arm pain is more mild. |
| 904489 | 12/20/2020 | MO | 52 | F | 12/18/2020 | 12/18/2020 | Sudden onset of fainting sensation . Followed by dizziness moderate shortness of breath lightheaded ness panic tingling in hands feet top of head headache distress. |

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| 904215 | 12/19/2020 | | 33 | F | 12/19/2020 | 12/19/2020 | brief lightheadedness Pt arrived at observation area at 1500. Was informed she has a history of allergies in teh past so instructed patient to wait or 30 minutes in observation area. Around 1505, pt stated she was feeling lightheaded, near syncope. Advised pt to lay on ground. Vitals taken - BP 140s/90s, with HR 118, pulse ox 100%. After 5 min, pt stated she was feeling better while laying down. At 1515, vitals retaken with BP 120s/80s HR 90s. At 1520, pt sat up from floor still feeling better. At 1525 pt sat in chair feeling better and at 1530 pt stated feeling no side effects. |
| 904082 | 12/19/2020 | IL | 36 | F | 12/18/2020 | 12/18/2020 | was in waiting area and about 10 min after vaccine said she got tachycardiac and checked her heart rate on the apple watch and it was 140. She felt tunnel vision also did not alert staff in waiting area as did not want to call attention to herself. Symptoms subsided after 1-2 minutes. said she would have passed out if she stood up at the time. Went back to work and told coworker. Vaccine clinic staff called her this am and she is fine- no further symptoms. |
| 904040 | 12/19/2020 | CO | 41 | M | 12/17/2020 | 12/18/2020 | I had no adverse events immediately after the vaccine was given. I waited 15 minutes at the facility after the administration, and I went to sleep that evening without any issues. Approximately 5 hours after administration I woke up to use the restroom. I then had 3 syncopal events in succession (I have never had syncope or a vaccine reaction in the past). I have remained lightheaded for 24 hours after the syncopal events. However I did not have fevers, myalgias, or other adverse events other than fatigue and arm pain. I took my vitals throughout the next day. Hr 65-75, BP 120/70, afebrile, SpO2 98%. |
| 903407 | 12/18/2020 | MA | 29 | F | 12/18/2020 | 12/18/2020 | Patient with a h/o syncope to vaccines, felt light headed and laid down on floor roughly 3-5 minutes after vaccination in the observation area. Patient pale, pulse regular in mid-60's, A&O x3, conversant. Medical assistance team called, bp 94/60, lightheaded after attempt at standing for 90 seconds. Transported to ED for observation. |

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| 903876 | 12/18/2020 | IA | 32 | F | 12/18/2020 | 12/18/2020 | Within half hour of receiving COVID vaccine, patient developed headache, then began feeling lightheaded and began pale. Attempted to lay down, upon standing felt lightheaded and noted some numbness around her lips, arms, and legs. Symptoms include faintness, near syncope, and numbness. After about 10-15 minutes of not feeling well, patient was escorted to the Emergency Room. Patient received fluids and was discharged home. Patient reports at 5pm that she continues to have slight headache and arm soreness with no further near syncopal episodes. |
| 903863 | 12/18/2020 | | 30 | F | 12/18/2020 | 12/18/2020 | Pt complaint: "heart racing, hot flash, feeling like fainting if I stand up" approx. 10 mins post 16:30 vaccine admin. RN & another RN checked pt's vitals & BS. 16:45- BP 130/105, HR 160, O2 100%. 16:48- BP 148/93, HR 96, O2 98%. 17:00- BP 123/86, HR 68, O2 100%. 17:20- BP 122/86, HR 97, O2 92%. BS 83 @17:15. Pt received H2O, ice pack & elevated feet on chair. Pt noted symptom resolution & MD evaluated & walked pt back to work site. |
| 903510 | 12/18/2020 | CO | 24 | F | 12/16/2020 | 12/17/2020 | PATIENT FAINTED AT WORK THE DAY FOLLOWING HER VACCINE. BLOOD SUGAR AND VITALS WE'RE CHECKED FOLLOWING THE FAINTING SPELL AND WERE IN NORMAL RANGE. SHE WAS PASSED OUT FOR "A FEW MINUTES" PER WITNESSES AND WRITTEN REPORT. SHE SLEPT WELL THE NIGHT BEFORE. SHE WAS UNINJURED AS A COWORKER CAUGHT HER. AFTER HER VITALS WE'RE CHECKED SHE FELT WELL AND RETURNED TO WORK AND WORKED THE ENTIRE REST OF HER SHIFT WITHOUT INCEIDENT OR COMPLAINT. |
| 903338 | 12/18/2020 | VA | 30 | F | 12/17/2020 | 12/17/2020 | 5-10 minutes after vaccination, vasovagal syncope: pallor, diaphoresis, dizziness, tunnel vision, nausea, weakness, tingling in arms/legs, BP 103/69 |
| 903827 | 12/18/2020 | IL | 49 | F | 12/17/2020 | 12/17/2020 | Head felt like she was swimming, headache, heaviness in chest, lump in throat, BP spiked then dropped, Fainted - was given benadryl by mouth and Solumedrol IM |

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| 902746 | 12/16/2020 | FL | 37 | F | 12/15/2020 | 12/15/2020 | Following first dose, patient became hypotensive, pale, and diaphoretic. Denies syncope. Patient went to nearby emergency department at Hospital. Was monitored for several hours and was discharged in stable condition. |
| 902464 | 12/15/2020 | LA | 42 | M | 12/15/2020 | 12/15/2020 | within 15 minutes progressive light-headedness leading to near-syncope and diaphoresis. After 20 minutes symptoms subsided. |